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Part 1 of 31	Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 www.abbottdiagnostics.com	Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 www.abbottdiagnostics.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	AxSYM/AxSYM Plus/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 1,275/12,937 cont. random access/stat, batch floor-standing/segment $60.5 \times 63 \times 33.5/14.6$	ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. U.S./U.S. 468/6,752 batch, random access, cont. random access/floor-standing/track & LAS 48 × 61 × 49/20.3, i2000, 48 × 68 × 44/22.7 per module
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	AFP, CA 125, CA 15-3, CEA, free PSA, total PSA, BNP, CK-MB, myoglobin, troponin-I, CMV IgG, rubella IgG, rubella IgM, Toxo IgG, Toxo IgM, acetaminophen, amphetamine/methamphetamine, barbiturates II U, benzodiazepines, cannabinoids, cocaine metabolite, methadone, opiates, phencyclidine (PCP), REA ethanol, salicylate, tricyclic antidepressants, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin. testosterone, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBs, anti-HCV, HBsAg, HBsAg confirmatory, active-B12 (HoloTC), anti-CCP, vitamin B12, cortisol, ferritin, folate, glycated hemoglobin, homocysteine, carbamazepine, digoxin, gentamicin, N-acetyl-procainamide, phenobarbital, phenytoin, procainamide, quinidine, theophylline, tobramycin, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, ultrasensitive hTSH II	(i2000/i2000SR) CA 125, CA 15-3, CA 19-9 XR, CEA, Free PSA, total PSA, BNP, CK-MB, myoglobin, troponin-I, DHEA-S, estradiol, FSH, hCG (total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBs, anti-HCV, HBsAg, HBsAg confirmatory, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus, anti-CCP; (i4000SR) CA 125, CA 15-3, CA 19-9 XR, CEA, free PSA, total PSA, BNP, CK-MB, myoglobin, troponin-I, DHEA-S, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBs anti-HCV, HBsAG, HBsAg confirmatory, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, others HE-4
Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	CA 19-9, D-dimer, CMV IgG, HBe, beta2 microglobulin, insulin, digitoxin, 3rd gen TSH, cyclosporine, HIV Ag/Ab combo, anti-HIV-1/HIV-2	AFP, HE-4, anti-HAV IgG, vitamin B12, folate, NGAL, proGRP, MPO, SCC, anti-HAV IgG, anti-HBe, HBeAg, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, anti-HTLV-I/HTLV-II, HIV Ag/Ab combo, syphilis, others — vitamin D, carbamazepine, gentamicin, methotrexate, Tg
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	Ξ	— — — — — — — — — — — — — — — — — — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 	no
Methods supported/Separation methods	FDIA MFIA ion canture REA/hateragon, head (micronartials), fiber metric filter	CHEMIFLEX (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle
Methods supported/Separation methods No. of different measured assays onboard simultaneously	FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter 20	CHEMIFLEX (ennanced chemiluminescence) w/5 flexible protocols/magnetic microparticle 25
No. of different assays programmed, calibrated at once	20	25
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 20/100	
containers onboard at once/Tests per container set	20/100	23/100-test & 300-test per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	onboard reagent stability: 112, 224, 336/no	30 days/30 days/yes (2°-12°C)
Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code	no yes yes/assay name, reag. lot No., expir. date, pack No. ID	yes yes yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability
	you accept manney roady reaction, or part accept manney partition in	time, master calibration curve
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	••	no/<0.1ppm
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	60/90/90 no/liquid	300/135/12,500 no/liquid
Uses disposable cuvettes/Max. No. stored	yes/90 reaction vessels	yes/1,200
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	83 µL/150 µL	50 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10 μL/73 μL for sample cup, 450 μL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional	150 µL/50 µL for all tube types yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	52–68 decibels	48-70 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	NO 100 % 75 mm/no	NO 100 100 100 100 100 100 100 100 100 10
Sample bar-code reading capability/Autodiscrimination	yes/100 & 75 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	yes/yes yes	yes/yes yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/	yes/yes no/no	yes/yes no/no
Increased to rerun out-of-linear range low results	10,110	10/110
Time between initial result & reaspiration of sample for rerun	seconds	<20 seconds
Autocalibration or autocalibration alert No. of calibrators required for each analyte	no 6 pt. or 2 pt. w/ master calib., 6 pt., index calib.	yes 2–6 pt. curve
Calibrants can be stored onboard/Avg. calibration frequency	no/4 weeks	no/minimum 30 days or once per lot
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes (up to 4 curves/analyte)	yes/yes 3 layels every 24 hours for quantitative 2 levels for qualitative
Onboard real-time QC/Support multiple QC lot Nos. per analyte	shortest interval: 8 hours, longest: 24 hours yes/yes	3 levels every 24 hours for quantitative, 2 levels for qualitative yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/1 minute	—/no/10 minutes
Stat time to completion of β-hCG test	10 minutes	15.6 minutes
Time delay from ordering stat test to aspir. of sample	30 seconds from standby	<20 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	68-120 tests/flexible platform—load list dependent (assay dependent)	67/200 tests per hour
Specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	all major LIS vendors yes	all major LIS vendors yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	was (breadeast download 9 best sween)	woo (broadcost download 9 boot swam)
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) yes	yes (broadcast download & host query) yes
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	yes, AbbottLink	yes, AbbottLink
On-site response time of service engineer	12 hours	12 business hours
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	5 months/within 12 hours per customer request yes	10.4 weeks/— yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 14 min, weekly: 65 min, monthly: 11 min no/no	daily: 16 min, weekly: <10 min, monthly: none (for both manual & auto procedures) yes/yes
List price/Targeted bed size or daily volume	\$124,000/up to 200 immunoassays tests per day	\$169,500/>200 immunoassays per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	flexible options available yes/yes	flexible options available yes/yes
		• •
Distinguishing features (supplied by vendor)	menu, reliability, online exception help, pressure monitoring, foam avoidance, ratio calculation, stat TAT; see operations manual for additional information	CHEMIFLEX tech. delivers excellent sensitivities and extended linearities, RSH allows priority and routine samples to be processed simultaneously w/o compromising stats; see operations manual for additional information

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Part 2 of 31	Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 www.abbottdiagnostics.com	Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 www.abbottdiagnostics.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ARCHITECT ci4100, ci8200, ci16200/2003, 2007/U.S. U.S./U.S. 41 (ci4100), 281 (ci8200), 15 (ci16200)/157 (ci4100), 1,487 (ci8200), 201 (ci16200) batch, random access, cont. random access/floor-standing/robotic sample handler uses multi-dimensional sample handling 48 × 127 × 49/43.2	ARCHITECT i1000SR/2008/U.S. U.S./U.S. 162/1,438 continuous random access/floor-standing/robotic sample handler allows batch, random access, cont. access and reagent loading and unloading $49\times59\times30/14.7$
Tests available on instrument in U.S.	CA 125, CA 15-3, CA 19-9 XR, CEA, free PSA, total PSA, BNP, CK-MB, troponin-I, DHEA-S, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, anti-HBc IgM, anti-HCV, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus, acetaminophen, amphetamine/methamphetamine, barbiturates, benzodiazepines, benzodiazepines-serum, cannabinoids, cocaine, ecstasy, ethanol, methadone, opiates,	CA 125, CA 15-3, CA 19-9 XR, CEA, Free PSA, Total PSA, BNP, CK-MB, troponin-I, DHEA-S, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, Anti-HBc IgM, anti-HCV, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	phencyclidine (PCP), propoxyphene, salicylate, tricyclic antidepressants, others HE-4, anti-HBs, HBsAg, HBsAg confirmatory AFP, HE-4, proGRP, NGAL, B12, folate, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, syphilis, HIV Ag/Ab combo, alpha-1-	HE-4, anti-HBs, HBsAg, HBsAg confirmatory — AFP, HE-4, ProGRP, NGAL, vitamin B12, folate, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, syphilis, HIV Ag/Ab
Research-use-only assays Tests in development User-defined methods implemented for what analytes	antitrpysin, alpha-1-glycoprotein, ASO, beta 2 microglobulin, ceruloplasim, IgE, others AFP, anti-HAV IgG, anti-HBc, vitamin B12, folate, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, Tg	combo AFP, anti-HAV IgG, anti-HBc, vitamin B12, folate, vitamin D, NGAL, carbamazepine, fentamicin, methotrexate, Tg
Tests not available on other manufacturers' analyzers Fully automated microplate system No. of each analyte performed in separate disposable unit	- =	
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to reru	photometric, potentiometric, & CHEMIFLEX (enhanced chemiluninescence) 93 93 220 93/50–1,700 3 days/28 days/yes yes yes yes/sasay name, reagent No., lot No., tests per kit, expiration date, others open system/SmartWash technology 300/367/>75,000 yes/liquid both disposable and semi-permanent glass/1,200 or 165/330 yes/as needed, 1-year minimum 2 µL 50 µL yes/yes yes/25 L per hour (ci8200)/52 L per hour (ci16200) 48-70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes/yes yes/yes yes/yes yes/yes fom 2 levels after calibration, to 3 per 24 hours yes/yes —/no/10 minutes	chemiluninescence/magnetic particle 25 25 none 25/25–100 —/30 days/yes yes yes yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others no/<0.1 PPM 3 hrs/65/25 no/liquid yes/360 no/— 60 µL 60 µL/50 µL yes/no no/— 50 decibels during normal operation, 62 decibels maximum no/— yes/pediatric, 5, 7, 10 mL tubes and sample cups/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes/yes yes/yes no/no <20 seconds yes 2-6 pt. curve no/minimum 30 days or once per lot yes/yes from 2 levels for qualitative to 3 levels every 24 hrs yes/yes no/no/6.5 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	<15.6 minutes <20 seconds 400/1,200 yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes no yes/yes/yes yes, AbbottLink 8 business hours 10.4 weeks/— yes daily: <15 min, weekly: <35 min, monthly: 15 min (for manual & automated procedures) yes/yes	15.6 minutes <20 seconds up to 100 are 1-step STAT TDMs TPH/— yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes yes yes yes/yes/yes yes 12 business hours —/— yes daily: 10 min, weekly: 17 min, monthly: 90 min. yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$375,000/200–500 immunoassay tests per day flexible options available yes/yes	\$125,000/40–250 tests per day flexible options available yes/yes
Distinguishing features (supplied by vendor)	integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWash technology, which minimizes carryover to <0.1 ppm, reagent capacity of 93 assays, with sample load up to 367; see operations manual for additional information	streamlined workload mgmt., contin. access to reagents, samples, and supplies, 65 samp. load cap., 13 univ. bay, up to 7 custom. priority bays, refrig. reagent carousel w/25×100 test kit sizes, reagents stable onboard up to 30 days, priority tests, 15.6-min. TAT on stat assays; see operations manual for additional information

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	Awareness Technology Inc. Robert Guerin info@awaretech.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com
	1935 SW Martin Hwy., Palm City, FL 34990	250 S. Kraemer Blvd, Brea, CA 92821
Part 3 of 31	772-283-6540 www.awaretech.com	714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	ChemWell/1998/U.S.	Access/Access 2 Immunoassay System/2001/U.S.
Country where manufactured/Where reagents manufactured	U.S./open system	U.S./U.S, France, Ireland
No. of units in clinical use in U.S./Outside U.S.	50+/2,500+	>2,400/>4,000
Operational type/Model type/Sample handling system	batch, random access/benchtop/rack	continuous random access/benchtop/rack
Dimensions in inches (H $ imes$ W $ imes$ D)/Instrument footprint in sq. feet	16 × 34 × 20/4	18.5 × 39 × 24/6.5
Tests available on instrument in U.S.	unlimited—open system	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic
100to available of illocations in 0.07		factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,
		ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin,
		rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,
		hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,
		unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin,
		thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-
		3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO
Tests cleared but not clinically released		PSA, WHO free PSA
Tests not available in U.S. but submitted for clearance		
Tests not available in U.S. but available in other countries	unlimited—open system	HAV Ab, HAV IgM, HBc Ab, HBc IgM, HBs Ab, HBsAg, HBsAg confirmatory, CMV IgG,
		CMV IgM, rubella IgM
Research-use-only assays	unlimited—open system	IL-6, PAPP-A
Tests in development	_	vitamin D, PIGF, sVEGF R1
User-defined methods implemented for what analytes	general biochemistries	-
Tests not available on other manufacturers' analyzers	_	_
Fully outomated missoulate aristone	100	no
Fully automated microplate system	yes un to 12	
No. of each analyte performed in separate disposable unit	up to 12	
No. of wells in microplate	min. strip, 8; max. full plate, 96	
Methods supported/Separation methods	EIA/coated microwell	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	up to 12	24
No. of different assays programmed, calibrated at once	unlimited	24
No. of user-definable (open) channels	unlimited	0
No. of different analytes for which system accommodates reagent	27/assay dependent	24/100 tests per kit; 50 tests per cartridge
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard	assay dependent/assay dependent/yes (10°C below ambient)	336 hours/28 days/yes (3° to 10°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no no/none	yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No.
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/96/12	no/<10 ppm up to 180 based on consumable capacity/60/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/96	ves/294
Uses washable cuvettes/Replacement frequency	yes/assay dependent	no/—
Minimum specimen vol. required	2 μL	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 μL/—	5 μL/100 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption	no e	no/—
Noise generated	-	<70 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/12×100 mm/no	yes/100 μL yes/12 × 75, 13 × 75 & 100, 16 × 75 & 100/no
Sample bar-code reading capability/Autodiscrimination	yes/12 × 100 mm/m0 no/—	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	—	yes
Onboard test auto inventory (determines vol. in container)	yes	no
Measures No. of tests remaining/Short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	no/yes	yes/yes (Access 2 only)
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	no/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/yes	no/no
Time between initial result & reaspiration of sample for rerun	assay dependent	36 seconds
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay dependent	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	yes/assay dependent	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	shortest interval: each run; longest: daily	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/2 minutes	no/no/remains in ready mode
Stat time to completion of β-hCG test	assay dependent	15 minutes
Time delay from ordering stat test to aspir. of sample	assay dependent 30 seconds	≥36 seconds
Throughput per hour for three analytes on each specimen, in No. of	assay dependent	33/100 (36 seconds)
specimens/No. of tests (cycle time)	,	
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (included)	onboard/yes (included or additional cost—negotiable)
Interfaces up and running in active user sites with	-	all major LIS vendors
LIS interface operates simultaneously w/running assays	no 	yes
Uses LOINC to transmit orders and results	no 	no
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes (broadcast download & nost query) yes	yes (bioaucast download & nost query) yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/	yes/yes	no/no/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	within 48 hours	per negotiated service contract
Mean time between failures/To repair failures	-/-	_/_ ''
Onbeaud away ander to fortilitate two III III		yes
Onboard error codes to facilitate troubleshooting	yes doilu. =10 min. wookhu. =10 min. monthhu. =10 min.	
Avg. time to complete maintenance by lab personnel	daily: <10 min; weekly: <10 min; monthly: <10 min	daily: 15 min; weekly: 30 min
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: <10 min; weekly: <10 min; monthly: <10 min no/no	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume	daily: <10 min; weekly: <10 min; monthly: <10 min no/no \$25,000/up to 500 tests per day	daily: 15 min; weekly: 30 min
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: <10 min; weekly: <10 min; monthly: <10 min no/no	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions \$149,800/all volumes & hospital sizes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	daily: <10 min; weekly: <10 min; monthly: <10 min no/no \$25,000/up to 500 tests per day \$4,000 3 days on site/no	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions \$149,800/all volumes & hospital sizes \$15,800 yes/yes (Access 2 only)
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	daily: <10 min; weekly: <10 min; monthly: <10 min no/no \$25,000/up to 500 tests per day \$4,000	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions \$149,800/all volumes & hospital sizes \$15,800 yes/yes (Access 2 only) ability to network up to four Access 2 systems using one LIS interface with remote
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	daily: <10 min; weekly: <10 min; monthly: <10 min no/no \$25,000/up to 500 tests per day \$4,000 3 days on site/no	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions \$149,800/all volumes & hospital sizes \$15,800 yes/yes (Access 2 only) ability to network up to four Access 2 systems using one LIS interface with remote diagnostics; fully automated user-defined reflex testing; continuous
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	daily: <10 min; weekly: <10 min; monthly: <10 min no/no \$25,000/up to 500 tests per day \$4,000 3 days on site/no	daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions \$149,800/all volumes & hospital sizes \$15,800 yes/yes (Access 2 only) ability to network up to four Access 2 systems using one LIS interface with remote

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Part 4 of 31	714-961-3140 www.beckmancoulter.com	714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel Dxl 600 Access Immunoassay System/2007/U.S.	UniCel Dxl 800 Access Immunoassay System/2003/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S., France, Ireland	U.S./U.S., France, Ireland
No. of units in clinical use in U.S./Outside U.S.	>200/>100	>500/>500
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack, drect track sampling	continuous random access/floor standing/rack, direct track sampling
	67 × 61.5 × 37.5/16.02	67 × 67.5 × 37.5/17.6
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	01 \ 01.0 \ 01.0/10.0L	OF A OF A A DESTITE
Teste qualishie an in-t	continued from the plants and and the Line PRO C. 10. 1897. 10. C.	coulded formula places and a labellar PRO C. U
Tests available on instrument in U.S.	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic
	factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,	factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,
	ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin,	ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin,
	rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,	rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,
	hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,	hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,
	unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin,	unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin,
	thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA	thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-
	15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA,	3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO
	WHO PSA, WHO free PSA	PSA, WHO free PSA
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance	_	-
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HBc Ab, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG,	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV
	CMV IgM, rubella IgM	IgM, rubella IgM
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	vitamin D, PIGF, sVEGF R1	vitamin D, PIGF, sVEGF R1
100to in dovolopinone	Transmit Diff Total Control of the C	Transmit by François Earl 111
User-defined methods implemented for what analytes	_	_
		<u> </u>
Tests not available on other manufacturers' analyzers	_	_
		no
Fully automated microplate system	10	IIV
No. of each analyte performed in separate disposable unit	-	-
No. of wells in microplate	_	
T		_
Mathods supported/Congretion methods	chemiluminescence/magnetic narticle	chemiluminescence/magnetic particle
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	50	50
No. of different assays programmed, calibrated at once	50	50
No. of user-definable (open) channels	_	0
No. of different analytes for which system accommodates reagent	50/100 and 300 tests per kit; 50 tests per cartridge	50/100 and 300 tests per kit; 50 tests per cartridge
containers onboard at once/Tests per container set	. ,	• , • • • • • •
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (3°-10°C)	336 hours/28 days/yes (3°-10°C)
Multiple reagent configurations supported		
	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration	yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration
	expiration, within lot calibration	expiration, within lot calibration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<10 ppm	yes/< 10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	180 to 240 based on consumable capacity/60/assay dependent	180 to 240 based on consumable capacity/120/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,000	yes/>1,000
·		• •
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	specimen container dependent	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/80 μL	5 μL/160 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	<60 decibels	<60 decibels
Has dedicated pediatric sample cup/Dead vol.	ves/100 uL	ves/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/12×75, 13×75 & 100, 16×75 & 85 & 100 mm/no	yes/12×75, 13×75 & 100, 16×75, 85, & 100 mm/no
, , ,	• •	• , , , ,
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	no _	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	no/no
Increased to rerun out-of-linear range low results		
Time between initial result & reaspiration of sample for rerun	26 seconds	26 seconds
· · · · ·	36 seconds	36 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	assay dependent	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hours	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of β-hCG test	15 minutes	15 minutes
Time delay from ordering stat test to aspir. of sample	18 seconds	18 seconds
Throughput per hour for three analytes on each specimen, in No. of		
	—/200 (18 seconds)	≤133/≤400 (9–18 seconds)
specimens/No. of tests (cycle time)		
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (included in instrument price & additional cost)	onboard/yes (included or additional cost—negotiable)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	10	no
How labs get LOINC codes for reagent kits	_	_
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	· · · · · · · · · · · · · · · · · · ·	* *
· ·	yes	yes voc /Rockman Coulter automation systems)
Interface available (or will be) to auto specimen handling system	yes, Beckman Coulter automation systems	yes (Beckman Coulter automation systems)
Modem servicing/Can diagnose own malfunctions/	yes/yes/yes	yes/yes/yes
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	no no	no
On-site response time of service engineer	per negotiated contract	per negotiated contract
Mean time between failures/To repair failures	_/_	_/_
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <10 min	daily: <10 min
Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	yes/online help with maintenance instructions
Chiboara maniferiance records/maniferiance training ucino module	Joor offiling from maintenance instructions	Joor offilito froip with maintenance monuclions
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List price/Targeted bed size or daily volume	\$199,500/200–300 beds or 100–300 tests per day	\$325,000/300+ beds or >400 tests per day
Annual service contract cost (24 hours/7 days)	per negotiated contract	\$29,900
Training provided w/purchase/Advanced operator training	yes/yes	yes/yes
Distinguishing features (supplied by vendor)	integrates with UniCel DxC chemistry systems; uses chemiluminescent technology	high-throughput immunoassay analyzer; integrates w/UniCel DxC chemistry systems;
Distinguishing reaction (supplied by Velluti)	and same reagent packs to deliver consistent results with other UniCel immunoassay	uses chemiluminescent technology and same reagent packs for consistent results
	systems; allows operators to load consumables on-the-fly, without interacting with	w/other UniCel systems; allows operators to load consumables on-the-fly, without
	• • • • • • • • • • • • • • • • • • • •	
	the system	interacting with the system

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Part 5 of 31	714-961-3140 www.beckmancoulter.com	714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	Unifed DvC 600i Synchron Access Clinical System/2006/U.S	UniCal Dyl 660i Synahran Accase Clinical System/2000/II S
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	UniCel DxC 600i Synchron Access Clinical System/2006/U.S. U.S./U.S., France, Ireland	UniCel Dxl 660i Synchron Access Clinical System/2009/U.S. U.S./U.S., France, Ireland
No. of units in clinical use in U.S./Outside U.S.	>400/100	>75/>50
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack-closed tube	continuous random access/floor standing/rack closed-tube
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	62 × 128 × 48/42.7	68×147×48/49
Tests available on instrument in U.S.	continue (comme planes union) total lat EDO familia and Dil familia falata intuincia	continue (comme planes unine) total lat EDO familia and Dil familia falata intrinsia
lests available on instrument in U.S.	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,
	ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin,	ultrasensitive hGH, CK-MB, digoxin, myogobin, triage BNP, ultrasensitive insulin,
	rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,	rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,
	hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,	hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,
	unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin,	unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin,
	thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-	thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA
	3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoterics,	15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, , plus >100 Synchron chemistry tests, including critical care,
	urine & CSF chemistries, DATs, TDMs, proteins, serologies)	general esoterics, urine & CSF chemistries, DATs, TDMs, proteins, serologies)
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance		
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM (BVID assays can only be run on the Access 2 portion of DxC	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM
	600i in standalone mode)	igini, tubcila igini
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	vitamin D, PIGF, sVEGF R1	vitamin D, PIGF, sVEGF R1
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers		
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	-	-
No. of wells in microplate	-	-
Mathods supported/Congretion methods	chamiluminessance anzuma immunessasu/magnetia nertiale	chamiluminessense enzume immunessessulmessetie nertiale
Methods supported/Separation methods No. of different measured assays onboard simultaneously	chemiluminescence, enzyme immunoassay/magnetic particle 89	chemiluminescence, enzyme immunoassay/magnetic particle 115
No. of different assays programmed, calibrated at once	89	115
No. of user-definable (open) channels	100	100
No. of different analytes for which system accommodates reagent	89/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)	115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (3° to 10°C)/yes	336 hours/28 days/yes (3° to 10°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration	yes/specific cartridge ID, No. of available tests, expiration date, lot No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	expiration, within lot calibration	calibration expiration, within lot calibration yes/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	60/76/assay dependent	60/76/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	closed/liquid
Uses disposable cuvettes/Max. No. stored	yes/125	yes/125
Uses washable cuvettes/Replacement frequency	yes/—	yes/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	container dependent 3 µL/20 µL (gen. chem)	container dependent 3 µL/20 µL (gen. chem.)
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption	yes/16 L per hour	yes/up to 16 L per hour
Noise generated	- .	- .
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—	yes/—
Sample bar-code reading capability/Autodiscrimination	yes/13 \times 75 & 100, 15 \times 75 & 92, 16 \times 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/13 \times 75 & 100, 15 \times 92 & 75, 16 \times 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/yes	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes (gen. chem.)	yes/yes (gen. chem.)
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/	yes/yes	yes/yes
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun	chemistry dependent	chemistry dependent
Autocalibration or autocalibration alert	dependent	— appointed
No. of calibrators required for each analyte	assay dependent	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes 24 hours	yes/yes 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of 2 bCC test	15 minutes	15 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	15 minutes 1 minute (gen. chem.)	15 minutes 1 minute (gen. chem.)
Throughput per hour for three analytes on each specimen, in No. of	90/720 (40 seconds) (gen. chem.)	90/720 (40 seconds) (gen. chem.)
specimens/No. of tests (cycle time)	veelvee	vesture
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/yes optional add-on/yes (additional cost)	yes/yes —/—
Interfaces up and running in active user sites with	all major LIS vendors	_
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no 	no
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes (Beckman Coulter automation systems)	yes, Beckman Coulter automation systems
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/validate for the DxC 600i	yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	per negotiated service contract	per negotiated service contract
Mean time between failures/To repair failures Ophoard error codes to facilitate troublesheeting	_/_ NOC	
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes —	yes —
Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	yes/online help with maintenance instructions
		<u> </u>
List price/Targeted bed size or daily volume	\$325,000/moderate volume, <300 samples per day	\$575,000/high volume, 300–750 samples per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	per negotiated contract yes/yes	per negotiated contract yes/yes
	,,, -	,,, -
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system;	performs parallel processing of immunoassay and chemistry tests on one
	ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual	system; ClozCap technology (closed-tube aliquot and closed-tube sampling)
	processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems	eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems
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Part 6 of 31	714-961-3140 www.beckmancoulter.com	714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel DxC 680i Synchron Access Clinical System/2009/U.S.	UniCel Dxl 860i Synchron Access Clinical System/2009/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S., France, Ireland	U.S./U.S., France, Ireland
No. of units in clinical use in U.S./Outside U.S.	4/2	8/0
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	continuous random access/floor standing/rack closed-tube $68 \times 153 \times 48/51$	continuous random access/floor standing/rack closed-tube $68 \times 155 \times 48/51.7$
Dimensions in inches (n × w × D)/instrument lootprint in sq. reet	00 × 133 × 40/31	00 × 133 × 40/31./
Tests available on instrument in U.S.	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic	cortisol (serum, plasma, urine), total IqE, EPO, ferritin and Dil ferritin, folate, intrinsic
	factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase,	factor Ab, RBC folate, STfR, vitamin B12, intact PTH (routine or intraoperative), ostase,
	ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella	ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin,
	IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin	rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH,
	A, progesterone, prolactin, SHBG, testosterone, total ßhCG and Dil ßhCG, unconjugated	hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG,
	estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), Gl monitor	unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-
	(CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO	3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO
	free PSA, >100 Synchron chemistry tests (critical care, general esoterics, urine & CSF	PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoterics,
	chemistries, DATs, TDMs, proteins, serologies)	urine & CSF chemistries, DATs, TDMs, proteins, serologies)
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance		
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV
Possarch use only essays	IgM, rubella IgM IL-6, PAPP-A	IgM, rubella IgM IL-6, PAPP-A
Research-use-only assays Tests in development	vitamin D, PIGF, sVEGF R1	vitamin D, PIGF, sVEGF R1
1000 in dottolophioni	Thanini 5,1 lar, or Ear 111	
User-defined methods implemented for what analytes	_	none
Tests not available on other manufacturers' analyzers	_	_
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit		
No. of wells in microplate		
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay/magnetic particle	chemiluminescence, enzyme immunoassay/magnetic particle
No. of different measured assays onboard simultaneously	115	120
No. of different assays programmed, calibrated at once	115	120
No. of user-definable (open) channels	100	100
No. of different analytes for which system accommodates reagent	115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)	120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)
containers onboard at once/Tests per container set	0001 (00.1 ((00.1 (00.0)	0001 (001 (000)
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (2° to 10°C)	336 hours/28 days/yes (2° to 10°C)
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes	yes ves
Reagents bar coded/Information in bar code	yes/specific cartridge ID, No. of available tests, expiration date, lot No.	yes/specific cartridge ID, No. of available tests, expiration date, lot No.,
nougonic sur couca, information in sur couc	calibration expiration, within lot calibration	calibration expiration, within lot calibration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover		yes/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	60/76/assay dependent	60/112/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	closed/liquid
Uses disposable cuvettes/Max. No. stored	yes/125	yes/125
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	yes/—	yes/—
Minimum sample vol. aspirated precisely at once/Min. dead vol.	container dependent 3 µL/20 µL (gen. chem.)	container dependent 3 µL/20 µL (gen. chem.)
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption	yes/up to 16 L per hour	yes/up to 16 L per hour
Noise generated		_ ` `
Has dedicated pediatric sample cup/Dead vol.	yes/—	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 & 100, 15 × 75 & 92, 16 × 100 mm/yes	yes/13 × 75 & 100, 15 × 75 & 92, 16 × 100 mm/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container)	yes yes	yes yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes (gen. chem.)	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/	yes/yes	yes/yes
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun	chemistry dependent	chemistry dependent
Autocalibration or autocalibration alert	—	-
No. of calibrators required for each analyte	assay dependent	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required Ophograf real-time QC/Support multiple QC let Nee per analyte	24 hours	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes no/no/remains in ready mode	yes/yes no/no/remains in ready mode
Stat time to completion of β -hCG test	15 minutes	15 minutes
Time delay from ordering stat test to aspir. of sample	1 minute (gen. chem.)	1 minute (gen. chem.)
Throughput per hour for three analytes on each specimen, in No. of	90/720 (40 seconds) (gen. chem.)	90/720 (40 seconds) (gen. chem.)
specimens/No. of tests (cycle time)	vonhun	venture
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/yes —/—	yes/yes —/—
Interfaces up and running in active user sites with		
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits		-,
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes ves Reckman Coulter automation systems	yes yes Rackman Coulter automation systems
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	yes, Beckman Coulter automation systems yes/yes/validate for the DxC 600i	yes, Beckman Coulter automation systems yes/yes/yes
Determine malfunctioning component	,,,,	,, you you
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	per negotiated service contract	per negotiated service contract
Mean time between failures/To repair failures	-	
Onboard error codes to facilitate troubleshooting	yes 	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	yes/online help with maintenance instructions
	,	,
List price/Targeted bed size or daily volume	\$610,000/high volume, 300-750 samples per day	\$615,000/high to very high volume, 500-1,500 samples per day
Annual service contract cost (24 hours/7 days)	per negotiated contract	per negotiated contract
Training provided w/purchase/Advanced operator training	yes/yes	yes/yes
Diskinguishing feetures (augustis I bereards)	novforme nevallel processing of immunity	nowforms novelled researcher of the second s
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling)
	eliminates manual processes; chemistry and immunoassay reagent packs are	eliminates manual processes; chemistry and immunoassay reagent packs are
	identical across the UniCel family of systems	identical across the UniCel family of systems

	utomated immunoassay analy	
Part 7 of 31	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Binding Site Faranak Atrzadeh faranak.atrzadeh@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.thebindingsite.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	UniCel DxC 880i Synchron Access Clinical System/2008/U.S. U.S./U.S., France, Ireland >65/>65 continuous random access/floor standing/rack closed-tube	SPA PLUS (Specialist Protein Analyzer)/2007/Japan Japan/United Kingdom batch, random access/two sample carousels (each holds 45 samples, 30 primary tubes, 15 non-bar-coded sample tubes/cups)
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	68×161×48/53.7	20.5 × 31.5 × 25.2/14
Tests available on instrument in U.S. Tests cleared but not clinically released	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total ßhCG and Dil ßhCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thryoglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), Gl monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, , WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoterics, urine, and more)	freelite kappa (free kappa light chain), freelite lambda (free lambda light chain), beta-2-microglobulin, lgG, lgA, lgM, lgD, lgG1, lgG2, lgG3, lgG4, cystatin C, T. tox plasma screen only (RUO)
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays	— HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A	
Tests in development User-defined methods implemented for what analytes	vitamin D, PIGF, sVEGF R1	hevylite IgG kappa, hevylite IgG lambda, hevylite IgA kappa, hevylite IgA lambda, hevylite IgM Kappa, hevylite IgM lambda, C3, C4, CH50
Tests not available on other manufacturers' analyzers	_	_
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	<u>no</u> 	no
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels	chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100	turbidimetry 24 —
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hrs/28 days/yes (2° to 10°C) yes	24/100 672 hrs/30 days/yes (9° to 12°C) yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/112/assay dependent	yes yes/— no/— ~60/45/6
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	closed/liquid no/125 yes/— container dependent	closed/liquid no/60 yes/when it reaches threshold OD (0.33), cuvettes should be changed. 150 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol.	3 μL/20 μL (gen. chem.) yes yes/up to 16 L per hour — yes/—	3 µL/150 µL yes/no no/3.5 L — no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes/13 \times 75 & 100, 15 \times 75 & 92, 16 \times 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes	yes/most tube sizes including 12 × 75 mm/no yes (Codabar, codes 39 & 128)/— yes no yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes yes/yes yes/yes (gen. chem.) yes	yes no/no no/no yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	yes/yes chemistry dependent	yes/yes <10 min yes
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	assay dependent no/28 days yes/yes	6 no/— yes/ <i>—</i>
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	24 hrs yes/yes no/no/remains in ready mode	yes/no no/no/<15 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	15 minutes 1 minute (gen. chem.) 90/720/40 seconds (gen. chem.)	
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	yes/yes —/— —	yes/yes optional add-on/no Cerner Classic, Cerner Millenium, SCC Soft Computer, Cyberlab, Sunquest, Meditech
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	yes no	Middleware, Creative Computing Applications Inc., Data Innovations yes no — (Accorded to be a between the computing Applications Inc., Data Innovations
Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes	yes (broadcast download & host query) yes no no/no/no
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	no per negotiated service contract —/— yes	no 24 hrs 258 days, with 2 scheduled preventative maintenance visits/4 hrs on-site yes daily: <10 min; weekly: <10 min; monthly: <15 min
Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$650,000/high to very high volume, 750–2,250 samples per day — —/—	— — 5 days (includes installation)/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems	low maintenance; prozone detection, autodilution; dual compartment reaction cuvettes, air pressure mixing system and extensive washing processes; ideal for latex assays

Part 8 of 31	bioMérieux Inc. Stephane Gelin, U.S. Marketing stephane.gelin@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2430 www.biomerieux-usa.com	Bio-Rad Laboratories Clinical Diagnostics Group Ginger Weeden ginger_weeden@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-741-4680 www.bio-rad.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	VIDAS Immunoassay Analyzer/1991/U.S. Italy/France 2,200/25,000 batch, random access/benchtop/— Vidas 30 system: $16\times32\times2/4.5$; MiniVidas system: $21\times21\times17/4$	BioPlex 2200/2006/Australia Australia/U.S. 103/17 continuous random access/floor standing/rack $58 \times 72 \times 34/12$
Tests available on instrument in U.S.	TSH, FT4, T4, T3, total PSA, HCG, LH, FSH, estradiol 2, prolactin, progesterone, testosterone, ferritin, D-dimer, procalcintonin, troponin I, NT pro BNP, CKMB, C. difficile toxin A&B, measles IgG, mumps IgG, rubella IgG, varicella zoster virus IgG, LYME IgG & IgM, chlamydia & chlamydia blocking, helicobacter pylori, Toxo competition, Toxo IgG, Toxo IgM, rotavirus, CMVM, CMVG, digoxin, lyme IgG & IgM, total IgE	ANA Screen, anti-dsDNA (quant.), anti-SS-A, anti-SS-B, anti-SmRNP, anti-Sm, anti-RNP, anti-Scl-70, anti-Jo-I, anti-centromere B, anti-chromatin, anti-ribosomal P, EBV-nuclear antigen IgG, EBV-viral capsid antigen IgG, EBV-early antigen diffuse IgG, EBV-viral capside antigen IgM, heterophile antibodies, anti-GBM IgG, anti-MPO IgG, anti-PR3 IgG, syphilis IgG, toxoplasma gondii IgG, rubella IgG, CMV IgG, HSV, HSV 1 and HSV 2 IgG, measles IgG, mumps IgG, quantitative rubella IgG, varicella zoster IgG
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— toxo IgG avidity HBs Ag, anti HBs-total, anti-HBc total, anti-HBc IgM, anti HBe, HAV IgG, anti HAV total, HIV duo, myoglobin, B-12 microglobulin, EBV	anti-CCP lgG, toxoplasma lgM, rubella lgM, CMV lgM syphilis lgM, anti-CCP lgG, toxoplasma lgM, rubella lgM, CMV lgM
Research-use-only assays Tests in development		gastrointestinal disease, phospholipid, rheumatoid arthritis, cardiac damage and risk, measles, mumps, VZV, lyme, HSV, HIV and hepatitis
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	all assays for use on Vidas instruments only	none heterophile antibodies
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 1 test per strip —	no
Methods supported/Separation methods	fluorescence, EIA/EIA coated, solid phase receptacle pipetting device	bead flow cytometric (multiplex)/magnetic particle
No. of different measured assays onboard simultaneously	MiniVidas: 12; Vidas: 30	440
No. of different assays programmed, calibrated at once	total menu	440
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 unit dose format 30 or 60/—	
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard	_/_/no	720 hours/30 days/yes (2°–8°C)
Multiple reagent configurations supported Reagent container placed directly on system for use	no placed directly on system	no ves
Reagents bar coded/Information in bar code	yes/assay name, lot No., calibration, expiration	yes/kit type, lot No., kit serial No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/2 ppm
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	assay dependent/12-30/12-30 no/dry	480 minutes/280/17,600 closed/liquid
Uses disposable cuvettes/Max. No. stored	no/_	yes/800
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 100–200 µL, dependent on assay	no 5 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	100 μL, dependent on assay/—	5 μL/70 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/—	yes/no no/0.5 L per hour
Noise generated		<67 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/— no/—/no	no yes/10–16 mm diameter and 41–100 mm height/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no	yes (2 of 5 interleaved, Codabar, codes 39 &128)/yes
Bar-code placement per CLSI standard Auto2A	no no	yes
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	no no/no	yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	no no/no	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no no/no	yes/yes no/no
Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/	no/no no/no	yes/no
Increased to rerun out-of-linear range low results	110/110	_
Time between initial result & reaspiration of sample for rerun		_
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes —	yes analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/14 or 28 days, assay dependent	no/30 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	no/yes shortest interval: 8 hours, longest: 24 hours	yes/no 24 hours/24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/always remains ready	no/no/10 min
Stat time to completion of β -hCG test	30 minutes	
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	no delay —/Vidas: 20, MiniVidas: 8 Vidas: 60, MiniVidas: 24	
specimens/No. of tests (cycle time)		
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/yes onboard/yes (additional cost)	yes/yes onboard/no
Interfaces up and running in active user sites with	Misys, Medtech, McKesson, Advanced Lab systems, Citation, Cerner, Dawning, Geneysis, Compulab, others	-
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no —	no
Bidirectional interface capability	yes (broadcast download)	yes
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	no no/yes/yes	no yes/yes
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator		
On-site response time of service engineer	no within 24 hrs	no —
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	Vidas: 350 days/MiniVidas: 1,000 days	— ves
Avg. time to complete maintenance by lab personnel	yes weekly: 10–15 min	yes daily: 5 minutes; weekly: 30–40 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail)/—	yes/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	Vidas 30: \$53,875; MiniVidas: \$29,225/>400 bed hospitals full service Vidas 30: \$6,180; MiniVidas: \$3,096 yes (2–3 days on site/vendor offices)/yes	\$350,000/≥200 tests per day inquire 5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	routine batch testing as well as emergency stat testing; ELISA methodology; dual-	fully automated/random access; innovative multiplex chemistry; eFlex software with
	function combination solid phase & pipetting device results in no fluid contact with instrument or sample carryover; single-dose assay format readily adaptable to batch	bidirectional interface
	or single test runs; broad assay menu (antigen detection, serology, fertility, thyroid,	
	endocrine, coagulation); D-dimer test FDA-cleared for exclusion of PE and DVT (with pre-test assessment); short time-to-results, color-coded test components; long	
	MTBF intervals; GUI-driven VIDAS PC software can support up to two instruments	
	simultaneously	

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	Bio-Rad Laboratories Clinical Diagnostics Group	Bio-Rad Laboratories Clinical Diagnostics Group
	Greg Stewart greg_stewart@bio-rad.com	Mary Borick mary_borick@bio-rad.com
D 10 (0)	4000 Alfred Nobel Dr., Hercules, CA 94547	4000 Alfred Nobel Dr., Hercules, CA 94547
Part 9 of 31	510-724-7000 www.bio-rad.com	510-741-4791 www.bio-rad.com
Name of instrument/First year sold/Where designed	PR 3100TSC Photometer/2006/Austria	PhD System/2000/Belgium
Country where manufactured/Where reagents manufactured	Austria/U.S.	France/U.S.
No. of units in clinical use in U.S./Outside U.S.	30/—	200/300
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch/benchtop/rack
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	7×13×13/2	35 × 66 × 35/16
Tests available on instrument in U.S.	contact Bio-Rad representative	EIA testing to include: ANA, CCP, tTG IgA/IgG, glaidin IgA/IgG, dsDNA, ENA,
	·	SSA, SSB, SM, SM/RNP, Jo-1, SCL-70, anti-cardiolipin G/A/M, B2GPI G/A/M,
		anti-phosphotidylserine G/A/M, anti-prothrombin G/M, anti-saccharomyuces
		cerevisiae, lyme, CMV G/M, EBV VCA G/M, EBNA G, H. pylori G/A, HSV G, measles G, mumps G, rubella G/M, toxoplasma G/M, VZV G; IFA testing to include: HEp-2,
		crithidia, mouse stomach/kidney, ANCA (formalin & ethanol)
		, , , , , , , , , , , , , , , , , , ,
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	none	_
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	none ANA screen, ENA Plus screen, anti-dsDNA, anti-Jo-1, anti-SS-A, anti-SS-B, anti-	
1000 not available in 0.0. sat available in other obtained	ScI-70, anti-Sm, anti-Sm/RNA, anti-centromere, antiphospholipid tests, toxo IqG,	
	toxo IgM, rubella IgG, rubella IgM, EBV VCA IgM, EBV VCA IgG, CMV IgG, measles IgG,	
Research use only esseue	mumps IgG, VZV IgG not in U.S.	
Research-use-only assays Tests in development	iii iii 0.5.	
User-defined methods implemented for what analytes	none	_
Tests not available on other manufacturers' analyzers	none	_
Fully automated microplate system	no	no.
No. of each analyte performed in separate disposable unit	<u>no</u>	no 1
No. of wells in microplate	min. strip: 1; max. full plate: 96	min. strip: 1; max. full plate: 96
		THE OFFICE AND ADDRESS OF THE OFFICE AND ADDRESS OF THE OFFICE ADD
Methods supported/Separation methods	EIA/coated microwell	EIA & IFA/coated microwell or slide 8 EIA or 4 IFA
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	1	8 EIA OF 4 IFA 8 EIA OF 4 IFA
No. of user-definable (open) channels	none	no limit
No. of different analytes for which system accommodates reagent	0/—	8/192
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	_/_/no	4 hours/—/no
Multiple reagent configurations supported	—/—/no no	4 110urs/—/110 ves
Reagent container placed directly on system for use	10	requires operator prehandling/preparation
Reagents bar coded/Information in bar code	no/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	yes/— —/192/—
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	1/up to 96/1 no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL —/—	1 μL specimen 1 μL/200 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption	no/—	no no
Noise generated	- _	_
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/— no/—/no	no yes/micro-100 mm height/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 &128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no
Bar-code placement per CLSI standard Auto2A	no	yes
Onboard test auto inventory (determines vol. in container)	no	no _.
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	no/no no	no/yes yes
Clot detection/Reflex testing capability	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	assay dependent	1–5
Multipoint calib. supported/Multiple calibs. stored for same assay	no/weekly no/no	no/each run yes/no
How often QC required	shortest interval: weekly; longest interval: monthly	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	—/no	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/5 min	no/no/5 minutes
Stat time to completion of β-hCG test	_	_
Time delay from ordering stat test to aspir. of sample	=	=
Throughput per hour for three analytes on each specimen, in No. of	-/-	-/-
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	no/no	no/yes
Data-management capability/Instrument vendor supplies LIS interface	no/no	onboard/no
Interfaces up and running in active user sites with	-	-
LIS interface operates simultaneously w/running second	no	VAC
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	no no	yes can be customized
How labs get LOINC codes for reagent kits	-	-
Bidirectional interface capability	no	yes
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes (via USB thumb drive to separate you) no	yes no
Modem servicing/Can diagnose own malfunctions/	no/yes/yes	no/no/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	NO unite returned for corvice	no <24 hours
On-site response time of service engineer Mean time between failures/To repair failures	units returned for service —/—	<24 nours 6 months/4 hours
Onboard error codes to facilitate troubleshooting	no	yes
Avg. time to complete maintenance by lab personnel	daily: 0; weekly: 5 minutes; monthly: 5 minutes	daily: 5 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/—	no/no
List price/Targeted bed size or daily volume	\$9,500/5-500 tests per day	\$44,100/>50 tests per day
Annual service contract cost (24 hours/7 days)	inquire	inquire
Training provided w/purchase/Advanced operator training	1 day on site	2 days on site/no
Distinguishing features (supplied by vendor)	compact, standalone microplate photometer; onboard computer allowing user control	accurate pipetting at 1 µL; connection of one to 10 pipetting stations together through
Pisanguisining reatures (supplied by Venuor)	of instrument and data reduction; colored touchscreen with wizard interface provides	an ethernet hub, graphical user interface; added module for IFA slide processing
	streamlined operation of all assays	,

	dutomateu immunoassay anaiy	
	Bio-Rad Laboratories Clinical Diagnostics Group	Diamedix Corp.
	Greg Stewart greg.stewart@bio-rad.com	Pat Ahmad pat_ahmad@ivaxdiagnostics.com
	4000 Alfred Nobel Dr., Hercules, CA 94547	2140 N. Miami Ave., Miami FL 33127
Part 10 of 31	510-724-7000 www.bio-rad.com	305-324-2300 www.diamedix.com
Name of instrument/First year sold/Where designed	Evolis/2001/Germany	Mago Plus Automated EIA Processor/1997/Italy (MAGO 4S to be added)
namo or modernonor not your solu/innere designed	2.0or 200 in definiting	go i ido natomatou Ein i 10003301/1331/Italy (MNCO 45 to be duceu)
Country where manufactured/Where reagents manufactured	Germany/U.S.	Italy/U.S.
No. of units in clinical use in U.S./Outside U.S.	225/1,160	250/—
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	batch/benchtop/rack 37 × 44 × 30/10	batch, random access/benchtop/rack 28 × 48 × 26/8.7
Surrousions in mones (ii × w × D)/msu unicit tootpillit iii sq. teet	VI A 17 A UV/ IV	LO ∧ ∃O ∧ LO/O(I
Tests available on instrument in U.S.	contact Bio-Rad representative	autoimmune: ANA ELISA screen, ENA-6 screen, SSA, SSB, Sm, Sm/RNP, Jo-1, ScI-70,
	·	dsDNA, $\beta 2$ glycoprotein lgG/lgM, cardiolipin screen/lgA/lgG/lgM, gliadin lgA/lgG, MPO,
		PR3, TP0,TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/
		IgM, B burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, <i>H. pylori</i> IgG, measles IgG, mumps IgG, VZV IgG, mycoplasma IgG
		iaz igarigin, <i>n. pyton</i> iga, incasics iga, mainps iga, vzv iga, mycopiasma iga
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance		— contact company
Tests not available in U.S. but available in other countries	HIV Ab, HIV Ab/Ag, HIV Ag, HBSAg, HBc Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, syphilis total Ab,	contact company
	CMV total Ab	
Research-use-only assays	not in U.S.	_
Tests in development	infectious disease & autoimmune panels	
User-defined methods implemented for what analytes	contact Bio-Rad representative	96-well plate enzyme immunoassays
Tests not available on other manufacturers' analyzers	none	_
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	min abilin 4, many 6-11 min 200	1 analyte per well
No. of wells in microplate	min. strip, 1; max. full plate, 96	min. 1 $ imes$ 8 wells; max. 96 wells
Methods supported/Separation methods	EIA/coated microwell	EIA/coated microwell (MAGO 4S, EIA & IFA in parallel)
ошоцо эцррогоці эсрагацогі пісціоцо	Life vocator inici ometi	Enviouded interested (made 40; EIA & IFA III parallel)
No. of different measured assays onboard simultaneously	4–8	9
No. of different assays programmed, calibrated at once	4–8	~50 currently preprogrammed assays
No. of user-definable (open) channels	contact Bio-Rad representative	20 per diskette, unlimited diskette capability
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	4/96	9/96
Shortest/Median onboard reagent stability/Refrigerated onboard	30 minutes/assay dependent/—	—/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes	yes/ lot No., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/no (disposable tips) varies by assay/180/4	no/not susceptible, continuous cleaning up to 2.5 hours—assay dependent/120/384
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	microplates	yes/120
Uses washable cuvettes/Replacement frequency	microplates	no/—
Minimum specimen vol. required	0.2 µL	50 µL (pediatric)
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10 µL/200 µL yes/no	4 μL/25 μL (pediatric) ves/no
Requires dedicated water system/Water consumption	yes/no no	yes/no no/—
Noise generated	60 decibels	_
Has dedicated pediatric sample cup/Dead vol.	no (7 T and 14)	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/11-15 mm × 75-100 mm/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no no	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes —
Onboard test auto inventory (determines vol. in container)	yes	_
Measures No. of tests remaining/Short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	no usa/sa	yes no / to
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/no no/no	no/no no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no yes/no	no/no yes/no
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	no/no
Increased to rerun out-of-linear range low results		
Time between initial result & reaspiration of sample for rerun	_	
Autocalibration or autocalibration alert No. of calibrators required for each analyte	no assay dependent	no assay dependent, 2–6
Calibrants can be stored onboard/Avg. calibration frequency	no/with each run	yes/per run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	user determined	per run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes (through Unity QC program)	yes/yes —/—/-5 minutes
Automatic shutdown/Startup is programmable/Startup time	no/no/5 min	—/—/<5 minutes
Stat time to completion of β -hCG test	-	_
Time delay from ordering stat test to aspir. of sample	-	-
Throughput per hour for three analytes on each specimen, in No. of	assay dependent	120/360 (2.5 hours—assay dependent)
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes	onboard/yes (included in price)
Interfaces up and running in active user sites with	in development	Cerner, Misys, others
110 interference of the control of th		
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no 	<u>no</u>
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no voo/no/no	no no/no/no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/no/no	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hours	24 hours
Mean time between failures/To repair failures	-/-	-/-
Onboard error codes to facilitate troubleshooting	yes daily 5 min; monthly 60 min	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 5 min; monthly: 60 min yes/no	daily: <5 minutes; weekly: <10 minutes; monthly: none no/no
Should maintenance records/maintenance training utility include	journit	
List price/Targeted bed size or daily volume	\$65,000/30-500 tests per day	\$62,000/all bed sizes, all test volumes
Annual service contract cost (24 hours/7 days)	inquire	service during normal business hours included in reagent rental agreement
Training provided w/purchase/Advanced operator training	4 days in Redmond, Wash./no	1–2 days on site/yes
Distinguishing features (cumplied by wonder)	fully automated microplate system that mosts a high lovel of sofety (assistive identifie	EDA_cleared cyclem (inctruments and reasonts); moderate complexity atria by atria
Distinguishing features (supplied by vendor)	fully automated microplate system that meets a high level of safety (positive identifi- cation of samples, reagents, microplates, clot detection, no contamination), flexibility	FDA-cleared system (instruments and reagents); moderate complexity; strip-by-strip timing, accommodates primary reagent packaging; safeguards against insufficient
	(reagents and microplates) and productivity (four to six plates, up to 180 specimens,	reagent/sample volume; functions dependably (mean time between failures greater
	four to eight different assays can be processed simultaneously)	than five months).

June 2010		CAP TODAY / 35
	utomated immunoassay analy	
Part 11 of 31	DiaSorin Inc. Lance Schlenker lance.schlenker@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	DiaSorin Inc. Greta Schwichtenberg greta.schwichtenberg@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ETI-MAX 3000/2002/Germany Germany/U.S., Italy 160/972 batch, random access/benchtop/rack 40 × 45 × 30/10	LIAISON/1997/Germany Germany/U.S., Italy 250/3,000 batch, continuous random access/benchtop/rack 63 × 136 × 66 cm/9.9
Tests available on instrument in U.S.	EA(D) IgG, EBNA-IgG, VCA-IgG, VCA-IgM reverse capture, measles IgG, varicella zoster IgG, mumps IgG, <i>H. pylori</i> IgG, HSV I/II IgG, Trep-Sure syphilis, CMV IgG & IgM capture, rubella IgG, toxoplasma IgG & IgM capture, ANA screen, ENA 6 screen, anti-dsDNA, anti-Sm, anti-Sm/RNP, anti-SS-A, anti-SS-B, anti-Jo-1, anti-Scl-70, anti-MPO, anti PR3 (cANCA), anti-TPO, anti-cardiolipin, IgG, IgM, anti-CCP, anti-B2 glycoprotein 1 IgG and IgM, anti-mitochondria, anti-thyroglobulin, anti-cardiolipin total	25 hydroxyvitamin D total, intact PTH, EBV IgM, EBNA IgG, VCA IgG, EA IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM, treponema IgG/IgM, VZV IgG, hGH, Borrelia burgdorferi, HAV IgM, HAV total antibodies, rubella IgG, HSV-1 type specific IgG, HSV-2 type specific IgG, insulin
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	contact company	cortisol, ACTH, dsDNA, CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, toxo IgG avidity, HSV I/II IgM, HSV I/II IgG, HCG, β -2-microglobulin, prolactin, LH, FSH, S-100, AFP, HCG, ferritin, TSH, FT $_3$, FT $_4$, T $_3$, T $_4$, anti-TG, TG, anti-TPO, rubella IgM, HBsAg, HBsAg confirmatory, anti-HBs, anti HBc, HBc IgM, HBeAg, anti-HBe, troponin I, CK-MB, myoglobin, C-peptide, Brahms procalcitonin, borrelia IgG & IgM, tTG IgA, testosterone, NSE, progesterone, estradiol, VZV IgM, calcitonin, ANA screen, ENA screen, direct renin, BAP OSTASE, biotrin parvovirus B19 IgG and IgM
Research-use-only assays	\$100	S100, TK
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— — HBeAg, anti-HBe	cardiolipin, measles IgG, mumps IgG — 25 hydroxy vitamin D total, Borrelia burgdorferi, VZV IgG, CMV IgM, HSV-1 type spe- cific IgG, HSV-2 type specific IgG, biotrin parvovirus B19
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time	no /
Methods supported/Separation methods	EIA/coated microplate	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	open	15
No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	open O volume dependent	15 0 15/100
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	no/no/no	7/28 days/yes (12°C)
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes	no yes
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/— yes/no	yes/all lot information no/no
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	assay dependent/180/variable no/liquid	360/144/1,500 no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no no	yes/720 no
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10 μL 10 μL/200 μL	assay dependent 5 μL/200 μL
Requires dedicated water system/Water consumption Noise generated	yes/no no/no 	yes/no no/— —
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes (multiple)/no	no/75 µL yes/—/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes/yes yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes yes/yes	yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/no	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no yes/no	no/no yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	yes/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	no	2 minutes no
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	varies per kit no/each run	2 yes/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/no per run	yes/no 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes no/yes/5 minutes	no/yes no/no/2 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	assay dependent	
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability//partyment vander cumplies LIS interface	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	yes/yes yes	yes/yes (additional) Cerner, Soft, others
Uses LOINC to transmit orders and results	yes —	yes —
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes	yes (host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	yes no no/no/no	yes no no/no/no
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	24 hours —/— ves	24 hours —/— vas
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes daily: 5 minutes; weekly: 30 minutes yes/no	yes daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$79,000 (includes first year of service)/all bed sizes, all test volumes \$10,500 3 days/yes	\$145,000/all bed sizes, all volumes inquire 3 days on site/yes
B. F. 11. () () () ()		

selectively open system; multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bidirectional interface

fully automated benchtop analyzer with high throughput; unique menu offering; up to 15 assays onboard with ready-to-use, reagent-integral, random-access, batch & stat operation

Distinguishing features (supplied by vendor)

Adtomated inimanoassay analyzers		
	Orifolo HCA 11 O	Ilwan Diamadiael Inc
	Grifols USA, LLC Stephanie Sorensen stephanie.sorensen@grifols.com	Hycor Biomedical Inc. Alex Draffan adraffan@hycorbiomedical.com
	2410 Lillyvale Ave., Los Angeles, CA 90032	7272 Chapman Ave., Garden Grove, CA 92841
Part 12 of 31	323-227-7415 www.grifols.com	714-933-30000 www.hycorbiomedical.com
		,
Name of instrument/First year sold/Where designed	Triturus/1999/Spain	HYTEC 288 PLUS/outside U.S. 1998, U.S. 1999/Netherlands
Country where manufactured/Where reagents manufactured	Spain/Spain, U.S., Italy	Netherlands/U.S., Scotland
No. of units in clinical use in U.S./Outside U.S.	>200/>1,700	60/175
Operational type/Model type/Sample handling system	batch, random access & cont. random access/benchtop/universal carousel	random batches/benchtop/rack-robotics
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	28.3×41.3×34.3/10	29.5 × 42.5 × 27.5/8
Tests available on instrument in U.S.	system is completely open; any U.S. clinically cleared and research-use-only EIA	total/specific IgE, ANA scr, TG, TPO, dsDNA, RF IgG, RF IgM, RF IgA, PR-3 (c-ANCA),
lests available on instrument in 0.5.	procedure can be programmed; infectious diseases, autoimmune diseases, bone	MPO (p-ANCA), anti-mitochondrial, ENA-6 Scr., SS-A, SS-B, Sm, Sm/RNP, Scl-70, Jo-1,
	markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles	gliadin IgA & IgG, GBM, GPC, anti-cardiolipin IgG & IgM, anti-cardiolipin scr., β -2 BPI
	markoro, onadormology, nomocado, ondology markoro, nopalitio, and my promoc	IgG, IgA & IgM, user-defined channels
Tests cleared but not clinically released	_	anti-tissue transglutaminase IgA and IgG
Tests not available in U.S. but submitted for clearance	_	none
Tests not available in U.S. but available in other countries	_	specific IgG, ssDNA, total rheumatoid factor, anti-tissue transglutaminase IgA and IgG,
		circulating immune complex -C1q and circulating immune complex -C3d
Research-use-only assays	_	ANCA nyofile, contyamore, CCD
Tests in development	_	ANCA profile, centromere, CCP
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers	_	_
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	8	8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)
No. of wells in microplate	96, 1 minimum strip, 4 maximum full plate	96-min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells
	PIA PIA LL L. P. C. L. L. C.	
Methods supported/Separation methods	EIA, EIA-coated microwell plates, onboard shaker, four individually	EIA, tube-based & microplate-based assays/activated cellulose & coated well
No. of different magazined account and a facility them.	temperature-controlled microplate positions/coated microwell	version by account to 200 allegance on 0 and increase
No. of different measured assays onboard simultaneously	1–8 tests on 1–4 plates	varies by assay, up to 288 allergens or 8 autoimmune
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	8	multiple
No. of different analytes for which system accommodates reagent		varies by assay, up to 288 allergens or 8 autoimmune
containers onboard at once/Tests per container set	W 10	Tailoo by accus, up to 200 anoigene of a autominitude
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	8 hours/12 hours/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	minimal operator preparation, handling	yes
Reagents bar coded/Information in bar code	no	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/no	yes/<1 part in 10,000
Walkaway capacity in minutes/Specimens/Tests-assays	180/92/8	assay dependent/100/288
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no	no
Uses washable cuvettes/Replacement frequency	NO	00 10 ut 110 ut w/ dood vol
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	300 μL 2 μL/200 μL	10 μL, 110 μL w/ dead vol. 10 μL–50 μL, assay dependent//100 μL
Supplied with UPS (backup power)/Requires floor drain	2 μ1/200 μ1. yes/no	Ves/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	has external waste port to drain into sink or floor drain	_
Has dedicated pediatric sample cup/Dead vol.	no/—	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/12, 13, 16 mm/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—
Bar-code placement per CLSI standard Auto2A	yes	no
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/yes	yes no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	no/no
Increased to rerun out-of-linear range low results		
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–14	1-6
Calibrants can be stored onboard/Avg. calibration frequency	no/check every month	no/monthly
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	each run ves/no	every assay yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/1–2 minutes	yes/yes yes/no/2–3 minutes
	yy. 	· · · · · · · · · · · · · · · · · · ·
Stat time to completion of β-hCG test	system is open, depends on reagent methodology	_
Time delay from ordering stat test to aspir. of sample		_
Throughput per hour for three analytes on each specimen, in No. of	dependent on reagent methodology/—	-
specimens/No. of tests (cycle time)		,
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	yes, onboard/no CHCS Softmay Sunguest	onboard/optional
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	CHCS, Softmax, Sunquest	25
Uses LOINC to transmit orders and results	yes no	no no
How labs get LOINC codes for reagent kits	LIS—unidirectional or bidirectional	_
Bidirectional interface capability	yes (host query & broadcast download)	yes
Results transmitted to LIS as soon as test time complete	yes	optional
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/	yes/yes	yes/yes/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	NO within 24 hours	NO 49 hours
On-site response time of service engineer Mean time between failures/To repair failures	within 24 hours —/—	48 hours 7 months/4 hours
Onboard error codes to facilitate troubleshooting		/ months/4 nours yes
Avg. time to complete maintenance by lab personnel	yes daily: 5–20 minutes	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	\$79,000/300+	\$55,000/all sites, variable test vols.
Annual service contract cost (24 hours/7 days)	varies, multiple types available	\$5,500
Training provided w/purchase/Advanced operator training	—/yes	3 days on site/yes
BU		
Distinguishing features (supplied by vendor)	multibatch or continuous throughput EIA analyzer; user-defined menu, completely	fully automated allergy and autoimmune testing; user-defined software channels for
	open system; easy color-coded worksheet and setup for operator; two probes for	microtiter plate and tube-based assays
	high-speed processing; unique cross-well washing; able to use fixed probes or disposable tips	
	aiopouusio tipo	

	ditomated immunoassay analy	
	Immunodiagnostic Systems Inc. (IDS Inc.)	Inova Diagnostics
	Ken Gibbs kenneth.gibbs@idsplc.com	Ed Bass ebass@inovadx.com
Part 13 of 31	8425 N. 90th Street, Suite 8, Scottsdale, AZ 85258 480-278-8333 www.idsplc.com	9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com
rait is oil si	400-2/0-0333 www.luspio.com	000-040-9450 www.iiiova.com
Name of instrument/First year sold/Where designed	IDS-iSYS/2009/France	DS2/2006/U.S.
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	France/Belgium —/74	U.S./U.S., U.K. —/—
Operational type/Model type/Sample handling system	continuous random access/benchtop/sample loading rack	batch, with continuous load/benchtop/rack
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	28 × 42 × 28/—	30 × 17 × 26/3.07
Tests available on instrument in U.S.	_	ANA screen, ENA screen, dsDNA, SS-A, SS-B, Sm, Sm/RNP, Jo-1, ScL-70, GBM, MPO,
lests available on filst union in 0.5.		PR3, Tg-TPO, cardiolipin screen & IgG, IgA, IgM, B2GP-1 screen & IgG, IgA, IgM,
		phosphatidylserine screen, IgG/IgA/IgM, C1q, gliadin IgG/IgA & screen, +TG IgA/
		lgG, RF, A-CCP, histone, ASCA lgA/lgG, tetanus toxoid, diptheria toxoid, EBV VCA lgG, lgM, EBV-EA lgG, EBV EBNA-1 lgG/lgM, toxo lgG/lgM, rubella lgG/lgm, CMV lgG/lgM &
		IgG capture, HSV 1/2 IgG, HSV type specific 1&2, measles IgG/IgM, mumps IgG, high
		avidity dsDNA, PLAC test, others
Tests cleared but not clinically released	_	none
Tests not available in U.S. but submitted for clearance	_	-
Tests not available in U.S. but available in other countries	25-hydroxyvitamin D, intact PTH, hGH, IGF-1, intact PINP, N-MID Osteocalcin	open system—ELISA
Research-use-only assays	25-hydroxyvitamin D	open system
Tests in development	CTX-I, BAP, Bone Trap (TRAcP 5b), IGFBP3, aldosterone, renin, PTH 1-34,	
	bioactive PTH (1-84)	
User-defined methods implemented for what analytes	_	open system
Tests not available on other manufacturers' analyzers	_	open system
Fully automated microplate system	no	Voc
No. of each analyte performed in separate disposable unit	——————————————————————————————————————	yes —
No. of wells in microplate	-	min. strip 1 \times 8; max. full plate: 96 wells \times 2 plates
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA/coated microwell
No. of different measured assays onboard simultaneously	15	12 assays per plate
No. of different assays programmed, calibrated at once	15	unlimited
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 15/100	unlimited 8/96
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	48 hours/7 days/yes (8°–10°C)	24 hours/—/no
Reagent container placed directly on system for use	yes no, requires operator prehandling/preparation	yes yes
Reagents bar coded/Information in bar code	yes/LOT key, No. within lot, XML	yes/yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/— —/64/960	—/0 with disposable tips assay dependent/98/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/960 ·	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 10 μL	no/— 200 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/tube dependent ~80 μL	5 μL/200 μL (50 μL with microtubes)
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/—
Requires dedicated water system/Water consumption Noise generated	no/— —	<u>no</u>
Has dedicated pediatric sample cup/Dead vol.	yes/80 µL	yes/50 μL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/all up to 16 × 100 mm/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, codes 39 & 128)/yes —	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container)	yes	no
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	yes/yes	no/yes
Clot detection/Reflex testing capability	yes yes/yes	yes yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/	yes/yes no/no	yes/no no/no
Increased to rerun out-of-linear range low results	10/110	110/110
Time between initial result & reaspiration of sample for rerun	_	-
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 2	no varies
Calibrants can be stored onboard/Avg. calibration frequency	no/test dependent ~7 days	yes/each assay
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	each assay yes/no
Automatic shutdown/Startup is programmable/Startup time	yes/yes/10 minutes	no/yes/1–2 minutes
Stat time to completion of β-hCG test	_	_
Time delay from ordering stat test to aspir. of sample	-	-
Throughput per hour for three analytes on each specimen, in No. of	-	assay dependent
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no, additional cost	onboard/yes (additional cost)
Interfaces up and running in active user sites with	_	_
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (host query)	yes (host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	yes	no no/no/no
Determine malfunctioning component	yes/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no oat	no
On-site response time of service engineer Mean time between failures/To repair failures	24 hours —/—	— —/<24 hours
Onboard error codes to facilitate troubleshooting	yes	/ <z4 ilours="" td="" yes<=""></z4>
Avg. time to complete maintenance by lab personnel	daily: 15 min; weekly: 30 min; monthly: 15 min	daily: 5 minutes; weekly: —; monthly: —
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/no	yes/no
List price/Targeted bed size or daily volume	—/—	\$50,000/100-200 heds
Annual service contract cost (24 hours/7 days)		\$7,000
Training provided w/purchase/Advanced operator training	—/yes	8 days on site/yes
Distinguishing features (supplied by vendor)	unique analytical platform combining three technologies: luminometry, potentiometry,	graphical interface wtih drag-and-drop icons; large sample throughput for a two-plate
	and spectrophotometry	microplate system, with 98 samples and continuous load feature; consumable status
		window shows location and volume requirements during loading

	atomatea illimaneassay ahaiy	
	Inova Diagnostics	Inova Diagnostics
	Ed Bass ebass@inovadx.com	Ed Bass ebass@inovadx.com
	9900 Old Grove Road, San Diego, CA 92131	9900 Old Grove Road, San Diego, CA 92131
Part 14 of 31	800-545-9495 www.inova.com	800-545-9495 www.inova.com
Name of instrument/First year sold/Where designed	DSX/2000/Guernsey, U.K.	ASP1200/2008/UK
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	U.S./U.K. 300/>500	U.K./U.K. 2/24
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	32 × 42 × 36/7	22 × 20 × 24/2
Simple in money (17×17×5)/monathing to spring in eq. 1660		
Tests available on instrument in U.S.	ANA screen, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, MPO, PR3,	ANA, dsDNA, ANCA, GBM, EMA
	TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine	
	lgG/lgM/lgA, C1q CIC, gliadin lgG/lgA & scr, tTG lgA, tTG lgG, RF, anti-CCP, histone,	
	EBV VCA IgG/IgM, EBV EA-D IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM.	
	CMV IgG/IgM.IgM capture, HSV 1/2 IgG, measles IgG/IgM, mumps IgG, VZV IgG, IgM, lyme IgM/IgG & scr, <i>H. pylori</i> , syphilis, chlamydia, mycoplasma, legionella IgG/IgM,	
	legionella UA, CCP, HSV 1/2 IgG type specific, tetanus toxoid, ASCA IgG/IgA, diptheria	
	toxoid, high avidity dsDNA, PLAC test	
Tests cleared but not clinically released	none	_
Tests not available in U.S. but submitted for clearance	_	_
Tests not available in U.S. but available in other countries	open system—any ELISA	_
Decearch use only energy	anan ayatam	
Research-use-only assays	open system	_
Tests in development	_	_
User-defined methods implemented for what analytes	open system	_
Tests not available on other manufacturers' analyzers	open system	_
Fully automated microplate system	yes	NO 5 24
No. of each analyte performed in separate disposable unit	min ctring 1 × 9; may full plate; 00 × 4 plates	5-24
No. of wells in microplate	min. strip: 1 \times 8; max. full plate: 96 \times 4 plates	
Methods supported/Separation methods	EIA/coated microwell	fluorescence, immunoperoxidase/substrate
No. of different measured assays onboard simultaneously	12 assays per plate	4
No. of different assays programmed, calibrated at once	unlimited	4
No. of user-definable (open) channels	unlimited	unlimited
No. of different analytes for which system accommodates reagent	25/96 per 4 plates	4/250
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	24 hours/—/no	8 hours/1 day/no
Multiple reagent configurations supported	yes	Ves
Reagent container placed directly on system for use	requires operator prehandling/preparation	yes, some pouroff required
Reagents bar coded/Information in bar code	yes/yes	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/0	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/92/assay dependent	105/96/96
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	open/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no no	no/— —/—
Minimum specimen vol. required	200 μL	250 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/200 μL (50 μL with microtubes)	5 μL/250 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no/—
Noise generated	–	- ,
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL ves/various/no	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—	yes/—no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interieaved, obdabal, codes 35 & 120)/—	— Sinteriorated, obdabal, codes 35 & 120//yes
Onboard test auto inventory (determines vol. in container)	10	110
Measures No. of tests remaining/Short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no yes/no	no/no yes/no
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	—/—
Increased to rerun out-of-linear range low results		
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	no	no .
No. of calibrators required for each analyte	assay specific	
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	yes/once per analyte per plate yes/yes	yes/— no/no
How often QC required	per plate	no/no each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	no/no
Automatic shutdown/Startup is programmable/Startup time	yes/—/1–2 minutes	no/no/—
A		
Stat time to completion of β-hCG test	-	-
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	assay dependent	
specimens/No. of tests (cycle time)	accar acpointed	OE, OO, 1 HOW WIN TO HIRM
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/—
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional)	no/yes, included in price
Interfaces up and running in active user sites with	Cerner Classic & Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW,	-
LIC interfess operator simultaneous transfer	LabLink	
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes no	yes no
How labs get LOINC codes for reagent kits	<u>no</u>	<u>no</u>
Bidirectional interface capability	yes (host query)	no
Results transmitted to LIS as soon as test time complete	yes (manual transmission available)	no
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/	no/yes/yes	no/—/—
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	70	
On-site response time of service engineer	no within 24 hours	— 24 hours
Mean time between failures/To repair failures	—/<24 hours	227 days/4 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: none; monthly: none	daily: 2 min; weekly: 15 min
Onboard maintenance records/Maintenance training demo module	no/no	no/—
List price/Targeted bed size or daily volume	\$125,000 (dependent on modules)/200+ beds	\$37 /50/50 toets par day
Annual service contract cost (24 hours/7 days)	\$125,000 (dependent on modules)/200+ deas \$12,950	\$37,450/50 tests per day \$3,000
Training provided w/purchase/Advanced operator training	8 days on site, 2 days at vendor offices/yes	yes/yes
	. ,	
Distinguishing features (supplied by vendor)	fully open, true four-plate system; modular design of reader, washer, incubators;	download of worklist from LIS; sample/reagent retry option immediately
	bar-code reader and ambient drawer enables easy upgrades and express shipping of	rectifies sampling errors; automated monkey kidney GBM
	replacement modules, reducing downtime; software can be trained for learned error	
	recovery	

Adternated infinialisassay dilaryzers		
	Inova Diagnostica	Innua Diagnostica
	Inova Diagnostics Ed Bass ebass@inovadx.com	Inova Diagnostics Ed Bass ebass@inovadx.com
	9900 Old Grove Road, San Diego, CA 92131	9900 Old Grove Road, San Diego, CA 92131
Part 15 of 31	800-545-9495 www.inova.com	800-545-9495 www.inova.com
Name of instrument/First year sold/Where designed	Quanta Lyser 240/2008/Switzerland, Italy	Quanta Lyser 2/2008/—
Country where manufactured/Where reagents manufactured	Switzerland/U.K.	Switzerland/U.K.
No. of units in clinical use in U.S./Outside U.S.	110/95	0/50
Operational type/Model type/Sample handling system	batch/benchtop/racks	batch/benchtop/racks
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	36 × 47 × 32/10.5	29.5 × 25.6 × 27.6/—
Tests available on instrument in U.S.	open system, Inova autoimmune, diaDexus PLAC test, Trinity assays, TrepSure	Inova autoimmune menu
lesis available on instrument in 0.5.	open system, mova autominiume, urabexus PLAG test, minty assays, mepsure	mova autommune menu
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance	_	_
Tests not available in U.S. but available in other countries	_	_
Barranda ara anda arana		
Research-use-only assays	_	_
Tests in development		_
lests in development		_
User-defined methods implemented for what analytes	_	IFA slides
Tests not available on other manufacturers' analyzers	_	_
·		
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	1	-
No. of wells in microplate	96	96
Makhada aumandad/O	fluorescence common F18/	
Methods supported/Separation methods	fluorescence, enzyme EIA/coated microwell	enzyme immunoassay, IFA slides/coated microwell
No. of different measured assays onboard simultaneously	9	9
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	open system	open system
No. of different analytes for which system accommodates reagent	9/88	—/EIA: 180; IFA: 240
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard	24 hrs/—/no	—/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	placed directly on system
Reagents bar coded/Information in bar code	_/ _	yes/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/<10	no/<10 ⁻⁶
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/up to 240/9 quantitative, 21 qualitative	240/96/192
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 200 µL	no/— 100 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	200 μL 5 μL/200 μL	100 μL 5 μL/150 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	Ves/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	_	_
Has dedicated pediatric sample cup/Dead vol.	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10 to 16 mm/no	yes/10 to 16 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	-	_
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	no/yes	no/yes
Clot detection/Reflex testing capability	no yes/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	—/—	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/	_/_	
Increased to rerun out-of-linear range low results		
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	no	no .
No. of calibrators required for each analyte	assay dependent	varies
Calibrants can be stored onboard/Avg. calibration frequency	yes/per run	—/varies
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/no per run	yes/— ner run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	per run no/—
Automatic shutdown/Startup is programmable/Startup time	no/no/2 min	no/—/—
1 - 1 - 3		
Stat time to completion of β -hCG test	-	_
Time delay from ordering stat test to aspir. of sample	-	-
Throughput per hour for three analytes on each specimen, in No. of	-/-	- /-
specimens/No. of tests (cycle time)		
Con outo transfer OO results to LIO/Out sout	vee hee	und
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/—
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	yes/— onboard/yes (additional cost) —
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (additional cost) 3	onboard/yes (additional cost) —
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	onboard/yes (additional cost) 3 yes	onboard/yes (additional cost) — yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	onboard/yes (additional cost) 3	onboard/yes (additional cost) —
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	onboard/yes (additional cost) 3 yes	onboard/yes (additional cost) — yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	onboard/yes (additional cost) 3 yes no	onboard/yes (additional cost) yes no
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	onboard/yes (additional cost) 3 yes no yes (host query) yes no	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	onboard/yes (additional cost) 3 yes no yes (host query) yes	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no no 24 hrs	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6–8 months/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6–8 months/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6–8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6–8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min
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Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$125,000/500 tests/day	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$64,995/150-350 tests/day
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$125,000/500 tests/day \$14,250 yes (8 days on site)/yes	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$64,995/150-350 tests/day \$9,500 yes (4-8 days on site)/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$125,000/500 tests/day \$14,250 yes (8 days on site)/yes fast processing time; low operating costs due to elimination of disposable tips;	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$64,995/150-350 tests/day \$9,500 yes (4-8 days on site)/— processes IFA slides and ELISA assays simultaneously, LIS interface, large menu, and
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	onboard/yes (additional cost) 3 yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$125,000/500 tests/day \$14,250 yes (8 days on site)/yes	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$64,995/150-350 tests/day \$9,500 yes (4-8 days on site)/—
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	onboard/yes (additional cost) 3 yes no yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$125,000/500 tests/day \$14,250 yes (8 days on site)/yes fast processing time; low operating costs due to elimination of disposable tips;	onboard/yes (additional cost) yes no yes (broadcast download, host query) yes no no/—/— 24 hrs 6-8 months/— yes daily: 5 min; weekly: 10 min; monthly: 10 min no/— \$64,995/150-350 tests/day \$9,500 yes (4-8 days on site)/— processes IFA slides and ELISA assays simultaneously, LIS interface, large menu, and

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Part 16 of 31	877-546-8633 www.invernessmedicalpd.com	609-627-8029 www.invernessmedicalpd.com
Name of instrument/First year call BUIL tt	A+b-01/4/2002/II C	AIRAC (2007 Curitaryland
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	AtheNA/2002/U.S. U.S./U.S.	AIMS/2007/Switzerland Switzerland/U.S.
No. of units in clinical use in U.S./Outside U.S.	150/—	15/—
Operational type/Model type/Sample handling system	batch/benchtop/multichannel pipetting or automated with front end	batch/benchtop/rack
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	9.5 × 17 × 20/—	40 × 67 × 35/—
Tests available on instrument in U.S.	AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm,	AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm, RNP,
	RNP, ScI-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM),	ScI-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM), TPO/Tg
	TPO/Tg (thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral	(thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral capsid
	capsid antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella,	antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella, varicella
	varicella zoster), MMV IgG (measles, mumps, varicella zoster), HSV 1&2 IgG (herpes	zoster), MMV IgG (measles, mumps, varicella zoster), HSV 1&2 IgG (herpes simplex
Tests cleared but not clinically released	simplex virus, type 1 & type 2)	virus, type 1 & type 2) and wampole ELISA II assays
Tests not available in U.S. but submitted for clearance	ToRCH IgG, borrelia VisE-1/pepC10	ToRCH IgG, borrelia VIsE-1/pepC10
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	_	_
Tests in development	HIV-1, cardiolipin IgG, syphilis	HIV-1, cardiolipin IgG, syphilis
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers		
lests not available on other manufacturers analyzers		
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	1–10	assay dependent
		, ·
No. of wells in microplate	min. strip: 1; max. full plate: 96-well plate	min. strip: 8; max. full plate: 96-well plate
Methods supported/Separation methods	fluorescence/bead	enzyme immunoassay, multiflexing/bead, coated microwell
No. of different measured assays onboard simultaneously	nuorescence/dead 10	onzyme minumoassay, munimexing/seau, coaleu microwen 4
No. of different assays programmed, calibrated at once	10	multiple
No. of user-definable (open) channels	0	unlimited
No. of different analytes for which system accommodates reagent	 /96	4/96
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard	_/_/no	—/—/no
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	no, requires operator prehandling/preparation no/—	yes no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<0.9%	ves/3%
Walkaway capacity in minutes/Specimens/Tests-assays	30 ±10/—/—	assay dependent/240/4
System is open (home-brew methods can be used)/Liquid or dry system	open/liquid	open/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	10 µL	210 µL based on 16-mm tube
Minimum sample vol. aspirated precisely at once/Min. dead vol.	_/_ 	10 μL/200 μL based on 16-mm tube
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/—	yes/no no/—
Noise generated	——————————————————————————————————————	——————————————————————————————————————
Has dedicated pediatric sample cup/Dead vol.	no/—	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/—	yes/10 $ imes$ 16 mm outer dimensions/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—
Bar-code placement per CLSI standard Auto2A	yes	
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	no —/—	yes no/yes
Auto detection of adequate reagent or specimen		yes
Clot detection/Reflex testing capability	-/-	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	-/-	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/	-/-	-/-
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun		
Autocalibration or autocalibration alert	yes	
No. of calibrators required for each analyte	5 per well	5 per well
Calibrants can be stored onboard/Avg. calibration frequency	no/calibration in every well	no/calibration in every well
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	1 per month	every assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/—	—/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/30 minutes	yes/yes/10 minutes
Stat time to completion of β-hCG test	_	_
Time delay from ordering stat test to aspir. of sample	_	-
Throughput per hour for three analytes on each specimen, in No. of	48/84	assay dependent/—/—
specimens/No. of tests (cycle time)	noluna	hina
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	no/yes yes, onboard/yes (additional cost)	—/yes
Interfaces up and running in active user sites with	yes, onboard/yes (additional cost) Cerner, Sunquest	yes, onboard/yes (additional cost) —
	,	
LIS interface operates simultaneously w/running assays	no	no
Uses LOINC to transmit orders and results	no	-
How labs get LOINC codes for reagent kits	_ m	
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	no yes	yes
Interface available (or will be) to auto specimen handling system	yes, AIMS	_
Modem servicing/Can diagnose own malfunctions/	no/—/—	no/—/—
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	T	T
On-site response time of service engineer	24–48 hours	24–48 hours
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	6 months/<1 day	_/_ voc
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 15 min; weekly: 30 min; monthly: 5 min	yes daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes
Onboard maintenance records/Maintenance training demo module	no/—	no/—
List price/Targeted bed size or daily volume	\$60,000/8 tests per day	\$149,900/>150 beds
Annual service contract cost (24 hours/7 days)	\$8,000	\$19,500
Training provided w/purchase/Advanced operator training	yes/—	5 days on site
Distinguishing features (supplied by vendor)	large FDA-cleared menu on the Luminex platform; every sample has a unique	fully automated integrated open system that allows processing of Athena MultiLyte
Sissingularing located to tappinou by Vellaut)	calibration curve generated at the time the beads are read; at least 50 discrete	multiplexing assays and ELISA on one platform
	readings for every analyte in every test system	

Part 17 of 31	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	DS2/2007/U.S. U.S./U.S. — batch/benchtop/rack 27 × 21 × 26/4	DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchtop/rack 32 × 42 × 36/7
Tests available on instrument in U.S.	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, H. Pylori, HSV, legionella,lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; Al: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, ScI-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella,lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; Al: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	= = = = = = = = = = = = = = = = = = = =	
Research-use-only assays Tests in development		=
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 96)	yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 96)
Methods supported/Separation methods	enzyme immunoassay/coated microwell	enzyme immunoassay/coated microwell
No. of different measured assays onboard simultaneously	24	48
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	24 unlimited	48 unlimited
No. of different analytes for which system accommodates reagent	18/24	24/48
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	8 hrs/1 day/no	8 hrs/1 day/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	placed directly on system no/—	placed directly on system no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover		10/0
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	120 min/98/24 yes/liquid	120 min/98/48 yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 10 μL	no/— 10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL/50 μL	5 μL/50 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption Noise generated	no/— —	no/— —
Has dedicated pediatric sample cup/Dead vol.	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/primary, pouroff/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/primary, pouroff/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes no/yes	yes no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/no no/no	yes/no no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	NO analyte dependent	NO analyte dependent
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	analyte dependent no/within each run	analyte dependent no/within each run
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	no/no
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	with every assay no/yes	with every assay no/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/5 min	yes/yes/5 min
Stat time to completion of β-hCG test	-	_
Time delay from ordering stat test to aspir. of sample	-,	-,
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	<i>-</i> /-	<i>-</i> /-
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (additional cost) Cerner, Millenium, Sunquest, Soft, Mysis, etc.	onboard/yes (additional cost) Cerner, Millenium, Sunquest, Soft, Mysis, etc.
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes no	yes no
How labs get LOINC codes for reagent kits	- <u> </u>	- <u>- </u>
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (host query)	yes (host query)
Interface available (or will be) to auto specimen handling system	yes no	yes no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/no	no/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer Mean time between failures/To repair failures	24 hrs	24 hrs 4 months/2 hrs
Onboard error codes to facilitate troubleshooting	— (recently launched)/— yes	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 5 min; weekly: 20 min; monthly: 20 min no/no	daily: 10 min; weekly: 20 min; monthly: 20 min no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	\$48,200/<350 beds \$9,000	\$76,660/>350 beds \$10,000
Training provided w/purchase/Advanced operator training	3 days on site/yes	3 days on site/no
Distinguishing features (supplied by yandar)	combined with the Inverses ELICA product line and the shifts to extends extends	anan DSY nightform anables austamare to run virtually any ELICA based asserts
Distinguishing features (supplied by vendor)	combined with the Inverness ELISA product line and the ability to automate enteric assays and front-end dilute Inverness AtheNA assays, the DS2 provides an efficient, open, fully automated solution for customers looking for laboratory automation	open DSX platform enables customers to run virtually any ELISA-based assay; modular design allows users to customize the system to their unique needs by adding extra incubators, incorporating a bar-code scanner, or choosing among certain types of sample racks; work list load wizard walks you through set up; shows graphically where to place your reagents, samples, and plates at the beginning of each run; complete daily maintenance in less than 5 min, including removal of consumables and
		rinsing the washer

Part 18 of 31	Ortho Clinical Diagnostics Kunal Chokshi kchokshi@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 908-218-8172 www.orthoclinical.com	Ortho Clinical Diagnostics Kunal Chokshi kchokshi@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 908-218-8172 www.orthoclinical.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	VITROS ECi Immunodiagnostic System/1997/U.S. U.S./U.K. $> 3,000$ worldwide cont. random access/floor standing/universal sample trays (circular) accommodate primary & secondsondary containers without need for adapters $51 \times 44 \times 29/8.9$	VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK >150 worldwide continuous random access/floor standing/universal sample trays (circular) accommodate primary & secondary containers without need for adapters 68 × 83.5 × 34.9/20.2
Tests available on instrument in U.S.	3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total β -hCG, estradiol, progesterone, LH, FSH, prolactin, N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, troponin I, aHBs, B12, folate, RBC folate, equimolar PSA, HBsAg, aHCV, HBsAg (conf.), myoglobin, aHBc, aHBc IgM, aHBs, testosterone, NT-proBNP, CA 19-9,	3rd-gen TSH, TT3, TT4, FT3, FT4, T3-uptake, total B-hCG, LH, FSH, CEA, AFP, ferritin, CK-MB, troponin I , NT-proBNP, equimolar PSA, myoglobin, B12, RBC folate, CA 19-9, CA 125 II, cortisol (serum, urine), testosterone, prolactin, estradiol, progesterone, rubella IgG, NTx, aHBs, HBsAg, HBsAg(conf), aHCV, aHBc, aHBc IgM, aHIV 1+2
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	aHAV total, aHAV IgM, rubella IgG, aHIV 1+2 —— aHBe , HBeAg aHBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM	— aHBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM —
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	iPTH, HIV Combo, syphilis (Ex-U.S.) NTx	iPTH, HIV Combo, aHBe (U.S.), HbeAg (U.S.), syphilis (Ex-U.S.) NTx
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 	no
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	chemiluminescence (enhanced)/individual coated microwell 20 20 programmed & calibrated at once; up to 25 lots calibrated per assay	chemiluminescence, enhanced chemiluminescence/coated microwell 31 31 programmed and calibrated at once, up to 25 lots calibrated per assay
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	0 20/100 56 days/56 days/yes (2°–8°C)	
Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	yes yes yes/test ID, expir., lot No., pack ID —/zero carryover 720/60/800 (with EPM—enhanced productivity module)	yes yes/test ID, expiration date, lot No., pack ID no/— varies/90/3,100
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	no/liquid no no 10 μL 10 μL/80 μL	closed/liquid no/— no/— 10 µL 10 µL/35 µL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no but it is available/no no/— 60 decibels no yes/mult. ped., microtainers & cups, 5 mL, 7 mL, 10 mL on same univ. sample tray/no	no/no no/— — no/— no/— yes/1.5 mL micro-collection containers, 0.5- and 2.0-mL cups, 5 mL, 7mL, 10 mL on
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes (2 of 5 interleaved, Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes yes/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes yes yes yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/	yes yes/yes no/no yes/yes no/no	yes yes/yes yes/yes yes/yes no/no
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	assay dependent yes 1–3 no/28 days	assay dependent yes 1–3 depending on assay no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes once per 24 hours yes/yes yes/yes/immediate upon completion of last sample metering	yes/yes once per 24 hours yes/yes —/—/0
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	24 minutes immediate upon completion of last sample metering 30/90 (40 seconds)	24 minutes immediate upon completion of last sample metering assay dependent/assay dependent (19 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	yes/yes onboard/no Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning	yes/yes yes, onboard and optional add-on (Data Innovations)/yes, additional cost Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability	yes yes yes (broadcast download)	yes no — yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	yes yes (all systems) yes/yes/yes no	yes yes, enGen yes/yes no
On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	<4 hours (contract dependent) —/dependent on corrective action yes daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes no/yes	<4 hours (contract dependent) dependent on corrective action/dependent on corrective action yes daily: 10 minutes; weekly: 25 minutes; monthly: 15 minutes yes, includes audit trail/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$140,000/flexible for majority of customer demand varies w/ service level choices 3.5 days at vendor offices/yes, as needed on site	—/350 tests per day varies —/yes
Distinguishing features (supplied by vendor)	uses proprietary Intellicheck technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce the potential of misreported results; IntelliReport provides real-time status and traceability on the quality of reported results; uses enhanced chemiluminescence, MicroWell technology; provides simple-to-use, fully automated, true random access stat testing for routine and specialty immunodiagnostic testing	diagnostic checks throughout sample and assay processing reduces misreported results; real-time status and traceability on the quality of reported results; fully automated, true random access stat testing for routine and specialty immunodiagnostic testing; single-use tips for sample and reagent metering eliminates carryover; measures and flags results, if hemolysis, icterus, and turbidity levels might affect results

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	Phadia	Phadia
	Nicole Vosters nicole.vosters@phadia.com	Nicole Vosters nicole.vosters@phadia.com
	4169 Commercial Ave., Portage, MI 49002	4169 Commercial Ave., Portage, MI 49002
Part 19 of 31	800-346-4364 www.phadia.us	800-346-4364 www.phadia.us
Name of instrument/First year sold/Where designed	Phadia Laboratory System 250/2004/Japan, Sweden	Phadia Laboratory System 1000/2003/Japan, Sweden
Country where manufactured/Where reagents manufactured	Japan, Sweden/Sweden	Japan, Sweden/Sweden
No. of units in clinical use in U.S./Outside U.S.		
Operational type/Model type/Sample handling system	continuous random access/floor standing/racks	continuous random access/floor standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	$73 \times 50 \times 30 + 26$ -in. wide computer stand/—	83×71×40 + 26-in. wide computer stand/—
Tests available on instrument in U.S.	hundreds of ImmunoCAP specific IgE allergens, ImmunoCAP total IgE, and Immu-	hundreds of ImmunoCAP specific IgE tests and ImmunoCAP total IgE
	noCAP TG and TPO tests. ELiA autoimmune products currently include: CCP, dsDNA,	, , , , , , , , , , , , , , , , , , ,
	Symphony ANA Screen, individual ENA's, Celikey IgA and IgG (tissue transglutami-	
Tacts cleared but not clinically released	nase), and gliadin IgA and IgG	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	— EliA cardiolipin IgG, EliA cardiolipin IgM, EliA β2-glycoprotein I IgG and	_
	EliA β2-glycoprotein I IgM, EliA gliadin DP IgA/IgG	
Tests not available in U.S. but available in other countries	EliA PR3S, EliA GBM, EliA MPO, EliA CTD Screen, EliA Cardioliopin IgA, EliA ß2 GPI IgA,	_
	EliA PM/Sc, EliA Fibrillarin, EliA RNA Pol III, EliA PCNA, EliAMi-2, EliA Borrelia, EliA M2,	
Research-use-only assays	EliA MPOS, EliA Anti-IgA	_
Tests in development	_	_
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers	Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays	Phadia US Inc. ImmunoCAP specific IgE blood tests
Fully outomated microplete quatern		
Fully automated microplate system No. of each analyte performed in separate disposable unit	<u>no</u>	no
No. of wells in microplate	_	_
Methods supported/Separation methods	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	3 methods not limited, though inventory manager software will instruct operator of reagent	3 methods not limited, though inventory manager software will instruct operator of reagent
or amorous accaso programmon cambiation at once	insufficiencies in the onboard inventory	insufficiencies in the onboard inventory
No. of user-definable (open) channels	0, closed system	0, closed system
No. of different analytes for which system accommodates reagent	3/400 or 100 depending on the conjugate type	3/400 or 100 depending on the conjugate type
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/1 year/yes (2°-8°C)	5 days/1 year/yes (2°-8°C)
Multiple reagent configurations supported	s days/1 year/yes (2*-8*C) yes	o days/ i year/yes (2'-8'0) ves
Reagent container placed directly on system for use	yes (wash solution requires preparation)	yes (wash solution requires preparation)
Reagents bar coded/Information in bar code	yes/product name, lot No., expiration date	yes/product name, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	no/zero carryover (disposable sample tips)
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	470/50 simultaneously/370 tests no/liquid	460/200 simultaneously/2,400 tests no/liquid
Uses disposable cuvettes/Max. No. stored	no	no
Uses washable cuvettes/Replacement frequency	_	_
Minimum specimen vol. required	40 µL for ImmunoCAP tests and 50 µL for EliA tests	40 µL per test
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 μL/40–200 μL for ImmunoCAP tests and 50 μL/50–200 μL for EliA tests (varies w/tube type)	40 μL/40–200 μL (varies with tube type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/10 L	no/10 L
Noise generated	65 decibels	68 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no ves/10-17 mm × 50-105 mm/no	no ves/10-17 mm × 50-105 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	no	no
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/yes	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	no/yes
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	no/no
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun	100 minutes	100 minutes
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	6 per analyte for calibration run, and 2 per analyte when using stored curve	6 per analyte for calibration run, and 2 per analyte when using stored curve
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days or sooner if conjugate lots change	yes/28 days or sooner if conjugate lots change
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes once per work shift (user defined)	yes/yes once per work shift (user defined)
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/30 minutes unattended	yes/yes/30 minutes unattended
Stat time to completion of 0 kgC test		
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample	— 6 minutes	— 6 minutes
Throughput per hour for three analytes on each specimen, in No. of	20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds)	80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds)
specimens/No. of tests (cycle time)		
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/yes onboard/yes (instrument side only)	yes/yes onboard/yes (instrument side only)
Interfaces up and running in active user sites with	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net,	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim,
3	Antrim, others	others
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no 	no
Bidirectional interface capability	yes (broadcast download & host query)	ves (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/Can diagnose own malfunctions/	yes/yes	yes/yes
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<24 hours	<24 hours
Mean time between failures/To repair failures	_/_ 	-/-
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes	yes daily: 1 minutes: weekly: 10 minutes: monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/—	daily: 1 minutes; weekly: 10 minutes; monthly: 15 minutes yes/—
List price/Targeted bed size or daily volume	\$75,000/>20,000–95,000 tests per year	\$235,000/>95,000 tests per year
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training		4.5 days at vendor offices/yes
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Distinguishing features (supplied by vendor)	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP
	family of products and autoimmune markers with the EliA family of products; innova-	family of products; innovative products, comprehensive clinical and technical
	tive products, comprehensive clinical and technical research, and extensive medical	research, and extensive medical information and education, make ImmunoCAP a
	information and education, makes ImmunoCAP a choice for IgE testing worldwide; 3 automated ImmunoCAP instruments offer labs the ability to measure and report	choice for IgE testing worldwide; three automated ImmunoCAP instruments offer laboratories the ability to measure and report specific IgE quantitative results
	specific IgE quantitative results accurately across the clinical range	accurately and precisely across the clinical range

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	Phadia	Radiometer Medical ApS
	Nicole Vosters nicole.vosters@phadia.com	info@radiometeramerica.com
Part 20 of 31	4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	810 Sharon Drive, Westlake, OH 44145 +1 (440) 871-8900 www.radiometeramerica.com
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Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	Phadia Laboratory System 100 ^E /1995/Sweden Sweden/Sweden	AQT90/2008/Denmark Denmark/Finland
No. of units in clinical use in U.S./Outside U.S.	-	_/_
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	batch/benchtop/carousel $18 \times 28 \times 24 + \text{computer/}{}$	random access/benchtop/inlet 17.7 × 18.1 × 18.9/2.4
Differences (ii × w × b)/iiisuument tootpinit iii sq. teet	10 × 20 × 24 + Computer/—	11.1 \(\) 10.1 \(\) 10.3/2.4
Tests available on instrument in U.S.	hundreds of ImmunoCAP specific IgE Allergens, ImmunoCAP total IgE, and	_
	ImmunoCAP TG and TPO tests. ELiA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, individual ANA's, Celikey IqA and IqG (tissue	
	transglutaminase), and gliadin IgA and IgG.	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	— EliA cardiolipin IgG, EliA cardiolipin IgM, EliA β2-glycoprotein I IgG and	
lests not available in 0.0. But submitted for olearance	EliA β2-glycoprotein I IgM, EliA gliadin DP IgA/IgG	
Tests not available in U.S. but available in other countries	EliA PR3S, EliA GBM, EliA MPO, EliA CTD Screen, EliA Cardioliopin IgA, EliA B2 GPI IgA, EliA PM/Sc, EliA Fibrillarin, EliA RNA Pol III, EliA PCNA, EliAMi-2, EliA Borrelia, EliA M2,	Tnl, CKMB, MYO, NT-proBNP, β hcG, CRP, D-dimer
	EliA MPOS, EliA Anti-IgA	
Research-use-only assays		
Tests in development	_	BNP, TnT, hsCRP, APTT, PT-INR
User-defined methods implemented for what analytes	-	_
Tests not available on other manufacturers' analyzers	Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays	_
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit No. of wells in microplate	_	_
Methods supported/Separation methods No. of different measured assays onboard simultaneously	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	time-resolve fluorescence/coated microwell 6
No. of different assays programmed, calibrated at once	7	6
No. of user-definable (open) channels	0, closed system	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	48–96 depending on the conjugate type	15/16
Shortest/Median onboard reagent stability/Refrigerated onboard	_	96 hours/7 days/no
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes (wash solution requires preparation)	yes yes
Reagents bar coded/information in bar code	yes/product name, lot No., expiration date	yes/lot number, expiry date, checksum, parameter code, cartridge ID
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	no/<100 ppm
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	180 minutes/varies with analyte/48 no/liquid	—/2/10 tests yes (home brew methods can be used)/dry
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	—/— 40 μL for ImmunoCAP tests and 50 μL for EliA tests	no/— 2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 μL/40–200 μL for ImmunoCAP tests and 50 uL/50–200 μL for EliA tests (varies with	2.5 µL/53.5 µL
Own lind with UDO (bushess over a 100 miles flow daily	tube type)	
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/1 L per run	no/no no/—
Noise generated	_	_
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/10-16 mm × 50-105 mm/no	no/— yes/11 × 66 to 13 × 78 mm/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container)	no 	
Measures No. of tests remaining/Short sample detection	no no/yes	yes yes/—
Auto detection of adequate reagent or specimen	yes	no /
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes no/no	—/no no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	no/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	— /—
Time between initial result & reaspiration of sample for rerun	2.5 hours-batch run	_
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 6 per analyte for calibration run, and 2 per analyte when using stored curve	— 2-level adjuster supplied in kit
No. or cambrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days or sooner if conjugate lots change	2-level adjuster, supplied in kit yes/once per lot
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	<u>-/-</u>
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	once per work shift (user defined) yes/yes	customer determined (longest interval: 1 per month) —/—
Automatic shutdown/Startup is programmable/Startup time	yes/yes/20 minutes including request entry or downloading	, —/—/30 minutes
Stat time to completion of β-hCG test	_	18 minutes
Time delay from ordering stat test to aspir. of sample	-	30 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	batch analyzer/48/180 minutes processing time for batch to finish	10/30
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes, instrument side only (included)	onboard/no
Interfaces up and running in active user sites with	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	_
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	<u>no</u>	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes ves	yes no
Modem servicing/Can diagnose own malfunctions/	yes yes/yes	yes/yes
Determine malfunctioning component Can order (via modern) malfunctioning part(c) w/o operator		
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no —, swap	no per negotiated contract
Mean time between failures/To repair failures	— / —	<u>-</u> /-
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes	yes —
Onboard maintenance records/Maintenance training demo module	yes/no	yes, includes auidt trail/no
List price/Targeted bed size or daily volume	\$22,000/>7,000-20,000 tests per year	—
Annual service contract cost (24 hours/7 days)		flexible options available
Training provided w/purchase/Advanced operator training	3.5 days at vendor offices/yes	_
Distinguishing features (supplied by vendor)	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP	POC instrument measures whole blood with lab quality; broad menu and parameter
	family of products and autoimmune markers with the EliA family of products; innova-	flexibility; closed tube and closed waste system
	tive products, comprehensive clinical and technical research, and extensive medical information and education, makes ImmunoCAP a choice for IgE testing worldwide;	
	3 automated ImmunoCAP instruments offer labs the ability to measure and report	
	specific IgE quantitative results accurately across the clinical range	

	ditomated immunoassay anaiy	
	Randox Laboratories Ltd.	Roche Diagnostics
	Gareth Soye evidence.support@randox.com 55 Diamond Road, Crumlin, County Antrim, BT29 40Y	Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46250
Part 21 of 31	0044 28 9442 2413 www.randox.com	800-428-5074 www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed	Evidence/2002/Northern Ireland	Elecsys 2010/1996/—
Country where manufactured/Where reagents manufactured	Northern Ireland/Northern Ireland	Japan/Germany
No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	8/27	>800/>6,000 cont. random access/benchtop/rack or disk
Dimensions in inches $(H \times W \times D)$ /Instrument footprint in sq. feet	batch/floor standing/carousel 68 × 78 × 39/22.75	22.1 × 47.2 × 28.7/9.4
	accoing methamphatamine DOD suitates complete the last to the control of the cont	
Tests available on instrument in U.S.	cocaine, methamphetamine, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol	ferritin, folate II, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, proges-
	progostorior, protectin, Err, Forr, container	terone, prolactin, SHBG, testosterone, total & βHCG, anti-TG, anti-TPO, FT3, FT4, T3,
		T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, HBsAg, HBsAg
		confirmatory, anti-HBs, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, anti-TSH receptor, anti-CCP
Tests cleared but not clinically released	_	_
Tests not available in U.S. but submitted for clearance	MDMA, LSD, fentanyl, propoxyphene, methaqualone, generic opioids, ketamine, buprenorphine	anti-HBc IgM, anti HCV, anti HAV IgM
Tests not available in U.S. but available in other countries	TT4, FT4, TT3, FT3, TSH, AFP, CEA, hCG, fPSA, tPSA, testosterone, CK-MB, cTNi,	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV IgM, anti-HBc, anti-Hbe, HBeAg, HIV
Research-use-only assays	myoglobin, FABP GPBB, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-3, IL-4, IL-6,	antigen, HIV antigen confirmatory, P1NP, 25-OH vitamin D3
nesedicii-use-viiiy assays	IL-7, IL-8, IL-10, IL-13, IL-23, IL-12p70, VEGF, TNFa, IFNg, IL-1a, IL-1b, MCP-1, EGF,	_
	GFAP, S100B, hsCRP, BDNF, D-dimer, NSE, NGAL, thrombomodulin, slL-2Ra, slL-6R,	
Tests in development	STNFRI, STNFRII, MMP-9, IL5, IL15, GMCSF, MIP-1α, TNFα, endocrine array IL1-1Ra, IGF-1 free, RANTES, PDGF-AA, PDGF-BB, eotaxin, IP-10, cortisol, DHEA-S,	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc,
Total III detalopment	leptin, 17-OH progesterone, IL12-p40, maternal screening array, sepsis array,	HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, HIV combi, He4, vitamin D 25-OH
Hear defined methods implemented for what analytes	metabolic arrays, and additional drugs-of-abuse arrays	toxo lgM, rubella lgM
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— GPBB, FABP, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-4, VEGF,	9-minute PTH, Tnt
·	IFNg, IL-1a, MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6r, sTNFRI, sTNFRII, MMP-9	
Fully automated microplate system	=	no
No. of each analyte performed in separate disposable unit	-	_
No. of wells in microplate	_	_
Methods supported/Separation methods	chemiluminescence/—	electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	8	15
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	12 0	60 0
No. of different analytes for which system accommodates reagent	96/360	15/100–200 tests per kit
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	accay danandant/1_1/ days/yes /2°_00°\	56 days/56 days/yes (20°C)
Multiple reagent configurations supported	assay dependent/1–14 days/yes (2°–8°C) yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/product component, size, lot No., expir. date	yes/calib. curve, application params., lot No., expir., reag. name no/zero carryover (disposable sample tips)
Walkaway capacity in minutes/Specimens/Tests-assays	100/180/540–1,080	120/disk: 30, rack: 100/180
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/— no/—	yes/180 no
Minimum specimen vol. required		10 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	7 μL/7–350 μL (varies with cup type) no/no	10 μL/100 μL yes/no
Requires dedicated water system/Water consumption	no/—	no/3 L for 250 tests
Noise generated	60 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/100 µL yes/12 mm, 16 mm/no	no ves/13–16 mm diam./no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container)	yes yes	yes yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes no trop	yes
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	no/yes no/no	yes/yes (with middleware) no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	yes/yes
Time between initial result & reaspiration of sample for rerun	12 min	_
Autocalibration or autocalibration alert No. of calibrators required for each analyte	no 9 (multi-analyte calibrators)	yes 2
Calibrants can be stored onboard/Avg. calibration frequency	yes/weekly (dependent on panel)	no/monthly
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes user defined	yes/yes once per 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/13 minutes	no/no/4 minutes
Stat time to completion of β-hCG test	_	9 minutes (hCG intact)
Time delay from ordering stat test to aspir of sample		42 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	108/324 (5 minutes)	30/88 (42 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/Randox, included in price yes	onboard/yes (additional cost) all major LISs
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no —	no
Bidirectional interface capability	yes (host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	no yes/yes	yes (CLAS & Roche task targeted automation) no/yes/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no <24 hours (contract dependent)	no <24 hours
Mean time between failures/To repair failures	-/- · · · · ·	-/-
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 min; weekly: 10 min; monthly: 30 min	yes daily: 1 minutes; weekly: 5 minutes; biweekly: 25 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	no/—	no/no (training CD-ROM)
List price/Targeted had size or daily values	contract dependent/500.	varies based on contract
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	contract dependent/500+ contract dependent	varies based on contract included w/ reagent rental
Training provided w/purchase/Advanced operator training	—/yes	3 days at Indianapolis offices/yes
Distinguishing features (supplied by vendor)	biochip enables simultaneous analysis of multiple parameters in a single patient sample;	liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic
, , , , , , , , , , , , , , , , , , , ,	max. throughput of 1,188 test results per hour; unreported tests can be retrieved retro-	ranges, and fast turnaround time, stat interrupt; onboard reag. storage; minimal
	spectively; arrays contain multiple tests applicable to clinical and research applications	maintenance

	utomateu immunoassay anaiy	
Part 22 of 31	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Nathan Patton nathan.patton@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	cobas e411/2006/Japan Japan/Germany —/—	MODULAR ANALYTICS E170/2001/Japan Japan/Germany >500/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)
Operational type/Model type/Sample handling system Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	continuous random access/benchtop/rack, disk 31.4 \times 47.2 \times 28.7 (disk); 31.4 \times 67 \times 37.4 (rack)/94 (disk), 17.4 (rack)	continuous random access/floor-standing/rack $47 \times 47 \times 31.5$ (Modular E configuration)/approx. 60 (one module system)
Tests available on instrument in U.S.	ferritin, folate II, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total & β HCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, total PSA (screening), free PSA, HBsAg, HBsAg conf, anti-HBs, anti-TSH receptor, anti-CCP	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and β hCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, HBsAg, HBsAg confirmatory, anti-HBs, toxo IgG, rubella IgG, anti-TSH receptor
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	anti-HCV anti HAV IgM, anti HbC IgM	anti-HCV anti HAV IgM, PCT, anti HbC IgM
Tests not available in U.S. but available in other countries	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, P1NP, 25-0H vitamin D3	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3
Research-use-only assays Tests in development	— interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, HIV combi, He4, vitamin D 25-OH toxo IgM, rubella IgM	— interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, anti-HBc, HBc IgM, HBeAg, anti-HBe, HIV combi, He4, vitamin D 25-OH, toxo IgM, rubella IgM
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	9-minute PTH and cardiac assays, 9-minute PTH, TnT	— TnT
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 	no
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	electrochemiluminescence, magnetic particle/magnetic particle 18 18	electrochemiluminescence/magnetic particle, electrochemiluminescence 25 per module, maximum of 60 25 per module
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	0 18/100–200 tests per kit	
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	—/56 days/yes (20°C) yes	14 days/35 days/yes (20° C) yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes yes/calib. curve, application params., lot No., expir., reag. name	yes yes/calib. curve, application params., lot No., expir., reag. name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	no/zero carryover (disposable sample tips) disk: 120/30/180; rack: —/100/18 no/liquid	-/zero, uses disposable sample tips 360/-/1,006 no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/360 assay tips; 180 assay cups no/—	yes/1,006 no
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	-10 μL 10 μL/100 μL	10 µL —/100 µL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/3 L for 250 tests	yes/yes yes/30 L per hour in full operation
Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	<70 decibels no veo/13, 16 mm diemeter/no	<65 decibels yes/100 µL yes/13 × 75 to 16 × 100/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes/13–16 mm diameter/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes yes/yes	yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/yes (with middleware)	yes yes/yes (with middleware)
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no yes/no	no/no yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/yes	yes/yes
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 2	yes 2
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/monthly for lot; weekly for rack	no/monthly yes/yes
How often QC required	yes/yes once per day	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes yes/no/4 minutes	yes/yes yes/yes/11 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	9 minutes 42 seconds 30/86 (42 seconds)	18 minutes — 56/176 (21 seconds)
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (additional cost) —	onboard/yes (addt'l cost) all major LISs
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labe get LOINC codes for reagent kits	yes no	yes no
How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) yes	yes (broadcast download & host query) yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes no/yes/no	yes (Roche MODULAR PRE-ANALYTICS systems and task targeted automation) yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures	no <24 hours	no ≤24 hours
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	—/— yes daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes no/no	—/— yes daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	varies based on contract/varies; primary IA system or back-up unit included with reagent rental 4 days on site/yes	varies, based on contract included with reagent rental 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAT; stat	expandable liquid ready-to-use reagents that are compatible with other Elecsys
	interrupt; minimal maintenance	systems, compatible with Pre-Analytic Automation; ECL technology provides broad measuring range and market, low-end sensitivity, troponin T, auto-rerun and dilute

Automated immunoassay analyzers

	Roche Diagnostics	Siemens Healthcare Diagnostics
	Sheila Brewer sheila.brewer@roche.com	Pamela Curtin pamela.curtin@siemens.com
David 00 - 6 0 4	9115 Hague Rd., Indianapolis, IN 46250-0457	1717 Deerfield Road, Deerfield, IL 60015
Part 23 of 31	800-428-5074 www.roche.com/labsystems/us	914-524-3824 diagnostics.siemens.com
Name of instrument/First year sold/Where designed	cobas e601/2006/—	Dimension Vista 500 Intelligent Lab System/2009/U.S.
Country where manufactured/Where reagents manufactured	Japan/Germany	U.S./U.S., Germany
No. of units in clinical use in U.S./Outside U.S.	>500/—	117/22
Operational type/Model type/Sample handling system	continuous random access/floor-standing/rack	continuous random access/floor standing/rack and aliquot plate system, batch
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	46.1×71.8×40/19.73	55.5 × 84.75 × 43.8/26
Tests available on instrument in U.S.	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-	>125 (includes vendor supported applications), 35 general chemistry,
	9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone,	16 immunoassay, 14 TDM, 17 DATs, 36 plasma proteins
	prolactin, SHBG, testosterone, total and β -hCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH,	
	T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps,	
	osteocalcin, carbamazepine, gentamicin, theophylline, tobramycin, valproic acid, vanco- mycin, cortisol, toxo IgG, rubella IgG, HBsAg, HBsAg conf, anti-HBs, total PSA (screening),	
	free PSA, anti-TSH receptor, 9-minute (STAT) assays for myoglobin, CK-MB, PTH, HCG, Tnl	
Tests cleared but not clinically released	anti-HCV	_
Tests not available in U.S. but submitted for clearance	anti HAV IgM, PCT, anti HbC IgM	_
Tests not available in U.S. but available in other countries	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc	PSA, FPSA, 4 IgG subclasses
	IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH	
	vitamin D3, HIV combi, He4, vitamin D 25-OH, toxo IgM, rubella IgM	
Research-use-only assays	—	—
Tests in development	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc,	CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins,
	HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, 9-minute (STAT) applications for TnT	hormones, infectious disease
User-defined methods implemented for what analytes		specialty chemistry, plasma proteins, TDMs, DATs
Tests not available on other manufacturers' analyzers	TnT	LOCI immunoassay, nephelometric assays, general chemistry
		your and a second and a second of goldenic orioninou y
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	_	_
No. of wells in microplate	-	-
<u> </u>		
Methods supported/Separation methods	electrochemiluminescence/magnetic particle	chemiluminescence, LOCI advanced chemiluminescence, EMIT, PETINIA, nephelometry/
		magnetic particle, homogeneous immunoassay
No. of different measured assays onboard simultaneously	25 per module	>100
No. of different assays programmed, calibrated at once	25 per module	>100
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent		10 >100/20 to 1,200
containers onboard at once/Tests per container set	25 per module/100 to 200	>100/20 to 1,200
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (20° C)	72 hours/30 days/yes (2°-8°C)
Multiple reagent configurations supported	yes	10 no
Reagent container placed directly on system for use	ves	ves
Reagents bar coded/Information in bar code	yes/calib. curve, application params., lot No., expir., reag. name	yes/test method, lot number, expiration date, number of tests
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/zero, uses disposable sample tips	yes/<1 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	360/300/1,000	>45/150/61,404
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,006	yes/>1,600
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic as needed
Minimum specimen vol. required	10 µL	50 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL/100 μL	50 uL/10 uL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption Noise generated	yes/up to 30 L/hour in full operation <65 decibels	no/20 L per hour <65 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/100 μL	no, can use small sample cup/10
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13×75 to 16×100/no	yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes (with middleware)	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/yes	can decrease, but cannot increase sample volumes
Time between initial result & reaspiration of sample for rerun	_	<2 minutes
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2	varies 2–6
Calibrants can be stored onboard/Avg. calibration frequency	no/every 28 days	yes/30 to 90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hours	once per 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/11 minutes	no/no/always ready
Stat time to completion of 0 k00 test	10 minutos	10
Stat time to completion of β -hCG test	18 minutes	10
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	42 seconds 56/176 (21 seconds)	<2 minutes 200/600 (variable 3.6 to 20 seconds)
specimens/No. of tests (cycle time)	00/110 (£1 000011d0)	200/000 (44/145/0 0.0 to 20 0000/140)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/Misys, Soft, Meditech, Cerner, others
Interfaces up and running in active user sites with	all major laboratory information systems	_
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	yes Wak aita	no
How labs get LOINC codes for reagent kits Bidirectional interface capability	Web site	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) yes	yes (droadcast download & nost query) ves
Interface available (or will be) to auto specimen handling system	yes (Roche Modular Pre-Analytics)	yes, StreamLAB automation system in development
Modem servicing/Can diagnose own malfunctions/	yes/yes/no	yes/yes/yes
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	≤24 hours	2 to 8 hours
Mean time between failures/To repair failures	- -	-/-
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 5 minutes.; weekly: 10 minutes; monthly: 15 minutes yes (includes audit trail of who replaced parts)/yes	daily: <10 min; monthly: 10 to 20 min
Onboard maintenance records/maintenance training demo module	yes (monuces audit trail of who replaced parts)/yes	no/yes
List price/Targeted bed size or daily volume	varies, based on contract/—	—/1,500 tests per day per system
Annual service contract cost (24 hours/7 days)		, 1,000 toolo poi uuy pei systeili —
Training provided w/purchase/Advanced operator training	5 days at vendor offices/yes	4 days on site, 4 days at vendor offices/yes
J. J		. , , ,
Distinguishing features (supplied by vendor)	ECL technology provides brand measuring ranges and low-end sensitivity; TnT; ready	ultra-integrated chemistry platform with LOCI advanced chemiluminescence, and
, , ,	to use bar-coded reagents compatible with other Elecsys Systems; compatible with	nephelometry onboard; enhanced workflow efficiency with automated features like
	Modular Pre-Analytics for walkaway automation	autocalibration and auto QC and system twinning; proactive service and support
		through RealTime Solutions

through RealTime Solutions

and "Bill Coal (120), and sign functions of the Part (120) and 150, and 150			
Courty of the control	Part 24 of 31	Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015	Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015
entire of the Big May 100 and Margin States and the Big Margin States	Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	Germany/U.S. >200/>400 batch, random access, continuous random access/benchtop/7 \times 12 position racks	Ireland/U.S. 475/425 continuous random access/floor standing/5-position multiple size rack or puck via ADVIA LabCell and WorkCell
entire of the Big May 100 and Margin States and the Big Margin States			
The control and only 100 to be an above of the countries	Tests cleared but not clinically released	cortisol, HAV IgM, HAV total, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc IgM, anti-HBc total, HCV, rubella IgG, rubella IgM, AFP, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAS, carbamazapine, digitoxin, digoxin, gentamicin, phenobarbitol, phenytoin, theophylline, tobramycin, valproic acid, vancomycin, cyclosporine, aTG, aTPO, FT3, FT4, TSH, 3g-TSH, T-uptake, total T3, total T4, iPTH, CA15-3, CEA, CA-125, PSA, cPSA, BR27-29, CA19-9, HER2/neu-serum — cyclosporine, DHEAS, SHBG, digitoxin, aTG, aTPO, TSH3 ultra, Her2/neu,	cortisol, HAV IgM, HAV total, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc IgM, anti-HBc total, HCV, eHIV, toxo IgG, toxo IgM, rubella IgG, rubella IgM, AFP, estradiol-6, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAS, carbamazapine, digitoxin, digoxin, gentamicin, phenobarbitol, phenytoin, theophylline, tobramycin, valproic acid, vancomycin, cyclosporine, aTG, aTPO, FT3, FT4, TSH, 3g-TSH, T-uptake, total T3, total
Since the production of implacement for want of analyzing by control a			_
Ber- office mission imbode impolemental enter and authorise of an authorise of mission at a	l	— CUDC toyo IgC toyo IgM D_dimor fDCA UDoAg anti-UDo oUIV	— CUDC proceeds tonin URAAs anti-URA FDSA D-timor
Fully administed micrographs systems recommended in promotion and the control of			– "
Note that submit performed in support disposation mittods of a stella in introduction about a proportion of personal properties in support and personal properties in the supp	Tests not available on other manufacturers' analyzers	cPSA, HER-2/neu	cPSA, Her2/neu
No. of different ancegoriament, callanched at concess of different ancegoriament, callanched and concess of a concessor or con	No. of each analyte performed in separate disposable unit	no _	_
No. of III fernet asseys programment, climated at once 1 150 to 100 150 to 10		· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·
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Contrains on short at a coordinate part configurations apported of the contrained of	No. of user-definable (open) channels	_` `	_
Shorted Michael and make of reagent at shallow free in partial from an analysis of short of shallow free in the shallow free i	, , , , , , , , , , , , , , , , , , , ,	15/50 to 100	30/50, 100, 200 tests per pack
Reageth act ordination in year for use Same capabilities when 36 yearly regards to sociologibility to carryove regards that cool federation are in year to specify the property of the same party of the specify of the	Shortest/Median onboard reagent stability/Refrigerated onboard		
Respects to code/difformation in the code Machinery spectry in minimes (Speciment) feets—swaps or a control of the prespect to speciment of the swaps of the prespect to pres			
Walksaws capacity in minutes/September (1965-assays) Zeptem is quep (from any matched can be supplied for year) Walksaws (1965) Walksaws (1965	Reagents bar coded/Information in bar code	yes/reagent ID, lot No., expiration date	yes/assay name, lot No., expiration date, pack ID, No. of tests
System is open (home-throw methods can be used), Liquid or dry system Uses washable counters/Replacement frequency Miniman specimes of the character frequency With IIVS (hockup power/Requires floor drin Requires deficiated water yestem/Water consumption Noise generated Has deficiated pediatrie sample cup/Deat vol. Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states Pirrors caps on primary tubes Primary take sampling flute states primary tubes Primary take sampling		•	
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Minimum sample vot. aspirate precisely at once/Minimum sample vot. aspirate processing on primary tubes aspirate proces			
Supplied with IPS (backup power)Requires floor drain Roles generated Requires dedicated by the system/Water consumption in the Requires dedicated polithic sample cup/Dead vol. Primary bitos sample floor scales. Primary tubos Sample sur-ode residencial cupatibility Auditoritations and the Regular Sample sur-ode residencial cupatibility Auditoritations and the Regular Sample sur-ode residencial cupatibility Auditoritations and the Regular Sample sur-ode residencial cupatibility Auditoritation and the Regular Sample sur-ode residencial cupatibility Auditoritation and the Regular Sample sur-ode residencial cupatibility Auditoritation and the Regular Sample sur-ode residencial sur-ode sur-o		· · · · ·	
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Has deficiently designed per curplicant vol. Financy tobe sampling fruse sizes Princes cape on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement pr CSL standard Auto/2A yes Onboard test ando inventory (electronic vol. in ordinate) Heavester No. In extra per deviction Auto detection of adequate reaguelity of specimen Auto-alterior post of speci	Requires dedicated water system/Water consumption		
Sample har-code roading capability/Autodiscrimination Person Code Sample har-code roading capability/Autodiscrimination Person Code Sample Autod Code Sample (Code Sample Code Sample Co		· F · · · · · · · · · · · · ·	
Bar-code placement por CLS standard AutoZA Measures No. of tests remaining/Short sample defection Measures No. of tests remaining/Short sample defection Auto defection of adequate reagent or specimen Unition of patient samples onbound/Automatic rem capability Hemolysis detection-quantitation Turbidly detection-quantitation Dilution of patient samples onbound/Automatic rem capability Hemolysis detection-claunitation/Turbidly detection-quantitation Dilution of patient samples onbound/Automatic rem capability Persys Sample vol. can be increased for rem unit-diliver and the increased for term unit-diliver and the increased for the increased for term unit-diliver and the increased			•
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Auto detaction of adequate magent or specimen (clied detaction/Reflex testing capability Hemolysis detection—quantitation/Turbidity detection—quantitation Dilution of patient samples on borar/fulculantation run quability Sample vol. can be increased to rerun out-of-linear range high results/ Increased for renun out-of-linear gap bor vestults Time between initial result it areaspiration of sample for rerun Autocalibration on autocalibration and read to return out-of-linear gap bor vestults Time between initial result it areaspiration of sample for rerun Autocalibration on autocalibration allert Ves			
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Increased to rerun out-of-linear range low results Time between infall result it reaspitation of sample for rerun Autocalibration or autocalibration alert Ves	Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Time between initial result & reaspiration of sample for rerun Autocalibration and rent was always and uncalibration and rent was between hours of autocalibration and results and transfer december of the property of the pr		yes/yes	no (does have autodilution)/no (does have autodilution)
No. of calibrators required for each analyte Calibrants can be stored onboard/Wultiple calibs, stored for same assay How often QC required Onboard real-time OCS/support multiple QC lot Nos, per analyte Automatic shutdown/Startup is programmable/Startup time Uses Lot Immediary from ordering stat test to aspir, of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of lest sists (yeld time) LIS interface operates simultaneously w/running assays Uses LONG to transmit orders and results Uses LONG to transmit orders and results How labs get LONG codes for reapent kits How l	Time between initial result & reaspiration of sample for rerun	20 seconds	15 seconds
Calibrats can be stored onboard/Ayc, calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay Multipoint calib. supported/Multiple calibs. supported/Multiple calibs. stored for same assay Multipoint calib. supported for same assay Multipoint calib. stored for same assay Multipoint cali			
How often QC required user defined 22 hours/24 hours Onboard real-time QC/Support multiple QC lot Nos. per analyte yes/yes yes/yes Automatic shuldown/Startup is programmable/Startup time 15.6 minutes 18 minutes Stat time to completion of β-hCG test 15.6 minutes 15.6 minutes Time delay from ordering stat test to aspit, of sample 15.6 minutes 15.6 minutes Throughput per hour for three analytes on each specimens/No. of tests (cycle time) 60/180 (20 seconds) 15.5 econds Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability furtiment vendor supplies LIS interface on Interfaces up and running in active user sites with yes/yes yes/yes Dawning, NLFC, DI, Triple G, and most other major vendors yes/yes yes/yes Uses LOINC to transmit orders and results — — Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Uses LOINC to desired to reagent kits — — — Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Uses LOINC to ransmit orders and results — — — Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Uses LOINC to desire fro	Calibrants can be stored onboard/Avg. calibration frequency	no/varies, avg. 21 days	no/average 28 days
Onboard real-time QCSupport multiple QC lot Nos, per analyte Automatic shutdown/Startup is programmable/Startup time Stat time to completion of Ij-hCG test Time delay from ordering stat test to aspir, of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LLS/Onboard capability review QC Data-management capability/Instrument vendor supplies LLS interface up and running in active user sites with Cemer, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors Uses LDMC to transmit orders and results Uses LDMC to transmit			
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results Now labs get LOINC codes for reagent kits Sidirectional interface expalability Nesults transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Nodem servicing/Can diagnose own maltrunctioning Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator Nean time between failures/To repair failures Nean time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module 15.6 minutes 15.6 minutes 15.6 minutes 15.6 conds 80/240/15 seconds 80/240/15	Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Time delay from ordering stat test to aspir of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Ohboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Ediferctional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via moden) malfunctioning part(s) w/o operator Near time between failures/To repair failures Near time between failures/To repair failures Near time between failures/To repair failures Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module 1 or 2 minutes 50 seconds 80/240/15 seconds 9/28/yes Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Daboradyes (LIS allowance) Determine maffunctorior and results 9 (ps (broadcast download & host query) 9 (ps (b	Automatic strutuown/startup is programmable/startup time	yes/yes/ <a minutes<="" td=""><td>nornornone, aiways ready</td>	nornornone, aiways ready
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interfaces up and running in active user sites with Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors LIS interface operates simultaneously w/running assays US ses LOINC to transmit orders and results no no lidirectional interface capability yes (broadcast download & host query) yes (broadcast download & host query) yes (broadcast download & host query) yes (proadcast download & host query) yes (proadcast download & host query) yes/postage and running in active user sites with no yes (broadcast download & host query) yes (proadcast download & host query) yes (proadcast download & host query) yes (proadcast download & host query) yes/postage and running in active user sites with no petermine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 4 hours, 24 hours max. 4-24 hours max Onboard error codes to facilitate troubleshooting yes Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module yes/yes yes/yes cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes yes yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes yes yes (proadcast download & host query) yes (proadcast download & host query) yes (proadcast download & host query) yes yes/yes/yes 10 10 10 10 10 10 10 10 11	Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	<1 to 2 minutes 50 seconds	15 seconds
Interfaces up and running in active user sites with Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors Uses LOINC to transmit orders and results no Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, antrin, Soft, CCA, Triple G, others yes Cerner, Misys, Meditech, McKesson, Citation, antrin, Soft, CCA, Triple G, others yes (broadcast download & host query) yes (broadcast download & h	Can auto transfer QC results to LIS/Onboard capability to review QC		
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results 100		Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare,	
How labs get LOINC codes for reagent kits — no Bidirectional interface capability yes (broadcast download & host query) yes (broadcast download & host query) yes (broadcast download & host query) Results transmitted to LIS as soon as test time complete yes yes Interface available (or will be) to auto specimen handling system no yes/ADVIA WorkCell, ADVIA LabCell, others Modem servicing/Can diagnose own malfunctions/ yes/yes/— yes/yes/yes Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator no On-site response time of service engineer 4 hours, 24 hours max. 4-24 hours max Mean time between failures/To repair failures not available/not available —/— Onboard error codes to facilitate troubleshooting yes Avg. time to complete maintenance by lab personnel daily: 15 minutes; weekly: 20 minutes; monthly; 30 minutes Onboard maintenance records/Maintenance training demo module yes/yes New Hord Total Complete maintenance training demo module yes/yes Hord Total Complete maintenance training demo module yes/yes No hord Total Complete maintenance training demo module yes/yes No hord Total Complete maintenance training demo module yes/yes No hord Total Complete maintenance training demo module yes/yes		yes	
Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module yes (broadcast download & host query) yes (broadcast download & host query) yes (broadcast download & host query) yes yes yes/ADVIA WorkCell, ADVIA LabCell, others yes/yes/yes no no no no no	How labs get LOINC codes for reagent kits	_	•
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module yes/yes no yes/ADVIA WorkCell, ADVIA LabCell, others yes/yes/yes no yes/yes/yes no no no 4-24 hours max 4-24 hours max —/— yes yes yes ves yes Avg. time to complete maintenance by lab personnel onboard maintenance records/Maintenance training demo module yes/yes yes/yes yes/yes	Bidirectional interface capability	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 4 hours, 24 hours max. Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Determine malfunctioning component 1 on 1 on 1 4-24 hours max 4-24 hours max /- 9 yes 4 ves 4 ves 4 ves 4 ours max 4-24 hours max /- 4 hours max 4-24 hours max /- 4 hours max /- 4 hours max /- Onboard error codes to facilitate troubleshooting 4 ves 4 ves 4 ves 4 ves 4 ves 4 ves 4 ves/yes 4 ves/yes 4 daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes 9 yes/yes	Interface available (or will be) to auto specimen handling system	no	yes/ADVIA WorkCell, ADVIA LabCell, others
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 4 hours, 24 hours max. Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module on no 4-24 hours max —/— yes yes yes daily: 15 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes yes/yes		yes/yes/—	yes/yes
Mean time between failures/To repair failures not available/not available ——— Onboard error codes to facilitate troubleshooting yes Avg. time to complete maintenance by lab personnel daily: 15 minutes; weekly: 20 minutes; monthly; 30 minutes daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes Onboard maintenance records/Maintenance training demo module yes/yes ——— daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes	Can order (via modem) malfunctioning part(s) w/o operator		
Onboard error codes to facilitate troubleshooting yes Avg. time to complete maintenance by lab personnel daily: 15 minutes; weekly: 20 minutes; monthly; 30 minutes daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes			
Onboard maintenance records/Maintenance training demo module yes/yes yes/yes	Onboard error codes to facilitate troubleshooting		yes daily: 3 minutes: weekly: 20 minutes: monthly: 20 minutes
	, , ,		
List price/Targeted bed size or daily volume denends on GPO affiliation/community bosnitals satellite labs \$225 000/2004 bads or 400 tacts nor day	List price/Targeted bed size or daily volume	depends on GPO affiliation/community hospitals, satellite labs	\$225,000/300+ beds or 400 tests per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training 3 days at vendor sites plus online training/yes 4.5 days on site/yes	Annual service contract cost (24 hours/7 days)		varies, GPO dependent
disposables, and reagents without pausing sampling or processing; onboard and reagents w/o pausing sampling or processing; onboard automatic dilutions, repeats, automatic dilutions, repeats, STATs and cascade reflex testing; disposable tips; uses STATs and cascade reflex testing; disposable tips; no start-up procedures; always ready; same reagents/consumables as ADVIA Centaur/ADVIA Centaur XP with concordant uses same reagents/consumables as Centaur CP w/concordant results; processes 240 tests	Distinguishing features (supplied by vendor)	disposables, and reagents without pausing sampling or processing; onboard automatic dilutions, repeats, STATs and cascade reflex testing; disposable tips; uses same reagents/consumables as ADVIA Centaur/ADVIA Centaur XP with concordant	STATs and cascade reflex testing; disposable tips; no start-up procedures; always ready; uses same reagents/consumables as Centaur CP w/concordant results; processes 240 tests/hour; avg. time first result ~18 min.; comprehensive hep. A, B, C, and HIV testing (incl. acute

Automated inimunoassay analyzers			
Part 25 of 31	Siemens Healthcare Diagnostics Colleen Grier colleen.m.grier@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 302-631-8773 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jason Ong jason.f.ong@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	Dimension Vista 1500 Intelligent Lab System/2006/U.S. U.S./U.S. and Germany 350/110	Dimension Xpand Plus Integrated Chemistry System/2004/U.S. U.S./U.S. —/—	
Operational type/Model type/Sample handling system Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	batch, random access continuous random access/floor standing/sample rack and aliquot plate system $55\% \times 84\% \times 43\%/26$	random access, cont. random access/floor-standing/racks $45\times51\times31 \text{ (without monitor)/10.6}$	
Tests available on instrument in U.S.	>125 (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4 cardiac, 14 TDM, 17 DATs, 36 plasma proteins, 3 anemia, 2 cancer markers (AFP, CEA), fertility (HCG)	thyronine uptake, total T4/thyroxine, triiodothyronine, cardiac troponin I, ferritin, free PSA, free T4/thyroxine, human chorionic gonadotropin hormone, mass CK-MB, myoglobin, NT-pro BNP, thyroid stimulating hormone, total PSA CardioPhase hsCRP, complement C3, complement C4, C-reactive protein, C-reactive protein extended range, IgA, IgG, IgM, transferrin, cyclosporine extended range, hemoglobin A1c, carbamazepine, cyclosporine, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomy-	
Tests cleared but not clinically released	_	cin, valproic acid, acetaminophen, ethyl alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricylic antidepressants, myeloperoxidase, sirolimus, others	
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays	PSA, FPSA, 4 IgG subclasses	_ _ _	
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease TDM, DAT LOCI technology, nephelometry, general chemistry	mycophenolic acid — performs heterogeneous immuno. & general assays on single platform—fully auto. ISD assays	
·			
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no _/	no 	
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	chemiluminescence, enzyme immunoassay, ACMIA, EMIT, LOCI, PETINIA, NEPH/none >100 >100 10 >100/20 to 1,200	ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle 91 190 10 47/15–360	
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	72 hours/30 days/yes (2°–8°C) no yes	48 hours/30 days/yes (2°–8°C) yes yes	
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryove Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	yes/test ID, lot No., individual-sequence No., exp. date r yes/<1 ppm >45/150/61,404 yes/liquid yes/>2,000	yes/lot No., unique flex ID, stability, expiration date yes/— due to probe washing can be hours/60/>2,000 yes/reconstitutes onboard, no reagent prep required by operator/liquid yes/12,000	
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated	yes/automatic, as needed 2 μL analytical, 50 μL aliquot 2 μL (GLU=1.2)/20 μL yes/no no/20 L per hour 67 decibels	no/— 2 µL 2 µL/ 2 µL/ yes/no yes/no yes/up to 2 L per hours <70 decibels	
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	no (can use small sample cup)/10 µL yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no yes (2 of 5 interleaved, Codabar, codes 39 &128)/yes yes	no/can use small sample cup/10–20 μL yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes	
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes yes/yes yes yes/yes yes/yes	yes yes/yes yes no/yes yes/yes	
Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	yes/yes no/no (does have autodilution) <2 min	yes/yes yes/yes <20 seconds	
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes varies, 2–6 yes/30–90 days yes/yes shortest interval: 24 hours/—	yes varies—3 levels for most assays yes (Na, K, CI)/most 90 days yes/yes 24 hours	
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes no/no/always ready	no/yes not required	
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	10 minutes <2 minutes 200/600 (variable 3.6–20 seconds)	16 minutes 24 seconds up to 83/up to 250 (14.4 seconds)	
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	yes/yes yes/yes Mysis, Soft, Meditech, Cerner, others	yes/yes optional/yes (additional) all major LIS vendors	
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability	yes no — yes (breedeast daymland 8 hast guery)	yes no	
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes (broadcast download & host query) yes yes (StreamLab, ADVIA LabCell in development) yes/yes/yes	yes (broadcast download & host query) yes yes yes/yes/yes	
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	no 2–8 hours —/— yes	no 2-8 hours / yes	
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: <10 minutes; weekly: none; monthly: 10–20 minutes no/no/yes	daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes	
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$552,240/>4,000 tests per day inquire 4 days on site, 4 days at vendor offices/yes	—/— multiple types 5 days on site; 4 days at vendor offices/no	
Distinguishing features (supplied by vendor)	homogeneous LOCI tech. for high-sensitivity IA assays; fast analytical time, 10-min. cardiac markers, 21-min. anemia methods; ultra-integrated platform w/nephelometry eliminates sample sharing/splitting and streamlines lab workflow; can be configured as a Dimension Vista 3000T twin system; enhances operator efficiency with automatic calib. & AC processing; support through RealTime Solutions	consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet more than 95 percent of testing needs; eliminates sample splitting, aliquotting	

Automated inimaneassay analyzers			
	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics	
	Christina Tassone christina.tassone@siemens.com	Christina Tassone christina.tassone@siemens.com	
Part 00 at 04	1717 Deerfield Rd., Deerfield, IL 60015	1717 Deerfield Rd., Deerfield, IL 60015	
Part 26 of 31	800-242-3233 www.siemens.com/diagnostics	800-242-3233 www.siemens.com/diagnostics	
Name of instrument/First year sold/Where designed	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension	Dimension EXL with LM Integrated Chemistry System/2009/U.S.	
i i	RxL Integrated Chemistry System/1997/U.S.	• • • •	
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.	
No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	—/— batch, random access, cont. random access/floor-standing/racks	—/— batch, random access, continuous random access/floor standing/racks	
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	44 × 62.5 × 30.5/13.2	49 × 82 × 44 (without monitor)/25.1	
		,	
Tests available on instrument in U.S.	thyronine uptake, total T4/thyroxine, triiodothyronine, cardiac troponin I, ferritin,	CardioPhase hsCRP, ferritin, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin,	
	free PSA, free T4/thyroxine, human chorionic gonadotropin hormone, mass CK-MB, myoglobin, NT-pro BNP, thyroid stimulating hormone, total PSA CardioPhase hsCRP,	ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine,	
	complement C3, complement C4, C-reactive protein, C-reactive protein extended	lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus,	
	range, IgA, IgG, IgM, transferrin, cyclosporine extended range, hemoglobin A1c,	theophylline, tobramycin, vancomycin, valproic acid, hemoglobin A1c, thyronine uptake,	
	carbamazepine, cyclosporine, digoxin, digitoxin, gentamicin, lidocaine, lithium,	total T4, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, LOCI free thyroxine, LOCI	
	N-acetylprocainamide, phenobarbital, phenytoin, procainamide,tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, acetaminophen, ethyl	thyroid stimulating hormone, LOCI cardiac troponin I, LOCI LV NT-pro BNP, urine screens: amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine metabolite, metha-	
	alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricylic	done, opiates, phencyclidine; serums: TCA, barbiturates, benzodiazepine; propoxyphene,	
Toda alasmed but and allering the males and	antidepressants, myeloperoxidase, sirolimus, others	methaqualone, C3, C4, IgA, IgG, IgM, transferrin, general chemistry menu, sirolimus	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance		_	
Tests not available in U.S. but available in other countries	_	_	
Research-use-only assays			
Tests in development User-defined methods implemented for what analytes	mycophenolic acid —	LOCI free T3, LOCI B12, LOCI folate, MPA, total PSA, free PSA —	
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on a single	system performs homogeneous LOCI and heterogeneous immunoassays plus complete	
•	platform—fully automated ISD assays	routine gen. chemistry menu on single platform; fully auto., no-pretreatment ISD assays	
Fully automated microplate system	no	no	
No. of each analyte performed in separate disposable unit	-	-	
No. of wells in microplate	-	-	
Methods supported/Separation methods	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle	chemiluminescence, enzyme immunoassay, LOCI, ACMIA, EMIT, PETINIA, photometry,	
outous supportour sopuration initiations		potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous	
No. of different measured assays onboard simultaneously	91 (with optional reagent management system)	91	
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	190 10	190 10	
No. of different analytes for which system accommodates reagent	10 Max=47, Max Suite=91/15 to 360	91/15–360	
containers onboard at once/Tests per container set	·		
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/30 days/yes (2°–8°C)	72 hours/30 days/yes (2°–8° C)	
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes	yes placed directly on system	
Reagents bar coded/Information in bar code	yes/lot No., unique flex ID, stability, expiration date	yes/lot No., unique flex ID, stability, expiration date	
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/— due to probe washing	yes/none (due to probe washing)	
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	can be hours/60/>2,000/>5,000 yes/no reagent prep required by operator for liquid	can be hours/60/>2,000 yes/liquid, reconstitutes on board (no reagent prep required by the operator)	
Uses disposable cuvettes/Max. No. stored	yes/no reagent prep required by operator for inquid yes/12,000	yes/nquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000	
Uses washable cuvettes/Replacement frequency	no/—	no/—	
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 μL 2 μL/primary tube capable	2 μL	
Supplied with UPS (backup power)/Requires floor drain	2 μι/primary tube capable ves/no	2 μL/primary tube capable yes/no	
Requires dedicated water system/Water consumption	yes/3 L per hour/up to 5 L per hour	yes/up to 5 L	
Noise generated	<70 decibels	<75 decibels	
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–20 µL yes/5, 7, 10 mL/no	yes/30 µL yes/5, 7, 10 mL/no	
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	
Bar-code placement per CLSI standard Auto2A	yes	yes	
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes vec/ves	yes vec/ves	
Auto detection of adequate reagent or specimen	yes/yes yes	yes/yes yes	
Clot detection/Reflex testing capability	no/yes	no/yes	
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	yes/yes	
Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/	yes/yes yes/yes	yes/yes yes/no	
Increased to rerun out-of-linear range low results			
Time between initial result & reaspiration of sample for rerun	<20 seconds	<20 seconds	
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes varies—3 levels for most assays	yes varies (3 levels for most assays)	
Calibrants can be stored onboard/Avg. calibration frequency	yes (Na, K, CI)/most 90 days	yes (NA, K, CI)/most 90 days	
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hours no/yes	24 hours or with lot change no/yes	
Automatic shutdown/Startup is programmable/Startup time	not required	no/no/not required	
	·	·	
Stat time to completion of β -hCG test Time delay from ordering stat test to senir of sample	16 minutes 24 seconds	16 minutes 24 seconds	
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	24 seconds up to 166/up to 500 (7.2 seconds)	24 seconds up to 146/437 (7.2 seconds)	
specimens/No. of tests (cycle time)			
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes optional/yes (additional cost)	yes/yes onboard ontional add-on (Facul ink Informatics System)/yes (additional cost)	
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	optional/yes (additional cost) all major LIS vendors	onboard, optional add-on (EasyLink Informatics System)/yes (additional cost) all major LIS vendors	
LIS interface operates simultaneously w/running assays	yes	yes	
Uses LOINC to transmit orders and results	no	no	
How labs get LOINC codes for reagent kits Bidirectional interface capability	ves (broadcast download & host query)	yes (broadcast download, host query)	
Results transmitted to LIS as soon as test time complete	yes	yes (aroundad; most query)	
Interface available (or will be) to auto specimen handling system	yes	yes	
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes	
Can order (via modem) malfunctioning part(s) w/o operator	no	no	
On-site response time of service engineer	2–8 hours	2–8 hours	
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	—/— yes	—/— yes	
Avg. time to complete maintenance by lab personnel	daily: 5 minutes, weekly: 10 minutes, monthly: 15 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes	
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no	
List price/Tarneted had size or daily values		_	
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	—/— multiple types	multiple types	
Training provided w/purchase/Advanced operator training	5 days on site, 4 days at vendor offices/yes	yes (5 days on site, 4 days at vendor offices)/no	
		analyzas intermetes harmanana 1001 and but any	
		anguizor integrates nomegonogue I III'l and heterogeneous immunecessus enhand w/	
Distinguishing features (supplied by vendor)	analyzer integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates	analyzer integrates homogeneous LOCI and heterogeneous immunoassays onboard w/ other chemistries: allows single platform for >95 percent of most tests: eliminates sample	
Distinguishing features (supplied by vendor)	analyzer integrates neterogeneous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	other chemistries; allows single platform for >95 percent of most tests; eliminates sample splitting between gen. chemistry tests and immunoassays; fully auto. onboard ISD assays	

Siemens Healthcare Diagnostics Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 1717 Deerfield Road, Deerfield, IL 60015 Part 27 of 31 914-631-8000 www.siemens.com/diagnostics 914-524-3828 www.siemens.com/diagnostics Name of instrument/First year sold/Where designed IMMULITE 1000/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S. IMMULITE 2000/1998/U.S. Country where manufactured/Where reagents manufactured U.S./U.S., U.K. U.S./U.S., U.K. >5,500 worldwide No. of units in clinical use in U.S./Outside U.S. >7,000 worldwide Operational type/Model type/Sample handling system continuous random access/benchtop/loading platform continuous random access/floor-standing/rack Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet $19\times46\times26/7.98$ $47\times60\times30/12.5$ 3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, Tests available on instrument in U.S. 3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, anti-HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcitonin, canine TLI, anti-HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcicanine total T4, canine TSH, carbamazepine, CEA, CK-MB, CMV IgG, cortisol, C-peptide, tonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CKMB, cortisol, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, C-peptide, DHEA-SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, growth hormone (hGH), H. pylori IgG, HBs Ag, HBs Ag confirmatory, HCG, herpes I & II IgG, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori lgG, HBs Ag, HBs Ag high sensitivity CRP, homocysteine, IGFBP-3, IGF-I, insulin, intact PTH, LH, microalbumin, confirmatory, HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I myoglobin, OM-MA (CA 125), PAP, phenobarbital, phenytoin, progesterone, prolactin, PSA, insulin, intact PTH, LH, microalbumin, myoglobin, OM-MA (CA 125), PAP, phenobarbital, PYRILINKS-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, phenytoin, progesterone, prolactin, PSA, PYRILINKS-D, rapid TSH, RBC folate, theophylline, 3gPSA, 3gTSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gG TSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma testosterone, toxoplasma quant, IqG, Troponin I, Unconjugated Estriol, Valproic Acid, Vitamin B12; Turbo STAT menu: CK-MB, HCG, Intact PTH, Myoglobin, Troponin I, others IgM, toxoplasma quant. IgG, troponin I, unconjugated estriol, valproic acid, others Tests cleared but not clinically released none none Tests not available in U.S. but submitted for clearance GI-MA (CA 19-9), nicotine metabolite, free $\beta\text{-hCG},$ IL-6, IL-8, IL-10, LBP, PAPP-A, osteo-GI-MA (CA 19-9), nicotine metabolite, free β -hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, Tests not available in U.S. but available in other countries osteocalcin, NT-proBNP, CMV IgM, ECP, cannabinoids (THC), D-dimer calcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer Research-use-only assays Tests in development D-dimer, turbo D-dimer, CMV IgM anti-CCP IgG, D-dimer, CMV IgM, HBsAb quantitative, EBV-EBNA IgG, EBV-VCA IgG, EBV-VCA IgM, lyme screen User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers IGF-I, IGFBP-3, androst., 3rd-gen PSA, gastrin, canine TLI, canine TSH 3gPSA, IGF-I, IGFBP-3, H. pylori IgG , androst., gastrin, canine TLI, canine TSH Fully automated microplate system no no No. of each analyte performed in separate disposable unit No. of wells in microplate Methods supported/Separation methods chemiluminescence/bead, centrifugation chemiluminescence/bead, centrifugation No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once unlimited unlimited No. of user-definable (open) channels No. of different analytes for which system accommodates reagent 12; 5 for Turbo/100; 50 for Turbo i-PTH 24/200 containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard -/30 days/yes (15°C) —/90 days/yes (4°C) Multiple reagent configurations supported yes yes Reagent container placed directly on system for use yes yes yes/test, lot No., expir. yes/test, lot No., expir. Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover no/<10 ppm no/<3 ppm 300/90/1,300 Walkaway capacity in minutes/Specimens/Tests-assays 100/—/70 System is open (home-brew methods can be used)/Liquid or dry system no/liquid no/liquid Uses disposable cuvettes/Max. No. stored yes/1,300 ves/-Uses washable cuvettes/Replacement frequency no Minimum specimen vol. required 5 μL 5 μL to 100 μL sample Minimum sample vol. aspirated precisely at once/Min. dead vol. 5 μL/50 μL 5 μL/100 μL Supplied with UPS (backup power)/Requires floor drain yes/no yes/no Requires dedicated water system/Water consumption no/0.5 L per hour no/— 55-68 decibels 52 decibels Noise generated yes/50 µL Has dedicated pediatric sample cup/Dead vol. no/-Primary tube sampling/Tube sizes/Pierces caps on primary tubes no/—/yes/75-100 mm height; 12-16 mm width/no Sample bar-code reading capability/Autodiscrimination yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes Bar-code placement per CLSI standard Auto2A yes Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection yes/yes yes/yes Auto detection of adequate reagent or specimen yes Clot detection/Reflex testing capability no/no yes/yes Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability ves/no yes/yes Sample vol. can be increased to rerun out-of-linear range high results/ no/no no/no Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun min. 18 seconds Autocalibration or autocalibration alert No. of calibrators required for each analyte 2-level adjustors, supplied in kit 2-level adjustors, supplied in kit Calibrants can be stored onboard/Avg. calibration frequency no/1-4 weeks (assay dependent); 2 weeks for Turbo no/1-4 weeks (assay dependent) Multipoint calib. supported/Multiple calibs. stored for same assay no/ves yes/yes How often QC required cutomer determined customer determined Onboard real-time QC/Support multiple QC lot Nos. per analyte no/yes yes/yes yes/no/4 minutes Automatic shutdown/Startup is programmable/Startup time no/no/5 minutes Stat time to completion of $\beta\text{-hCG}$ test 42 minutes; 15 minutes for Turbo (total hCG) 35 minutes (total HCG) Time delay from ordering stat test to aspir. of sample 2.5 minutes 18 seconds Throughput per hour for three analytes on each specimen, in No. of 120/120 (---) 200/200 (18 seconds) specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface onboard/yes (additional cost) onboard/yes (additional cost) CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, others Interfaces up and running in active user sites with Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits yes (broadcast download & host query) Bidirectional interface capability yes (broadcast download & host query) Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system yes (universal interface) Modem servicing/Can diagnose own malfunctions/ yes/yes/no yes/yes/yes **Determine malfunctioning component** Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 4 hours 4 hours Mean time between failures/To repair failures 10 months/4 hours 3 months/5 hours Onboard error codes to facilitate troubleshooting daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20 to 30 minutes Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module List price/Targeted bed size or daily volume \$75,000; Turbo: \$77,500/>1,000 tests per month \$124,500/>6,000 tests per month \$16.500 (RealTime Solutions) Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training varies on site, 5 days at vendor offices/yes 3.5 days at vendor offices/yes Distinguishing features (supplied by vendor) system reliability and performance; large test menu high-throughput system, combines specific allergens & routine esoteric testing on one platform; clot detection; sample/reagent level detection; autodilution & autoreflex testing; remote diagnostics; QM & logistics reports

Automated inimaneassay analyzers			
	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics	
	Martu Richards martu.richards@siemens.com	Christina Tassone christina.tassone@siemens.com	
	1717 Deerfield Road, Deerfield, IL 60015	1717 Deerfield Rd., Deerfield, IL 60015	
Part 28 of 31	914-631-8000 www.siemens.com/diagnostics	800-242-3233 www.siemens.com/diagnostics	
Name of instrument/First year sold/Where designed	IMMULITE 2500 SMS/2004/U.S.	Stratus CS Acute Care Diagnostic System/1998/U.S.	
Country where manufactured/Where reagents manufactured	U.S./U.S., U.K.	U.S./U.S.	
No. of units in clinical use in U.S./Outside U.S.	>600 worldwide	-/-	
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack	random access/benchtop/whole blood collection tube	
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	79×112×40/30.69	18×27×22/4.1	
Tests available on instrument in U.S.	3gAllergy specific IgE, ACTH, AFP, androstenedione, Anti-TG Ab, Anti-TPO Ab, beta-2	mass CK-MB, myoglobin, β-hCG, D-dimer, NT-proBNP, high-sensitivity troponin I,	
1000 0100000 0100000 0100000 0100000 0100000 0100000 01000000	microglobulin, BR-MA (CA15-3), calcitonin, carbamazepine, CEA, CK-MB, CMV IgG,	CardioPhase hsCRP	
	cortisol, C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free T3, free		
	T4, FSH, gastrin, growth hormone (hGH), H. <i>pylori</i> IgG, HCG, herpes I & II IgG, high		
	sensitivity CRP, IGFBP-3, IGF-1, insulin, intact PTH, LH, microalbumin, myoglobin, OM- MA (CA125), phenobarbital, phenytoin, progesterone, prolactin, PSA, Pyrilinks-D, rapid		
	TSH. RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA,		
	3gTSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone,		
	toxoplasma IgM, toxoplasma quant. IgG, troponin I, turbo CKMB; Turbo STAT menu:		
Tasks along a but not all along the coloured	Intact PTH, myoglobin, troponin I, unconjugated estriol, valproic acid, vitamin B12		
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	none —		
Tests not available in U.S. but available in other countries	GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteo-	_	
	calcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer		
Research-use-only assays	_	_	
Tests in development	_	_	
User-defined methods implemented for what analytes	none	_	
Tests not available on other manufacturers' analyzers	3gPSA, IGF-I, IGFBP-3, H. <i>pylori</i> IgG , androst., gastrin, canine TLI, canine TSH	_	
Fully automated microplate system	no	no	
No. of each analyte performed in separate disposable unit No. of wells in microplate			
no or none in illuropiate			
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	fluorescence, EIA, dendrimer technology/fiber matrix filter	
No. of different measured assays onboard simultaneously	24	up to 4	
No. of different assays programmed, calibrated at once	unlimited	1	
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent		0 up to 4 TestPaks/unit dose TestPak	
containers onboard at once/Tests per container set	24/200	up to 4 least and unit door lead an	
Shortest/Median onboard reagent stability/Refrigerated onboard	—/90 days/yes (4°C)	_	
Multiple reagent configurations supported	yes	yes	
Reagent container placed directly on system for use	yes yes/test, lot No., expiration	yes	
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<3 ppm	yes/assay ID, lot No., expir., calib. param. no/zero carryover	
Walkaway capacity in minutes/Specimens/Tests-assays	300/275/1,300	14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4	
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid	
Uses disposable cuvettes/Max. No. stored	yes/1,300	no	
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 5 µL to 100 µL sample	no 2.5 mL whole blood	
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/50 μL	50-90 μL/—	
Supplied with UPS (backup power)/Requires floor drain	yes/no	optional/no	
Requires dedicated water system/Water consumption	no/—	no/—	
Noise generated	52 decibels	<65 decibels	
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/50 µL yes/75–100 mm height; 12–16 mm width/no	no yes/4 or 5 mL/yes	
Sample bar-code reading capability/Autodiscrimination	yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	
Bar-code placement per CLSI standard Auto2A	yes	yes	
Onboard test auto inventory (determines vol. in container)	yes		
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	yes/yes yes	—/yes yes	
Clot detection/Reflex testing capability	yes/yes	yes/no	
Hemolysis detection-quantitation/Turbidity detection-quantitation	_/_	not affected	
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no	
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	
Time between initial result & reaspiration of sample for rerun	min. 18 seconds	_	
Autocalibration or autocalibration alert	yes	yes	
No. of calibrators required for each analyte	2-level adjustors, supplied in kit	1 Calpak	
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/1–4 weeks (assay dependent) yes/yes	no/30–90 days same lot, new lot yes/yes	
How often QC required	customer determined	shortest interval: daily electronic QC, longest: every 30 days for liquid controls	
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	
Automatic shutdown/Startup is programmable/Startup time	yes/no/4 minutes	no/no/30 minutes to warm up	
Stat time to completion of β-hCG test	15 minutes (total HCG)	14 minutes	
Time delay from ordering stat test to aspir. of sample	18 seconds	immediately	
Throughput per hour for three analytes on each specimen, in No. of	200/200 (18 seconds)	3/9	
specimens/No. of tests (cycle time)	venhun	venhan	
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/yes onboard/yes (additional cost)	yes/yes yes/yes (additional cost)	
Interfaces up and running in active user sites with	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	all major LIS vendors	
LIS interface operates simultaneously w/running assays	yes	yes	
Uses LOINC to transmit orders and results	no	no	
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (broadcast download & host query)	— no	
Results transmitted to LIS as soon as test time complete	yes (broducast download & nost query) yes	yes	
Interface available (or will be) to auto specimen handling system	yes (universal interface)	no	
Modem servicing/Can diagnose own malfunctions/	yes/yes	no/yes/yes	
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	no	no	
On-site response time of service engineer	4 hours	2 to 8 hours	
Mean time between failures/To repair failures	3 months/5 hours	>225 days/2.9 hours	
Onboard error codes to facilitate troubleshooting	yes	yes	
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20 to 30 minutes no/yes	daily: none; weekly: none; monthly: 10 minutes no/yes	
Substantial Industriance records/maintenance training utility intoutie	110/ 300	110/ 100	
List price/Targeted bed size or daily volume	\$200,000 includes SMS & RealTime Solutions/200+ beds	—/any size emergency department	
Annual service contract cost (24 hours/7 days)	\$21,500 (RealTime Solutions with SMS)	multiple types	
Training provided w/purchase/Advanced operator training	varies on site, 5 days at vendor offices/yes	3 days on site/no	
Distinguishing features (supplied by vendor)	large automated IA test menu; 15-minute stat assays, flexible sample handling,	whole blood collection tubes or precentrifuged plasma; onboard centrifugation; unit-dose	
	user-definable testing; runs specific allergen testing alongside routine IAs; flexible	test packs; color-coded calibrators packaged on Calpacks; diluent packs; self-contained	
	connectivity to automation via SMS; autoreflex, autodilute; QM and logistics reports	system; closed container sampling; electronic QC; POCT1-A compliant when interfaced to	
		Telcor or MAS Data Managers; also available as the Stratus CS Kiosk System, a standalone	
		workstation featuring its own cart, refrigerator, & uninterruptible power supply	

	Siemens Healthcare Diagnostics	TOSOH Bioscience Inc.
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Part 29 of 31	914-631-8000 www.siemens.com/diagnostics	800-248-6764 www.tosoh.com
Name of instrument/First year sold/Where designed	IMMULITE 2000 XPi Immunoassay System*/2009/U.S.	AIA-2000/2008/Japan
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	U.S./Wales, UK —/—	Japan/Japan 5/75
Operational type/Model type/Sample handling system	random access/floor standing/rack	continuous random access/floor standing/rack, sorter drawer
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	47 × 60 × 30/12.5	49.6 × 59.1 × 35.7/14.66
Tests available on instrument in U.S.	3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, anti-	TSH 3rd-Gen, TSH, FT4, FT3, T4, T3, T-uptake, TPOAb, TgAb, bHCG, estradiol, FSH, LH,
	HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcitonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CK-MB, cortisol, C-peptide, DHEA-	progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, beta 2 microglobulin, C-peptide, cortisol, hGH, IgEII, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen, ferritin, folate,
	SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH,	B12, testosterone, CA 19-9, intact PTH, RBC folate
	gastrin, growth hormone (hGH), H. <i>pylori</i> IgG, HBs Ag, HBs Ag confirmatory, HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I, insulin, intact PTH, LH,	
	microalbumin, myoglobin, OM-MA (CA 125), PAP, phenobarbital, phenytoin, progesterone,	
	prolactin, PSA, PYRILINKS-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gG TSH, thyroglobulin, thyroid uptake, total IgE, total	
	T3, total T4, total testosterone, toxoplasma IgM, toxoplasma quant. IgG, troponin I, uncon-	
Tests cleared but not clinically released	jugated estriol, valproic acid, vitamin B12, syphilis, HBsAg express (hotzone), others —	_
Tests not available in U.S. but submitted for clearance		cystatin C and HbA1c
Tests not available in U.S. but available in other countries	GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteo- calcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer	BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen, PSA II
Research-use-only assays		ACTU and DUFA C
Tests in development User-defined methods implemented for what analytes	D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, lyme screen —	ACTH and DHEA-S —
Tests not available on other manufacturers' analyzers	3gPSA, IGF-I, IGFBP-3, H. <i>pylori</i> IgG , androst., gastrin, canine TLI, canine TSH	_
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit No. of wells in microplate	_	_
Methods supported/Separation methods No. of different measured assays onboard simultaneously	chemiluminescence/— 24	fluorescence/bead 48
No. of different assays programmed, calibrated at once	unlimited	48
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	_ _/_	0 48/— (this is a unitized test cup)
containers onboard at once/Tests per container set		72 hours/72 hours/no
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	_/_/_ _	72 hours/72 hours/no yes
Reagent container placed directly on system for use Reagents bar coded/information in bar code	_ _/_	yes yes/lot No., test code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover		no/zero
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	300/90/1,300 no/liquid	172/200/960 no/dry
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	—/— 5 μL to 100 μL	no/— 500 μL tube, 100 μL cup
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/50 μL	10 μL/500 μL tube, 100 μL cup
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/— no/—	yes/no no/—
Noise generated Has dedicated pediatric sample cup/Dead vol.	ves/uses specialized racks	 no/
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75-100 mm/no	yes/ 7mL and 10 mL or 15 × 75 & 100, 13 × 75 & 100/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes	yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	yes/yes yes	yes/yes yes
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes yes/yes	yes/yes no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	_	varies
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 2 level adjustors, supplied in kit	no 2 or 6 (analyte dependent)
Calibrants can be stored onboard/Avg. calibration frequency	no/1–4 weeks (assay dependent)	no/90 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes customer determined	yes/yes 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	—/— yes/yes/15 minutes	yes/yes no/no/5 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	35 minutes 18 seconds	approx. 18 minutes 40 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	200/200 (18 seconds)	66/200 (18 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard (\$2,000 QC software only, Siemens)/yes —	—/no —
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no 	yes package insert
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query)	yes (broadcast download & host query)
Interface available (or will be) to auto specimen handling system	yes yes, universal interface	yes yes (Hitachi, A&T, Bayer, Thermo, iLAS)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no odd
On-site response time of service engineer Mean time between failures/To repair failures	4 hours 3 months/5 hours	24 hours 5 months/24 hours
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 to 10 min; weekly: 20 min; monthly: 20 to 30 min	yes daily: 5 min; weekly: 5 min
Onboard maintenance records/Maintenance training demo module	no/yes	yes, includes audit trail/no
List price/Targeted bed size or daily volume	under development/>6,000 per months	\$185,000/65+ beds, 1,500-2,000 tests
Annual service contract cost (24 hours/7 days)	under development	depends on aquisition option
Training provided w/purchase/Advanced operator training	_/ <u>_</u>	4 days at vendor's office/no
Distinguishing features (supplied by vendor)	-	available in two models: standard and LA; unitized test cups similar to all AIA systems; three separate incubators to minimize processing time; no reagent preparation;
		dual clot detection, automated sample dilution, and pretreatment; appropriate for
	* IMMULITE 2000 XPi Immunoassay System is under development, not for sale in U.S.	stat and routine use

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Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	AlA-360/2004/Japan Japan/Japan 775/2,347 continuous random access/benchtop/carousel $21\times19\times16/2.1$	AIA-1800/2003/Japan Japan/Japan 80/550 continuous random access/floor standing/rack, sort drawer, standard and LA $65\times50\times37/12.8$
Tests available on instrument in U.S.	10 minutes short time (ST) assays: TSH, FT4, T3, T4, T-uptake, FT3, β -hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β -2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, testosterone, CA 19-9, intact PTH	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, βhCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β-2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, RBC folate, intact PTH
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays	cystatin C, HbA1c BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., PSA II	cystatin C, HbA1c BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., PSA II
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	ACTH, DHEA-S — —	ACTH, DHEA-S — — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	=	Ξ
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	flourescence, EIA/bead 25 entire menu	flourescence, EIA/bead 31 trays entire menu
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	0 —/unitized test cup	0 —/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	72hours/72hours/— yes yes	72 hours/72 hours/— yes yes
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	yes/lot No., test code no/zero carryover 58/25/25 no/dry	yes/lot No., test code no/zero carryover 58/170/640 no/dry
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no no 500 µL tube, 100 µL cup	
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	10 μL/500 μL tube, 100 μL cup no/no no/—	10 μL/500 μL tube, 100 μL cup yes/no no/—
Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	no yes/primary draw tubes: 13×75 & 100; 16×75 & 100/no yes/yes	no yes/primary draw tubes: 7 mL & 10 mL or 15 \times 75 & 100; 13 \times 75 & 100/no yes/yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes yes yes/yes	yes yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes yes/no no/no no/no	yes yes/yes no/no yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun	no/no 	no/no varies
Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	no 2 or 6-analyte dependent no/90 days	no 2 or 6-analyte dependent no/90 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes 24 hours no/no no/no/5 minutes	yes/yes 24 hours yes/yes no/no/5 to 8 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample	~18 minutes 60 seconds	~18 minutes 40 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	12/36 (1 minutes) yes/no Antek. Schuyler House, more	60/180 (20 seconds) yes/yes yes/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays		yes yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes package insert no yes	yes package insert yes (broadcast download & host query) yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no no/no/no	yes (Hitachi, Siemens, Thermo, iLAS) no/no/no
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures	no — >6 months/24 hours	no 24 hours 5 months/24 hours
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes daily: 5 minutes no/no	yes daily: 5 to 8 minutes; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$25,000/200 to 1,000 tests per month \$2,050-\$3,500 training DVD; on-site install	\$175,000/65+ beds, 1,500 to 2,000 tests \$11,458 4 days at vendor offices/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation, room-temp. stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use; compact size; four tests per sample; random access	two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room-temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

June 2010		CAP TODAY /
A	utomated immunoassay analy	yzers
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Part 31 of 31	6000 Shoreline Court, Ste. 101, South San Francisco, CA 94080 800-248-6764 www.tosoh.com	4 Connell Drive, Ste. 7100, Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Name of instrument/First year sold/Where designed	AIA-600 II/2000/Japan	Nexgen Four/2003/Italy
Country where manufactured/Where reagents manufactured	Japan/Japan	Italy/U.S., Italy, Ireland
No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	555/1,398 cont. random access/benchtop/chain	—/— batch, random access, continuous random access/benchtop/ring (carousel)
Dimensions in inches $(H \times W \times D)$ /Instrument footprint in sq. feet	19.8 × 31.6 × 29.1/6.4	28 × 53.2 × 29.5 (includes carousel)/—
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, β-hCG, estradiol, FSH,	open system—any microplate assay
	hCG, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β-2-microglobulin,	opon oyees any mistopians arealy
	C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, intact PTH, RBC folate	
	,,	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance		open system—any microplate assay open system—any microplate assay
Tests not available in U.S. but available in other countries	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP, cTnl 3rd gen., PSA II	open system—any microplate assay
Research-use-only assays Tests in development	— Acth, Dhea-s	open system—any microplate assay open system—any microplate assay
User-defined methods implemented for what analytes	none	open system—any microplate assay
Tests not available on other manufacturers' analyzers	none	open system—any microplate assay
Fully automated microplate system	m	100
No. of each analyte performed in separate disposable unit	<u>no</u>	yes —
No. of wells in microplate	_	min. strip: 1; max. full plate: 96 × 4 plates
Methods supported/Separation methods	fluorescence, EIA/bead	EIA/coated microwell
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	26 entire menu	500+ 500+
No. of user-definable (open) channels	0	500+
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	—/unitized test cup	16/manufacturer defined
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/72 hours/—	—/—/no
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes	yes requires operator prehandling, preparation
Reagents bar coded/Information in bar code	yes/lot No., test code	yes/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/zero carryover 52/26/26	yes/zero carryover with plastic tips varies/varies/varies
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	yes/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	—/unitized test cup —	yes/— yes/—
Minimum specimen vol. required	500 μL tube, 100 μL cup	200 μL dead vol. plus amount required by test
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10 μL/500 μL tube, 100 μL cup yes/no	10 μL/200 μL yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated Has dedicated pediatric sample cup/Dead vol.	no	 no/
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/primary draw tubes: 7 mL & 10 mL or 15 × 75 & 100, 13 × 75 & 100/no	yes/—/no
Bar-code placement per CLSI standard Auto2A	yes/yes yes	yes (2 or 5 interleaved, Codabar, codes 39 & 128)/— yes
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	yes yes/yes	yes no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/no no/no	yes/yes no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/yes	no/no
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert No. of calibrators required for each analyte	no 2 or 6—analyte dependent	manufacturer dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/90 days	manufacturer dependent/manufacturer dependent
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes 24 hours	yes/manufacturer dependent manufacturer dependent
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	no/no no/no/5 minutes	—/— no/no/10 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample	~18 minutes 60 seconds	manufacturer dependent —
Throughput per hour for three analytes on each specimen, in No. of	20/60 (1 minute)	—/open system—depends on kit
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/no	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson,	onboard/yes
Interfaces up and running in active user sites with	Antrim, Data Innovations)/yes (additional cost) Schuyler House, Fletcher Flora	_
LIS interface operates simultaneously w/running assays	yes	_
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	yes package insert	
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query)	yes
Interface available (or will be) to auto specimen handling system	yes no	yes no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer Mean time between failures/To repair failures	24 hours 98% uptime/—	by contract —/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 5 minutes; weekly: 5 minutes; monthly: none no/no	daily: 5 minutes; weekly: 5 to 10 minutes; monthly: 10 to 15 minutes —/no
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List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	\$70,000/500–2,500 tests per month \$5,941	\$72,900/>100 varies
Training provided w/purchase/Advanced operator training	3 days at vendor offices/no	3–4 days on site/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation; dual clot detec-	dual-arm pipetting with independent wash capabilities; specimen delivery
	tion; room-temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and	with metal needle or plastic tip within same run; continuous loading; remote
	routine use	desktop operation via Internet/modem; touchscreen