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Abbott Diagnostics Abbott Diagnostics Neal Nash neal.nash@abbott.com Neal Nash neal.nash@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 100 Abbott Park Rd. Abbott Park IL. 60064 Part 1 of 31 847-937-4332 www.abbott.com 847-937-4332 www.abbott.com Name of instrument/First year sold/Where designed AxSYM/AxSYM Plus/1993 worldwide, 1994 U.S./U.S. ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. Country where manufactured/Where reagents manufactured U.S./U.S. No. of units in clinical use in U.S./Outside U.S. 1,400/13,000 434/6.009 cont. random access/stat, batch floor-standing/segment Operational type/Model type/Sample handling system batch, random access, cont. random access/floor-standing/track & LAS Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet $60.5 \times 63 \times 33.5/14.6$ $48\times61\times49/20.3;$ i2000, $48\times68\times44/22.7$ per module Tests available on instrument in U.S. total T3, total T4, free T3, free T4, T-uptake, total B-hCG, progesterone, estradiol, cardiac: STAT troponin I, CK-MB, myoglobin, BNP; fertility/pregnancy: total B-hCG, LH, prolactin, STAT CK-MB, troponin-I ADV, total PSA, free PSA, rubella IgG, rubella IgM, FSH, prolactin, progesterone, estradiol, DHEA-S, SHBG; cancer: total PSA, free PSA, AFP, toxo IgG, toxo IgM, carbamazepine, digoxin, N-Acetylprocainamide (NAPA), pheno-CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3, free T4, total T3, total T4, barbitol, procainamide, theophylline II, valproic acid, vancomycin, amphetamine/ T-uptake, anti-Tg, anti-TPO; metabolic: iPTH, ferritin, cortisol, insulin, homocysteine; methamphetamine II, barbiturates II U, benzodiazepines, cannabinoids, cocaine hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB (anti-HBs), CORE-M metabolite, phencyclidine II, acetaminophen, REA ethanol, salicylate, tricyclic an-(anti-HBc IgM), HAVAB-M, CORE; transplant: sirolimus, tacrolimus, cyclosporin; TDM: tidepressants, HAVAB 2.0 (Anti HAV), AxSYM CORE 2.0, HAVAB 2.0, AUSAB, AxSYM theophylline, phenytoin, phenobarbital, vancomycin, digoxin CORE 2.0, HBsAg and HBsAg confirmatory, AxSYM active-B12, AxSYM anti-CCP Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance CA 19-9, HAVAB 2.0 Quantitative, CMV IgM, β -2-microglobulin, insulin, 3rd gen TSH, Tests not available in U.S. but available in other countries fertility/pregnancy: testosterone; cancer: SCC, AFP; metabolic: B12, folate; hep/retro/ congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-IgG, anti-HBc, CMV digitoxin, HBe, HIV 1/2gO, HIV Ag/Ab combo, D-dimer IgG, CMV IgM, rubella IgM, rubella IgG, HTLV I/II, HCV core Ag, toxo IgM, toxo IgG, CMV IgG Avidity, Toxo IgG Avidity Research-use-only assays (U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility: Tests in development testosterone; metabolic: vit B12, folate, vitamin D, anti-CCP, NGAL; thyroid: TG; hep retro/congenitals: HAVAB-G, HIV combo; cancer: AFP, HE-4; (INT Ex U.S.) Hep retro/congenitals: HCV combo, HBsAg qual; cancer: cyfra 21-1, PIVKA 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 Methods supported/Separation methods FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter Chemiflex (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle No. of different measured assays onboard simultaneously 20 No. of different assays programmed, calibrated at once 20 No. of user-definable (open) channels No. of different analytes for which system accommodates reagent 20/100 25/100-test & 500-test per kit containers onboard at once/Tests per container set 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 no yes Reagent container placed directly on system for use yes yes yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability Reagents bar coded/Information in bar code yes/assay name, reag. lot No., expir. date, pack No. ID time, master calibration curve Same capabilities when 3rd-party reagents used/Susceptibility to carryover no/<0.1ppm no/<0.1 ppm Walkaway capacity in minutes/Specimens/Tests-assays 60/90/90 300/135/12.500 System is open (home-brew methods can be used)/Liquid or dry system no/liquid no/liquid Uses disposable cuvettes/Max. No. stored yes/90 reaction vessels yes/1,200 no/— Uses washable cuvettes/Replacement frequency Minimum specimen vol. required 83 µL/150 µL $50 \, \mu L$ Minimum sample vol. aspirated precisely at once/Min. dead vol. 10 μL/73 μL for sample cup, 450 μL for aliquot, 4.5 mL for primary 150 µL/50 µL for all tube types Supplied with UPS (backup power)/Requires floor drain yes (soft close of files only)/optional yes/no Requires dedicated water system/Water consumption 48-70 decibels 52-68 decibels Noise generated Has dedicated pediatric sample cup/Dead vol. no no Primary tube sampling/Tube sizes/Pierces caps on primary tubes yes/100 & 75 mm/no 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) 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 Hemolysis detection-quantitation/Turbidity detection-quantitation იი/ⴄი ทก/ทูด 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 seconds <20 seconds Autocalibration or autocalibration alert yes No. of calibrators required for each analyte 6 pt. or 2 pt. w/ master calib., 6 pt., index calib. 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 yes/yes (up to 4 curves/analyte) yes/yes How often QC required shortest interval: 8 hours, longest: 24 hours 3 levels every 24 hours for quantitative, 2 levels for qualitative Onboard real-time QC/Support multiple QC lot Nos. per analyte yes/yes ves/ves 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 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 Data-management capability/Instrument vendor supplies LIS interface onboard/no onboard/no 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 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 Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ no/ves/ves ves/ves/ves **Determine malfunctioning component** ves. AbbottLink Can order (via modem) malfunctioning part(s) w/o operator yes, AbbottLink On-site response time of service engineer 12 hours 12 business hours Mean time between failures/To repair failures 5 months/within 12 hours per customer request 10.4 weeks/---Onboard error codes to facilitate troubleshooting daily: 14 min; weekly: 65 min; monthly: 11 min daily: 16 min; weekly: <10 min; monthly: none (for both manual & auto procedures) Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module 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) flexible options available flexible options available Training provided w/purchase/Advanced operator training yes/yes yes/yes menu, reliability, online exception help, pressure monitoring, Chemiflex tech. delivers excellent sensitivities and extended linearities; RSH allows Distinguishing features (supplied by vendor) foam avoidance, ratio calculation, stat TAT priority and routine samples to be processed simultaneously w/o compromising stats

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Part 2 of 31	972-518-6775 www.abbott.com	847-937-4332 www.abbott.com
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Name of instrument/First year sold/Where designed	ARCHITECT ci8200, ci16200/2003, 2007/U.S.	ARCHITECT i1000SR/2008/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.	269 (ci8200), 5 (ci16200)/1,302 (ci8200), 170 (ci16200)	39/449
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/robotic sample handler	continuous random access/floor-standing/robotic sample handler allows batch,
	uses multi-dimensional sample handling	random access, cont. access and reagent loading and unloading
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	48 × 127 × 49/43.2	49 × 59 × 30/14.7
Tests available on instrument in U.S.	cardiac: STAT troponin I, CK-MB, myoglobin, BNP; fertility/pregnancy: total <i>B</i> -hCG,	anti-Tg, anti-TPO, free T3, free T4, total T3, total T4, TSH, T-uptake, Total <i>B</i> -hCG,
	LH, FSH, prolactin, progesterone, estradiol, DHEA-S, SHBG; cancer: total PSA, free	estradiol FSH, LH, progesterone, prolactin, DHEA-S, SHBG, BNP, CK-MB, ferritin, insulin,
	PSA, AFP, CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3, free T4, total	intact PTH CA 125-II, CA 15-3, CA 19-9XR, CEA, tacrolimus, sirolimus, theophylline,
	T3, total T4, T-uptake, anti-Tg, anti-TPO; metabolic: ferritin, cortisol, insulin, iPTH,	HAVAB-M, vancomycin, phenytoin, phenobarbital, STAT troponin-I, homocysteine,
	homocysteine; hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB	cyclosporine, cortisol, vancomycin, digoxin
	(anti-HBs), CORE-M (anti-HBc IgM), HAVAB-M, CORE; transplant: sirolimus, tacrolimus,	
	cyclosporin; TDM: theophylline, phenytoin, phenobarbital	
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	fertility/pregnancy: testosterone; cancer: SCC, AFP; metabolic: B12, folate; hep/retro/	free PSA, SCC, total PSA, AFP, anti-HBc, anti-HBc IgM, anti-HBe, anti-HBs, anti-HCV,
lests not available in 0.5. but available in other countries	congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV	rubella IgG, testosterone, others
	IgG, CMV IgM, rubella IgM, rubella IgG, HTLV I/II, HCV core Ag, toxo IgM, toxo IgG, MPO,	Tuboliu igu, tostostorollo, otilors
	CMV IgG Avidity, Toxo IgG Avidity	
Research-use-only assays	—	_
Tests in development	(U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility:	(U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility: testosterone;
	testosterone; metabolic: vit B12, folate, vitamin D, anti-CCP, NGAL; thyroid: TG;	metabolic: vit B12, folate, vitamin D, anti-CCP, NGAL; thyroid: TG; hep retro/congenitals:
	hep retro/congenitals: HAVAB-G, HIV Combo; cancer: AFP, HE-4; (INT Ex U.S.) hep	anti-HCV, HBsAg + conf, CORE-M, AUSAB, CORE, HAVAB-G, HIV combo; cancer: AFP, HE-4;
	retro/congenitals: HCV combo, HBsAg qual; cancer: cyfra 21-1, PIVKA	(INT Ex U.S.) hep retro/congenitals: HCV combo, HBsAg qual; cancer: cyfra 21-1, PIVKA
User-defined methods implemented for what analytes	_	_
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	-	-
Methods supported/Separation methods	photometric, potentiometric, & Chemiflex (enhanced chemiluninescence)	chemiluninescence/magnetic particle
No. of different measured assays onboard simultaneously	93	25
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	93	25
No. of different analytes for which system accommodates reagent	220 93/50–1,700	none 25/25–100
containers onboard at once/Tests per container set	93/30-1,/00	23/23-100
Shortest/Median onboard reagent stability/Refrigerated onboard	2 days/29 days/yee	/20 days/yes
Multiple reagent configurations supported	3 days/28 days/yes yes	—/30 days/yes yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, reagent No., lot No., tests per kit, expiration date, others	yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	open system/SmartWash technology	no/<0.1 PPM
Walkaway capacity in minutes/Specimens/Tests-assays	300/367/>75,000	3 hrs/65/25
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	both disposable and semi-permanent glass/1,200 or 165/330	yes/360
Uses washable cuvettes/Replacement frequency	yes/as needed, 1-year minimum	no/—
Minimum specimen vol. required	2 μL	60 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	50 μL	60 μL/50 μL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/no
Requires dedicated water system/Water consumption	yes/25 L per hour (ci8200)/52 L per hour (ci16200)	no/—
Noise generated	48-70 decibels	50 decibels during normal operation, 62 decibels maximum
Has dedicated pediatric sample cup/Dead vol.	no	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/pediatric, 5, 7, 10 mL tubes and sample cups/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 Clot detection/Reflex testing capability	yes voo voo	yes yes/yes
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
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	<20 seconds	<20 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2 or 6 pt.	2–6 pt. curve
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/minimum 30 days or once per lot
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	from 2 levels after calibration, to 3 per 24 hours	from 2 levels for qualitative to 3 levels every 24 hrs
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	—/no/10 minutes	no/no/6.5 minutes
Stat time to completion of R_hCC test	<15.6 minutes	15.6 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	<15.6 minutes <20 seconds	15.6 minutes <20 seconds
Throughput per hour for three analytes on each specimen, in No. of	400/1,200	up to 100 are 1-step STAT TDMs TPH/—
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	all major LIS vendors	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	—	- was (hyperdeced days) and 0 bank are
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 ves
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	NO voc/voc/voc	yes ves/ves/ves
Determine malfunctioning component	yes/yes	yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	yes, AbbottLink	VPS
On-site response time of service engineer	8 business hours	yes 12 business hours
Mean time between failures/To repair failures	10.4 weeks/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <15 min; weekly: <35 min; monthly: 15 min (for manual & automated procedures)	daily: 10 min; weekly: 17 min; monthly: 90 min.
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
List price/Targeted bed size or daily volume	\$375,000/200-500 immunoassay tests per day	\$125,000/40–250 tests per day
Annual service contract cost (24 hours/7 days)	flexible options available	flexible options available
Training provided w/purchase/Advanced operator training	yes/yes	yes/yes
Distinguishing features (supplied by vendor)	integration of CC and IA without compromising stat TAT, results, or throughput	streamlined workload mgmt.; contin. access to reagents, samples, and supplies; 65 samp.
	because of patented SmartWash technology, which minimizes carryover to	load cap., 13 univ. bay; up to 7 custom. priority bays, refrig. reagent carousel w/25×100 test
	<0.1 ppm; reagent capacity of 93 assays, with sample load up to 367	kit sizes, reagents stable onboard up to 30 days; priority tests, 15.6-min. TAT on stat assays
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A	utomated immunoassay anal	yzers
	Awareness Technology Inc.	Beckman Coulter Inc.
	Chris Schneider info@awaretech.com	Linh Ho tho@beckman.com
Part 3 of 31	1935 SW Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com	200 S. Kraemer Blvd., Brea, CA 92821 714-993-8736 www.beckmancoulter.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	ChemWell/1998/U.S. U.S./open system	Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S. & France
No. of units in clinical use in U.S./Outside U.S.	50+/2,200+	>2,400/>3,700
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	batch, random access/benchtop/rack $16 \times 34 \times 20/4$	continuous random access/benchtop/rack $18.5 \times 39 \times 24/6.5$
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Tests available on instrument in U.S.	unlimited—open system	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnl
		troponin I, BNP, free T3, free T4, hypersensitive hTSH, fast hTSH, thyroglobulin,
		thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone,
		DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estriol,
		inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble
		transferrin receptor, rubella IgM
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	unlimited—open system	HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV
Research-use-only assays	unlimited—open system	IgG, rubella IgM IL-6, PAPP-A
Tests in development	_	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol
User-defined methods implemented for what analytes	general biochemistries	_
Tests not available on other manufacturers' analyzers	_	intrinsic factor Ab, inhibin A
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit No. of wells in microplate	up to 12 min. strip, 8; max. full plate, 96	=
<u> </u>		
Methods supported/Separation methods No. of different measured assays onboard simultaneously	EIA/coated microwell up to 12	chemiluminescence/magnetic particle 24
No. of different assays programmed, calibrated at once	unlimited	24
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	unlimited 27/assay dependent	U 24/100 tests per kit; 50 tests per cartridge
containers onboard at once/Tests per container set	and the second and th	
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	assay dependent/assay dependent/yes (10°C below ambient) yes	336 hours/28 days/yes (4°C) yes
Reagent container placed directly on system for use Reagents bar coded/information in bar code	yes	yes yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no no/none	no/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	assay dependent/96/12 yes/liquid	180/60/300 no/liquid
Uses disposable cuvettes/Max. No. stored	yes/96	yes/294
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	yes/assay dependent 2 µL	no/— 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 Requires dedicated water system/Water consumption	no/no no	no/no 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 Bar-code placement per CLSI standard Auto2A	no/—	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Onboard test auto inventory (determines vol. in container)	yes	yes yes
Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen	no/no yes	yes/yes yes
Clot detection/Reflex testing capability	no/yes	no/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/	yes/yes	no/no
Increased to rerun out-of-linear range low results 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 Calibrants can be stored onboard/Avg. calibration frequency	assay dependent yes/assay dependent	assay dependent no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes shortest interval: each run; longest: daily	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	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 Throughput per hour for three analytes on each specimen, in No. of	30 seconds assay dependent	36 seconds 33/100 (36 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 (included)	yes/yes 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 Uses LOINC to transmit orders and results	no 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/	no yes/yes	no yes/yes/yes
Determine malfunctioning component	, , oo, , vo	,, jou, jvo
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no within 48 hours	no 24 hours max., usually in 6 hours
Mean time between failures/To repair failures	-/-	—/—
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: <10 min; weekly: <10 min; monthly: <10 min	yes daily: 15 min; weekly: 30 min
Onboard maintenance records/Maintenance training demo module	no/no	yes, includes audit trail/no
List price/Targeted bed size or daily volume	\$25,000/up to 500 tests per day	\$149,800/all volumes & hospital sizes
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$4,000 3 days on site/no	\$15,800 4 days at vendor offices/yes
	•	•
Distinguishing features (supplied by vendor)	ability to perform general biochemistries; optional reagent cooling module	ability to network up to four Access 2 systems using one LIS interface with remote diagnostics; fully automated user-defined reflex testing; continuous
		random-access benchtop analyzer

Automateu immunoassay anaryzers		
Part 4 of 31	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 (714) 961-3779 www.beckmancoulter.com	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 (714) 961-3779 www.beckmancoulter.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	UniCel Dxl 800 Access Immunoassay System/2003/U.S. U.S./U.S., France >400/>400 continuous random access/floor standing/rack, direct track sampling $67\times67.5\times37.5/17.6$	UniCel DxC 600i Synchron Access Clinical System/2006/U.S. U.S./U.S. 171/0 continuous random access/floor standing/rack-closed tube $62 \times 128 \times 48/42.7$
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estriol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella lgG, toxo lgM, total lgE, cortisol, soluble transferrin receptor, rubella lgM	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estriol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella lgG, toxo lgM, total lgE, cortisol, soluble transferrin receptor, rubella lgM, plus >100 Synchron chemistry tests
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	SHBG HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM IL-6, PAPP-A CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol	SHBG HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM IL-6, PAPP-A CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	intrinsic factor Ab, inhibin A	intrinsic factor Ab, inhibin A
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 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	chemiluminescence/magnetic particle 50 50 0 50/100 and 300 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (3°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration	chemiluminescence, enzyme immunoassay/magnetic particle 89 89 100 89/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2°-10°C)/yes yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration
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	yes/< 10 ppm 288/120/1,200 no/liquid yes/>1,000 no/— 5 μL/160 μL no/no no/— <60 decibels	yes/<10 ppm 60/76/608 no/liquid no/125 yes/— 23 μL 3 μL/20 μL yes/yes yes/16 L per hour
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/	yes/100 µL yes/12 × 75, 13 × 75 & 100, 16 × 75, 85, & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes/yes yes/yes no/no yes/yes no/no	yes/— yes/13 × 75 & 100, 15 × 75 & 92, 16 × 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes
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 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	<9 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	chemistry dependent dependent assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode
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	15 minutes 18 seconds ≤133/≤400 (9–18 seconds) yes/yes onboard/yes (included or additional cost—negotiable) all major LIS vendors yes no — yes (broadcast download & host query) yes yes (Beckman Coulter automation systems) yes/yes/yes no per negotiated contract —/— yes	15 minutes 1 minute 90/720 (40 seconds) yes/yes optional add-on/yes (additional cost) all major LIS vendors yes no — yes (broadcast download & host query) yes yes (Beckman Coulter automation systems) yes/yes/yes no — — — yes
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 yes, includes audit trail/yes \$325,000/300+ beds or >400 tests per day	yes, includes audit trail/— \$325,000/moderate volume, <300 samples per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$29,900 yes/yes	per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	high-throughput immunoassay analyzer; integrates w/UniCel DxC chemistry systems; uses chemiluminescent technology and same reagent packs for consistent results w/other UniCel and Access systems; allows operators to load consumables on-the-fly, without interacting with the system	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 identical across the UniCel and Access family of systems.

Adtomated inimanoassay analyzers		
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Part 5 of 31	(714) 961-3779 www.beckmancoulter.com	(714) 961-3779 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel Dxl 600 Access Immunoassay System/2007/U.S.	UniCel DxC 880i Synchron Access Clinical System/2008/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.	>40/>40	0/0
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack, drect track sampling	continuous random access/floor standing/rack closed-tube
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	67 × 61.5 × 37.5/16.02	68 × 161 × 48/53.7
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor
1000 transfer on moralism motor	(CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnI	(CA 15-3 antigen), Gl monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnl
	troponin I, BNP, free T3, free T4, hypersensitive hTSH, fast hTSH, thyroglobulin,	troponin I, BNP, free T3, free T4, hypersensitive hTSH, fast hTSH, thyroglobulin,
	thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin,	thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin,
	folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total \(\beta\)-hCG and Dil \(\beta\)-hCG, unconjugated estriol,	folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estriol,
	inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase, intact PTH (routine	inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase, intact PTH (routine
	and intraoperative), ultrasensitive hGH, rubella lgG, toxo lgM, total lgE, cortisol,	and intraoperative), ultrasensitive hGH, rubella lgG, toxo lgM, total lgE, cortisol, soluble
	soluble transferrin receptor, rubella IgM	transferrin receptor, rubella IgM, plus >100 Synchron chemistry tests
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	SHBG HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV	SHBG HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV
15515 Hot available in 5151 but available in 54151 554114165	IgG, Rubella IgM	IgG, rubella IgM
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol
Hear defined methods implemented for what analytes		
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	intrinsic factor Ab and inhibin A	intrinsic factor Ab, inhibin A
100to flot available of other manufacturers analyzers	א מווע וווועווו א מווע ווווועווו א	intiliolo lateta Auj inilium A
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/magnetic particle	chamiluminescence enzyme immunossay/magnetic particle
No. of different measured assays onboard simultaneously	cnemiuminescence/magnetic particle 50	chemiluminescence, enzyme immunoassay/magnetic particle 120
No. of different assays programmed, calibrated at once	50	120
No. of user-definable (open) channels	_	100
No. of different analytes for which system accommodates reagent	50/100 and 300 tests per kit; 50 tests per cartridge	120/100 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°-10°C)	336 hrs/28 days/yes (2°-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
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	expiration, within ot calibration	expiration, within lot calibration
Walkaway capacity in minutes/Specimens/Tests-assays	yes/<10 ppm 240/—/—	yes/<10 ppm 60/112/896
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	closed/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,000	no/125
Uses washable cuvettes/Replacement frequency	no/—	yes/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	specimen container dependent	23 μL 3 μL/20 μL
Supplied with UPS (backup power)/Requires floor drain	5 μL/160 μL no/no	yes
Requires dedicated water system/Water consumption	no/—	yes/up to 16 L per hour
Noise generated	<60 decibels	- '- '
Has dedicated pediatric sample cup/Dead vol.	yes/100 μL	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/12 × 75, 13 × 75 & 100, 16 × 75 & 85 & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/13 × 75 & 100, 15 × 75 & 92, 16 × 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interreaved, obtabar, codes 35 & 120)/ 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 voc/vos	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes no/no	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	yes/yes
Increased to rerun out-of-linear range low results	10 accords	ah awitahu danandank
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	18 seconds yes	chemistry dependent —
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 Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hours yes/yes	24 hrs 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 — (200 (9 seconds)	1 minute
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/200 (9 seconds)	90/720/40 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	onboard/yes (included in instrument price & additional cost)	_/_
Interfaces up and running in active user sites with	all major LIS vendors	
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	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 Modem servicing/Can diagnose own malfunctions/	yes, Beckman Coulter automation systems	yes, Beckman Coulter automation systems
Determine malfunctioning component	yes/yes	yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	per negotiated contract	-,
Mean time between failures/To repair failures Onboard error codes to facilitate troublesheating	_/_ voc	_/_ voc
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: <10 min	yes —
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail)/—	yes, includes audit trail/—
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List price/Targeted bed size or daily volume	\$199,500/200-300 beds or 100-300 tests per day	\$650,000/high to very high volume, 750–2,250 samples per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	per negotiated contract —/yes	 _/_
Talling provided w/purenase/Advanced operator trailing	7,300	, .
Distinguishing features (supplied by vendor)	integrates with UniCel DxC chemistry systems; uses chemiluminescent technology	performs parallel processing of immunoassay and chemistry tests on one system;
	and same reagent packs to deliver consistent results with other UniCel and Access	ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates
	immunoassay systems; allows operators to load consumables on-the-fly, without	manual processes; chemistry and immunoassay reagent packs are identical across
	interacting with the system	the UniCel and Access family of systems

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Part 6 of 31	(714) 961-3779 www.beckmancoulter.com	(714) 961-3779 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel Dxl 660i Synchron Access Clinical System/2009/U.S.	UniCel DxC 680i Synchron Access Clinical System/2009/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	3/1 continuous random access/floor standing/rack closed-tube	0/2 continuous random access/floor standing/rack closed-tube
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	68 × 147 × 48/49	68 × 153 × 48/51
	CEA hubritoch DCA hubritoch fuce DCA OV manitar (OA 405 anti) DC	CEA hubritagh DCA hubritagh free DCA OV manitar (OA 405 anti) DC
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin,	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin,
	myoglobin, AccuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast	myoglobin, AccuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast
	hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb,	hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb,
	EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total	EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total
	β -hCG and Dil β -hCG, unconjugated estriol, inhibin A, ultrasensitive insulin,	$\beta\text{-hCG}$ and Dil $\beta\text{-hCG}$, unconjugated estriol, inhibin A, ultrasensitive insulin,
	ostase bone alkaline phosphotase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin	ostase bone alkaline phosphotase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin
	receptor, rubella IgM, plus >100 Synchron chemistry tests	receptor, rubella IgM, plus >100 Synchron chemistry tests
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	SHBG HIV ½, HBs Aq confirm, HBs Ab, HCV Ab, HAV Ab, HAV IqM, HBcAb, HBc IqM,	SHBG HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM,
16363 Hot available in 6.6. But available in other countries	IL-6, CMV IgG, rubella IgM	IL-6, CMV IgG, rubella IgM,
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol
User-defined methods implemented for what analytes	_	-
Tests not available on other manufacturers' analyzers	intrinsic factor Ab, inhibin A	intrinsic factor Ab, inhibin A
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	115 115	115 115
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	115 100	115 100
No. of different analytes for which system accommodates reagent	115/100 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 (2°-10°C)	336 hours/28 days/yes (2°-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 expiration, within lot calibration	yes/specific cartridge ID, No. of available tests, expiration date, lot No. 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	60/76/608	60/76/608
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	closed/liquid no/125	closed/liquid no/125
Uses washable cuvettes/Replacement frequency	yes/—	yes/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	23 µL	23 μL 3 μL/20 μL
Supplied with UPS (backup power)/Requires floor drain	3 μL/20 μL 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/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 & 100, 15 × 92 & 75, 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 Clot detection/Reflex testing capability	yes yes/yes	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	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	yes/yes
Time between initial result & reaspiration of sample for rerun	chemistry dependent	chemistry dependent
Autocalibration or autocalibration alert	— accay danandant	— accay dependent
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	assay dependent no/28 days	assay dependent no/28 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 yes/yes	24 hours 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 RubCC 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	15 minutes 1 minute
Throughput per hour for three analytes on each specimen, in No. of	90/720 (40 seconds)	90/720 (40 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	_/ <u></u>	_/
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	wee (hreadeast download 9, host mioris)	was (hroadeast download 9, host quant)
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, Beckman Coulter automation systems	yes, Beckman Coulter automation systems
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 Mean time between failures/To repair failures		
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	<u> </u>	<u> </u>
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/—	yes, includes audit trail/—
List price/Targeted bed size or daily volume	\$575,000/high volume, 300–750 samples per day	\$610,000/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
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Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one	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	system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs are
	identical across the UniCel and Access family of systems	identical across the UniCel and Access family of systems

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	Beckman Coulter Inc.	The Binding Site Inc.
	Leonard Bachicha LABachicha@beckman.com	Gary Tremain gary.tremain@thebindingsite.com
P-47-404	200 S. Kraemer Blvd., Brea, CA 92821	5889 Oberlin Dr., Ste. 101, San Diego, CA 92121
Part 7 of 31	(714) 961-3779 www.beckmancoulter.com	800-633-4484 www.bindingsite.co.uk
Name of instrument/First year sold/Where designed	UniCel Dxl 860i Synchron Access Clinical System/2009/U.S.	DS2/2006/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	1/0	
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 $68 \times 147 \times 48/51.7$	batch, with continuous load/benchtop/rack $30 \times 17 \times 26/3.07$
Dimensions in inches (H \times W \times D)/instrument footprint in Sq. feet	08 × 147 × 48/51.7	30 × 17 × 26/3.07
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor	ANA screen, ENA screen, dsDNA, SS-A, SS-B, Sm, Sm/RNP, Jo-1, ScL-70, GBM, MPO,
	(CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, Ac-	PR3, Tg-TP0, cardiolipin screen & IgG, IgA, IgM, B2GP-1 screen & IgG, IgA, IgM,
	cuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast hTSH, thyroglobu-	phosphatidylserine screen, IgG/IgA/IgM, C1q, gliadin IgG/IgA & screen, +TG IgA/
	lin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor Ab, estradiol, hFSH, hLH,	IgG, RF, A-CCP, histone, ASCA IgA/IgG, tetanus toxoid, diptheria toxoid, EBV VCA IgG, IgM, EBV-EA IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/Igm, CMV IgG/IgM &
	progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, uncon-	IgG capture, HSV 1/2 IgG, HSV type specific 1&2, measles IgG/IgM, mumps IgG, high
	jugated estriol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphotase,	avidity dsDNA, PLAC test, others
	intact PTH (routine and intraoperative), ultrasensitive hGH, rubella lgG, toxo lgM,	
Tests cleared but not clinically released	total IgE, cortisol, soluble transferrin receptor, rubella IgM, >100 chemistry tests —	nono
Tests not available in U.S. but submitted for clearance	SHBG	none —
Tests not available in U.S. but available in other countries	HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM,	open system—ELISA
	IL-6, CMV IgG, rubella IgM	
Research-use-only assays Tests in development	IL-6, PAPP-A CMV IqG, CMV IqM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive	open system phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgA, phosphatidylglycerol
lests in development	estradiol	IgG/IgM, phosphatidlycholine, IgG/IgA, phosphatidic Acid, IgG/IgM, prothrombin, C3d,
	ou date.	SMA, LKM, modified gliadin peptide
User-defined methods implemented for what analytes	none	open system
Tests not available on other manufacturers' analyzers	intrinsic factor Ab, inhibin A	open system
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	_	_
No. of wells in microplate	-	min. strip 1 \times 8; max. full plate: 96 wells \times 2 plates
		FINAL ALL ALL TO
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay/magnetic particle	EIA/coated microwell
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	120 120	12 assays per plate unlimited
No. of user-definable (open) channels	100	unlimited
No. of different analytes for which system accommodates reagent	120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)	8/96
containers onboard at once/Tests per container set	226 haura/20 daug/uga /20 1000\	24 hours/ Inc.
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	336 hours/28 days/yes (2°-10°C) yes	24 hours/—/no yes
Reagent container placed directly on system for use	yes Ves	yes
Reagents bar coded/Information in bar code	yes/specific cartridge ID, No. of available tests, expiration date, lot No.,	yes/yes
	calibration expiration, within lot calibration	
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	yes/<10 ppm 60/112/896	—/0 with disposable tips assay dependent/98/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	ves/liquid
Uses disposable cuvettes/Max. No. stored	no/125	no/—
Uses washable cuvettes/Replacement frequency	yes/—	no/—
Minimum specimen vol. required	23 µL	200 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	3 µL/20 µL yes/yes	5 μL/200 μL (50 μL with microtubes) ves/—
Requires dedicated water system/Water consumption	yes/up to 16 L per hour	no
Noise generated		=
Has dedicated pediatric sample cup/Dead vol.	yes/—	yes/50 μL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes 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/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes (2 of 3 interieaved, codabat, codes 35 & 120)/yes	yes (2 of 3 interfeaved, codabal, codes 39 & 120/1yes
Onboard test auto inventory (determines vol. in container)	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes voc/voc	yes yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes yes/yes	no/no
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/	yes/yes	no/no
Increased to rerun out-of-linear range low results	chamictry dependent	_
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	chemistry dependent —	— no
No. of calibrators required for each analyte	assay dependent	varies
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	yes/each assay
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes 24 hours	yes/no
Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hours yes/yes	each assay ves/no
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/yes/1–2 minutes
0.11		
Stat time to completion of β-hCG test	15 minutes	
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	1 minute 90/720 (40 seconds)	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/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 Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) ves	yes (host query) yes
Interface available (or will be) to auto specimen handling system	yes, Beckman Coulter automation systems	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 On-site response time of service engineer	<u>no</u>	no
Mean time between failures/To repair failures	Ξ	
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	use includes audit trail/	daily: 5 minutes; weekly: —; monthly: —
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/—	yes/no
List price/Targeted bed size or daily volume	\$615,000/high to very high volume, 500–1,500 samples per day	\$50,000/100-200 beds
Annual service contract cost (24 hours/7 days)	per negotiated contract	\$7,000
Training provided w/purchase/Advanced operator training	yes/yes	8 days on site/yes
Distinguishing feetures (supplied by yeards)	norforms narellal processing of immunescent at the state of the state	graphical interface with dress and dress in the laws and dress in
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)	graphical interface wtih drag-and-drop icons; large sample throughput for a two-plate microplate system with 98 samples and continuous load feature; consumable status
	eliminates manual processes; chemistry and immunoassay reagent packs are	window shows location and volume requirements during loading
	identical across the UniCel and Access family of systems	,

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Part 8 of 31	800-633-4484 www.bindingsite.co.uk	800-633-4484 www.bindingsite.co.uk
Name of instrument/First year sold/Where designed	DSX Automated System/2000/Guernsey, U.K.	ASP1200/2008/UK
Country where manufactured/Where reagents manufactured	U.S./U.K.	UK/UK
No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	200/>500 batch/benchtop/rack	2/24 batch/benchtop/rack
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	$32 \times 42 \times 36/7$	$22 \times 20 \times 24/2$
Tests available on instrument in U.S.	ANA screen, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, ScI-70, dsDNA, GBM, MPO, PR3,	ANA, dsDNA, ANCA, GBM, EMA
	TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine IgG/IgM/IgA, C1g CIC, gliadin IgG/IgA & scr, tTG IgA, tTG IgG, 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	_
Research-use-only assays	open system	_
Tests in development	phosphatidylinositol lgG/lgM, phosphatidylethanolamine lgG/lgM/lgA,	_
	phosphatidylglycerol lgG/lgM, phosphatidylcholine lgG/lgM, phosphatidic acid lgG/	
User-defined methods implemented for what analytes	lgM, prothrombin, C3d CIC, SMA, LKM, modified gliadin peptide 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 No. of wells in microplate	min. strip: 1×8 ; max. full plate: 96×4 plates	5-24 —
Methods supported/Separation methods	EIA/coated microwell	fluorescence, immunoperoxidase/substrate
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	12 assays per plate unlimited	4 4
No. of different assays programmed, canorated at once No. of user-definable (open) channels	unimited	4 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	24 hours / Inc	O house/1 day/ac
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	24 hours/—/no	8 hours/1 day/no
Reagent container placed directly on system for use	yes 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 System is open (home-brew methods can be used)/Liquid or dry system	assay dependent/92/assay dependent yes/liquid	105/96/96 open/liquid
Uses disposable cuvettes/Max. No. stored	965/11quiu NO	no/—
Uses washable cuvettes/Replacement frequency	no	_/_
Minimum specimen vol. required	200 μL	250 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	5 μL/200 μL (50 μL with microtubes)	5 μL/250 μL
Requires dedicated water system/Water consumption	yes/no no	yes/no no/—
Noise generated	-	-
Has dedicated pediatric sample cup/Dead vol.	yes/50 μL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/various/no	yes/—no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/— yes	yes (2 of 5 interleaved, Godabar, codes 39 & 126)/yes
Onboard test auto inventory (determines vol. in container)	10	no
Measures No. of tests remaining/Short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/no	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	-/-
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
No. of calibrators required for each analyte	assay specific	_
Calibrants can be stored onboard/Avg. calibration frequency	yes/once per analyte per plate	yes/—
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes 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/—
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	32/96/1 hour and 45 min.
specimens/No. of tests (cycle time)		med.
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)	no/— 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 interfers annual and in the control of the cont	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	_	—
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 Modem servicing/Can diagnose own malfunctions/	no no/yes/yes	no no/—/—
Determine malfunctioning component	,,	
Can order (via modem) malfunctioning part(s) w/o operator	no	
On-site response time of service engineer Mean time between failures/To repair failures	within 24 hours —/<24 hours	24 hours 227 days/4 hours
Onboard error codes to facilitate troubleshooting	—/<24 nours 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	\$55,000-\$70,000 (dependent on modules)/200+ beds	\$37,450/50 tests per day
Annual service contract cost (24 hours/7 days)	\$12,950	\$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
Distinguishing reatures (supplied by Vellaut)	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	The same of the sa
	recovery	

Part 9 of 31	The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk	bioMérieux Inc. Reggie Carr, U.S. Marketing Manager reggie.carr@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2656 www.biomerieux-usa.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	ESP600/2008/Switzerland, Italy Switzerland/UK 22/0 batch/benchtop/racks $36\times47\times32/10.5$	VIDAS Immunoassay Analyzer/1989/U.S. Italy/France 2,200/25,000 batch, random access/benchtop/— Vidas 30 system: $16\times32\times2/4.5$; mini Vidas system: $21\times21\times17/4$
Tests available on instrument in U.S.	open system, Binding Site autoimmune and infectious disease menu, diaDexus PLAC test, Trinity assays, TrepSure	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
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		tumor markers: CEA, AFP, CA- 125, 15-3, 19-9 & free PSA HBs Ag, anti HBs-total, anti-HBc total, anti-HBc IgM, anti HBe, HAV IgG, anti HAV total, HPV, HIV 1/2, HIV duo, myoglobin, B-12 microglobulin, toxo IgG avidity none
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	antiphosphatidylglycerol, antiphosphatidic acid deamidated gliadin peptide —	vitamin D, EBV none all assays for use on Vidas instruments only
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes 1 96	no 1 test per strip
100 01 11010 111 11100 print		
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	fluorescence, enzyme EIA/coated microwell 9 — open system	fluorescence, EIA/EIA coated, solid phase receptacle pipetting device MiniVidas: 30; Vidas: 12 total menu 0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	9/88 24 hrs/—/no	unit dose format 30 or 60/— —/—/no
Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes requires operator prehandling/preparation —/—	no placed directly on system yes/assay name, lot No., calibration, expiration
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	—/<10 assay dependent/up to 240/9 quantitative, 21 qualitative yes/liquid	no/zero carryover assay dependent/12–30/12–30 no/dry
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/— no/— 200 μL 5 μL/200 μL	no/— no/— 100–200 ng/mL dependent on assay 100 ng/mL dependent on assay/—
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated	yes/no no/—	yes/no no/— —
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/10 to 16 mm/no yes (2 of 5 interleaved, Codabar, code 39, code 128)/yes	no/— no/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no
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	no no/yes no	no no no/no no
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/no / yes/no	no/no no/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 Time between initial result & reaspiration of sample for rerun		no/no
Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	no assay dependent yes/per run	yes — no/14 or 28 days, assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/no	no/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	per run no/yes	shortest interval: 8 hours, longest: 24 hours yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/2 min	no/no/always remains ready
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)		30 minutes no delay —/Vidas: 20, MiniVidas: 8, Vidas: 60, MiniVidas: 24
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/yes (additional cost) 3	yes/yes onboard/yes (additional cost) Misys, Medtech, McKesson, Advanced Lab systems, Citation, Cemer, Dawning, Geneysis, Compulab, others
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	yes no —	yes no —
Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes (host query) yes no	yes (broadcast download) yes no
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	no/no/no no 24 hrs	no/yes/yes no within 24 hrs
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly:10 min	Vidas: 350 days/MiniVidas: 1,000 days yes weekly: 10–15 min
Onboard maintenance records/Maintenance training demo module	no/—	yes (includes audit trail)/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$95,000/500 tests/day \$14,250 yes (8 days on site)/yes	Vidas 30: \$51,800; MiniVidas: \$28,100/>400 bed hospitals \$2,340–\$4,680 yes (2–3 days on site/vendor offices)/yes
Distinguishing features (supplied by vendor)	fast processing time; low operating costs due to elimination of disposable tips; completely open high-throughput batch analyzer	routine batch testing as well as emergency stat testing; gold-standard ELISA methodology; dual-function combination solid phase & pipetting device results in no fluid contact with instrument or sample carryover; single-dose assay format readily adaptable to batch 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; very long MTBF intervals; GUI-driven VIDAS PC software can support up to two VIDAS instruments simultaneously

Tabulation does not represent an endorsement by the College of American Pathologists.

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Part 10 of 31	510-741-4680 www.bio-rad.com	510-724-7000 www.bio-rad.com
Name of instrument/First year sold/Where designed	BioPlex 2200/2006/Australia	PR 3100TSC Photometer/2006/Austria
Country where manufactured/Where reagents manufactured	Australia/U.S.	Austria/U.S.
No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	103/17 continuous random access/floor standing/rack	30/— batch/benchtop/rack
Dimensions in inches ($H \times W \times D$)/Instrument footprint in sq. feet	58 × 72 × 34/12	7×13×13/2
Tests sucilable on instrument in H.C.	ANA Cavage anti-deputa (avent) anti-CC A anti-CC D anti-Cm-DND anti-Cm-anti-	contest Die Ded verwesentative
Tests available on instrument in U.S.	ANA Screen, anti-dsDNA (quant.), anti-SS-A, anti-SS-B, anti-SmRNP, anti-Sm, anti-RNP, anti-ScI-70, anti-Jo-I, anti-centromere B, anti-chromatin, anti-ribosomal P,	contact Bio-Rad representative
	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	
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	none	none
Tests not available in U.S. but available in other countries	syphilis IgM	ANA screen, ENA Plus screen, anti-dsDNA, anti-Jo-1, anti-SS-A, anti-SS-B, anti-Scl-70, anti-Sm, anti-Sm/RNA, anti-centromere, anti-phospholipid tests, toxo IgG, toxo IgM,
		rubella IgG, rubella IgM, EBV VCA IgM, EBV VCA IgG, CMV IgG, measles IgG, mumps
Research-use-only assays	none	IgG, VZV IgG not in U.S.
Tests in development	gastrointestinal disease, phospholipid, rheumatoid arthritis, cardiac damage and risk,	_
User-defined methods implemented for what analytes	measles, mumps, VZV, lyme, HSV, HIV and hepatitis none	none
Tests not available on other manufacturers' analyzers	heterophile antibodies	none
Followsky and advisorable system		
Fully automated microplate system No. of each analyte performed in separate disposable unit	<u>no</u>	no
No. of wells in microplate	-/-	min. strip: 1; max. full plate: 96
Mathode cunnerted/Separation methods	head flow extensitie (multinles)/magnetic porticle	FIA/coated microwell
Methods supported/Separation methods No. of different measured assays onboard simultaneously	bead flow cytometric (multiplex)/magnetic particle 440	EIA/coated microwell 1
No. of different assays programmed, calibrated at once	440	1
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	none 440/100	none 0/—
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	720 hours/30 days/yes (2°–8°C) no	—/—/no no
Reagent container placed directly on system for use	yes	no
Reagents bar coded/Information in bar code	yes/kit type, lot No., kit serial No.	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/2 ppm 480 minutes/280/17,600	no/— 1/up to 96/1
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/800 no	no/— no/—
Minimum specimen vol. required	5 μL	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/70 μL	_/_
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/0.5 L per hour	no/no no/—
Noise generated	<67 decibels	-
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/10–16 mm diameter and 41–100 mm height/no	no/— no/—/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	no no
Measures No. of tests remaining/Short sample detection	yes yes/yes	no no/no
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/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	- /-	no/no
Time between initial result & reaspiration of sample for rerun	_	_
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	analyte dependent no/14 days	assay dependent no/weekly
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	no/no
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hours/24 hours no/yes	shortest interval: weekly; longest interval: monthly —/no
Automatic shutdown/Startup is programmable/Startup time	no/no/10 min	no/no/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)	100/300/36 seconds	<i>-</i> /-
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/no
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	no/no
Interfaces up and running in active user sites with		
LIS interface operates simultaneously w/running assays	yes	no
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	<u>no</u>	<u>no</u>
Bidirectional interface capability	yes	no () NOD III - I - I - I - I - I - I - I - I -
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes no	yes (via USB thumb drive to separate you) 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		units returned for service
Mean time between failures/To repair failures	_/_ voc	_/_ no
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 minutes; weekly: 30–40 minutes; monthly: none	no daily: 0; weekly: 5 minutes; monthly: 5 minutes
Onboard maintenance records/Maintenance training demo module	——————————————————————————————————————	no/—
List price/Targeted bed size or daily volume	\$350,000/≥200 tests per day	\$9,500/5-500 tests per day
Annual service contract cost (24 hours/7 days)	inquire	inquire
Training provided w/purchase/Advanced operator training	7 days on site, 7 days at vendor offices/yes	1 day on site
Distinguishing features (supplied by vendor)	fully automated/random access; innovative multiplex chemistry; eFlex software with	compact, standalone microplate photometer; onboard computer allowing user control
	bidirectional interface	of instrument and data reduction; colored touchscreen with wizard interface provides streamlined operation of all assays
		Sucuminiou Operation of all assays

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June 2009

	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg.stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547
Part 11 of 31	510-724-7000 www.bio-rad.com	510-724-7000 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	PhD System/2000/Belgium France/U.S. 200/300 batch/benchtop/rack $35 \times 66 \times 35/16$	Evolis/2001/Germany Germany/U.S. 225/1,160 batch/benchtop/rack 37 × 44 × 30/10
Tests available on instrument in U.S. Tests cleared but not clinically released	ANA (EIA), anti-centromere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (qEIA), anti-SS-B (EIA), anti-ScI-70 (EIA), anti-Sm (EIA), anti-SmRNP (EIA), anti-ssDNA (EIA), aCL IgM, aCL IgA, aCL IgA, anti- β 2GPI IgA, anti- β 2GPI IgA, aPS IgA, aPS IgA, anti-gliadin IgA/IgG, anti-tTg IgA/IgG, ASCA IgA/IgG, IFA-, HEp-2, crithidia, mouse stomach/kidney, ANCA (formalin & ethanol)	contact Bio-Rad representative
Tests not available in U.S. but submitted for clearance 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, CMV total Ab
Research-use-only assays Tests in development User-defined methods implemented for what analytes		not in U.S. infectious disease & autoimmune panels contact Bio-Rad representative
Tests not available on other manufacturers' analyzers		none
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 1 min. strip: 1; max. full plate: 96	yes — min. strip, 1; max. full plate, 96
Methods supported/Separation methods	EIA & IFA/coated microwell or slide	EIA/coated microwell
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	8 EIA or 4 IFA 8 EIA or 4 IFA	4–8 4–8
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	no limit 8/192	contact Bio-Rad representative 4/96
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	4 hours/—/no	30 minutes/assay dependent/—
Multiple reagent configurations supported Reagent container placed directly on system for use	yes requires operator prehandling/preparation	yes yes
Reagents bar coded/information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/— yes/—	yes no/no (disposable tips)
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	—/192/— yes/liquid	varies by assay/180/4 no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/— no/—	microplates microplates
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	1 μL specimen 1 μL/200 μL	0.2 μL 10 μL/200 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption Noise generated	<u>no</u>	no 60 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/micro–100 mm height/no	no yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no no
Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection	no	yes
Auto detection of adequate reagent or specimen	no/yes yes	no/no no
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no no/no	yes/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/no no/no	yes/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	no
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	1–5 no/each run	assay dependent no/with each run
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/no each run	yes/no user determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	no/no no/no/5 minutes	yes/yes (through Unity QC program) no/no/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	_ _/_	 assay dependent
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	no/yes onboard/no —	yes/yes onboard/yes in development
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes can be customized	yes no
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes	— yes (broadcast download)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes no	yes no
Modem servicing/Can diagnose own malfunctions/	no/no/no	yes/no/no
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	00	00
On-site response time of service engineer Mean time between failures/To repair failures	<24 hours 6 months/4 hours	24 hours —/—
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 min; weekly: 15 min; monthly: 30 min	yes daily: 5 min; monthly: 60 min
Onboard maintenance records/Maintenance training demo module	no/no	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	\$40,000/>50 tests per day inquire 2 days on site/no	\$65,000/30–500 tests per day inquire 4 days in Redmond, Wash./no
Distinguishing features (supplied by vendor)	accurate pipetting at 1 µL; connection of one to 10 pipetting stations together through	fully automated microplate system that meets a high level of safety (positive identifi-
	an ethernet hub, graphical user interface; added module for IFA slide processing	cation of samples, reagents, microplates, clot detection, no contamination), flexibility (reagents and microplates) and productivity (four to six plates, up to 180 specimens, four to eight different assays can be processed simultaneously)

	utomateu immunoassay anaiy	20.0
	Diamedix Corp.	DiaSorin Inc.
	Pat Ahmad pat_ahmad@ivaxdiagnostics.com	Huizhen Li huizhen.li@diasorin.com
Part 12 of 31	2140 N. Miami Ave., Miami FL 33127 305-324-2300 www.diamedix.com	1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com
Name of instrument/First year sold/Where designed	Mago Plus Automated EIA Processor/1997/Italy (MAGO 4S to be added)	ETI-MAX 3000/2002/Germany
Country where manufactured/Where reagents manufactured	Italy/U.S.	Germany/U.S., Italy
No. of units in clinical use in U.S./Outside U.S.	250/—	160/972
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	batch, random access/benchtop/rack 28 × 48 × 26/8.7	batch, random access/benchtop/rack $40 \times 45 \times 30/10$
Difficultions in motios (if \wedge if \wedge D)/matument tootprint in sq. rect	20 ^ 40 ^ 20/0.1	TO A TO A CON TO
Tests available on instrument in U.S.	autoimmune: ANA screen, ENA screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA,	EA(D) lgG, EBNA-lgG, VCA-lgG, VCA-lgM reverse capture, measles lgG, varicella zoster
	β2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPO, PR3, TPO,TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, B	lgG, mumps lgG, <i>H. pylori</i> lgG, HSV I/II lgG, Trep-Sure syphilis, CMV lgG & lgM capture, rubella lgG, toxoplasma lgG & lgM capture, ANA screen, ENA 6 screen, anti-dsDNA,
	burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/	anti-Sm, anti-Sm/RNP, anti-SS-A, anti-SS-B, anti-Jo-1, anti-Scl-70, anti-histone, anti-
	IgM, <i>H. pylori</i> IgG, measles IgG, mumps, IgG, VZV IgG, mycoplasma IgG	MPO, anti PR3 (cANCA), anti-TPO, anti-cardiolipin IgA, IgG, IgM, anti-CCP, anti-B2 gly- coprotein 1 IgG and IgM, anti-mitochondria, anti-thyroglobulin, anti-cardiolipin total
		opposition rigo and igni, and introduction, and anyrogrossim, and outdoublin total
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	contact company
Research-use-only assays	_	S100
Tests in development	-	<u> </u>
User-defined methods implemented for what analytes	96-well plate enzyme immunoassays	— HBeAg, anti-HBe
Tests not available on other manufacturers' analyzers	_	nong, and no
Fully automated migraplets quotam	Mae	Nos
Fully automated microplate system No. of each analyte performed in separate disposable unit	yes 1 analyte per well	yes —
No. of wells in microplate	min. 1 × 8 wells; max. 96 wells	min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time
Methods supported/Separation methods	FIA/coated microwall (MACO AC FIA 9 IEA in nevallal)	EIA/coated microplate
wethous supported/separation methous	EIA/coated microwell (MAGO 4S, EIA & IFA in parallel)	EIA/Coated micropiate
No. of different measured assays onboard simultaneously	9	open
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	~50 currently preprogrammed assays 20 per diskette, unlimited diskette capability	open unlimited
No. of different analytes for which system accommodates reagent	9/96	volume dependent
containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	no/no/no
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	yes/ lot No., expir. date no/not susceptible, continuous cleaning	yes/— yes/no
Walkaway capacity in minutes/Specimens/Tests-assays	up to 2.5 hours—assay dependent/120/384	assay dependent/180/variable
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	yes/liquid yes/120	yes/liquid
Uses washable cuvettes/Replacement frequency	no/—	no no
Minimum specimen vol. required	50 µL (pediatric)	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	4 µL/25 µL (pediatric) yes/no	10 μL/200 μL 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	yes/— yes/11–15 mm × 75–100 mm/no	no yes (multiple)/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/yes
Bar-code placement per CLSI standard Auto2A 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 no/no	yes wee/re
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	no/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	NO varies per kit
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	assay dependent, 2–6 yes/per run	varies per kit no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	per run yes/yes	per run ves/yes
Automatic shutdown/Startup is programmable/Startup time	—/—/<5 minutes	no/yes/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	120/360 (2.5 hours—assay dependent)	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 (included in price)	yes/yes
Interfaces up and running in active user sites with	Cerner, Misys, others	yes
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	-
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (broadcast download & host query)	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/no/no	no no/no/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no 24 hours	no 24 hours
Mean time between failures/To repair failures	_/—	24 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 minutes; weekly: <10 minutes; monthly: none no/no	daily: 5 minutes; weekly: 30 minutes ves/no
		•
List price/Targeted bed size or daily volume	\$62,000/all bed sizes, all test volumes	\$79,000 (includes first year of service)/all bed sizes, all test volumes
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	service during normal business hours included in reagent rental agreement 1–2 days on site/yes	\$10,500 3 days/yes
	•	• •
Distinguishing features (supplied by vendor)	FDA-cleared system (instruments and reagents); moderate complexity; strip by strip timing, accommodates primary reagent packaging	selectively open system; multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling;
	פיייים פייים אייים אייים פייים פיים פייים	bidirectional interface

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	Greta Schwichtenberg greta.schwichtenberg@diasorin.com	Stephanie Sorensen stephanie.sorensen@grifols.com
	1951 Northwestern Ave., Stillwater, MN 55082	2410 Lillyvale Ave., Los Angeles, CA 90032
Part 13 of 31	800-328-1482/651-439-9710 www.diasorin.com	323-227-7415 www.grifols.com
Name of instrument/First year sold/Where designed	LIAISON/1997/Germany	Triturus/1999/Spain
Country where manufactured/Where reagents manufactured	Germany/U.S., Italy	Spain/Spain, U.S., Italy
No. of units in clinical use in U.S./Outside U.S.	250/3,000	>200/>1,700
Operational type/Model type/Sample handling system	batch, continuous random access/benchtop/rack	batch, random access & cont. random access/benchtop/universal carousel
Dimensions in inches (H $ imes$ W $ imes$ D)/Instrument footprint in sq. feet	63×136×66 cm/9.9	28.3 × 41.3 × 34.3/10
Tests available on instrument in U.S.	25 hydroxyvitamin D total, intact PTH, EBV IgM, EBNA IgG, VCA IgG, EA IgG, toxo IgG,	system is completely open; any U.S. clinically cleared and research-use-only EIA
	toxo IgM, CMV IgG, CMV IgM, treponema, IgG/IgM, VZV IgG, hGH, Borrelia burgdor-	procedure can be programmed; infectious diseases, autoimmune diseases, bone
	feri, HAV IgM, HAV total antibodies, rubella IgG, HSV-1 type specific IgG, HSV-2 type	markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles
Toda also and had and allering the males and	specific IgG	
Tests cleared but not clinically released	—	_
Tests not available in U.S. but submitted for clearance	cortisol, ACTH, dsDNA, CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, toxo IgG	_
Tests not available in U.S. but available in other countries	avidity, HSV 2 IgG, 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 lgM, HBsAg, HBsAg confirmatory, anti-HBs, anti HBc, HBc lgM, HBeAg, anti-HBe, anti-HAV	
	total, anti-HAV IgM, 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 OSTAS E	
Research-use-only assays	S100	_
nescuron use only assays	0100	
Tests in development	cardiolipin	_
User-defined methods implemented for what analytes	—	_
Tests not available on other manufacturers' analyzers	25 hydroxy vitamin D, total, treponema lgG/lgM, Borrelia burgdorferi, VZV lgG, CMV	_
local not available on early maintactarers analyzers	IgM, HSV-1 type specific IgG, HSV-2 type specific IgG	
	5 . VI . V	
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	-	8
No. of wells in microplate	-/-	96, 1 minimum strip, 4 maximum full plate
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA, EIA-coated microwell plates, onboard shaker, four individually temperature-con-
		trolled microplate positions/coated microwell
No. of different measured assays onboard simultaneously	15	1–8 tests on 1–4 plates
No. of different assays programmed, calibrated at once	15	8
No. of user-definable (open) channels	0	
No. of different analytes for which system accommodates reagent	15/100	8/48
containers onboard at once/Tests per container set	T(00 I / (4000)	, ,
Shortest/Median onboard reagent stability/Refrigerated onboard	7/28 days/yes (12°C)	—/—/no
Multiple reagent configurations supported	no no	yes
Reagent container placed directly on system for use	yes	minimal operator preparation, handling
Reagents bar coded/Information in bar code	yes/all lot information	no (
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/no 360/144/1,500	yes/no 180/92/8
System is open (home-brew methods can be used)/Liquid or dry system		
Uses disposable cuvettes/Max. No. stored	no/liquid	yes/liquid
Uses washable cuvettes/Replacement frequency	yes/720	no no
Minimum specimen vol. required	no assay dependent	no 300 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL/200 μL	2 μL/200 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/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.	yes/75 μL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/12, 13, 16 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
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	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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/	yes/no	no/no
Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun	2 minutes	_
Autocalibration or autocalibration alert	2 minutes no	yes
No. of calibrators required for each analyte	2	yes 1–14
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days	no/check every month
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	24 hours	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/no
Automatic shutdown/Startup is programmable/Startup time	no/no/2 minutes	yes/yes/1–2 minutes
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	2 minutes	-
Throughput per hour for three analytes on each specimen, in No. of	-	dependent on reagent methodology/—
specimens/No. of tests (cycle time)	una luna	
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	no/yes (additional)	yes, onboard/no CHCS Softmay Sunguest
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	Cerner, Soft, others	CHCS, Softmax, Sunquest
Uses LOINC to transmit orders and results	yes —	yes no
How labs get LOINC codes for reagent kits	_	LIS—unidirectional or bidirectional
Bidirectional interface capability	yes (host query)	yes (host query & broadcast download)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no no	no no
Modem servicing/Can diagnose own malfunctions/	no/no/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	24 hours	within 24 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: 10 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: 5–20 minutes
Onboard maintenance records/Maintenance training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
List price/Targeted had size or daily volume	\$1/5 000/all had sizes all volumes	\$79,000/300+
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	\$145,000/all bed sizes, all volumes inquire	\$79,000/300+ varies, multiple types available
Training provided w/purchase/Advanced operator training	a days on site/yes	varies, multiple types available —/yes
Training provided tripuloidate/revenied operator indiffing	o aajo on ono/joo	,,,,,
Distinguishing features (supplied by vendor)	benchtop analyzer with high throughput; unique menu offering; up to 15 assays	multibatch or continuous throughput EIA analyzer; user-defined menu, completely
, , , , , , , , , , , , , , , , , , ,	onboard, reagent integral, batch & stat	open system; easy color-coded worksheet and setup for operator; 2 probes for
		high-speed processing; unique cross-well washing; able to use fixed probes or
		myn-speeu processing, unique cross-wen washing, able to use fixeu probes of
		disposable tips

Actornated infinitianed and years		
	Hycor, An Agilent Technologies Division	Immunodiagnostic Systems Inc. (IDS Inc.)
	webmaster@hycorbiomedical.com	Ken Gibbs kenneth.gibbs@idsplc.com
Doub44 of 04	7272 Chapman Ave., Garden Grove, CA 92841	P. O. Box 17063, Fountain Hills, AZ 85269-7063
Part 14 of 31	714-933-30000 www.hycorbiomedical.com	480-836-7435 www.idsplc.com
Name of instrument/First year sold/Where designed	HY•TEC 288 PLUS/outside U.S. 1998, U.S. 1999/Netherlands	IDS-iSYS/2009/France
Country where manufactured/Where reagents manufactured	Netherlands/U.S., Scotland	France/Belgium
No. of units in clinical use in U.S./Outside U.S.	62/165	
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	random batches/benchtop/rack-robotics	continuous random access/benchtop/rack
Dimensions in inches (H \times W \times D)/instrument footprint in Sq. feet	29.5 × 42.5 × 27.5/8	28 × 40 × 28/—
Tests available on instrument in U.S.	total/specific IgE, ANA scr, TG, TPO, dsDNA, RF IgG, RF IgM, RF IgA, PR-3 (c-ANCA),	_
	MPO (p-ANCA), anti-mitochondrial, ENA-6 Scr., SS-A, SS-B, Sm, Sm/RNP, Scl-70, Jo-1,	
	gliadin IgA & IgG, GBM, GPC, anti-cardiolipin IgG & IgM, anti-cardiolipin scr., β -2 BPI	
	IgG, IgA & IgM, user-defined channels	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	anti-tissue transglutaminase IgA and IgG	_
Tests not available in U.S. but available in other countries	none specific IgG, ssDNA, total rheumatoid factor, anti-tissue transglutaminase IgA and IgG	25-hydroxyvitamin D, albumin, ALP, APO A1-APO B, amylase, bilirubin total/direct,
1000 Not available in 0.0. but available in other countries	oposito iga, sobita, total mountatola lattori, and access almogration mass iga and iga	calciumOCP, chloride (ISE), cholesterol, cholesterol HDL direct, CK, creatinine, CRP
		latex, gamma-GT, glucose, GOT/ASAT, GPT/ALAT, iron, LDH, magnesium, phosphorus,
		potassium(ISE), protein total & urine, sodium(ISE), triglycerides, urea, uric acid
Research-use-only assays	ANCA profile contramere CCD	DT IND ADTE fibrings on TT factors D dimer UIT (benevin induced thrombononic)
Tests in development	ANCA profile, centromere, CCP	PT, INR, APTT, fibrinogen, TT, factors, D-dimer, HIT (heparin-induced thrombopenia), AT III, heparins, intact PTH, bioactive PTH (1-84), 1,25-dihydroxyvitamin D
		BAP, CTX-I (CrossLaps), N-MID osteocalcin, TRACP 5b, hGH, IGF-I, IGF-BP3
		renin, aldosterone, ACTH, cortisol, C-peptide, insulin
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers	_	_
Fully outsmated missoulate aveter	100	
Fully automated microplate system No. of each analyte performed in separate disposable unit	yes 8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)	no
No. of each analyte performed in separate disposable unit	o (1 analyte per well, multiple analytes per well/soleens, up to 0 analytes per full)	
No. of wells in microplate	96-min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells	_
Methods supported/Separation methods	EIA, tube-based & microplate-based assays/activated cellulose & coated well	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	varies by assay, up to 288 allergens or 8 autoimmune	15
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	multiple 3	15 0
No. of different analytes for which system accommodates reagent	varies by assay, up to 288 allergens or 8 autoimmune	15/100
containers onboard at once/Tests per container set	variously about, up to 200 and gone of a date.	10/100
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/12 hours/no	48 hours/7 days/yes (12°-15°C, run mode; 8°-10°C, sleep mode)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	no, requires operator prehandling/preparation
Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no yes/<1 part in 10,000	yes/LOT key, No. within lot, XML —/—
Walkaway capacity in minutes/Specimens/Tests-assays	assav dependent/100/288	—/— —/64/960
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	closed/liquid
Uses disposable cuvettes/Max. No. stored	no	yes/960 ·
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	10 μL, 110 μL w/ dead vol.	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10 μL–50 μL, assay dependent//100 μL ves/no	5 μL/tube dependent ~80 μL no/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	-	-
Has dedicated pediatric sample cup/Dead vol.	no	yes/80 μL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/all up to 16 $ imes$ 100 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—	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 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	no/no	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/no	yes/yes
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	yes	yes
No. of calibrators required for each analyte	1–6	2
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	no/test dependent ~7 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required	yes/yes every assay	yes/yes —
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	
Automatic shutdown/Startup is programmable/Startup time	yes/no/2-3 minutes	yes/yes/10 minutes
0.15		
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir of sample		
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	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/optional	onboard/no, additional cost
Interfaces up and running in active user sites with	25	— NOC
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	no no	yes —
How labs get LOINC codes for reagent kits	<u> </u>	_
Bidirectional interface capability	yes	yes (host query)
Results transmitted to LIS as soon as test time complete	optional	yes
Interface available (or will be) to auto specimen handling system	NO NOS/NO	yes vec/vec/vec
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/no	yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	48 hours	24 hours
Mean time between failures/To repair failures	7 months/4 hours	WIP/WIP
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes yes (includes audit trail of who replaced parts)/yes	daily: 15 min; weekly: 30 min; monthly: 15 min yes, includes audit trail/no
Onsoard maintenance records/maintenance daming defilo module	you (monutes addit than of who replaced parts)/yes	yos, moluucs auurt u anvilu
List price/Targeted bed size or daily volume	\$55,000/all sites, variable test vols.	_/_
Annual service contract cost (24 hours/7 days)	\$5,500	_
Training provided w/purchase/Advanced operator training	3 days on site/yes	—/yes
Distinguishing features (sometical bosons des)	fully outemaked allowers and autoimmune to the control of the cont	unique analytical platform combining these distributions of in-
Distinguishing features (supplied by vendor)	fully automated allergy and autoimmune testing; user-defined software channels for microtiter plate and tube-based assays	unique analytical platform combining three disciplines of immunoassay, biochemistry and coagulation
	iniorodici piate anu tube-bascu assays	ana ovaguianon

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Part 15 of 31	877-546-8633 www.invernessmedicalpd.com	609-627-8029 www.invernessmedicalpd.com
N	AU NA/0000/ILO	AUA40 (0000 / 0 - 1)
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.	143/—	10/—
Operational type/Model type/Sample handling system	batch/benchtop/multichannel pipetting or automated with front end	batch/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	9.5×17×20/—	35 × 67 × 40/—
	0.6 A 11 A 20	
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
	simplex virus, type 1 & type 2)	virus, type 1 & type 2) and wampole ELISA II assays
Toda alasand hadaad allaladha andaaad		
Tests cleared but not clinically released 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	ionon iga, portena visc-1/pepo to	ionon igu, portena visc-1/pepo to
lests not available in 0.5. but available in other countries		
Research-use-only assays	_	_
Tests in development	HIV-1, celiac IgG, celiac IgA cardiolipin IgG, syphilis	HIV-1, celiac IgG, celiac IgA, cardiolipin IgG, syphilis
	, , , , , , , , , , , , , , , , , , , ,	
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers	_	_
Fully outomated microplete avateur		100
Fully automated microplate system No. of each analyte performed in separate disposable unit	NO 1_10	yes assay denondent
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
or mone in innoropiate	min vary, 1, max run piato, 50 mon piato	mini sarpi oj maxi ian piatoi so mon piato
Methods supported/Separation methods	fluorescence/bead	enzyme immunoassay, multiflexing/bead, coated microwell
No. of different measured assays onboard simultaneously	10	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 Reagent container placed directly on system for use	no requires energter probability/proporation	yes
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	yes/no	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	no/—/—	ves/10 × 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	<u> </u>
Onboard test auto inventory (determines vol. in container)	no	yes
Measures No. of tests remaining/Short sample detection	—/—	no/yes
Auto detection of adequate reagent or specimen	- _	yes
Clot detection/Reflex testing capability	_/_	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	—/— no/no	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	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/calibration in every well	-
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	—
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	1 per month no/—	every assay —/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/30 minutes	/yes yes/yes/10 minutes
		yy
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)	no luca	han
Can auto transfer QC results to LIS/Onboard capability to review QC	no/yes	—/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	yes, onboard/yes (additional cost) Cerner, Sunquest	—/yes —
LIS interface operates simultaneously w/running assays	no	no
Uses LOINC to transmit orders and results	no	<u> </u>
How labs get LOINC codes for reagent kits	-	_
Bidirectional interface capability	no	-
Results transmitted to LIS as soon as test time complete	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	_	_
On-site response time of service engineer		
Mean time between failures/To repair failures	6 months/<1 day	24-40 Hours —/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 15 min; weekly: 30 min; monthly: 5 min	daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes
Onboard maintenance records/Maintenance training demo module	no/—	no/—
	A	A
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	\$18,500 5 days on cita
Training provided w/purchase/Advanced operator training	00	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
Distinguishing found to (supplied by vellus)	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	

	ditomated immunoassay anaiy	,
	Inverness Medical Professional Diagnostics	Inverness Medical Professional Diagnostics
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Part 16 of 31	609-627-8029 www.invernessmedicalpd.com	609-627-8029 www.invernessmedicalpd.com
	·	
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	DS2/2007/U.S. U.S./U.S.	DSX/2004/U.S. U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	recently launched	approx. 500/—
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	27 × 21 × 26/4	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,	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, H. Pylori, HSV, legionella,lyme, measles,
1000 000 000 000 000 000 000 000 000 00	mumps, myco, rubella, syphilis, toxo, VZV; Al: ANCA, ANA, CCP, ASCA, beta 2, cardios,	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,	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	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	— Control of the cont	— Garage State (1) - 100
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	_	_
Have defined matheds booking to the day of the sub-the-	AND NA MARK I Laboratorial Control of the Control o	Add NA NA IN the country of the street of th
User-defined methods implemented for what analytes	AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays	AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays
Tests not available on other manufacturers' analyzers	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko
Fully automated microplate system No. of each analyte performed in separate disposable unit	yes 1 analyte per well, multiple analytes per well	yes 1 analyte per well, multiple analytes per well
1.5. 51 odon analyse periorinea in separate aisposable unit	. analyte per trong manupic unarytes per troll	. analyte per from mentiple ununytee per from
No. of wells in microplate	96 (min: 1; max: 96)	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	24	48
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	unlimited 18/24	unlimited 24/48
containers onboard at once/Tests per container set	10/21	20.0
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hrs/1 day/no	8 hrs/1 day/no
Multiple reagent configurations supported Reagent container placed directly on system for use	yes placed directly on system	yes placed directly on system
Reagents bar coded/Information in bar code	no/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover		no/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	no/—	no/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL 10 μL/50 μL	10 μL 5 μL/50 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	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	yes/primary, pouroff/no	yes/primary, pouroff/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interl., 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	no/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/	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	no
No. of calibrators required for each analyte	analyte dependent	analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/within each run no/no	no/within each run no/no
How often QC required	with every assay	with every assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	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)		
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.
mioriaces up and running in active user sites with	oonio, minomum, ounquest, oon, mysis, etb.	oomo, minomum, ounquest, out, mysis, etb.
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 (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 no/yes/no	no no/yes/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	110 24 hrs	00 24 brs
On-site response time of service engineer Mean time between failures/To repair failures	24 hrs — (recently launched)/—	24 hrs 4 months/2 hrs
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 min; weekly: 20 min; monthly: 20 min no/no	daily: 10 min; weekly: 20 min; monthly: 20 min no/no
553a a maintenance recorder maintenance duming define module		
List price/Targeted bed size or daily volume	\$47,250/<350 beds	\$62,900/350+ beds
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$7,500 3 days on site/yes	\$7,500 3 days on site/no
Distinguishing features (supplied by vendor)	combined with the Inverness ELISA product line and the ability to automate enteric	open DSX platform enables customers to run virtually any ELISA-based assay;
	assays and front-end dilute Inverness AtheNA assays, the DS2 provides an efficient, open, fully automated solution for customers looking for laboratory automation	modular design allows user to customize the system to their unique needs by adding extra incubators, incorporating a bar-code scanner, or choosing among certain types
	,, and a second of second o	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
		•

Automated	immunoassa	v analvzers
	III III I GGGGG	, analy e

Part 17 of 31	Olympus America Inc. Susan Watanabe susan.watanabe@olympus.com 3500 Corporate Pkwy., Center Valley, PA 18034 800-223-0125 www.olympusamerica.com/AU3000i	Ortho Clinical Diagnostics Mark Steelman msteelma@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 585-453-3420 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	AU3000i Immunoassay System/2007/Japan Japan/Ireland 2/30 continuous random access/floor standing/racks	VITROS ECi Immunodiagnostic System/1997/U.S. U.S./U.K. >3,000 worldwide cont. random access/floor standing/universal sample trays (circular) accommodate
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	$57 \times 67 \times 47/22$ plus computer	primary & secondsondary containers without need for adapters $51 \times 44 \times 29/8.9$
Tests available on instrument in U.S.	4th-gen TSH, T3, T4, fT4, Ft3, t-uptake, LH, FSH, PROL, PROG, HCG, AFP, CEA	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, aHAV total, aHAV IgM, rubella IgG, 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	—	
Research-use-only assays Tests in development	— β-hCG-short, troponin I, Tni-stat, BNP, ferritin, folate, B12, vitamin D, PTH, IgE, OV-TC (CA125), anti-TG and anti-TPO	— iPTH, HIV Ab/Ag, preeclampsia, aHBe (U.S.), HbeAg (U.S.), syphilis (Ex-U.S.)
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	TSH, 4th generation	— NTx
Fully automated microplate system No. of each analyte performed in separate disposable unit	no	no
No. of wells in microplate		
Methods supported/Separation methods No. of different measured assays onboard simultaneously	chemiluminescence/magnetic particle 24	chemiluminescence (enhanced)/individual coated microwell 20
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	180 0	20 programmed & calibrated at once; up to 25 lots calibrated per assay 0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/assay dependent (200 or 100)	20/100
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	14 days/28 days/yes (4°-12° C) yes	56 days/56 days/yes (2°-8°C) yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes yes/lot specific master calibration information; calibrator set points; internal QC	yes yes/test ID, expir., lot No., pack ID
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	targets; product name, lot information, expiration date no/no, disposable tips used to prevent carryover	—/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	up to 240/300/4,800 no/liquid	720/60/800 (with EPM—enhanced productivity module) no/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/1,000 with on-the-fly bulk refill no	no no
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain	10–100 μL (test dependent) 10 μL/100 μL	10 µL 10 µL/80 µL 22 but it is available/22
Requires dedicated water system/Water consumption Noise generated	yes/no yes/8 L per hour at max. throughput <60.7 decibels	no but it is available/no no/— 60 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/— yes/11.5–16 mm (width) and 55–102 mm (height); microcups/no	no yes/mult. ped., microtainers & cups, 5 mL, 7 mL, 10 mL on same univ. sample tray/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128, & ISBT 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	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no 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	no/no	no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	run dependent yes	assay dependent yes
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	1 or 2 point master curves (test dependent) no/28 days	1–3 no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Ophograf real time OC/Support multiple OC let Noo per applyte	yes/yes user-defined	yes/yes once per 24 hours yes/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes yes/yes/~5 minutes	yes/yes/immediate upon completion of last sample metering
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)	18 minutes 2 minutes 80/240 (15 seconds after 1st result with 300 sample tube continuous loading)	24 minutes immediate upon completion of last sample metering 30/90 (40 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/yes (additional cost) —	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,
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes no	INS, Siemens, Dawning yes yes
How labs get LOINC codes for reagent kits Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes yes	yes yes (all systems)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	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	no — TBD/TBD	no <4 hours (contract dependent) —/dependent on corrective action
Onboard maintenance records/Maintenance training demo module	yes daily: <5 minutes; weekly: <30 minutes; monthly: 10 minutes yes/yes	—/dependent on corrective action yes daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$275,000, including ancillaries/>200—volume varies (contact Olympus rep) \$18,850 4.5 days on site, 4.5 days at vendor offices/yes	\$140,000/flexible for majority of customer demand varies w/ service level choices 3.5 days at vendor offices/yes, as needed on site
Distinguishing features (supplied by vendor)	fast throughput, high-capacity immunoassay system; Olympus standardized rack and software streamline workflow between AU Chemistry and the AU3000i; SupportVision delivers real-time monitoring for proactive service	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

Part 18 of 31	Ortho Clinical Diagnostics Mark Steelman msteelma@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com	Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK	Phadia Laboratory System 250/2004/Japan, 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/universal sample trays (circular) accommodate primary & secondary containers without need for adapters	continuous random access/floor standing/racks
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	64.5 × 83.5 × 33.5/19.4	$73 \times 50 \times 30 + 26$ -in. wide computer stand/—
Tests available on instrument in U.S.	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	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 ENA's, Celikey IgA and IgG (tissue transglutaminose), and diadia IgA, and IgC
Tests cleared but not clinically released	B12, RBC folate, folate, CA 19-9, CA 125 II, cortisol (serum, urine), testosterone, prolactin, estradiol, progesterone, rubella IgG, NTx	nase), and gliadin IgA and IgG —
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	aHBs Ag, aHBs Ag (conf), aHCV, aHBc, aHBc IgM, aHIV 1+2 — — —	= -
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	i-PTH, HIV combo, preeclampsia, syphillis — — —	— — 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	chemiluminescence, enhanced chemiluminescence/coated microwell	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	31 31 programmed and calibrated at once, up to 25 lots calibrated per assay	3 methods not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	31/100	0, closed system 3/400 or 100 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	1,008 hours/56 days/yes (2°–8°C) yes yes	5 days/1 year/yes (2°–8°C) yes yes (wash solution requires preparation)
Reagents bar coded/information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/test ID, expiration date, lot No., pack ID no/—	yes/product name, lot No., expiration date no/—
Walkaway capacity in minutes/Specimens/Tests-assays	varies/90/3,100	470/50 simultaneously/370 tests
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	closed/liquid no/	no/liquid no
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	no/— 10 μL 10 μL/35 μL	— 40 μL for ImmunoCAP tests and 50 μL for EliA tests 40 μL/40–200 μL for ImmunoCAP tests and 50 μL/50–200 μL for EliA tests (varies with
Supplied with UPS (backup power)/Requires floor drain	no/no	tube type) yes/no
Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol.	no/— — no/—	no/10 L 65 decibels no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/1.5 mL micro-collection containers, 0.5- and 2.0-mL cups, 5 mL, 7mL, 10 mL on same universal sample tray—no adapters/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes/10-17 mm × 50-105 mm/no
Bar-code placement per CLSI standard Auto2A	yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no
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	yes yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	no/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	assay dependent	100 minutes
Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 1–3 depending on assay	yes 6 per analyte for calibration run, and 2 per analyte when using stored curve
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/28 days yes/yes	yes/28 days or sooner if conjugate lots change yes/yes
How often QC required	once per 24 hours	once per work shift (user defined)
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes —/—/0	yes/yes yes/yes/30 minutes unattended
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	24 minutes immediate upon completion of last sample metering	— 6 minutes
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	assay dependent/assay dependent (19 seconds) yes/yes	20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds) yes/yes
Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	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,	onboard/yes (instrument side only) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	INS, Siemens, Dawning yes no	yes 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 Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	yes yes, enGen yes/yes	yes yes/yes/yes
Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no <4 hours (contract dependent)	no <24 hours
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	dependent on corrective action/dependent on corrective action yes	ves
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 10 minutes; weekly: 25 minutes; monthly: 15 minutes yes, includes audit trail/yes	daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes yes/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	—/350 tests per day varies —/yes	\$75,000/>20,000-95,000 tests per year 3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	diagnostic checks throughout sample and assay processing reduces misreported	provides widely accepted technology for serologic, specific IgE testing with the Immu-
Steamgardining routeres (supplied by Vellutt)	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	noCAP family of products and autoimmune markers with the EliA family of products; innovative 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

Automated inimanoassay analyzers		
	Phadia	Phadia
	Nicole Lampas nicole.lampas@phadia.com	Nicole Lampas nicole.lampas@phadia.com
Part 19 of 31	4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
	<u>'</u>	·
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	Phadia Laboratory System 1000/2003/Japan, Sweden Japan, Sweden/Sweden	Phadia Laboratory System 100 ^E /1995/Sweden Sweden/Sweden
No. of units in clinical use in U.S./Outside U.S.	Japan, Sweuen/Sweuen	— Sweden/Sweden
Operational type/Model type/Sample handling system	continuous random access/floor standing/racks	batch/benchtop/carousel_
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	83 × 71 × 40 + 26-in. wide computer stand/—	18 × 28 × 24 + computer/—
Tests available on instrument in U.S.	hundreds of ImmunoCAP specific IgE tests and ImmunoCAP total IgE	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 IgA and IgG (tissue transglutaminase), and gliadin IgA and IgG.
Tests cleared but not clinically released	_	— and grading set, and grading systems and syd.
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	Phadia US Inc. ImmunoCAP specific IgE blood tests	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	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	7
	insufficiencies in the onboard inventory	
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0, closed system 3/400 or 100 depending on the conjugate type	0, closed system 48–96 depending on the conjugate type
containers onboard at once/Tests per container set	or too or too depending on the conjugate type	TO SO depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/1 year/yes (2°-8°C)	_
Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes (wash solution requires preparation)	yes yes (wash solution requires preparation)
Reagents bar coded/Information in bar code	yes (wash solution requires preparation) yes/product name, lot No., expiration date	yes (wash solution requires preparation) yes/product name, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover (disposable sample tips)	no/—
Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system	460/200 simultaneously/2,400 tests no/liquid	180 minutes/varies with analyte/48 no/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	_	-/-
Minimum specimen vol. required	40 µL per test	40 μL for ImmunoCAP tests and 50 μL for EliA tests 40 μL/40–200 μL for ImmunoCAP tests and 50 uL/50–200 μL for EliA tests (varies with
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 μL/40–200 μL (varies with tube type)	tube type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/10 L 68 decibels	no/1 L per run
Noise generated Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10-17 mm × 50-105 mm/no	yes/10–16 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 Onboard test auto inventory (determines vol. in container)	no yes	no no
Measures No. of tests remaining/Short sample detection	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/yes no/no	yes/yes no/no
Dilution of patient samples onboard/Automatic rerun capability	no/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	100 minutes	2.5 hours-batch run
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 Multipoint calib. supported/Multiple calibs. stored for same assay	yes/28 days or sooner if conjugate lots change yes/yes	yes/28 days or sooner if conjugate lots change yes/yes
How often QC required	once per work shift (user defined)	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/20 minutes including request entry or downloading
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	6 minutes 80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds)	— batch analyzer/48/180 minutes processing time for batch to finish
specimens/No. of tests (cycle time)	os oposimonorato (100 minutos to mot rosult, uten 1 result per 10 secontos)	analyzor, to infinite processing time for patent to fillion
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 (instrument side only) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim,	onboard/yes, instrument side only (included) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim,
and turning in active user sites with	others	others
IIC interfere asserts about		
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	_	_
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 yes	yes yes
Modem servicing/Can diagnose own malfunctions/	yes/yes/yes	yes/yes/yes
Determine malfunctioning component	no	no
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no <24 hours	no —, swap
Mean time between failures/To repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	yes dailu 1 minutaa waakku 10 minutaa manthiu 15 minutaa	yes doilu 5 minutae weekhu 10 minutae menthu 15 minutae
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 1 minutes; weekly: 10 minutes; monthly: 15 minutes yes/—	daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/no
List price/Targeted bed size or daily volume	\$235,000/>95,000 tests per year	\$22,000/>7,000-20,000 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	— 3.5 days at vendor offices/yes
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Distinguishing features (supplied by vendor)	provides widely accepted technology for serologic, specific IgE testing with the	provides widely accepted technology for serologic, specific IgE testing with the
	ImmunoCAP family of products; innovative products, comprehensive clinical and technical research, and extensive medical information and education, make	ImmunoCAP family of products and autoimmune markers with the EliA family of products; innovative products, comprehensive clinical and technical research, and
	ImmunoCAP a choice for IgE testing worldwide; three automated ImmunoCAP	extensive medical information and education, makes ImmunoCAP a choice for IgE
	instruments offer laboratories the ability to measure and report specific IgE quantitative results accurately and precisely across the clinical range	testing worldwide; 3 automated ImmunoCAP instruments offer labs the ability to measure and report specific IqE quantitative results accurately across the clinical

Adtomated inimaricaccay analyzore		
	Radiometer Medical ApS	Randox Laboratories Ltd.
	info@radiometeramerica.com	David Ferguson evidence.support@randox.com
	810 Sharon Drive, Westlake, OH 44145	Diamond Road, Crumlin, County Antrim, BT29 40Y
Part 20 of 31	+1 (440) 871-8900 www.radiometeramerica.com	+44 28 94 422413 www.randox.com
Name of instrument/First year cold (Mhara designed	A OTOO (0000 /Degree of c	Fuidance Custom (0004/Illuited Vinadom
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	AQT90/2008/Denmark Denmark/Finland	Evidence System/2004/United Kingdom United Kingdom/United Kingdom
No. of units in clinical use in U.S./Outside U.S.	—/—	—/—
Operational type/Model type/Sample handling system	random access/benchtop/inlet	batch/floor standing/carousel
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	17.7 × 18.1 × 18.9/2.4	68 × 78 × 39/35.75
Tests available on instrument in U.S.	_	cocaine, methamphetamine, amphetamine, methadone, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol
Tests cleared but not clinically released	_	none
Tests not available in U.S. but submitted for clearance	Tnl, CKMB, MYO, βhcG	MDMA, LSD, fentanyl, propoxyphene, methaqualone, generic opioids, ketamine,
	· · · · · ·	buprenorphine
Tests not available in U.S. but available in other countries	Tnl, CKMB, MYO, NT-proBNP, βhcG, CRP, D-dimer	TT4, FT4, TT3, FT3, TSH, AFP, CEA, hCG, fPSA, tPSA, testosterone, CK-MB, cTNi, myo-
Research-use-only assays		globin, FABP GPBB, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-3, IL-4, IL-6,
nestal cli-use-only 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,
		stnfri, stnfrii, mmp-9, il5, il15, gmcsf, mip-1 $lpha$, tnf eta
Tests in development	BNP, TnT, hsCRP, APTT, PT-INR	IL1-1Ra, IGF-1 free, RANTES, PDGF-AA, PDGF-BB, eotaxin, IP-10, cortisol, DHEA-S, lep-
		tin, 17-OH progesterone, IL12-p40, maternal screening array, sepsis array, endocrine array, metabolic arrays, and additional drugs of abuse array
User-defined methods implemented for what analytes	_	none
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,
		IFNg, IL-1a, MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6r, sTNFRI, sTNFRII, MMP-9
Fully automated mis-roll-to-		
Fully automated microplate system No. of each analyte performed in separate disposable unit	no 	no
No. of each analyte performed in separate disposable unit No. of wells in microplate	_	-
- State of the sta		
Methods supported/Separation methods	time-resolve fluorescence/coated microwell	chemiluminescence/—
No. of different measured assays onboard simultaneously	15	8
No. of different assays programmed, calibrated at once	1	12
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 15/16	0 96/360
containers onboard at once/Tests per container set		
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hours/7 days/no	assay dependent 1–14 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes	yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/lot number, expiry date, checksum, parameter code, cartridge ID no/<100 ppm	yes/product component, size, lot No., expir. date no/—
Walkaway capacity in minutes/Specimens/Tests-assays	—/2/10 tests	100/180/540-1,980
System is open (home-brew methods can be used)/Liquid or dry system	yes (home brew methods can be used)/dry	no/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	no/— 2 μL	no/— 7 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 μL 2.5 μL/53.5 μL	7 μL/70–350 μL (varies with cup type)
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	_	- ,
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/— yes/11 × 66 to 13 × 78 mm/yes	no/— yes/12 mm, 16 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	<u> </u>	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/—	yes/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	no —/no	yes no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/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		
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	_	
No. of calibrators required for each analyte	2-level adjuster, supplied in kit	9 (multi-analyte calibrators)
Calibrants can be stored onboard/Avg. calibration frequency	yes/once per lot	yes/weekly (dependent on panel)
Multipoint calib. supported/Multiple calibs. stored for same assay	_/_	yes/yes
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	customer determined (longest interval: 1 per month) —/—	user defined yes/yes
Automatic shutdown/Startup is programmable/Startup time	_//30 minutes	yes/no/13 minutes
Stat time to completion of β-hCG test	18 minutes	-
Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of	30 seconds 10/30	
specimens/No. of tests (cycle time)	10/00	100/027 (0 Illiliatos)
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/Randox, included in price
Interfaces up and running in active user sites with		yes
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	_	_
Bidirectional interface capability	yes (broadcast download & 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/	NO vectors to see	no ves ves
Determine malfunctioning component	yes/yes/yes	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	per negotiated contract	_
Mean time between failures/To repair failures	-/-	_/_ NO.
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel		yes daily: <5 min; weekly: 10 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	yes, includes auidt trail/no	no/—
List price/Targeted bed size or daily volume	_/_	varies based on contract/500+
Annual service contract cost (24 hours/7 days)	flexible options available	varies based on contract
Training provided w/purchase/Advanced operator training	<u>-</u>	5 days on site/yes
Distinguishing features (supplied by vendor)	POC instrument measures whole blood with lab quality; broad menu and parameter	biochip enables simultaneous analysis of multiple parameters in a single patient
, , , , , , , , , , , , , , , , , , , ,	flexibility; closed tube and closed waste system	sample; maximum throughput of 1,188 test results per hour; unreported tests can
		be retrieved retrospectively; arrays contain multiple tests applicable to clinical and
		research applications

Adtomated inimarioussay analyzers		
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Part 21 of 31	800-428-5074 www.roche.com/labsystems/us	800-428-5074 www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed	Elecsys 2010/1996/—	cobas e411/2006/Japan
Country where manufactured/Where reagents manufactured	Japan/Germany	Japan/Germany
No. of units in clinical use in U.S./Outside U.S.	>800/>6,000	<u>-</u> /_
Operational type/Model type/Sample handling system	cont. random access/benchtop/rack or disk	continuous random access/benchtop/rack, disk
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	22.1 × 47.2 × 28.7/9.4	31.4 × 47.2 × 28.7 (disk); 31.4 × 67 × 37.4 (rack)/94 (disk), 17.4 (rack)
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	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3
1000	19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, proges-	II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH,
	terone, prolactin, SHBG, testosterone, total & β CG, anti-TG, anti-TPO, FT3, FT4, T3,	progesterone, prolactin, SHBG, testosterone, total & β CG, anti-TG, anti-TPO, FT3, FT4,
	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,	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,
	anti-TSH receptor	HBsAg conf, anti-HBs, anti-TSH receptor
Tests cleared but not clinically released	-	—
Tests not available in U.S. but submitted for clearance	toxo lgM, rubella lgM, anti-HBc lgM	toxo lgM, rubella lgM, anti-HCV
Tacks and qualishin in H.C. but qualishin in albor countries	TO OA 70 A sufus Of 4 C 400 distinguis and HAV and HAV land and HDs and Hbs	TO OA 70 A sufus Of 4 C 400 distinguis and HAV and HAV land and HDa and HDa
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-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, 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, 25-0H
	industry, invalidation, invalidation of the community of the control of the contr	vitamin D3
Research-use-only assays	_	_
Tests in development	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc,	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	HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM
User-defined methods implemented for what analytes	— Quanto DTU Tot	C.minuto DTU and cardiae account O minuto DTU ToT
Tests not available on other manufacturers' analyzers	9-minute PTH, Tnt	9-minute PTH and cardiac assays, 9-minute PTH, TnT
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	-	-
No. of wells in microplate	-	-
Methodo cumostod/Consestion mother to	alaska ahawili minaa ay sa (maamati a madi -1-	alaskashamiluminassansa manualis usukista (manualis usukista (manualis usukista manualis usukista (manualis usukista usukista usukista usukista (manualis usukista usuk
Methods supported/Separation methods No. of different measured assays onboard simultaneously	electrochemiluminescence/magnetic particle	electrochemiluminescence, magnetic particle/magnetic particle
No. of different assays programmed, calibrated at once	15 60	18 18
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent	15/100–200 tests per kit	18/100–200 tests per kit
containers onboard at once/Tests per container set	F0. Jan. /F0. Jan. (1999)	(FO days (1999))
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	56 days/56 days/yes (20°C) yes	—/56 days/yes (20°C) yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/calib. curve, application params., lot No., expir., reag. name	yes/calib. curve, application params., lot No., expir., reag. name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover		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	120/disk: 30, rack: 100/180 no/liquid	disk: 120/30/180; rack: —/100/18 no/liquid
Uses disposable cuvettes/Max. No. stored	yes/180	yes/360 assay tips; 180 assay cups
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	10 μL	10 μL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL/100 μL	10 μL/100 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	—/no no/3 L for 250 tests	no/no no/3 L for 250 tests
Noise generated	—	<70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13-16 mm diam./no	yes/13–16 mm diameter/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
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 (with middleware)	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/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	yes 2	yes 2
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	no/monthly for lot; weekly for rack
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	once per 24 hours	once per day
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes no/no/4 minutes	yes/yes
Automatic shutuowii/startup is programmable/startup time	no/no/4 minutes	yes/no/4 minutes
Stat time to completion of β-hCG test	9 minutes (hCG intact)	9 minutes
Time delay from ordering stat test to aspir. of sample	42 seconds	42 seconds
Throughput per hour for three analytes on each specimen, in No. of	30/88 (42 seconds)	30/86 (42 seconds)
specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	ves/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	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
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 (CLAS & Roche task targeted automation)	yes
Modem servicing/Can diagnose own malfunctions/	no/yes/no	no/yes/no
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	yes dailyr 1 minutaer weeklyr 5 minutaer hiweeklyr 25 minutaer menthyr none	yes dailyr E minutaer weeklyr 6 minutaer menthyr 10, 15 minutae
Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	daily: 1 minutes; weekly: 5 minutes; biweekly: 25 minutes; monthly: none no/no (training CD-ROM)	daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes no/no
	(numming op nom/	
List price/Targeted bed size or daily volume	varies based on contract	varies based on contract/varies; primary IA system or back-up unit
Annual service contract cost (24 hours/7 days)	included w/ reagent rental	included with reagent rental
Training provided w/purchase/Advanced operator training	3 days at Indianapolis offices/yes	4 days on site/yes
Distinguishing features (supplied by vendor)	liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic	liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAT; stat
Promisum reasures (Supplied by Venuol)	ranges, and fast turnaround time, stat interrupt; onboard reag. storage; minimal	inquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAI; state interrupt; minimal maintenance
	maintenance	

Adternated infinialisassay dilalyzers		
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Part 22 of 31	800-428-5074 www.roche.com/labsystems/us	800-428-5074 www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed	MODULAR ANALYTICS E170/2001/Japan	cobas e601/2006/—
Country where manufactured/Where reagents manufactured	Japan/Germany	Japan/Germany
No. of units in clinical use in U.S./Outside U.S.	>250/>300 (combination of E and EE systems) and >25 Integrated Modular Systems	>350/—
Overetional time/Model time/County handling costons	(U.S. only)	andinuous vandom assas (filesy shoulding (van)
Operational type/Model type/Sample handling system Dimensions in inches (H×W×D)/Instrument footprint in sq. feet	continuous random access/floor-standing/rack 47 × 47 × 31.5 (Modular E configuration)/approx. 60 (one module system)	continuous random access/floor-standing/rack $46.1 \times 71.8 \times 40/19.73$
Differsions in fileties (if \(\times\) \(\times\) \(\times\) \(\times\) \(\times\) \(\times\)	47 × 47 × 51.5 (modular E configuration)/approx. oo (one module system)	40.1 \(\lambda\) 13.73
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	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, progester-	19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, proges-
	one, prolactin, SHBG, testosterone, total and βhCG, anti-TG, anti-TPO, FT3, FT4, T3,	terone, 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,	T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, carbamazepine, gentamicin, theophylline, tobramycin, valproic
	anti-TSH receptor	acid, vancomycin, cortisol, toxo lgG, rubella lgG, HBsAg, HBsAg conf, anti-HBs, total PSA
	•	(screening), free PSA, anti-TSH receptor
Tests cleared but not clinically released		
Tests not available in U.S. but submitted for clearance	toxo lgM, rubella lgM, anti-HCV	toxo lgM, rubella lgM, anti-HCV
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	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	IgM, anti-HBe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH
	vitamin D3	vitamin D3
Research-use-only assays	- interventin C anti CMV InC anti CMV InC thursen about in NCC autic 21.1 anti UDa	- interlegation C. anti CMV InC. anti CMV InC. thurseslebulin MCE outro 21.1 anti UDa
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	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, 9 minute (STAT) applications for
	ibo igin, ibong, and ibo, and ibn, and ibn igin	Tnt, myoglobin, CKMB, PTH, HCG
User-defined methods implemented for what analytes	_	_
Tests not available on other manufacturers' analyzers	TnT	TnT
Fully automated microplate quatem	70	no.
Fully automated microplate system No. of each analyte performed in separate disposable unit	<u>no</u>	<u>no</u>
No. of wells in microplate	_	_
· .		
Methods supported/Separation methods	electrochemiluminescence/magnetic particle, electrochemiluminescence	electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	25 per module, maximum of 60	25 per module
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	25 per module —	25 per module —
No. of different analytes for which system accommodates reagent	25/100–200 tests per kit	25 per module/100-200
containers onboard at once/Tests per container set	·	·
Shortest/Median onboard reagent stability/Refrigerated onboard	14 days/35 days/yes (20° C)	56 days/56 days/yes (20° C)
Multiple reagent configurations supported Reagent container placed directly on system for use	yes	yes
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		—/zero, uses disposable sample tips
Walkaway capacity in minutes/Specimens/Tests-assays	360/—/1,006	360/300/1,000
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	yes/1,006	yes/1,006 no/—
Minimum specimen vol. required	no 10 µL	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	—/100 μL	10 μL/100 μL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption	yes/30 L per hour in full operation	yes/up to 30 L/hour in full operation
Noise generated Has dedicated pediatric sample cup/Dead vol.	<65 decibels yes/100 μL	<65 decibels yes/100 μL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 to 16 × 100/no	yes/13×75 to 16×100/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 voo/voo	yes year/yea
Auto detection of adequate reagent or specimen	yes/yes yes	yes/yes yes
Clot detection/Reflex testing capability	yes/yes (with middleware)	yes/yes (with middleware)
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/ 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	yes	yes
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/monthly	no/every 28 days
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	yes/yes/11 minutes	yes/yes/11 minutes
Stat time to completion of R has test	10 minutes	19 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	18 minutes	18 minutes 42 seconds
Throughput per hour for three analytes on each specimen, in No. of	56/176 (21 seconds)	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 (addt'l cost) all maior LISs	onboard/yes (additional cost) all major laboratory information systems
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	yes
How labs get LOINC codes for reagent kits	— — — — — — — — — — — — — — — — — — —	Web site
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) ves	yes (broadcast download & host query) ves
Interface available (or will be) to auto specimen handling system	yes (Roche MODULAR PRE-ANALYTICS systems and task targeted automation)	yes (Roche MODULAR PRE-ANALYTICS)
Modem servicing/Can diagnose own malfunctions/	yes/yes/no	yes/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	no ≤24 hours
Mean time between failures/To repair failures	≤24 nours —/—	≤24 nours —/—
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: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	varies, based on contract	varies, based on contract/—
Annual service contract cost (24 hours/7 days)	included with reagent rental	-
Training provided w/purchase/Advanced operator training	5 days at vendor offices/yes	5 days at vendor offices/yes
Distinguishing feetures (some lead to come l	avandable liquid weeks to see your total the total or and the see of the see	ECI toohnology wayidas broad massaring and the control of the cont
Distinguishing features (supplied by vendor)	expandable liquid ready-to-use reagents that are compatible with other Elecsys systems, compatible with Pre-Analytic Automation; ECL technology provides broad	ECL technology provides brand measuring ranges and low-end sensitivity; TnT; ready to use bar-coded reagents compatible with other Elecsys Systems; compatible with
	measuring range and market, best low-end sensitivity, troponin T, auto-rerun and	to use par-coded reagents compatible with other Elecsys Systems; compatible with Modular Pre-Analytics for walkaway automation
	dilute	,

	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics
	Diane Bandy diane.m.bandy@siemens.com	Louise Chang louise.chang@siemens.com
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Part 23 of 31	302-631-9435 diagnostics.siemens.com	310-645-8200 x7035 www.siemens.com/diagnostics
Name of instrument/First year sold/Where designed	Dimension Vista 500 Intelligent Lab System/2009/U.S.	ADVIA Centaur CP Immunoassay System/2005/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	Germany/U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	>200/>400
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack and aliquot plate system	batch, random access, continuous random access/benchtop/7 × 12 position racks
Dimensions in inches (H \times W \times D)/Instrument footprint in sq. feet	55.5 × 84.75 × 43.8/26	43 × 29/8.7
Tests available on instrument in U.S.	>115 (includes vendor supported applications), 35 general chemistry,	AFP, BNP, BR 27-29, CA 125II, CA 15-3, CA 19-9, carbamazepine, CEA, CKMB,
lesis available on instrument in o.s.	16 immunoassay, 14 TDM, 17 DATs, 27 plasma proteins	cortisol, C-peptide, cPSA, digoxin, estradiol-6 III, ferritin, folate, free T4, free T3, FSH,
	To initiatioassay, 14 fbm, 17 bA15, 27 plasma proteins	gentamicin, HAV IgM, homocysteine, insulin, i-PTH, LH, myoglobin, phenobarbital,
		phenytoin, progesterone, prolactin, PSA, T3, T4, TSH3, T-uptake, testosterone,
		theophylline, Tnl-Ultra, tobramycin, total hCG, total IgE, valproic acid, vancomycin,
		vitamin B12, others
Tests cleared but not clinically released	_	
Tests not available in U.S. but submitted for clearance	_	cyclosporine, DHEAs, SHBG, digitoxin, aTG, aTPO, TSH3 ultra, Her2/neu,
		HBsAg/confirmatory, HBsAb, HBcTotal, HBc IgM, HCV, rubella IgG, rubella IgM,
		toxo IgG, toxo IgM, fPSA, procalcitonin, syphilis
Tests not available in U.S. but available in other countries	_	_
Research-use-only assays	_	-
Tests in development	CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins,	D-dimer, E-HIV
Here defined with a definition and a few wheat and the	hormones, infectious disease	
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	specialty chemistry, plasma proteins, TDMs, DATs LOCI immunoassay, nephelometric assays, general chemistry	CPSA, HER-2/neu
lesis not available on other manufacturers, analyzers	Loci ininiunuassay, nepneiometric assays, general chemistry	CF3A, REn-2/IIeu
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, LOCI advanced chemiluminescence, EMIT, PETINIA, nephelometry/	chemiluminescence/magnetic particle
	magnetic particle, homogeneous immunoassay	→ ····•
No. of different measured assays onboard simultaneously	>100	15
No. of different assays programmed, calibrated at once	>100	31 (65 planned for 2008)
No. of user-definable (open) channels	10	_
No. of different analytes for which system accommodates reagent	144/20–1,200	15/50–100
containers onboard at once/Tests per container set	WO.1 (00.1 / 100.000)	001 /001 / /0 000
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/30 days/yes (2°–8°C)	96 hours/28 days/yes (2–8°C)
Multiple reagent configurations supported	no voo	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/test method, lot number, expiration date, number of tests	yes/reagent ID, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	yes/<1 ppm 225/150/3,150	no/zero carryover 210/400/400
System is open (home-brew methods can be used)/Liquid or dry system	223/130/3,130 yes/liquid	210/400/400 no/liquid
Uses disposable cuvettes/Max. No. stored	yes/>1,600	yes/400
Uses washable cuvettes/Replacement frequency	yes/automatic as needed	no
Minimum specimen vol. required	50 uL	10 uL, assay dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	50 uL/10 uL	10 uL/50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/no
Requires dedicated water system/Water consumption	yes/20 L per hour	no no
Noise generated	<65 decibels	up to 65 decibels
Has dedicated pediatric sample cup/Dead vol.	no, can use small sample cup/10	no .
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/2, 3, 5, 7, 10 mL and cups/no	yes/multiple/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 yes/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	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/	can decrease, but cannot increase sample volumes	yes/yes
Increased to rerun out-of-linear range low results	•	
Time between initial result & reaspiration of sample for rerun	<2 minutes	20 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	varies 2–6	2
Calibrants can be stored onboard/Avg. calibration frequency	yes/30–90 days	no/varies, avg. 21 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	once per 24 hours	user defined
Automatic shutdown/Startup is programmable/Startup time	yes/yes no/no/always ready	yes/yes yes/yes/<5 minutes
. a.comado onataomi/otartap io programmanic/otartap time	no, no, airrajo rodaj	you you to minute
Stat time to completion of β-hCG test	10	15.6 minutes
Time delay from ordering stat test to aspir. of sample	<2 minutes	<1 to 2 minutes 50 seconds
Throughput per hour for three analytes on each specimen, in No. of	200/600 (variable 3.6–20 seconds)	60/180 (20 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/no	onboard/no
Interfaces up and running in active user sites with	-	Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare,
LIC interfere energic simultaneously from	1100	Dawning, NLFC, DI, Triple G, and most other major vendors
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes	yes
Uses LUING to transmit orders and results How labs get LOINC codes for reagent kits	no 	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes (uroducast download & nost query) Ves	yes (uroaucast uowinoau & nost query) yes
Interface available (or will be) to auto specimen handling system	yes, StreamLAB automation system in development	no
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	2–8 hours	4 hours, 24 hours max.
Mean time between failures/To repair failures	_/_	not available/not available
Onboard error codes to facilitate troubleshooting	yes dailyy x10 miny manthlyy 10, 20 min	yes deity 15 minutes weekly 20 minutes monthly 20 minutes
Avg. time to complete maintenance by lab personnel	daily: <10 min; monthly: 10–20 min	daily: 15 minutes; weekly: 20 minutes; monthly; 30 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	yes/yes
List price/Targeted bed size or daily volume	—/1,500 tests per day per system	depends on GPO affiliation/community hospitals, satellite labs
Annual service contract cost (24 hours/7 days)	- / 1,000 του μοι μαγ μοι ογοτοιιι 	aopenas on ar o annianon/community nospitals, satemite iabs
Training provided w/purchase/Advanced operator training	4 days on site, 4 days at vendor offices/yes	3 days at vendor sites plus online training/yes
	,	
Distinguishing features (supplied by vendor)	ultra-integrated chemistry platform with LOCI advanced chemiluminescence, and	automates routine operations, including abiity to access/change solutions, waste,
	nephelometry onboard; enhanced workflow efficiency with automated features like	disposables, and reagents without pausing sampling or processing; onboard
	autocalibration and auto QC and system twinning; proactive service and support	automatic dilutions, repeats, STATs and cascade reflex testing; disposable tips; uses
	through RealTime Solutions services	same reagents/consumables as ADVIA Centaur/ADVIA Centaur XP with concordant
		results; throughput 180 tests/hour; average time to first result ~15.6 minutes

Automated	immunosees	v analyzore
Automated	immunoassa:	y analyzers

	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics
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rait 24 01 31	STO-043-0200 X 7033 WWW.sieinieris.com/uraginostics	000-242-3233 www.siemens.com/utagnosucs
Name of instrument/First year sold/Where designed	ADVIA Centaur XP/2006/U.S.	Dimension Vista 1500 Intelligent Lab System/2006/U.S.
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	Ireland/U.S. 475/425	U.S./U.S. and Germany 150/250
Operational type/Model type/Sample handling system	continuous random access/floor standing/5-position multiple size rack or puck via	batch, random access continuous random access/floor standing/sample rack and
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ADVIA LabCell and WorkCell 51.5 × 72.4 × 41/20.6	aliquot plate system 55 % × 84 % × 43 %/26
Differences in micros (if × w × D)/matument footprint in sq. feet	J1.3 ^ / L.4 ^ 41/20.0	33 70 A 04 70 A 40 70 Z0
Tests available on instrument in U.S.	anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, TSH-3, TUp, B12, ferritin, folate, estradiol,	>115 (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4
	estradiol III, FSH, HCG, LH, progesterone, prolactin, testosterone, AFP, BR27-29, CA 125 II, CA 15-3, CA 19-9, CEA, Her-2/NEU, PSA, cPSA, BNP, CKMB, homocysteine,	cardiac, 14 TDM, 17 DATs, 27 plasma proteins, 3 anemia, 2 cancer markers (AFP, CEA), fertility (HCG)
	myoglobin, Tnl ultra, cortisol, C-peptide (serum), insulin, intact PTH, rublla lgG, rubella	
	IgM, toxoplasma IgG, toxoplasma IgM, anti-HBs, HBsAg, HBsAg confirmatory, anti-HBc (total), anti-HBc (IgM), anti-HCV, HIV 1/0/2, anti-HAV (IgM), anti-HAV (total), anti-Hbe,	
	HbeAg, digoxin, digitoxin, tobramycin, carbamezepine, phenobarbital, phenytoin,	
Tests cleared but not clinically released	gentamicin, theoplylline, valproic acid, vancomycin, others none	
Tests not available in U.S. but submitted for clearance	——————————————————————————————————————	_
Tests not available in U.S. but available in other countries	_	PSA, FPSA, 4 IgG subclasses
Research-use-only assays Tests in development	cyclosporine, DHEAs, fPSA, HBeAb, HBeAg, procalcitonin, SHBG, syphilis,	CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones,
	TSH 3 ultra	cardiac, infectious disease
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	CPSA, Her2/neu	TDM, DAT LOCI technology, nephelometry, general chemistry
·		
Fully automated microplate system No. of each analyte performed in separate disposable unit	no 	no
No. of wells in microplate	_ _/_	_ _/_
Mathada aumantad/Canavatian mathada	ahamiluminaaanna/magustis sastisla	chamiluminaceana antima immunaceas: ACMA FART LOGI PETRIA MEDIL
Methods supported/Separation methods No. of different measured assays onboard simultaneously	chemiluminescence/magnetic particle 30 primary reagents	chemiluminescence, enzyme immunoassay, ACMIA, EMIT, LOCI, PETINIA, NEPH/none >100
No. of different assays programmed, calibrated at once	65	>100
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent		10 >100/20-1,200
containers onboard at once/Tests per container set		, and the second se
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	96 hours/28 days/yes (4°C)	72 hours/30 days/yes no
Reagent container placed directly on system for use	yes yes	yes
Reagents bar coded/Information in bar code	yes/assay name, lot No., expiration date, pack ID, No. of tests	yes/test ID, lot No., individual-sequence No., exp. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	—/none—uses zero carrryover 280/180/840	yes/<1 ppm >45/150/8,400
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/1,000 no	yes/>2,000 yes/automatic, as needed
Minimum specimen vol. required	10 µL—assay	2 μL analytical, 50 μL aliquot
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/50 µL	2 μL (GLU=1.2)/20 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/2.5 L per hour	yes/no no/20 L per hour
Noise generated	61.3 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/—/no	yes/ 10 µL 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 Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes yes/yes	yes yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes no/no	yes/yes 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	no (does have autodilution)/no (does have autodilution)	no/no (does have autodilution)
Time between initial result & reaspiration of sample for rerun	15 seconds	<2 min
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	2 no/average 28 days	varies, 2–6 yes/30–90 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	22 hours/24 hours yes/yes	shortest interval: 24 hours/— yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/none, always ready	no/no/always ready
Stat time to completion of R-MCC toot	18 minutes	10 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample	18 minutes 15 seconds	10 minutes <2 minutes
Throughput per hour for three analytes on each specimen, in No. of	80/240/15 seconds	200/600 (variable 3.6–20 seconds)
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	yes/yes	yes/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	onboard/yes (LIS allowance) Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others	Mysis, Soft, Meditech, Cerner, others yes
Uses LOINC to transmit orders and results	yes	no
How labs get LOINC codes for reagent kits Bidirectional interface capability	no 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 (broadcast download & nost query) yes
Interface available (or will be) to auto specimen handling system	yes/ADVIA WorkCell, ADVIA LabCell, others	yes (StreamLab, ADVIA LabCell in development)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no 4.04 h	yes
On-site response time of service engineer Mean time between failures/To repair failures	4-24 hours max —/—	2–8 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: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes	daily: <10 minutes; weekly: none; monthly: 10–20 minutes no/no/yes
	J, J0	
List price/Targeted bed size or daily volume	\$225,000/300+ beds or 400 tests per day	\$552,240/>4,000 tests per day
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	varies, GPO dependent —/4.5 days on site/yes	inquire 4 days on site, 4 days at vendor offices/yes
	•	• • •
Distinguishing features (supplied by vendor)	automates routine operations, including ability to access/change solutions, waste, disposables, and reagents w/o pausing sampling or processing; onboard automatic	homogeneous LOCI technology for high-sensitivity IA assays; fast analytical time, 10-minute cardiac markers, 21-minute anemia methods; ultra-integrated platform
	dilutions, repeats, STATs and cascade reflex testing; disposable tips; no start-up	with nephelometry that eliminates sample sharing/splitting & streamlines lab
	procedures; always ready; uses same reagents/consumables as Centaur CP w/ concordant results; processes 240 tests/hour; average time to first result ~18 min.;	workflow; can be configured as a Dimension Vista 3000T twin system; enhances operator efficiency with automatic calib. and AC processing
	comprehensive hepatitis A, B, C, and HIV testing (includes acute hepatitis panel);	
	auomated SMART algorithm for rerun and confirmatory testing for HBsAg testing	

Automated immunoassay analyzers			
Part 25 of 31	Siemens Healthcare Diagnostics Diane Bandy diane.m.bandy@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Terry Thompson terry.tt.thompson@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	
Name of instrument/First year sold/Where designed	Dimension Xpand Plus Integrated Chemistry System/2004/U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension	
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	U.S./U.S. —/—	RxL Integrated Chemistry System/1997/U.S. U.S./U.S. —/—	
Operational type/Model type/Sample handling system	random access, cont. random access/floor-standing/racks	batch, random access, cont. random access/floor-standing/racks	
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	$45 \times 51 \times 31$ (without monitor)/10.6	44×62.5×30.5/13.2	
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	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, vancomycin, valproic acid, acetaminophen, ethyl alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricylic antidepressants, others	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, vancomycin, valproic acid, acetaminophen, ethyl alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricylic antidepressants, others	
Tests not available in U.S. but available in other countries		=	
Research-use-only assays Tests in development	mycophenolic acid, sirolimus	mycophenolic acid, sirolimus	
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers		system performs heterogeneous immunoassays and general assays on a single platform—fully automated ISD assays	
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 No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels	ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle 91 190 10	ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle 91 (with optional reagent management system) 190 10	
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	47/15–360	Max=47, Max Suite=91/15–360	
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	48 hours/30 days/yes (2°–8°C) yes	48 hours/30 days/yes (2°-8°C) yes	
Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes 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 no/—	yes yes/lot No., unique flex ID, stability, expiration date yes/— due to probe washing can be hours/60/>2,000/>5,000 yes/no reagent prep required by operator for liquid yes/12,000 no/—	
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	2 µL 2 µL/primary tube capable yes/no yes/up to 2 L per hours <70 decibels yes/10–20 µL yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes	2 μL 2 μL/primary tube capable yes/no yes/3 L per hour/up to 5 L per hour <70 decibels yes/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 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	yes yes/yes yes/yes no/yes yes/yes yes/yes	yes yes/yes yes no/yes yes/yes yes/yes yes/yes	
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 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	<20 seconds yes varies—3 levels for most assays yes (Na, K, Cl)/most 90 days yes/yes 24 hours no/yes not required	<20 seconds yes varies—3 levels for most assays yes (Na, K, CI)/most 90 days yes/yes 24 hours 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) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/instrument vendor supplies LIS interface	16 minutes 24 seconds up to 83/up to 250 (14.4 seconds) yes/yes optional/yes (additional) all major LIS wonders	16 minutes 24 seconds up to 166/up to 500 (7.2 seconds) yes/yes optional (DBNet–Dade Behring)/yes (additional cost)	
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	all major LIS vendors yes no	all major LIS vendors yes no	
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/	yes (broadcast download & host query) yes yes yes yes/yes/yes	— yes (broadcast download & host query) yes yes yes yes/yes/yes	
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	no 2–8 hours —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes	no 2–8 hours —/— 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	—/— multiple types 5 days on site; 4 days at vendor offices/no	—/— multiple types 5 days on site, 4 days at vendor offices/yes	
Distinguishing features (supplied by vendor)	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	analyzer integrates heterogeneous 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	

Adtomated inimaneassay analyzers			
	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics	
	Christina Tassone christina.tassone@siemens.com	Christina Tassone christina.tassone@siemens.com	
David 00 of 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 EXL Integrated Chemistry System (upgradeable w/LOCI Module)/2007/U.S.	Dimension EXL with LM Integrated Chemistry System/2009/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 Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	batch, random access, continuous random access/floor standing/racks 49 × 82 × 34 (without monitor)/19.4	batch, random access, continuous random access/floor standing/racks $49 \times 82 \times 44$ (without monitor)/25.1	
Simonatona in monea (ii × w × D)/matiument tootprint iii aq. ieet		-10 ∧ 02 ∧ TT (WILLIOUX HIJHINUT)/20.1	
Tests available on instrument in U.S.	cardiac troponin I, LV cardiac troponin I, CardioPhase hsCRP, ferritin, free PSA, free T4/	CardioPhase hsCRP, ferritin, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin,	
	thyroxine, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, NT-pro BNP, LV	ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine,	
	NT-pro BNP, thyroid stimulating hormone, total PSA, ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended	cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus,	
	range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, pheno-	theophylline, tobramycin, vancomycin, valproic acid, hemoglobin A1c, thyronine uptake,	
	barbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin,	total T4, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, LOCI free thyroxine,	
	valproic acid, hemoglobin A1c, thyronine uptake, total T4/thyroxine, triiodothyronine,	LOCI thyroid stimulating hormone, LOCI cardiac troponin I, LOCI LV NT-pro BNP, urine	
	acetaminophen, ethyl alcohol, salicylate, urine ecstasy, urine screens: amphetamine, cocaine metabolite, methadone, opiates, phencyclidine; serums: TCA, barbituarates,	screens: amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine metabo- lite, methadone, opiates, phencyclidine; serums: TCA, barbiturates, benzodiazepine;	
	benzodiazepine; propoxyphene, methaqualone, C3, C4, IgA, IgG, IgM, transferrin, others	propoxyphene, methaqualone, C3, C4, IgA, IgG, IgM, transferrin, general chemistry 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 Research-use-only assays	_	_	
Tests in development	_	LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus, total PSA, free PSA	
User-defined methods implemented for what analytes	_		
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and complete routine general	system performs homogeneous LOCI and heterogeneous immunoassays plus a	
	chemistry menu on a single platform; fully automated, no-pretreatment ISD assays	complete routine general chemistry menu on a single platform; fully automated, no- pretreatment ISD assays	
	4004JU	p. va vanioni iou aodajo	
Fully automated microplate system	no	no	
No. of each analyte performed in separate disposable unit	-	-	
No. of wells in microplate	_	_	
Methods supported/Separation methods	enzyme immunoassay, ACMIA, EMIT, PETINIA, photometry, potentiometry/	chemiluminescence, enzyme immunoassay, LOCI, ACMIA, EMIT, PETINIA, photometry,	
	magnetic particle	potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous	
No. of different measured assays onboard simultaneously	91	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	91/15–360	91/15–360	
containers onboard at once/Tests per container set			
Shortest/Median onboard reagent stability/Refrigerated onboard	72 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 placed directly on system	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/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 yes/liquid, reconstitutes on board (no reagent prep required by the operator)	can be hours/60/>2,000	
Uses disposable cuvettes/Max. No. stored	yes/nquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000	yes/liquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000	
Uses washable cuvettes/Replacement frequency	no/—	no/—	
Minimum specimen vol. required	2 μL	2 μL	
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 μL/primary tube capable	2 μL/primary tube capable	
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no yes/up to 5 L	yes/no yes/up to 5 L	
Noise generated	<75 decibels	<75 decibels	
Has dedicated pediatric sample cup/Dead vol.	yes/30 μL	yes/30 μL	
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/5, 7, 10 mL/no	
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A	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)	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 no/wo	yes no luco	
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/yes yes/yes	no/yes 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/no	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	yes	yes	
No. of calibrators required for each analyte	varies (3 levels for most assays)	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 How often QC required	yes/yes 24 hours or with lot change	yes/yes 24 hours or with lot change	
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/yes	
Automatic shutdown/Startup is programmable/Startup time	no/no/not required	no/no/not required	
Stat time to completion of β-hCG test	16 minutes	16 minutes	
Time delay from ordering stat test to aspir. of sample	24 seconds	24 seconds	
Throughput per hour for three analytes on each specimen, in No. of	up to 146/437 (7.2 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	voc/voc	vac/vac	
Data-management capability/Instrument vendor supplies LIS interface	yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost)	yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost)	
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 How labs get LOINC codes for reagent kits	no 	no 	
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 Modem servicing/Can diagnose own malfunctions/	yes vec/vec/vec	yes yes/yes/yes	
Determine malfunctioning component	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	-/- ves	—/— ves	
Avg. time to complete maintenance by lab personnel	yes daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes	yes daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes	
Onboard maintenance records/Maintenance training demo module	no/no	no/no	
List price/Torrested had size or daily welves			
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	yes (5 days on site, 4 days at vendor offices)/no	yes (5 days on site, 4 days at vendor offices)/no	
Bi-th-mi-bi-n facts (B. H.		1001	
Distinguishing features (supplied by vendor)	analyzer integrates heterogeneous immunoassays onboard with other chemistries; upgradeable with LOCI module; allows a single platform for more than	analyzer integrates homogeneous LOCI and heterogeneous immunoassays onboard with other chemistries; allows a single platform for more than 95 percent of most	
	95 percent of most requested tests; eliminates sample splitting between general	requested tests; eliminates sample splitting between general chemistry tests and	
	chemistry tests and immunoassays; fully automated onboard ISD assays	immunoassays; fully automated onboard ISD assays	

Adternated infinialledssay driaryzers			
	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics	
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	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	
N. C. I. 1/2: I. 11011 I. I.	MANUAL TE 4000/4000 MANUAL TE T. 1. /4000 MANUAL TE 4000/0000/1/0	HARMILITE COOR (4 COO (II C	
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	IMMULITE 1000/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S. U.S./U.S., U.K.	IMMULITE 2000/1998/U.S. U.S./U.S., U.K.	
No. of units in clinical use in U.S./Outside U.S.	>7,000 worldwide	>5,500 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 × 46 × 26/7.98	47 × 60 × 30/12.5	
Tests and light on tests were to 110	On Allerman and Control of the ACTU AFD and and a serious discuss and the Lotte and the Actual	On Allianna and Strate ACTU AFD and analysis of the south UD. Lottle and UD. Actual	
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,	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), calci-	
	canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CKMB, CMV IgG, cortisol,	tonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CKMB, cortisol,	
	C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free	C-peptide, DHEA-SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA,	
	T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, HBs Ag, HBs Ag confirmatory,	free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, HBs Ag, HBs Ag	
	HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I, insulin,	confirmatory, HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I,	
	intact PTH, LH, microalbumin, myoglobin, OM-MA (CA 125), PAP, phenobarbital,	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, 3gTSH, thyroglobulin,	phenytoin, progesterone, prolactin, PSA, PYRILINKS-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gG TSH, thy-	
	thyroid uptake, total IqE, total T3, total T4, total testosterone, toxoplasma quant. IqG,	roglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma	
	Troponin I, Unconjugated Estriol, Valproic Acid, Vitamin B12; Turbo STAT menu: CKMB,	IgM, toxoplasma quant. IgG, troponin I, unconjugated estriol, valproic acid, vitamin	
	HCG, Intact PTH, Myoglobin, Troponin I, others	B12, others	
Tests cleared but not clinically released	none	none	
Tests not available in U.S. but submitted for clearance 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,	— GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteo-	
lests not available in 0.5. but available in other countries	osteocalcin, NT-proBNP, CMV IqM, ECP, cannabinoids (THC), D-dimer	calcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer	
Research-use-only assays	<u> </u>	<u> </u>	
Tests in development	D-dimer, turbo D-dimer, CMV IgM, HBsAb quantitative, procalcitonin	D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, syphillis, HBsAb	
Hear defined methods implemented for what analytic	none	quantitative, procalcitonin	
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none IGF-I, IGFBP-3, androst., 3rd-gen PSA, gastrin, canine TLI, canine TSH	none 3gPSA, IGF-I, IGFBP-3, H. <i>pylori</i> IgG , androst., gastrin, canine TLI, canine TSH	
- 100.0 HOL GEGING ON OTHER HIGHGIGGS GHAIY2GIS	isa ng san sa ng anan sang ara yan i ang yasan ng danilite i Eli, danilite i Sti	og. orginal iginal or ogin <i>pyloti</i> iga ganaroon, yasuni, vanine fili, valille fon	
Fully automated microplate system	no	no	
No. of each analyte performed in separate disposable unit	-	-	
No. of wells in microplate	<u> </u>	<u> </u>	
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	chemiluminescence/bead, centrifugation	
No. of different measured assays onboard simultaneously	12	24	
No. of different assays programmed, calibrated at once	unlimited	unlimited	
No. of user-definable (open) channels	0	_	
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	
Reagents bar coded/Information in bar code	yes/test, lot No., expir.	yes/test, lot No., expir.	
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	••	no/<3 ppm	
Walkaway capacity in minutes/Specimens/Tests-assays	100/—/70 no/liquid	300/90/1,300 no/liquid	
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	no/liquid yes/—	no/liquid yes/1,300	
Uses washable cuvettes/Replacement frequency	no	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/100 μL	5 μL/50 μL	
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	yes/no no/0.5 L per hour	yes/no no/—	
Noise generated	55-68 decibels	52 decibels	
Has dedicated pediatric sample cup/Dead vol.	no/—	yes/50 μL	
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	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	
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	no/no	yes/yes	
Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no	—/—	
Sample vol. can be increased to rerun out-of-linear range high results/	yes/no no/no	yes/yes 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	yes 2-layel adjustors symplied in kit	yes 2-level adjustors symplied in kit	
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	2-level adjustors, supplied in kit no/1–4 weeks (assay dependent); 2 weeks for Turbo	2-level adjustors, supplied in kit no/1–4 weeks (assay dependent)	
Multipoint calib. supported/Multiple calibs. stored for same assay	no/yes	yes/yes	
How often QC required	customer determined	cutomer determined	
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes	
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	yes/no/4 minutes	
Stat time to completion of β-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	no/yes	ves/yes	
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/yes (additional cost)	
Interfaces up and running in active user sites with	CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, others	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	yes no	yes no	
How labs get LOINC codes for reagent kits	no 	<u>no</u>	
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 Modem servicing/Can diagnose own malfunctions/	NO ves/no	yes (universal interface)	
Determine malfunctioning component	yes/yes/no	yes/yes	
Can order (via modem) malfunctioning part(s) w/o operator	no	no	
On-site response time of service engineer	4 hours	4 hours	
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	10 months/4 hours yes	3 months/5 hours yes	
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes	daily: 5–10 minutes; weekly: 20 minutes; monthly: 20–30 minutes	
Onboard maintenance records/Maintenance training demo module	—/yes	no/yes	
List union/Townshed bed also an dallar	67F 000. Turke, 677 F00/ 4 000 to to a series "	\$104 F00/. C 000 tests no	
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days)	\$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 nours/7 days) Training provided w/purchase/Advanced operator training	\$8,000 3.5 days at vendor offices/yes	\$16,500 (RealTime Solutions) varies on site, 5 days at vendor offices/yes	
	on any at total onlocal jou	on one, o way our rolling of the original of the original o	
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	

Part 28 of 31	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-631-8000 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Terry Thompson terry.tt.thompson@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. Operational type/Model type/Sample handling system	IMMULITE 2500 SMS/2004/U.S. U.S./U.S., U.K. >600 worldwide continuous random access/floor standing/rack	Stratus CS Acute Care Diagnostic System/1998/U.S. U.S./U.S. —/— random access/benchtop/whole blood collection tube
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet Tests available on instrument in U.S.	79×112×40/30.69 3gAllergy specific IgE, ACTH, AFP, androstenedione, Anti-TG Ab, Anti-TPO Ab, beta-2	$18 \times 27 \times 22/4.1$ mass CK-MB, myoglobin, β -hCG, D-dimer, NT-proBNP, high sensitivity troponin I,
Tests cleared but not clinically released	microglobulin, BR-MA (CA15-3), calcitonin, carbamazepine, CEA, CKMB, CMV IgG, 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-I, 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: Intact PTH, myoglobin, troponin I, unconjugated estriol, valproic acid, vitamin B12 none	CardioPhase hsCRP
Tests not available in U.S. but submitted for clearance 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, osteocalcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer	Ξ
Research-use-only assays Tests in development	— D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, syphillis, HBsAb, Quantitative	=
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none 3gPSA, IGF-I, IGFBP-3, H. <i>pylori</i> IgG , androst., gastrin, canine TLI, canine TSH	_
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 	no
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	fluorescence, EIA, dendrimer technology/fiber matrix filter
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	24 unlimited	up to 4 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 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 Reagents bar coded/information in bar code	yes	yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/test, lot No., expiration 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 Uses disposable cuvettes/Max. No. stored	no/liquid yes/1,300	no/liquid no
Uses washable cuvettes/Replacement frequency	no/—	no
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL to 100 μL sample 5 μL/50 μL	2.5 mL whole blood 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 Has dedicated pediatric sample cup/Dead vol.	52 decibels yes/50 µL	<65 decibels no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75–100 mm height; 12–16 mm width/no	yes/4 or 5 mL/yes
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 of 5 interleaved, Codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container)	yes	—
Measures No. of tests remaining/Short sample detection	yes/yes	—/yes
Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability	yes yes/yes	yes yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	_/_ 	not affected
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		
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	min. 18 seconds 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 Automatic shutdown/Startup is programmable/Startup time	yes/yes yes/no/4 minutes	yes/yes no/no/30 minutes to warm up
	•	·
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 (total HCG) 18 seconds 200/200 (18 seconds)	14 minutes immediately 3/9
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) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	yes/yes (additional cost) 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 regrent kits	no	<u>no</u>
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 Interface available (or will be) to auto specimen handling system	yes ves (universal interface)	yes no
Modem servicing/Can diagnose own malfunctions/	yes (universal interface) yes/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	no 4 hours	no 2–8 hours
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	3 months/5 hours	>225 days/2.9 hours
Avg. time to complete maintenance by lab personnel	yes daily: 5–10 minutes; weekly: 20 minutes; monthly: 20–30 minutes	yes daily: none; weekly: none; monthly: 10 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$200,000 includes SMS & RealTime Solutions/200+ beds \$21,500 (RealTime Solutions with SMS) varies on site, 5 days at vendor offices/yes	—/any size emergency department multiple types 3 days on site/no
Distinguishing features (supplied by vendor)	large automated IA test menu available; 15-minute stat assays, flexible sample	whole blood collection tubes or precentrifuged plasma; onboard centrifugation; unit-dose
3	handling, user-definable testing; runs specific allergen testing, alongside routine IAs; flexible connectivity to automation via SMS; autoreflex, autodilute; QM & logistics reports	test packs; color-coded calibrators packaged on Calpacks; diluent packs; self-contained 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

Part 29 of 31	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-631-8000 www.siemens.com/diagnostics	TOSOH Bioscience Inc. Shanti Narayanan shanti.narayanan@tosoh.com 6000 Shoreline Court, Ste. 101, South San Francisco, CA 94080 800-248-6764 www.tosoh.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	IMMULITE 2000 XPi Immunoassay System*/2009/U.S. U.S./Wales, UK —/— random access/floor standing/rack 47 × 60 × 30/12.5	AIA-2000/2008/Japan Japan/Japan 0/30 continuous random access/floor standing/rack, sorter drawer $49.6 \times 59.1 \times 35.7/14.66$
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, canine total T4, canine TSH, carbamazepine, CEA, CKMB, cortisol, C-peptide, DHEA-SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, 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, unconjugated estriol, valproic acid, vitamin B12, others	TSH 3rd-Gen, TSH, FT4, FT3, T4, T3, T-uptake, TPOAb, TgAb, bHCG, estradiol, FSH, LH, 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, B12, testosterone, CA 19-9, 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	none GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer	— RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen, PSA II, cystatin C.
Research-use-only assays Tests in development	D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, syphillis, HBsAb quantitative, procalcitonin	— HbA1c
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none 3gPSA, IGF-I, IGFBP-3, H. <i>pylori</i> IgG , androst., gastrin, canine TLI, canine TSH	- -
Fully automated microplate system No. of each analyte performed in separate disposable unit	no 	<u>no</u>
No. of wells in microplate		
Methods supported/Separation methods	chemiluminescence/—	fluorescence/bead
No. of different measured assays onboard simultaneously	24	48
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	unlimited —	48 0
No. of different analytes for which system accommodates reagent	 _/_	48/— (this is a unitized test cup)
containers onboard at once/Tests per container set		
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 ves
Reagents bar coded/Information in bar code	-/-	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	-/-	no/—
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μL to 100 μL	500 μL tube, 100 μL cup
Supplied with UPS (backup power)/Requires floor drain	5 μL/50 μL ves/—	10 μL/500 μL tube, 100 μL cup yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	-,	- ,
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/uses specialized racks yes/75–100 mm/no	no/— yes/ 7mL and 10 mL or 15 \times 75 & 100, 13 \times 75 & 100/no
Sample bar-code reading capability/Autodiscrimination	yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 or 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 yes/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 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/	yes/yes no/no	yes/yes no/no
Increased to rerun out-of-linear range low results		
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/30–90 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	customer determined —/—	24 hours yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/15 minutes	no/no/5 minutes
Stat time to completion of β-hCG test	35 minutes	annrov 18 minutes
Stat time to completion of β -not test Time delay from ordering stat test to aspir. of sample	18 seconds	approx. 18 minutes 40 seconds
Throughput per hour for three analytes on each specimen, in No. of	200/200 (18 seconds)	66/200 (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 (\$2,000 QC software only, Siemens)/yes	—/no
Interfaces up and running in active user sites with		_
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results	yes no	yes ves
How labs get LOINC codes for reagent kits	_	yes package insert
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 yes, universal interface	yes yes (Hitachi, A&T, Bayer, Thermo, iLAS)
Modem servicing/Can diagnose own malfunctions/	yes/yes/yes	no/no/no
Determine malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no 4 hours	no 24 hours
Mean time between failures/To repair failures	3 months/5 hours	5 months/24 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: 5–10 min; weekly: 20 min; monthly: 20–30 min no/yes	daily: 5 min; weekly: 5 min yes, includes audit trail/no
		y,
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) Training provided w/purchase/Advanced operator training	under development —/—	depends on aquisition option 4 days at vendor's office/no
manning provided w/purchase/Advanced operator training		T HAYS AL VOILLOI S UTITOC/IIU
Distinguishing features (supplied by vendor)	* Immulite 2000 XPi Immunoassay System is under development	available in two models: standard and LA; unitized test cups similar to all AIA systems; 3 separate incubators to minimize processing time; no reagent preparation; dual clot detection, automated sample dilution, and pretreatment; appropriate for stat and routine use

Part 30 of 31	TOSOH Bioscience Inc. Shanti Narayanan shanti.narayanan@tosoh.com 6000 Shoreline Court, Ste. 101, South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101, South San Francisco, CA 94080 800-248-6764 www.tosoh.com
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured	AIA-360/2004/Japan Japan/Japan	AIA-1800/2003/Japan Japan/Japan
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	525/1,825 continuous random access/benchtop/carousel $21 \times 19 \times 16/2.1$	64/486 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, TP0 Ab, Tg Ab, 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, folate, B12, testosterone, CA 19-9, 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	— RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., cystatin C, PSA II —	— RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., cystatin C, PSA II —
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	HbA1c — —	HbA1c — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	=	=
Methods supported/Separation methods	flourescence, EIA/bead	flourescence, EIA/bead
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	25 entire menu	31 trays entire menu
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	—/unitized test cup	—/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported	72hours/72hours/— yes	72 hours/72 hours/— yes
Reagent container placed directly on system for use Reagents bar coded/information in bar code	yes yes/lot No., test code	yes yes/lot No., test code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/zero carryover 58/25/25	no/zero carryover 58/170/640
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	no/dry
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no no	—/unitized test cup —
Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.	500 μL tube, 100 μL cup 10 μL/500 μL tube, 100 μL cup	500 μL tube, 100 μL cup 10 μL/500 μL tube, 100 μL cup
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption	no/no no/—	yes/no no/—
Noise generated Has dedicated pediatric sample cup/Dead vol.		 no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/primary draw tubes: 13×75 & 100 ; 16×75 & 100 /no yes/yes	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	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 no/no	no/no yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/	no/no	no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert		varies
No. of calibrators required for each analyte	no 2 or 6-analyte dependent	no 2 or 6-analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay	no/30–90 days yes/yes	no/30–90 days yes/yes
How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hours no/no	24 hours yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	no/no/5–8 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)	~18 minutes 60 seconds 12/36 (1 minutes)	~18 minutes 40 seconds 60/180 (20 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/no Antek. Schuyler House, more	yes/yes yes/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	Ξ	yes yes
Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	yes package insert	yes package insert
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	no yes	yes (broadcast download & host query) yes
Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/	no no/no/no	yes (Hitachi, Siemens, Thermo, iLAS) 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		24 hours 5 months/24 hours
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	yes daily: 5 minutes	yes daily: 5–8 minutes; weekly: 5 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	no/no	yes (includes audit trail of who replaced parts)/no
List price/Targeted bed size or daily volume	\$25,000/200-1,000 tests per month	\$175,000/65+ beds, 1,500-2,000 tests
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$2,050-\$3,500 training DVD; on-site install	\$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

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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.	AIA-600 II/2000/Japan Japan/Japan 495/1,085	Nexgen Four/2003/Italy Italy/U.S., Italy, Ireland —/—
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	cont. random access/benchtop/chain $19.8 \times 31.6 \times 29.1/6.4$	batch, random access, continuous random access/benchtop/ring (carousel) $28 \times 53.2 \times 29.5$ (includes carousel)/—
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TP0 Ab, Tg Ab, β -hCG, estradiol, FSH, hCG, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β -2-microglobulin, C-peptide, cortisol, hGH, lgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, intact PTH	open system—any microplate assay
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	— RBC folate HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP, cTnl 3rd gen., cystatin C, PSA II — HbA1c	open system—any microplate assay open system—any microplate assay open system—any microplate assay open system—any microplate assay open system—any microplate assay
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	open system—any microplate assay open system—any microplate assay
Fully automated microplate system No. of each analyte performed in separate disposable unit	no	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 No. of different analytes for which system accommodates reagent	0 —/unitized test cup	500+ 16/manufacturer defined
containers onboard at once/Tests per container set 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/lot No., test code no/zero carryover	yes/— yes/zero carryover with plastic tips
Walkaway capacity in minutes/Specimens/Tests-assays	52/26/26	varies/varies
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored	no/dry —/unitized test cup	yes/liquid yes/—
Uses washable cuvettes/Replacement frequency Minimum specimen vol. required	— 500 µL tube, 100 µL cup	yes/— 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 Noise generated	no/— —	no/— —
Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no yes/primary draw tubes: 7 mL & 10 mL or 15×75 & 100 , 13×75 & 100 /no	no/— yes/—/no
Sample bar-code reading capability/Autodiscrimination 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 Clot detection/Reflex testing capability	yes	yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/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/ Increased to rerun out-of-linear range low results	yes/no no/yes	yes/no no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	no	
No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency	2 or 6—analyte dependent no/60–90 days	manufacturer dependent 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	~18 minutes	manufacturer dependent
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)	60 seconds 20/60 (1 minute)	— —/open system—depends on kit
Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	yes/no optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson,	yes/yes 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 Uses LOINC to transmit orders and results	yes yes	Ξ
How labs get LOINC codes for reagent kits Bidirectional interface capability	package insert yes (broadcast download & host query)	yes
Results transmitted to LIS as soon as test time complete 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 On-site response time of service engineer	no 24 hours	no by contract
Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting	98% uptime/— 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: 5–10 minutes; monthly: 10–15 minutes —/no
List price/Targeted bed size or daily volume	\$70,000/500-2,500 tests per month	\$72,900/>100
Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$5,941 3 days at vendor offices/no	varies 3–4 days on site/no
Distinguishing features (supplied by vendor)	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	dual-arm pipetting with independent wash capabilities; specimen delivery with metal needle or plastic tip within same run; continuous loading; remote desktop operation via Internet/modem; touchscreen