

Automated immunoassay analyzers

| Part 1 of 31 | Abbott Diagnostics Neal Nash neal.nash@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-937-4332 www.abbott.com | Abbott Diagnostics Neal Nash neal.nash@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-937-4332 www.abbott.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | AxSYM/AxSYM Plus/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 1,400/13,000 cont. random access/stat, batch floor-standing/segment 60.5 × 63 × 33.5/14.6 | ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. U.S./U.S. 434/6,009 batch, random access, cont. random access/floor-standing/track & LAS 48 × 61 × 49/20.3; i2000, 48 × 68 × 44/22.7 per module |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance 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 | total T3, total T4, free T3, free T4, T-uptake, total B-hCG, progesterone, estradiol, prolactin, STAT CK-MB, troponin-I ADV, total PSA, free PSA, rubella IgG, rubella IgM, toxo IgG, toxo IgM, carbamazepine, digoxin, N-Acetylprocainamide (NAPA), pheno-barbital, procainamide, theophylline II, valproic acid, vancomycin, amphetamine/methamphetamine II, barbiturates II U, benzodiazepines, cannabinoids, cocaine metabolite, phenacyclidine II, acetaminophen, REA ethanol, salicylate, tricyclic antidepressants, HAVAB 2.0 (Anti HAV), AxSYM CORE 2.0, HAVAB 2.0, AUSAB, AxSYM CORE 2.0, HBsAg and HBsAg confirmatory, AxSYM active-B12, AxSYM anti-CCP — — CA 19-9, HAVAB 2.0 Quantitative, CMV IgM, β-2-microglobulin, insulin, 3rd gen TSH, digitoxin, HBe, HIV 1/2g0, HIV Ag/Ab combo, D-dimer — — | cardiac: STAT troponin I, CK-MB, myoglobin, BNP; fertility/pregnancy: total B-hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S, SHBG; cancer: total PSA, free PSA, AFP, CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3, free T4, total T3, total T4, T-uptake, anti-Tg, anti-TPO; metabolic: iPTH, ferritin, cortisol, insulin, homocysteine; hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB (anti-HBs), CORE-M (anti-HBc IgM), HAVAB-M, CORE; transplant: sirolimus, tacrolimus, cyclosporin; TDM: theophylline, phenytoin, phenobarbital, vancomycin, digoxin — — 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 IgG, CMV IgM, rubella IgM, rubella IgG, HTLV I/II, HCV core Ag, toxo IgM, toxo IgG, CMV IgG Avidity, Toxo IgG Avidity — (U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility: 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 — — |
| 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter 20 20 0 20/100 onboard reagent stability: 112, 224, 336/no no yes yes/assay name, reag. lot No., expir. date, pack No. ID no/<0.1 ppm 60/90/90 no/liquid yes/90 reaction vessels no 83 µL/150 µL 10 µL/73 µL for sample cup, 450 µL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional no/— 52–68 decibels no yes/100 & 75 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no seconds no 6 pt. or 2 pt. w/ master calib., 6 pt., index calib. no/4 weeks yes/yes (up to 4 curves/analyte) shortest interval: 8 hours, longest: 24 hours yes/yes no/no/1 minute | Chemiflex (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle 25 25 — 25/100-test & 500-test per kit 30 days/30 days/yes (2°–12°C) yes yes yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve no/<0.1 ppm 300/135/12,500 no/liquid yes/1,200 no/— 50 µL 150 µL/50 µL for all tube types yes/no no/— 48–70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2–6 pt. curve no/minimum 30 days or once per lot yes/yes 3 levels every 24 hours for quantitative, 2 levels for qualitative yes/yes —/no/10 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 10 minutes 30 seconds from standby 68–120 tests/flexible platform—load list dependent (assay dependent) yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes yes no/yes/yes yes, AbbottLink 12 hours 5 months/within 12 hours per customer request yes daily: 14 min; weekly: 65 min; monthly: 11 min no/no | 15.6 minutes <20 seconds 67/200 tests per hour yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes yes yes/yes/yes yes, AbbottLink 12 business hours 10.4 weeks/— yes daily: 16 min; weekly: <10 min; monthly: none (for both manual & auto procedures) 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 | \$124,000/up to 200 immunoassays tests per day flexible options available yes/yes | \$169,500/>200 immunoassays per day flexible options available yes/yes |
| Distinguishing features (supplied by vendor) | menu, reliability, online exception help, pressure monitoring, foam avoidance, ratio calculation, stat TAT | Chemiflex tech. delivers excellent sensitivities and extended linearities; RSH allows priority and routine samples to be processed simultaneously w/o compromising stats |

Automated immunoassay analyzers

| Part 2 of 31 | Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, Irving, TX 75038 972-518-6775 www.abbott.com | Abbott Diagnostics Neal Nash neal.nash@abbott.com 100 Abbott Park Road, Abbott Park, IL 60064 847-937-4332 www.abbott.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | ARCHITECT ci8200, ci16200/2003, 2007/U.S. U.S./U.S. 269 (ci8200), 5 (ci16200)/1,302 (ci8200), 170 (ci16200) batch, random access, cont. random access/floor-standing/robotic sample handler uses multi-dimensional sample handling 48 x 127 x 49/43.2 | ARCHITECT i1000SR/2008/U.S. U.S./U.S. 39/449 continuous random access/floor-standing/robotic sample handler allows batch, random access, cont. access and reagent loading and unloading 49 x 59 x 30/14.7 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | cardiac: STAT troponin I, CK-MB, myoglobin, BNP; fertility/pregnancy: total <i>B</i> -hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S, SHBG; cancer: total PSA, free PSA, AFP, CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3, free T4, total T3, total T4, T-uptake, anti-Tg, anti-TPO; metabolic: ferritin, cortisol, insulin, iPTH, homocysteine; hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB (anti-HBs), CORE-M (anti-HBc IgM), HAVAB-M, CORE; transplant: sirolimus, tacrolimus, cyclosporin; TDM: theophylline, phenytoin, phenobarbital — — fertility/pregnancy: testosterone; cancer: SCC, AFP; metabolic: B12, folate; hep/retro/congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV IgG, CMV IgM, rubella IgM, rubella IgG, HTLV I/II, HCV core Ag, toxo IgM, toxo IgG, MPO, CMV IgG Avidity, Toxo IgG Avidity — (U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility: 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 — — | anti-Tg, anti-TPO, free T3, free T4, total T3, total T4, TSH, T-uptake, Total <i>B</i> -hCG, estradiol FSH, LH, progesterone, prolactin, DHEA-S, SHBG, BNP, CK-MB, ferritin, insulin, intact PTH CA 125-II, CA 15-3, CA 19-9XR, CEA, tacrolimus, sirolimus, theophylline, HAVAB-M, vancomycin, phenytoin, phenobarbital, STAT troponin-I, homocysteine, cyclosporine, cortisol, vancomycin, digoxin — — free PSA, SCC, total PSA, AFP, anti-HBc, anti-HBc IgM, anti-HBe, anti-HBs, anti-HCV, rubella IgG, testosterone, others — — (U.S.) TDM: valproic acid, methotrexate, carbamazepine, gentamicin; fertility: testosterone; metabolic: vit B12, folate, vitamin D, anti-CCP, NGAL; thyroid: TG; hep retro/congenitals: anti-HCV, HBsAg + conf, CORE-M, AUSAB, CORE, HAVAB-G, HIV combo; cancer: AFP, HE-4; (INT Ex U.S.) hep retro/congenitals: HCV combo, HBsAg qual; cancer: cyfra 21-1, PIVKA — — |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | — — — | — — — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | photometric, potentiometric, & Chemiflex (enhanced chemiluminescence) 93 93 220 93/50-1,700 3 days/28 days/yes yes yes yes/assay name, reagent No., lot No., tests per kit, expiration date, others open system/SmartWash technology 300/367/>75,000 yes/liquid both disposable and semi-permanent glass/1,200 or 165/330 yes/as needed, 1-year minimum 2 μ L 50 μ L yes/yes yes/25 L per hour (ci8200)/52 L per hour (ci16200) 48-70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes yes/yes no/no yes/yes no/no <20 seconds yes 2 or 6 pt. no/28 days yes/yes from 2 levels after calibration, to 3 per 24 hours yes/yes —/no/10 minutes | chemiluminescence/magnetic particle 25 25 none 25/25-100 —/30 days/yes yes yes yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others no/<0.1 PPM 3 hrs/65/25 no/liquid yes/360 no/— 60 μ L 60 μ L/50 μ L yes/no no/— 50 decibels during normal operation, 62 decibels maximum no/— yes/pediatric, 5, 7, 10 mL tubes and sample cups/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2-6 pt. curve no/minimum 30 days or once per lot yes/yes from 2 levels for qualitative to 3 levels every 24 hrs yes/yes no/no/6.5 minutes |
| Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | <15.6 minutes <20 seconds 400/1,200 yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes no yes/yes/yes yes, AbbottLink 8 business hours 10.4 weeks/— yes daily: <15 min; weekly: <35 min; monthly: 15 min (for manual & automated procedures) yes/yes | 15.6 minutes <20 seconds up to 100 are 1-step STAT TDMs TPH/— yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes yes yes/yes/yes yes 12 business hours —/— yes daily: 10 min; weekly: 17 min; monthly: 90 min. yes/yes |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$375,000/200-500 immunoassay tests per day flexible options available yes/yes | \$125,000/40-250 tests per day flexible options available yes/yes |
| Distinguishing features (supplied by vendor) | integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWash technology, which minimizes carryover to <0.1 ppm; reagent capacity of 93 assays, with sample load up to 367 | streamlined workload mgmt.; contin. access to reagents, samples, and supplies; 65 samp. load cap., 13 univ. bay; up to 7 custom. priority bays, refig. reagent carousel w/25x100 test kit sizes, reagents stable onboard up to 30 days; priority tests, 15.6-min. TAT on stat assays |

Automated immunoassay analyzers

| Part 3 of 31 | Awareness Technology Inc. Chris Schneider info@awaretech.com 1935 SW Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com | Beckman Coulter Inc. Linh Ho ltho@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 714-993-8736 www.beckmancoulter.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | ChemWell/1998/U.S. U.S./open system 50+/2,200+ batch, random access/benchtop/rack 16 × 34 × 20/4 | Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S. & France >2,400/>3,700 continuous random access/benchtop/rack 18.5 × 39 × 24/6.5 |
| 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, ostease bone alkaline phosphatase, 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 | — SHBG HIV ½, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBe IgM, IL-6, CMV IgG, rubella IgM |
| Research-use-only assays Tests in development | unlimited—open system — | 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 | general biochemistries — | — intrinsic factor Ab, inhibin A |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | yes up to 12 min. strip, 8; max. full plate, 96 | 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | EIA/coated microwell up to 12 unlimited unlimited 27/assay dependent assay dependent/assay dependent/yes (10°C below ambient) yes yes no no/none assay dependent/96/12 yes/liquid yes/96 yes/assay dependent 2 μL 2 μL/— no/no no — no yes/12 × 100 mm/no no/— — yes no/no yes no/yes no/no yes/no yes/yes assay dependent no assay dependent yes/assay dependent yes/yes shortest interval: each run; longest: daily yes/yes yes/yes/2 minutes | chemiluminescence/magnetic particle 24 24 0 24/100 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (4°C) yes yes yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No. no/<10 ppm 180/60/300 no/liquid yes/294 no/— specimen container dependent 5 μL/100 μL no/no no/— <70 decibels yes/100 μL yes/12 × 75, 13 × 75 & 100, 16 × 75 & 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes no/no yes/yes no/no 36 seconds no 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 Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | assay dependent 30 seconds assay dependent yes/yes onboard/yes (included) — no no — yes (broadcast download & host query) yes no yes/yes/yes no within 48 hours —/— yes daily: <10 min; weekly: <10 min; monthly: <10 min no/no | 15 minutes 36 seconds 33/100 (36 seconds) yes/yes onboard/yes (included or additional cost—negotiable) all major LIS vendors yes no — yes (broadcast download & host query) yes no yes/yes/yes no 24 hours max., usually in 6 hours —/— yes daily: 15 min; weekly: 30 min yes, includes audit trail/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$25,000/up to 500 tests per day \$4,000 3 days on site/no | \$149,800/all volumes & hospital sizes \$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 |

Automated immunoassay analyzers

| 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | UniCel DxI 800 Access Immunoassay System/2003/U.S. U.S./U.S., France >400/>400 continuous random access/floor standing/rack, direct track sampling 67 x 67.5 x 37.5/17.6 | 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 x 128 x 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 phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin receptor, rubella IgM | 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 phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble 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 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBe 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 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBe 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 |
| Research-use-only assays Tests in development | — intrinsic factor Ab, inhibin A | — intrinsic factor Ab, inhibin A |
| 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 yes/< 10 ppm 288/120/1,200 no/liquid yes/>1,000 no/— specimen container dependent 5 μ L/160 μ L no/no no/— <60 decibels yes/100 μ L yes/12 x 75, 13 x 75 & 100, 16 x 75, 85, & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <9 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode | 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 yes/<10 ppm 60/76/608 no/liquid no/125 yes/— 23 μ L 3 μ L/20 μ L yes/yes yes/16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 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 chemistry dependent dependent assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | 15 minutes 18 seconds $\leq 133/\leq 400$ (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 daily: <10 min yes, includes audit trail/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 — 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 | \$325,000/300+ beds or >400 tests per day \$29,900 yes/yes | \$325,000/moderate volume, <300 samples per day 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. |

Automated immunoassay analyzers

| Part 5 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | UniCel DxI 600 Access Immunoassay System/2007/U.S. U.S./U.S. >40/>40 continuous random access/floor standing/rack, direct track sampling 67 x 61.5 x 37.5/16.02 | UniCel Dx8 880i Synchron Access Clinical System/2008/U.S. U.S./U.S. 0/0 continuous random access/floor standing/rack closed-tube 68 x 161 x 48/53.7 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 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 estradiol, inhibin A, ultrasensitive insulin, ostease bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin receptor, rubella IgM — SHBG HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBe 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 — intrinsic factor Ab and inhibin A | 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 estradiol, inhibin A, ultrasensitive insulin, ostease bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin receptor, rubella IgM, plus >100 Synchron chemistry tests — SHBG HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBe 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 — 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/magnetic particle 50 50 — 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 of calibration yes/<10 ppm 240/—/— closed/liquid yes/1,000 no/— specimen container dependent 5 μ L/160 μ L no/no no/— <60 decibels yes/100 μ L yes/12 x 75, 13 x 75 & 100, 16 x 75 & 85 & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no 18 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode | chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hrs/28 days/yes (2°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/112/896 closed/liquid no/125 yes/— 23 μ L 3 μ L/20 μ L yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 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 chemistry dependent — assay dependent no/28 days yes/yes 24 hrs 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 Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 15 minutes 18 seconds —/200 (9 seconds) yes/yes onboard/yes (included in instrument price & additional cost) 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 daily: <10 min yes (includes audit trail)/— | 15 minutes 1 minute 90/720/40 seconds yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no — —/— yes — 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 | \$199,500/200–300 beds or 100–300 tests per day per negotiated contract —/yes | \$650,000/high to very high volume, 750–2,250 samples per day — —/— |
| Distinguishing features (supplied by vendor) | integrates with UniCel Dx8 chemistry systems; uses chemiluminescent technology and same reagent packs to deliver consistent results with other UniCel and Access immunoassay 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 |

Automated immunoassay analyzers

| Part 6 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | UniCel DxI 660i Synchron Access Clinical System/2009/U.S. U.S./U.S. 3/1 continuous random access/floor standing/rack closed-tube 68 x 147 x 48/49 | UniCel DxC 680i Synchron Access Clinical System/2009/U.S. U.S./U.S. 0/2 continuous random access/floor standing/rack closed-tube 68 x 153 x 48/51 |
| 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, ostease bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin receptor, rubella IgM, plus >100 Synchron chemistry tests | 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, ostease bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble 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 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBeAb, HBe IgM, IL-6, CMV IgG, rubella IgM | — SHBG HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBeAb, HBe IgM, IL-6, CMV IgG, rubella IgM, |
| Research-use-only assays Tests in development | IL-6, PAPP-A CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol | 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, enzyme immunoassay/magnetic particle 115 115 100 115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2°-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 115 115 100 115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2°-10°C) 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 Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | yes/<10 ppm 60/76/608 closed/liquid no/125 yes/— 23 μ L 3 μ L/20 μ L yes/yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 92 & 75, 16 x 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 chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode | yes/<10 ppm 60/76/608 closed/liquid no/125 yes/— 23 μ L 3 μ L/20 μ L yes/yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 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 chemistry 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 Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 15 minutes 1 minute 90/720 (40 seconds) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no — — yes — yes, includes audit trail/— | 15 minutes 1 minute 90/720 (40 seconds) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no — — yes — 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 | \$575,000/high volume, 300-750 samples per day per negotiated contract yes/yes | \$610,000/high volume, 300-750 samples per day per negotiated contract yes/yes |
| 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) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel and Access family of systems | 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 |

Automated immunoassay analyzers

| Part 7 of 31 | Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 (714) 961-3779 www.beckmancoulter.com | The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Dr., Ste. 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | UniCel Dxl 860i Synchron Access Clinical System/2009/U.S. U.S./U.S. 1/0 continuous random access/floor standing/rack closed-tube 68 × 147 × 48/51.7 | DS2/2006/U.S. U.S./U.S., U.K. —/— batch, with continuous load/benchttop/rack 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 (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, ostease bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgM, total IgE, cortisol, soluble transferrin receptor, rubella IgM, >100 chemistry tests | ANA screen, ENA screen, dsDNA, SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, GBM, MPO, PR3, Tg-TPO, cardiolipin screen & IgG, IgA, IgM, B2GP-1 screen & IgG, IgA, IgM, phosphatidylserine screen, IgG/IgA/IgM, C1q, gliadin IgG/IgA & screen, +TG IgA/IgG, RF, A-CCP, histone, ASCA IgA/IgG, tetanus toxoid, diphtheria toxoid, EBV VCA IgG, IgM, EBV-EA IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM, CMV IgG/IgM & IgG capture, HSV 1/2 IgG, HSV type specific 1&2, measles IgG/IgM, mumps IgG, high avidity dsDNA, PLAC test, others |
| Tests cleared but not clinically released 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 IgG, rubella IgM IL-6, PAPP-A | none — open system—ELISA |
| Research-use-only assays Tests in development | CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH vitamin D, ultrasensitive estradiol | open system phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgA, phosphatidylglycerol IgG/IgM, phosphatidylcholine, IgG/IgA, phosphatidic Acid, IgG/IgM, prothrombin, C3d, SMA, LKM, modified gliadin peptide |
| User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | none intrinsic factor Ab, inhibin A | open system open system |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — — | yes — min. strip 1 × 8; max. full plate: 96 wells × 2 plates |
| 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, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration | EIA/coated microwell 12 assays per plate unlimited unlimited 8/96 24 hours/—/no yes yes yes/yes |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | yes/<10 ppm 60/112/896 closed/liquid no/125 yes/— 23 µL 3 µL/20 µL yes/yes yes/up to 16 L per hour — 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 chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode | —/0 with disposable tips assay dependent/98/assay dependent yes/liquid no/— no/— 200 µL 5 µL/200 µL (50 µL with microtubes) yes/— no — yes/50 µL yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes no no/yes yes yes/no no/no yes/no no/no — no varies yes/each assay yes/no each assay yes/no no/yes/1–2 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 15 minutes 1 minute 90/720 (40 seconds) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no — — yes — yes, includes audit trail/— | — — assay dependent —/yes onboard/yes (additional cost) — yes no — yes (host query) yes no no/no/no no — —/ <24 hours yes daily: 5 minutes; weekly: —; monthly: — 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 | \$615,000/high to very high volume, 500–1,500 samples per day per negotiated contract yes/yes | \$50,000/100–200 beds \$7,000 8 days on site/yes |
| 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) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel and Access family of systems | graphical interface with drag-and-drop icons; large sample throughput for a two-plate microplate system with 98 samples and continuous load feature; consumable status window shows location and volume requirements during loading |

Automated immunoassay analyzers

| Part 8 of 31 | The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Dr., Ste. 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk | The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Dr., Ste. 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | DSX Automated System/2000/Guernsey, U.K. U.S./U.K. 200/>500 batch/benchtop/rack 32 x 42 x 36/7 | ASP1200/2008/UK UK/UK 2/24 batch/benchtop/rack 22 x 20 x 24/2 |
| Tests available on instrument in U.S. | ANA screen, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, MPO, PR3, TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine IgG/IgM/IgA, C1q 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, diphtheria toxoid, high avidity dsDNA, PLAC test | ANA, dsDNA, ANCA, GBM, EMA |
| 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 — open system—any ELISA | — — — |
| Research-use-only assays Tests in development | open system phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgM/IgA, phosphatidylglycerol IgG/IgM, phosphatidylcholine IgG/IgM, phosphatidic acid IgG/IgM, prothrombin, C3d CIC, SMA, LKM, modified gliadin peptide | — — |
| User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | open system open system | — — |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | yes — min. strip: 1 x 8; max. full plate: 96 x 4 plates | no 5-24 — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | EIA/coated microwell 12 assays per plate unlimited unlimited 25/96 per 4 plates 24 hours—/no yes requires operator prehandling/preparation yes/yes yes/0 assay dependent/92/assay dependent yes/liquid no no 200 µL 5 µL/200 µL (50 µL with microtubes) yes/no no — yes/50 µL yes/various/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/— yes no no/yes yes yes/no no/no yes/no no/no — no assay specific yes/once per analyte per plate yes/yes per plate yes/no yes/—/1-2 minutes | fluorescence, immunoperoxidase/substrate 4 4 unlimited 4/250 8 hours/1 day/no yes yes, some pouroff required no/— no/— 105/96/96 open/liquid no/— —/— 250 µL 5 µL/250 µL yes/no no/— — no/— yes/—no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes — no no/yes yes no/no yes/no —/— — no — yes/— no/no each run no/no 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 specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — — assay dependent yes/yes onboard/yes (additional) Cerner Classic & Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink yes no — yes (host query) yes (manual transmission available) no no/yes/yes no within 24 hours —/ <24 hours yes daily: 5 minutes; weekly: none; monthly: none no/no | — — 32/96/1 hour and 45 min. no/— no/yes, included in price — yes no — no no no/—/— — 24 hours 227 days/4 hours yes daily: 2 min; weekly: 15 min no/— |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$55,000-\$70,000 (dependent on modules)/200+ beds \$12,950 8 days on site, 2 days at vendor offices/yes | \$37,450/50 tests per day \$3,000 yes/yes |
| Distinguishing features (supplied by vendor) | fully open, true four-plate system, modular design of reader, washer, incubators; bar-code reader and ambient drawer enables easy upgrades and express shipping of replacement modules, reducing downtime; software can be trained for learned error recovery | download of worklist from LIS; sample/reagent RETRY option immediately rectifies sampling errors; automated monkey kidney GBM |

Automated immunoassay analyzers

| 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | ESP600/2008/Switzerland, Italy Switzerland/UK 22/0 batch/benchtot/racks 36 × 47 × 32/10.5 | VIDAS Immunoassay Analyzer/1989/U.S. Italy/France 2,200/25,000 batch, random access/benchtot/— Vidas 30 system: 16 × 32 × 2/4.5; mini Vidas system: 21 × 21 × 17/4 |
| 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, procalcitonin, 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 | — — — | — 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 |
| Research-use-only assays | antiphosphatidylethanolamine, antiphosphatidylcholine, antiphosphatidylinositol, antiphosphatidylglycerol, antiphosphatidic acid | vitamin D, EBV |
| Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | deamidated gliadin peptide — — | 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 — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | fluorescence, enzyme EIA/coated microwell 9 — open system 9/88 24 hrs/—/no yes requires operator prehandling/preparation —/— —/— —/— —/— yes/liquid no/— no/— 200 µL 5 µL/200 µL yes/no no/— — no/— yes/10 to 16 mm/no yes (2 of 5 interleaved, Codabar, code 39, code 128)/yes — no no/yes no yes/no —/— yes/no —/— — no assay dependent yes/per run yes/no per run no/yes no/no/2 min | fluorescence, EIA/EIA coated, solid phase receptacle pipetting device MiniVidas: 30; Vidas: 12 total menu 0 unit dose format 30 or 60/— —/—/no no placed directly on system yes/assay name, lot No., calibration, expiration no/zero carryover assay dependent/12–30/12–30 no/dry no/— no/— 100–200 ng/mL dependent on assay 100 ng/mL dependent on assay/— yes/no no/— — no/— no/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no no no/no no no/no no/no no/no — yes — no/14 or 28 days, assay dependent no/yes shortest interval: 8 hours, longest: 24 hours yes/yes 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) 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 | 30 minutes no delay —/Vidas: 20, MiniVidas: 8, Vidas: 60, MiniVidas: 24 yes/yes onboard/yes (additional cost) Misis, Medtech, McKesson, Advanced Lab systems, Citation, Cemer, Dawning, Geneysis, Computab, others |
| LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | yes no — yes (host query) yes no no/no/no no 24 hrs 8-9 months/less than 2 hours yes daily: 5 min; weekly: 10 min; monthly:10 min no/— | yes no — yes (broadcast download) yes no no/yes/yes no within 24 hrs Vidas: 350 days/MiniVidas: 1,000 days yes weekly: 10–15 min 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 |

Automated immunoassay analyzers

| Part 10 of 31 | Bio-Rad Laboratories Clinical Diagnostics Group Ginger Weeden ginger_weeden@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-741-4680 www.bio-rad.com | Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | BioPlex 2200/2006/Australia Australia/U.S. 103/17 continuous random access/floor standing/rack 58 × 72 × 34/12 | PR 3100TSC Photometer/2006/Austria Austria/U.S. 30/— batch/benchttop/rack 7 × 13 × 13/2 |
| 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-Scl-70, anti-Jo-1, anti-centromere B, anti-chromatin, anti-ribosomal P, EBV-nuclear antigen IgG, EBV-viral capsid antigen IgG, EBV-early antigen diffuse IgG, EBV-viral capsid antigen IgM, heterophile antibodies, anti-GBM IgG, anti-MPO IgG, anti-PR3 IgG, syphilis IgG, toxoplasma gondii IgG, rubella IgG, CMV IgG | contact Bio-Rad representative |
| 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 none syphilis IgM | none none 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 IgG, VZV IgG not in U.S. |
| Research-use-only assays Tests in development | none gastrointestinal disease, phospholipid, rheumatoid arthritis, cardiac damage and risk, measles, mumps, VZV, lyme, HSV, HIV and hepatitis | — |
| User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | none heterophile antibodies | none none |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — —/— | no — min. strip: 1; max. full plate: 96 |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | bead flow cytometric (multiplex)/magnetic particle 440 440 none 440/100 720 hours/30 days/yes (2°–8°C) no yes yes/kit type, lot No., kit serial No. no/2 ppm 480 minutes/280/17,600 closed/liquid yes/800 no 5 µL 5 µL/70 µL yes/no no/0.5 L per hour <67 decibels no yes/10–16 mm diameter and 41–100 mm height/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/no —/— — yes analyte dependent no/14 days yes/no 24 hours/24 hours no/yes no/no/10 min | EIA/coated microwell 1 1 none 0/— —/—/no no no no/— no/— 1/up to 96/1 no/liquid no/— no/— 10 µL —/— no/no no/— — no/— no/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no no no/no no no/no no/no no/no —/— — no assay dependent no/weekly no/no shortest interval: weekly; longest interval: monthly —/no 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) 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 | — — 100/300/36 seconds yes/yes onboard/no — | — — —/— no/no no/no — |
| LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | yes no — yes yes no yes/yes/yes no — —/— yes daily: 5 minutes; weekly: 30–40 minutes; monthly: none —/—/— | no no — no yes (via USB thumb drive to separate you) no no/yes/yes no units returned for service —/— no daily: 0; weekly: 5 minutes; monthly: 5 minutes no/— |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$350,000/≥200 tests per day inquire 7 days on site, 7 days at vendor offices/yes | \$9,500/5–500 tests per day inquire 1 day on site |
| Distinguishing features (supplied by vendor) | fully automated/random access; innovative multiplex chemistry; eFlex software with bidirectional interface | compact, standalone microplate photometer; onboard computer allowing user control of instrument and data reduction; colored touchscreen with wizard interface provides streamlined operation of all assays |

Automated immunoassay analyzers

| Part 11 of 31 | Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com | Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg.stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | PhD System/2000/Belgium France/U.S. 200/300 batch/benchtop/rack 35 x 66 x 35/16 | Evolis/2001/Germany Germany/U.S. 225/1,160 batch/benchtop/rack 37 x 44 x 30/10 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | ANA (EIA), anti-centromere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (qEIA), anti-SS-B (EIA), anti-Scl-70 (EIA), anti-Sm (EIA), anti-SmRNP (EIA), anti-ssDNA (EIA), aCL IgM, aCL IgG, aCL IgA, anti-β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPS IgG, aPS IgM, 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 — — HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBe 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 not in U.S. infectious disease & autoimmune panels contact Bio-Rad representative 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 No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | EIA & IFA/coated microwell or slide 8 EIA or 4 IFA 8 EIA or 4 IFA no limit 8/192 4 hours/—/no yes requires operator prehandling/preparation no/— yes/— —/192/— yes/liquid no/— no/— 1 µL specimen 1 µL/200 µL yes/no no — no yes/micro-100 mm height/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no yes no no/yes yes no/no no/no yes/no no/no no/no no 1-5 no/each run yes/no each run no/no no/no/5 minutes | EIA/coated microwell 4-8 4-8 contact Bio-Rad representative 4/96 30 minutes/assay dependent/— yes yes yes no/no (disposable tips) varies by assay/180/4 no/liquid microplates microplates 0.2 µL 10 µL/200 µL yes/no no 60 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no no yes no/no no yes/no no/no yes/no no/no no assay dependent no/with each run yes/no user determined 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 specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — — —/— no/yes onboard/no — yes can be customized — yes yes no no/no/no no <24 hours 6 months/4 hours yes daily: 5 min; weekly: 15 min; monthly: 30 min no/no | — — assay dependent yes/yes onboard/yes in development yes no — yes (broadcast download) yes no yes/no/no no 24 hours —/— yes daily: 5 min; monthly: 60 min 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 an ethernet hub, graphical user interface; added module for IFA slide processing | fully automated microplate system that meets a high level of safety (positive identification 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) |

Automated immunoassay analyzers

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| Part 12 of 31 | Diamedix Corp. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 N. Miami Ave., Miami FL 33127 305-324-2300 www.diamedix.com | DiaSorin Inc. Huizhen Li huizhen.li@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com |
| Name of instrument/First year sold/Where designed | 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 | batch, random access/benchttop/rack | batch, random access/benchttop/rack |
| Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | 28 × 48 × 26/8.7 | 40 × 45 × 30/10 |
| Tests available on instrument in U.S. | autoimmune: ANA screen, ENA screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β 2 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 burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, <i>H. pylori</i> IgG, measles IgG, mumps, IgG, VZV IgG, mycoplasma IgG | EA(D) IgG, EBNA-IgG, VCA-IgG, VCA-IgM reverse capture, measles IgG, varicella zoster IgG, mumps IgG, <i>H. pylori</i> IgG, HSV I/II IgG, Trep-Sure syphilis, CMV IgG & IgM capture, rubella IgG, toxoplasma IgG & IgM capture, ANA screen, ENA 6 screen, anti-dsDNA, anti-Sm, anti-Sm/RNP, anti-SS-A, anti-SS-B, anti-Jo-1, anti-Scl-70, anti-histone, anti-MPO, anti PR3 (cANCA), anti-TPO, anti-cardiolipin IgA, IgG, IgM, anti-CCP, anti-B2 glycoprotein 1 IgG and IgM, anti-mitochondria, anti-thyroglobulin, anti-cardiolipin 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 | — | — |
| User-defined methods implemented for what analytes | 96-well plate enzyme immunoassays | — |
| Tests not available on other manufacturers' analyzers | — | HBeAg, anti-HBe |
| Fully automated microplate system | yes | yes |
| No. of each analyte performed in separate disposable unit | 1 analyte per well | — |
| 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 | EIA/coated microwell (MAGO 4S, EIA & IFA in parallel) | EIA/coated microplate |
| No. of different measured assays onboard simultaneously | 9 | open |
| No. of different assays programmed, calibrated at once | ~50 currently preprogrammed assays | open |
| No. of user-definable (open) channels | 20 per diskette, unlimited diskette capability | unlimited |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 9/96 | volume dependent |
| 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 | yes/lot No., expir. date | yes/— |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover | no/not susceptible, continuous cleaning | 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 | yes/liquid | yes/liquid |
| Uses disposable cuvettes/Max. No. stored | yes/120 | no |
| Uses washable cuvettes/Replacement frequency | no/— | no |
| Minimum specimen vol. required | 50 μ L (pediatric) | 10 μ L |
| Minimum sample vol. aspirated precisely at once/Min. dead vol. | 4 μ L/25 μ L (pediatric) | 10 μ L/200 μ L |
| Supplied with UPS (backup power)/Requires floor drain | yes/no | yes/no |
| Requires dedicated water system/Water consumption | no/— | no/no |
| Noise generated | — | — |
| Has dedicated pediatric sample cup/Dead vol. | yes/— | no |
| Primary tube sampling/Tube sizes/Pierces caps on primary tubes | yes/11–15 mm × 75–100 mm/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 | — | yes |
| Onboard test auto inventory (determines vol. in container) | — | 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/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/Increased to rerun out-of-linear range low results | no/no | no/no |
| Time between initial result & reaspiration of sample for rerun | — | — |
| Autocalibration or autocalibration alert | no | no |
| No. of calibrators required for each analyte | assay dependent, 2–6 | varies per kit |
| Calibrants can be stored onboard/Avg. calibration frequency | yes/per run | no/each run |
| Multipoint calib. supported/Multiple calibs. stored for same assay | yes/no | yes/no |
| How often QC required | per run | per run |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | yes/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 specimens/No. of tests (cycle time) | 120/360 (2.5 hours—assay dependent) | assay dependent |
| 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 | no | no |
| Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component | no/no/no | no/no/no |
| Can order (via modem) malfunctioning part(s) w/o operator | no | no |
| On-site response time of service engineer | 24 hours | 24 hours |
| Mean time between failures/To repair failures | —/— | —/— |
| Onboard error codes to facilitate troubleshooting | yes | yes |
| Avg. time to complete maintenance by lab personnel | daily: <5 minutes; weekly: <10 minutes; monthly: none | daily: 5 minutes; weekly: 30 minutes |
| Onboard maintenance records/Maintenance training demo module | no/no | yes/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) | service during normal business hours included in reagent rental agreement | \$10,500 |
| Training provided w/purchase/Advanced operator training | 1–2 days on site/yes | 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; bidirectional interface |

Automated immunoassay analyzers

| Part 13 of 31 | DiaSorin Inc. Greta Schwichtenberg greta.schwichtenberg@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com | Grifols USA, LLC Stephanie Sorensen stephanie.sorensen@grifols.com 2410 Lillyvale Ave., Los Angeles, CA 90032 323-227-7415 www.grifols.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | LIAISON/1997/Germany Germany/U.S., Italy 250/3,000 batch, continuous random access/benchtop/rack 63 x 136 x 66 cm/9.9 | Triturus/1999/Spain Spain/Spain, U.S., Italy >200/>1,700 batch, random access & cont. random access/benchtop/universal carousel 28.3 x 41.3 x 34.3/10 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 25 hydroxyvitamin D total, intact PTH, EBV IgM, EBNA IgG, VCA IgG, EA IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM, treponema, IgG/IgM, VZV IgG, hGH, Borrelia burgdorferi, HAV IgM, HAV total antibodies, rubella IgG, HSV-1 type specific IgG, HSV-2 type specific IgG — cortisol, ACTH, dsDNA, CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, toxo IgG 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 IgM, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, 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 S100 cardiolipin — 25 hydroxy vitamin D, total, treponema IgG/IgM, Borrelia burgdorferi, VZV IgG, CMV IgM, HSV-1 type specific IgG, HSV-2 type specific IgG | system is completely open; any U.S. clinically cleared and research-use-only EIA procedure can be programmed; infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles — — — — — — — |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — —/— | yes 8 96, 1 minimum strip, 4 maximum full plate |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/magnetic particle 15 15 0 15/100 7/28 days/yes (12°C) no yes yes/all lot information no/no 360/144/1,500 no/liquid yes/720 no assay dependent 5 μ L/200 μ L yes/no no/— — yes/75 μ L yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes — yes yes/yes yes yes/yes no/no yes/yes yes/no 2 minutes no 2 yes/28 days yes/no 24 hours no/yes no/no/2 minutes | EIA, EIA-coated microwell plates, onboard shaker, four individually temperature-controlled microplate positions/coated microwell 1–8 tests on 1–4 plates 8 — 8/48 —/—/no yes minimal operator preparation, handling no yes/no 180/92/8 yes/liquid no no 300 μ L 2 μ L/200 μ L yes/no no/— has external waste port to drain into sink or floor drain no/— yes/12, 13, 16 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/no no/no — yes 1–14 no/check every month yes/yes each run yes/no yes/yes/1–2 minutes |
| Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — 2 minutes — yes/yes no/yes (additional) Cerner, Soft, others yes — — yes (host query) yes no no/no/no no 24 hours —/— yes daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes no/no | system is open, depends on reagent methodology — dependent on reagent methodology/— yes/yes yes, onboard/no CHCS, Softmax, Sunquest yes no LIS—unidirectional or bidirectional yes (host query & broadcast download) yes no yes/yes/yes no within 24 hours —/— yes daily: 5–20 minutes yes (includes audit trail of who replaced parts)/yes |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$145,000/all bed sizes, all volumes inquire 3 days on site/yes | \$79,000/300+ varies, multiple types available —/yes |
| Distinguishing features (supplied by vendor) | benchtop analyzer with high throughput; unique menu offering; up to 15 assays onboard, reagent integral, batch & stat | multibatch or continuous throughput EIA analyzer; user-defined menu, completely 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 disposable tips |

Automated immunoassay analyzers

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| Part 14 of 31 | Hycor, An Agilent Technologies Division webmaster@hycorbiomedical.com 7272 Chapman Ave., Garden Grove, CA 92841 714-933-30000 www.hycorbiomedical.com | Immunodiagnostic Systems Inc. (IDS Inc.) Ken Gibbs kenneth.gibbs@idsplc.com P. O. Box 17063, Fountain Hills, AZ 85269-7063 480-836-7435 www.idsplc.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 | HY•TEC 288 PLUS/outside U.S. 1998, U.S. 1999/Netherlands Netherlands/U.S., Scotland 62/165 random batches/benchtop/rack-robotics 29.5 × 42.5 × 27.5/8 | IDS-iSYS/2009/France France/Belgium —/— continuous random access/benchtop/rack 28 × 40 × 28/— |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 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 anti-tissue transglutaminase IgA and IgG none specific IgG, ssDNA, total rheumatoid factor, anti-tissue transglutaminase IgA and IgG — ANCA profile, centromere, CCP — — | — — — 25-hydroxyvitamin D, albumin, ALP, APO A1-APO B, amylase, bilirubin total/direct, calcium/OCp, 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 — 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 — — |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | yes 8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run) 96—min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells | 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | EIA, tube-based & microplate-based assays/activated cellulose & coated well varies by assay, up to 288 allergens or 8 autoimmune multiple 3 varies by assay, up to 288 allergens or 8 autoimmune 8 hours/12 hours/no yes yes no yes/<1 part in 10,000 assay dependent/100/288 yes/liquid no no 10 µL, 110 µL w/ dead vol. 10 µL-50 µL, assay dependent//100 µL yes/no no/— — no yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/— no yes yes/yes yes no/no no/no yes/no no/no — yes 1-6 no/monthly yes/yes every assay yes/yes yes/no/2-3 minutes | chemiluminescence/magnetic particle 15 15 0 15/100 48 hours/7 days/yes (12°-15°C, run mode; 8°-10°C, sleep mode) yes no, requires operator prehandling/preparation yes/LOT key, No. within lot, XML —/— —/64/960 closed/liquid yes/960 no/— 10 µL 5 µL/tube dependent ~80 µL no/no no/— — yes/80 µL yes/all up to 16 × 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes — yes yes/yes yes yes/yes no/no yes/yes no/no — yes 2 no/test dependent ~7 days yes/yes — —/— yes/yes/10 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — — — yes/yes onboard/optional 25 no no — yes optional no yes/yes/no no 48 hours 7 months/4 hours yes daily: 10-15 minutes; weekly: 20-25 minutes; monthly: 20-25 minutes yes (includes audit trail of who replaced parts)/yes | — — — yes/yes onboard/no, additional cost — yes — — yes (host query) yes yes yes/yes/yes no 24 hours WIP/WIP yes daily: 15 min; weekly: 30 min; monthly: 15 min yes, includes audit trail/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$55,000/all sites, variable test vols. \$5,500 3 days on site/yes | —/— — —/yes |
| 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 |

Automated immunoassay analyzers

| Part 15 of 31 | Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 877-546-8633 www.invernessmedicalpd.com | Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | AtheNA/2002/U.S. U.S./U.S. 143/— batch/benchtop/multichannel pipetting or automated with front end 9.5 × 17 × 20/— | AIMS/2007/Switzerland Switzerland/U.S. 10/— batch/benchtop/rack 35 × 67 × 40/— |
| Tests available on instrument in U.S. | AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm, RNP, Scl-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM), TPO/Tg (thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral capsid antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella, varicella zoster), MMV IgG (measles, mumps, varicella zoster), HSV 1&2 IgG (herpes simplex virus, type 1 & type 2) | AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm, RNP, Scl-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM), TPO/Tg (thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral capsid antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella, varicella zoster), MMV IgG (measles, mumps, varicella zoster), HSV 1&2 IgG (herpes simplex virus, type 1 & type 2) and wampole ELISA II assays |
| 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 | — ToRCH IgG, borrelia VisE-1/pepC10 — | — ToRCH IgG, borrelia VisE-1/pepC10 — |
| 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 automated microplate system No. of each analyte performed in separate disposable unit | no 1-10 | yes assay dependent |
| No. of wells in microplate | min. strip: 1; max. full plate: 96-well plate | min. strip: 8; max. full plate: 96-well plate |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | fluorescence/bead 10 10 0 —/96 —/—/no no no, requires operator prehandling/preparation no/— no/<0.9% 30 ±10/—/— open/liquid no/— no/— 10 µL —/— yes/no no/— — no/— no/—/— yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes no —/— —/— no/no —/— — yes 5 per well no/calibration in every well yes/no 1 per month no/— no/no/30 minutes | enzyme immunoassay, multiflexing/bead, coated microwell 4 multiple unlimited 4/96 —/—/no yes yes no/— yes/3% assay dependent/240/4 open/liquid no/— no/— 210 µL based on 16-mm tube 10 µL/200 µL based on 16-mm tube yes/no no/— — no yes/10 × 16 mm outer dimensions/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/— — yes no/yes yes yes/no no/no yes/no —/— — — assay dependent — — every assay —/yes yes/yes/10 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — — 48/84 no/yes yes, onboard/yes (additional cost) Cerner, Sunquest no no — no yes yes, AIMS no/—/— — 24-48 hours 6 months/<1 day yes daily: 15 min; weekly: 30 min; monthly: 5 min no/— | — — assay dependent/—/— —/yes —/yes — no — — — — — no/—/— — 24-48 hours —/— yes daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes no/— |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$60,000/8 tests per day \$8,000 no | \$149,900/>150 beds \$18,500 5 days on site |
| Distinguishing features (supplied by vendor) | large FDA-cleared menu on the Luminex platform; every sample has a unique calibration curve generated at the time the beads are read; at least 50 discrete readings for every analyte in every test system | fully automated integrated open system that allows processing of Athena MultiLyte multiplexing assays and ELISA on one platform |

Automated immunoassay analyzers

| Part 16 of 31 | Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com | Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | DS2/2007/U.S. U.S./U.S. recently launched batch/benchtop/rack 27 × 21 × 26/4 | DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchtop/rack 32 × 42 × 36/7 |
| Tests available on instrument in U.S. | ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella, Lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; AI: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko | ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella, Lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; AI: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko |
| Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development | — — — — — | — — — — — |
| User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko | AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 96) | yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 96) |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | enzyme immunoassay/coated microwell 24 24 unlimited 18/24 8 hrs/1 day/no yes placed directly on system no/— no/0 120 min/98/24 yes/liquid no/— no/— 10 µL 10 µL/50 µL no/no no/— — no/— yes/primary, pouroff/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes no/yes yes yes/no no/no yes/no no/no — no analyte dependent no/within each run no/no with every assay no/yes yes/yes/5 min | enzyme immunoassay/coated microwell 48 48 unlimited 24/48 8 hrs/1 day/no yes placed directly on system no/— no/0 120 min/98/48 yes/liquid no/— no/— 10 µL 5 µL/50 µL yes/no no/— — no/— yes/primary, pouroff/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes no/yes yes yes/no no/no yes/no no/no — no analyte dependent no/within each run no/no with every assay no/yes 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 Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with | — — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, SunQuest, Soft, Mysis, etc. | — — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, SunQuest, Soft, Mysis, etc. |
| LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | yes no — yes (host query) yes no no/yes/no no 24 hrs — (recently launched)/— yes daily: 5 min; weekly: 20 min; monthly: 20 min no/no | yes no — yes (host query) yes no no/yes/no no 24 hrs 4 months/2 hrs yes daily: 10 min; weekly: 20 min; monthly: 20 min no/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$47,250/<350 beds \$7,500 3 days on site/yes | \$62,900/350+ beds \$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 assays and front-end dilute Inverness AtheNA assays, the DS2 provides an efficient, open, fully automated solution for customers looking for laboratory automation | open DSX platform enables customers to run virtually any ELISA-based assay; modular design allows user to customize the system to their unique needs by adding extra incubators, incorporating a bar-code scanner, or choosing among certain types of sample racks; work list load wizard walks you through set up; shows graphically where to place your reagents, samples, and plates at the beginning of each run; complete daily maintenance in less than 5 min, including removal of consumables and rinsing the washer |

Automated immunoassay analyzers

| 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.nj.com 1001 US Highway Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system | 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 primary & secondsondary containers without need for adapters 51 × 44 × 29/8.9 |
| Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | 57 × 67 × 47/22 plus computer | |
| 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 | AFP, CEA, PSA, fPSA, Gi-TC (CA19-9), BR-TC (CA15-3), CKMB, CKMB-short, estradiol, testosterone, cortisol | fβ-hCG, a-HBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM |
| 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 | no |
| No. of each analyte performed in separate disposable unit | — | — |
| No. of wells in microplate | — | — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/magnetic particle 24 180 0 24/assay dependent (200 or 100) 14 days/28 days/yes (4°–12° C) yes yes yes/lot specific master calibration information; calibrator set points; internal QC targets; product name, lot information, expiration date no/no, disposable tips used to prevent carryover up to 240/300/4,800 no/liquid yes/1,000 with on-the-fly bulk refill no 10–100 µL (test dependent) 10 µL/100 µL yes/no yes/8 L per hour at max. throughput <60.7 decibels no/— yes/11.5–16 mm (width) and 55–102 mm (height); microcups/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no run dependent yes 1 or 2 point master curves (test dependent) no/28 days yes/yes user-defined yes/yes yes/yes/~5 minutes | chemiluminescence (enhanced)/individual coated microwell 20 20 programmed & calibrated at once; up to 25 lots calibrated per assay 0 20/100 56 days/56 days/yes (2°–8°C) yes yes yes/test ID, expir., lot No., pack ID —/zero carryover 720/60/800 (with EPM—enhanced productivity module) no/liquid no no 10 µL 10 µL/80 µL no but it is available/no no/— 60 decibels no yes/mult. ped., microtainers & cups, 5 mL, 7 mL, 10 mL on same univ. sample tray/no yes (2 of 5 interleaved, Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes 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) 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 | 18 minutes 2 minutes 80/240 (15 seconds after 1st result with 300 sample tube continuous loading) yes/yes onboard/yes (additional cost) — | 24 minutes immediate upon completion of last sample metering 30/90 (40 seconds) yes/yes onboard/no Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning |
| LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | yes no — yes (broadcast download & host query) yes yes yes/yes/yes no — TBD/TBD yes daily: <5 minutes; weekly: <30 minutes; monthly: 10 minutes yes/yes | yes yes — yes (broadcast download) yes yes (all systems) yes/yes/yes no <4 hours (contract dependent) —/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 Intellitect 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 |

Automated immunoassay analyzers

| Part 18 of 31 | Ortho Clinical Diagnostics Mark Steelman msteelma@its.nj.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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK —/— continuous random access/floor standing/universal sample trays (circular) accommodate primary & secondary containers without need for adapters 64.5 × 83.5 × 33.5/19.4 | Phadia Laboratory System 250/2004/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 73 × 50 × 30 + 26-in. wide computer stand/— |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 3rd-gen TSH, TT3, TT4, FT3, FT4, T3-uptake, total B-hCG, LH, FSH, CEA, AFP, ferritin, CK-MB, troponin I, NT-proBNP, equimolar PSA, myoglobin B12, RBC folate, folate, CA 19-9, CA 125 II, cortisol (serum, urine), testosterone, prolactin, estradiol, progesterone, rubella IgG, NTx aHBs Ag, aHBs Ag (conf), aHCV, aHBe, aHBe IgM, aHIV 1+2 — — i-PTH, HIV combo, preeclampsia, syphilis — — | 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 transglutaminase), and gliadin IgA and IgG — — — — — — Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — — | no — — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence, enhanced chemiluminescence/coated microwell 31 31 programmed and calibrated at once, up to 25 lots calibrated per assay — 31/100 1,008 hours/56 days/yes (2°–8°C) yes yes yes/test ID, expiration date, lot No., pack ID no/— varies/90/3,100 closed/liiquid no/— no/— 10 µL 10 µL/35 µL no/no no/— — no/— 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 yes yes/yes yes yes/yes yes/yes yes/yes yes/yes no/no assay dependent yes 1–3 depending on assay no/28 days yes/yes once per 24 hours yes/yes —/—/0 | fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 3 methods not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory 0, closed system 3/400 or 100 depending on the conjugate type 5 days/1 year/yes (2°–8°C) yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/— 470/50 simultaneously/370 tests no/liiquid no — 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 tube type) yes/no no/10 L 65 decibels no yes/10–17 mm × 50–105 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no yes/yes no/no 100 minutes yes 6 per analyte for calibration run, and 2 per analyte when using stored curve yes/28 days or sooner if conjugate lots change yes/yes once per work shift (user defined) 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 Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 24 minutes immediate upon completion of last sample metering assay dependent/assay dependent (19 seconds) yes/yes yes, onboard and optional add-on (Data Innovations)/yes, additional cost Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning yes no — yes (broadcast download & host query) yes yes, enGen yes/yes/yes no <4 hours (contract dependent) dependent on corrective action/dependent on corrective action yes daily: 10 minutes; weekly: 25 minutes; monthly: 15 minutes yes, includes audit trail/yes | — 6 minutes 20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds) yes/yes onboard/yes (instrument side only) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no — yes (broadcast download & host query) yes yes yes/yes/yes no <24 hours —/— 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 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 | provides widely accepted technology for serologic, specific IgE testing with the ImmunoCAP 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 immunoassay analyzers

| Part 19 of 31 | Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us | Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | Phadia Laboratory System 1000/2003/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 83 × 71 × 40 + 26-in. wide computer stand/— | Phadia Laboratory System 100 ^F /1995/Sweden Sweden/Sweden — batch/benchtop/carousel 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 | — | — |
| 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 No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once | fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 3 methods not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory | fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 4 7 |
| No. of user-definable (open) channels | 0, closed system | 0, closed system |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 3/400 or 100 depending on the conjugate type | 48–96 depending on the conjugate type |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 5 days/1 year/yes (2°–8°C) | — |
| Multiple reagent configurations supported | yes | yes |
| Reagent container placed directly on system for use | yes (wash solution requires preparation) | yes (wash solution requires preparation) |
| Reagents bar coded/Information in bar code | yes/product name, lot No., expiration date | yes/product name, lot No., expiration date |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover | no/zero carryover (disposable sample tips) | no/— |
| Walkaway capacity in minutes/Specimens/Tests-assays | 460/200 simultaneously/2,400 tests | 180 minutes/varies with analyte/48 |
| System is open (home-brew methods can be used)/Liquid or dry system | no/liquid | 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 |
| Minimum sample vol. aspirated precisely at once/Min. dead vol. | 40 µL/40–200 µL (varies with tube type) | 40 µL/40–200 µL for ImmunoCAP tests and 50 µL/50–200 µL for ELiA tests (varies with tube type) |
| Supplied with UPS (backup power)/Requires floor drain | yes/no | yes/no |
| Requires dedicated water system/Water consumption | no/10 L | no/1 L per run |
| Noise generated | 68 decibels | — |
| 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 | no | no |
| 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 | 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 | no/yes | yes/yes |
| Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results | no/no | no/no |
| Time between initial result & reaspiration of sample for rerun | 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 | yes/28 days or sooner if conjugate lots change | yes/28 days or sooner if conjugate lots change |
| Multipoint calib. supported/Multiple calibs. stored for same assay | yes/yes | 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 | 6 minutes | — |
| Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) | 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 |
| Can auto transfer QC results to LIS/Onboard capability to review QC | yes/yes | yes/yes |
| Data-management capability/Instrument vendor supplies LIS interface | onboard/yes (instrument side only) | onboard/yes, instrument side only (included) |
| Interfaces up and running in active user sites with | Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others | Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others |
| LIS interface operates simultaneously w/running assays | yes | yes |
| Uses LOINC to transmit orders and results | 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 | yes |
| Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component | yes/yes/yes | yes/yes/yes |
| Can order (via modem) malfunctioning part(s) w/o operator | no | no |
| On-site response time of service engineer | <24 hours | —, swap |
| Mean time between failures/To repair failures | —/— | —/— |
| Onboard error codes to facilitate troubleshooting | yes | yes |
| Avg. time to complete maintenance by lab personnel | daily: 1 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/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 |
| Distinguishing features (supplied by vendor) | 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 a choice for IgE testing worldwide; three automated ImmunoCAP instruments offer laboratories the ability to measure and report specific IgE quantitative results accurately and precisely across the clinical range | provides widely accepted technology for serologic, specific IgE testing with the ImmunoCAP 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 immunoassay analyzers

| Part 20 of 31 | Radiometer Medical ApS info@radiometeramerica.com 810 Sharon Drive, Westlake, OH 44145 +1 (440) 871-8900 www.radiometeramerica.com | Randox Laboratories Ltd. David Ferguson evidence.support@randox.com Diamond Road, Crumlin, County Antrim, BT29 40Y +44 28 94 422413 www.randox.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | AQT90/2008/Denmark Denmark/Finland —/— random access/benchtop/inlet 17.7 x 18.1 x 18.9/2.4 | Evidence System/2004/United Kingdom United Kingdom/United Kingdom —/— batch/floor standing/carousel 68 x 78 x 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 | TnI, CKMB, MYO, β hcG | MDMA, LSD, fentanyl, propoxyphene, methaqualone, generic opioids, ketamine, buprenorphine |
| Tests not available in U.S. but available in other countries | TnI, CKMB, MYO, NT-proBNP, β hcG, CRP, D-dimer | TT4, FT4, TT3, FT3, TSH, AFP, CEA, hCG, fPSA, tPSA, testosterone, CK-MB, cTNI, myoglobin, FABP |
| Research-use-only assays | — | GPBB, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-3, IL-4, IL-6, IL-7, IL-8, IL-10, IL-13, IL-23, IL-12p70, VEGF, TNF α , IFN γ , IL-1a, IL-1b, MCP-1, EGF, GFAP, S100B, hsCRP, BDNF, D-dimer, NSE, NGAL, thrombomodulin, sIL-2Ra, sIL-6R, sTNFR1, sTNFR2, MMP-9, IL5, IL15, GM-CSF, MIP-1 α , TNF β |
| 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, leptin, 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, IFN γ , IL-1a, MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6r, sTNFR1, sTNFR2, MMP-9 |
| Fully automated microplate system | no | no |
| No. of each analyte performed in separate disposable unit | — | — |
| No. of wells in microplate | — | — |
| 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 | 0 | 0 |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 15/16 | 96/360 |
| 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 | yes | yes |
| Reagents bar coded/Information in bar code | yes/lot number, expiry date, checksum, parameter code, cartridge ID | yes/product component, size, lot No., expir. date |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover | no/<100 ppm | 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 | no/— | no/— |
| Minimum specimen vol. required | 2 μ L | 7 μ L |
| Minimum sample vol. aspirated precisely at once/Min. dead vol. | 2.5 μ L/53.5 μ L | 7 μ L/70–350 μ L (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. | no/— | no/— |
| Primary tube sampling/Tube sizes/Pierces caps on primary tubes | yes/11 x 66 to 13 x 78 mm/yes | 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 | — | 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 | no | yes |
| Clot detection/Reflex testing capability | —/no | 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 |
| 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 | customer determined (longest interval: 1 per month) | user defined |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | —/— | 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 | 30 seconds | — |
| Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) | 10/30 | 108/324 (5 minutes) |
| 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 | 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 (host query) |
| Results transmitted to LIS as soon as test time complete | yes | yes |
| Interface available (or will be) to auto specimen handling system | no | no |
| Modem servicing/Can diagnose own malfunctions/ 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 | —/— | —/— |
| Onboard error codes to facilitate troubleshooting | — | yes |
| Avg. time to complete maintenance by lab personnel | — | daily: <5 min; weekly: 10 min; monthly: 30 min |
| Onboard maintenance records/Maintenance training demo module | yes, includes audit 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 | — | 5 days on site/yes |
| Distinguishing features (supplied by vendor) | POC instrument measures whole blood with lab quality; broad menu and parameter flexibility; closed tube and closed waste system | biochip enables simultaneous analysis of multiple parameters in a single patient 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 |

Automated immunoassay analyzers

| Part 21 of 31 | Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us | Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | Elecsys 2010/1996/— Japan/Germany >800/>6,000 cont. random access/benchtop/rack or disk 22.1 × 47.2 × 28.7/9.4 | cobas e411/2006/Japan Japan/Germany —/— continuous random access/benchtop/rack, disk 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. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance | ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total & βCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, HBsAg, HBeAg confirmatory, anti-HBs, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, anti-TSH receptor — toxos IgM, rubella IgM, anti-HBc IgM | ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total & βCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, total PSA (screening), free PSA, HBsAg, HBeAg conf, anti-HBs, anti-TSH receptor — toxos IgM, rubella IgM, 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-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3 | 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-OH vitamin D3 |
| Research-use-only assays | — | — |
| Tests in development | interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM | 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 |
| User-defined methods implemented for what analytes 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. 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | electrochemiluminescence/magnetic particle 15 60 0 15/100–200 tests per kit 56 days/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reagent name no/zero carryover (disposable sample tips) 120/disk: 30, rack: 100/180 no/liquid yes/180 no 10 µL 10 µL/100 µL —/no no/3 L for 250 tests — no yes/13–16 mm diam./no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no no/no — yes 2 no/monthly yes/yes once per 24 hours yes/yes no/no/4 minutes | electrochemiluminescence, magnetic particle/magnetic particle 18 18 0 18/100–200 tests per kit —/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reagent name no/zero carryover (disposable sample tips) disk: 120/30/180; rack: —/100/18 no/liquid yes/360 assay tips; 180 assay cups no/— 10 µL 10 µL/100 µL no/no no/3 L for 250 tests <70 decibels no yes/13–16 mm diameter/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no no/no — yes 2 no/monthly for lot; weekly for rack yes/yes once per day yes/yes yes/no/4 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 9 minutes (hCG intact) 42 seconds 30/88 (42 seconds) yes/yes onboard/yes (additional cost) all major LISs yes no — yes (broadcast download & host query) yes yes (CLAS & Roche task targeted automation) no/yes/no no <24 hours —/— yes daily: 1 minutes; weekly: 5 minutes; biweekly: 25 minutes; monthly: none no/no (training CD-ROM) | 9 minutes 42 seconds 30/86 (42 seconds) yes/yes onboard/yes (additional cost) — yes no — yes (broadcast download & host query) yes yes no/yes/no no <24 hours —/— yes daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes no/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | varies based on contract included w/ reagent rental 3 days at Indianapolis offices/yes | varies based on contract/varies; primary IA system or back-up unit included with reagent rental 4 days on site/yes |
| Distinguishing features (supplied by vendor) | liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, and fast turnaround time, stat interrupt; onboard reagent storage; minimal maintenance | liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAT; stat interrupt; minimal maintenance |

Automated immunoassay analyzers

| Part 22 of 31 | Roche Diagnostics Leslie Casciato leslie.casciato@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us | Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46250-0457 800-428-5074 www.roche.com/labsystems/us |
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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. | MODULAR ANALYTICS E170/2001/Japan Japan/Germany >250/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only) | cobas e601/2006/— Japan/Germany >350/— |
| 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 × 71.8 × 40/19.73 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and βhCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, HBsAg, HBsAg confirmatory, anti-HBs, toxo IgG, rubella IgG, anti-TSH receptor — toxog IgM, rubella IgM, anti-HCV TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3 — 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 — TnT | ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and β-hCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, carbamazepine, gentamicin, theophylline, tobramycin, valproic acid, vancomycin, cortisol, toxo IgG, rubella IgG, HBsAg, HBsAg conf, anti-HBs, total PSA (screening), free PSA, anti-TSH receptor — toxog IgM, rubella IgM, anti-HCV TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3 — 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 Tnt, myoglobin, CKMB, PTH, HCG — TnT |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — — | no — — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | electrochemiluminescence/magnetic particle, electrochemiluminescence 25 per module, maximum of 60 25 per module — 25/100–200 tests per kit 14 days/35 days/yes (20° C) yes yes yes/calib. curve, application params., lot No., expir., reagent name —/zero, uses disposable sample tips 360/—/1,006 no/liquid yes/1,006 no 10 µL —/100 µL yes/yes yes/30 L per hour in full operation <65 decibels yes/100 µL yes/13 × 75 to 16 × 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/yes yes/yes — yes 2 no/monthly yes/yes 24 hours yes/yes yes/yes/11 minutes | electrochemiluminescence/magnetic particle 25 per module 25 per module — 25 per module/100-200 56 days/56 days/yes (20° C) yes yes yes/calib. curve, application params., lot No., expir., reagent name —/zero, uses disposable sample tips 360/300/1,000 no/liquid yes/1,006 no/— 10 µL 10 µL/100 µL yes/yes yes/up to 30 L/hour in full operation <65 decibels yes/100 µL yes/13 × 75 to 16 × 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/yes yes/yes — yes 2 no/every 28 days yes/yes 24 hours yes/yes yes/yes/11 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 18 minutes — 56/176 (21 seconds) yes/yes onboard/yes (add'l cost) all major LISs yes no — yes (broadcast download & host query) yes yes (Roche MODULAR PRE-ANALYTICS systems and task targeted automation) yes/yes/no no ≤24 hours —/— yes daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes | 18 minutes 42 seconds 56/176 (21 seconds) yes/yes onboard/yes (additional cost) all major laboratory information systems yes yes Web site yes (broadcast download & host query) yes yes (Roche MODULAR PRE-ANALYTICS) yes/yes/no no ≤24 hours —/— yes daily: 5 minutes.; weekly: 10 minutes; monthly: 15 minutes yes (includes audit trail of who replaced parts)/yes |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | varies, based on contract included with reagent rental 5 days at vendor offices/yes | varies, based on contract/— — 5 days at vendor offices/yes |
| 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 measuring range and market, best low-end sensitivity, troponin T, auto-rerun and dilute | ECL technology provides broad measuring ranges and low-end sensitivity; TnT; ready to use bar-coded reagents compatible with other Elecsys Systems; compatible with Modular Pre-Analytics for walkaway automation |

Automated immunoassay analyzers

| Part 23 of 31 | Siemens Healthcare Diagnostics Diane Bandy diane.m.bandy@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 302-631-9435 diagnostics.siemens.com | Siemens Healthcare Diagnostics Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 310-645-8200 x7035 www.siemens.com/diagnostics |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | Dimension Vista 500 Intelligent Lab System/2009/U.S. U.S./U.S. —/— continuous random access/floor standing/rack and aliquot plate system 55.5 × 84.75 × 43.8/26 | ADVIA Centaur CP Immunoassay System/2005/U.S. Germany/U.S. >200/>400 batch, random access, continuous random access/benchtop/7 × 12 position racks 43 × 29/8.7 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | >115 (includes vendor supported applications), 35 general chemistry, 16 immunoassay, 14 TDM, 17 DATs, 27 plasma proteins — — — — CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins, hormones, infectious disease specialty chemistry, plasma proteins, TDMs, DATs LOCI immunoassay, nephelometric assays, general chemistry | AFP, BNP, BR 27-29, CA 125II, CA 15-3, CA 19-9, carbamazepine, CEA, CKMB, cortisol, C-peptide, cPSA, digoxin, estradiol-6 III, ferritin, folate, free T4, free T3, FSH, gentamicin, HAV IgM, homocysteine, insulin, i-PTH, LH, myoglobin, phenobarbital, phenytoin, progesterone, prolactin, PSA, T3, T4, TSH, TSH3, T-uptake, testosterone, theophylline, Tnl-Ultra, tobramycin, total hCG, total IgE, valproic acid, vancomycin, vitamin B12, others — 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 — — D-dimer, E-HIV — cPSA, HER-2/neu |
| 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence, LOCI advanced chemiluminescence, EMIT, PETINIA, nephelometry/ magnetic particle, homogeneous immunoassay >100 >100 10 144/20–1,200 72 hours/30 days/yes (2°–8°C) no yes yes/test method, lot number, expiration date, number of tests yes/<1 ppm 225/150/3,150 yes/liquid yes/>1,600 yes/automatic as needed 50 uL 50 uL/10 uL yes/yes yes/20 L per hour <65 decibels no, can use small sample cup/10 yes/2, 3, 5, 7, 10 mL and cups/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes can decrease, but cannot increase sample volumes <2 minutes yes varies 2–6 yes/30–90 days yes/yes once per 24 hours yes/yes no/no/always ready | chemiluminescence/magnetic particle 15 31 (65 planned for 2008) — 15/50–100 96 hours/28 days/yes (2–8°C) yes yes yes/reagent ID, lot No., expiration date no/zero carryover 210/400/400 no/liquid yes/400 no 10 uL, assay dependent 10 uL/50 uL yes/no no up to 65 decibels no yes/multiple/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/yes 20 seconds yes 2 no/varies, avg. 21 days yes/yes user defined yes/yes yes/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 specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 10 <2 minutes 200/600 (variable 3.6–20 seconds) yes/yes onboard/no — yes no — yes (broadcast download & host query) yes yes, StreamLAB automation system in development yes/yes/yes no 2–8 hours —/— yes daily: <10 min; monthly: 10–20 min no/yes | 15.6 minutes <1 to 2 minutes 50 seconds 60/180 (20 seconds) yes/yes onboard/no Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors yes no — yes (broadcast download & host query) yes no yes/yes/— no 4 hours, 24 hours max. not available/not available yes daily: 15 minutes; weekly: 20 minutes; monthly: 30 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 | —/1,500 tests per day per system — 4 days on site, 4 days at vendor offices/yes | depends on GPO affiliation/community hospitals, satellite labs — 3 days at vendor sites plus online training/yes |
| Distinguishing features (supplied by vendor) | ultra-integrated chemistry platform with LOCI advanced chemiluminescence, and nephelometry onboard; enhanced workflow efficiency with automated features like autocalibration and auto QC and system twinning; proactive service and support through RealTime Solutions services | automates routine operations, including ability to access/change solutions, waste, disposables, and reagents without pausing sampling or processing; onboard automatic dilutions, repeats, STATs and cascade reflex testing; disposable tips; uses same reagents/consumables as ADVIA Centaur/ADVIA Centaur XP with concordant results; throughput 180 tests/hour; average time to first result ~15.6 minutes |

Automated immunoassay analyzers

| Part 24 of 31 | Siemens Healthcare Diagnostics Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 310-645-8200 x 7035 www.siemens.com/diagnostics | Siemens Healthcare Diagnostics Colleen Grier 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | ADVIA Centaur XP/2006/U.S. Ireland/U.S. 475/425 continuous random access/floor standing/5-position multiple size rack or puck via ADVIA LabCell and WorkCell 51.5 × 72.4 × 41/20.6 | Dimension Vista 1500 Intelligent Lab System/2006/U.S. U.S./U.S. and Germany 150/250 batch, random access continuous random access/floor standing/sample rack and aliquot plate system 55 5/8 × 84 7/8 × 43 3/8/26 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, TSH-3, TUp, B12, ferritin, folate, estradiol, 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, myoglobin, Tnl ultra, cortisol, C-peptide (serum), insulin, intact PTH, rubella IgG, 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, carbamazepine, phenobarbital, phenytoin, gentamicin, theophylline, valproic acid, vancomycin, others none — — — cyclosporine, DHEAs, fPSA, HBeAb, HBeAg, procalcitonin, SHBG, syphilis, TSH 3 ultra — cPSA, Her2/neu | >115 (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4 cardiac, 14 TDM, 17 DATs, 27 plasma proteins, 3 anemia, 2 cancer markers (AFP, CEA), fertility (HCG) — — PSA, FPSA, 4 IgG subclasses — CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease TDM, DAT LOCI technology, nephelometry, general chemistry |
| 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/magnetic particle 30 primary reagents 65 — 30/50, 100, 200 tests per pack 96 hours/28 days/yes (4°C) yes yes yes/assay name, lot No., expiration date, pack ID, No. of tests —/none—uses zero carryover 280/180/840 no/liquid yes/1,000 no 10 µL—assay 10 µL/50 µL yes/no no/2.5 L per hour 61.3 decibels no yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no (does have autodilution)/no (does have autodilution) 15 seconds yes 2 no/average 28 days yes/yes 22 hours/24 hours yes/yes no/no/none, always ready | chemiluminescence, enzyme immunoassay, ACMA, EMIT, LOCI, PETINIA, NEPH/none >100 >100 10 >100/20–1,200 72 hours/30 days/yes no yes yes/test ID, lot No., individual-sequence No., exp. date yes/<1 ppm >45/150/8,400 yes/liquid yes/>2,000 yes/automatic, as needed 2 µL analytical, 50 µL aliquot 2 µL (GLU=1.2)/20 µL yes/no no/20 L per hour <70 decibels yes/ 10 µL yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes no/no (does have autodilution) |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 18 minutes 15 seconds 80/240/15 seconds yes yes/yes onboard/yes (LIS allowance) Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others yes no yes (broadcast download & host query) yes yes/ADVIA WorkCell, ADVIA LabCell, others yes/yes/yes no 4-24 hours max —/— yes daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes | 10 minutes <2 minutes 200/600 (variable 3.6–20 seconds) yes/yes yes/no Mysis, Soft, Meditech, Cerner, others yes no — yes (broadcast download & host query) yes yes (StreamLab, ADVIA LabCell in development) yes/yes/yes yes 2–8 hours —/— yes daily: <10 minutes; weekly: none; monthly: 10–20 minutes no/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 | \$225,000/300+ beds or 400 tests per day varies, GPO dependent —/4.5 days on site/yes | \$552,240/>4,000 tests per day 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 dilutions, repeats, STATs and cascade reflex testing; disposable tips; no start-up procedures; always ready; uses same reagents/consumables as Centaur CP w/ concordant results; processes 240 tests/hour; average time to first result ~18 min.; comprehensive hepatitis A, B, C, and HIV testing (includes acute hepatitis panel); automated SMART algorithm for rerun and confirmatory testing for HBsAg testing | homogeneous LOCI technology for high-sensitivity IA assays; fast analytical time, 10-minute cardiac markers, 21-minute anemia methods; ultra-integrated platform with nephelometry that eliminates sample sharing/splitting & streamlines lab workflow; can be configured as a Dimension Vista 3000T twin system; enhances operator efficiency with automatic calib. and AC processing |

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 RxL Integrated Chemistry System/1997/U.S. |
| Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. | U.S./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 × 51 × 31 (without monitor)/10.6 | 44 × 62.5 × 30.5/13.2 |
| Tests available on instrument in U.S. | 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 tricyclic 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 tricyclic antidepressants, others |
| 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 | 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 single platform—fully automated ISD assays | system performs heterogeneous immunoassays and general assays on a single platform—fully automated ISD assays |
| Fully automated microplate system | no | no |
| No. of each analyte performed in separate disposable unit | — | — |
| No. of wells in microplate | — | — |
| Methods supported/Separation methods | ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle | ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle |
| No. of different measured assays onboard simultaneously | 91 | 91 (with optional reagent management system) |
| No. of different assays programmed, calibrated at once | 190 | 190 |
| No. of user-definable (open) channels | 10 | 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 | 48 hours/30 days/yes (2°–8°C) | 48 hours/30 days/yes (2°–8°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/lot No., unique flex ID, stability, expiration date | yes/lot No., unique flex ID, stability, expiration date |
| Same capabilities when 3rd-party reagents used/Susceptibility to carryover | yes/— due to probe washing | yes/— due to probe washing |
| Walkaway capacity in minutes/Specimens/Tests-assays | can be hours/60/>2,000 | can be hours/60/>2,000/>5,000 |
| System is open (home-brew methods can be used)/Liquid or dry system | yes/reconstitutes onboard, no reagent prep required by operator/liquid | yes/no reagent prep required by operator for liquid |
| Uses disposable cuvettes/Max. No. stored | yes/12,000 | 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 | yes/no | yes/no |
| Requires dedicated water system/Water consumption | yes/up to 2 L per hours | yes/3 L per hour/up to 5 L per hour |
| Noise generated | <70 decibels | <70 decibels |
| Has dedicated pediatric sample cup/Dead vol. | yes/10–20 µL | yes/10–20 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 | yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes | yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes |
| Bar-code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines vol. in container) | yes | yes |
| Measures No. of tests remaining/Short sample detection | yes/yes | yes/yes |
| Auto detection of adequate reagent or specimen | yes | yes |
| Clot detection/Reflex testing capability | no/yes | no/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 | <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, Cl)/most 90 days | yes (Na, K, Cl)/most 90 days |
| Multipoint calib. supported/Multiple calibs. stored for same assay | yes/yes | yes/yes |
| How often QC required | 24 hours | 24 hours |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | no/yes | no/yes |
| Automatic shutdown/Startup is programmable/Startup time | not required | 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 specimens/No. of tests (cycle time) | up to 83/up to 250 (14.4 seconds) | up to 166/up to 500 (7.2 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 | optional/yes (additional) | optional (DBNet–Dade Behring)/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 | 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 | yes |
| Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component | yes/yes/yes | yes/yes/yes |
| Can order (via modem) malfunctioning part(s) w/o operator | no | no |
| On-site response time of service engineer | 2–8 hours | 2–8 hours |
| Mean time between failures/To repair failures | —/— | —/— |
| Onboard error codes to facilitate troubleshooting | yes | yes |
| Avg. time to complete maintenance by lab personnel | daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes | daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes |
| Onboard maintenance records/Maintenance training demo module | yes/yes | yes/yes |
| List price/Targeted bed size or daily volume | —/— | —/— |
| Annual service contract cost (24 hours/7 days) | multiple types | multiple types |
| Training provided w/purchase/Advanced operator training | 5 days on site; 4 days at vendor offices/no | 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 |

Automated immunoassay analyzers

| Part 26 of 31 | Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics | Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | Dimension EXL Integrated Chemistry System (upgradeable w/LOCI Module)/2007/U.S. U.S./U.S. —/— batch, random access, continuous random access/floor standing/racks 49 x 82 x 34 (without monitor)/19.4 | Dimension EXL with LM Integrated Chemistry System/2009/U.S. U.S./U.S. —/— batch, random access, continuous random access/floor standing/racks 49 x 82 x 44 (without monitor)/25.1 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | cardiac troponin I, LV cardiac troponin I, CardioPhase hsCRP, ferritin, free PSA, free T4/ thyroxine, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, NT-pro BNP, LV NT-pro BNP, thyroid stimulating hormone, total PSA, ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, pheno- barbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, hemoglobin A1c, thyronine uptake, total T4/thyroxine, triiodothyronine, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, urine screens: amphetamine, cocaine metabolite, methadone, opiates, phencyclidine; serums: TCA, barbiturates, benzodiazepine; propoxyphene, methaqualone, C3, C4, IgA, IgG, IgM, transferrin, others — — — — — — — system performs heterogeneous immunoassays and complete routine general chemistry menu on a single platform; fully automated, no-pretreatment ISD assays | CardioPhase hsCRP, ferritin, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, hemoglobin A1c, thyronine uptake, total T4, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, LOCI free thyroxine, LOCI thyroid stimulating hormone, LOCI cardiac troponin I, LOCI LV NT-pro BNP, urine screens: amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine metabo- lite, methadone, opiates, phencyclidine; serums: TCA, barbiturates, benzodiazepine; propoxyphene, methaqualone, C3, C4, IgA, IgG, IgM, transferrin, general chemistry menu — — — — — — — LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus, total PSA, free PSA — system performs homogeneous LOCI and heterogeneous immunoassays plus a complete routine general chemistry menu on a single platform; fully automated, no- pretreatment ISD assays |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — — | no — — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | enzyme immunoassay, ACMA, EMIT, PETINIA, photometry, potentiometry/ magnetic particle 91 190 10 91/15-360 72 hours/30 days/yes (2°-8° C) yes placed directly on system yes/lot No., unique flex ID, stability, expiration date yes/none (due to probe washing) can be hours/60/>2,000 yes/liquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000 no/— 2 µL 2 µL/primary tube capable yes/no yes/up to 5 L <75 decibels yes/30 µL yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes yes/yes yes/yes yes/no <20 seconds yes varies (3 levels for most assays) yes (NA, K, Cl)/most 90 days yes/yes 24 hours or with lot change no/yes no/no/not required | chemiluminescence, enzyme immunoassay, LOCI, ACMA, EMIT, PETINIA, photometry, potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous 91 190 10 91/15-360 72 hours/30 days/yes (2°-8° C) yes placed directly on system yes/lot No., unique flex ID, stability, expiration date yes/none (due to probe washing) can be hours/60/>2,000 yes/liquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000 no/— 2 µL 2 µL/primary tube capable yes/no yes/up to 5 L <75 decibels yes/30 µL yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes yes/yes yes/yes yes/no <20 seconds yes varies (3 levels for most assays) yes (NA, K, Cl)/most 90 days yes/yes 24 hours or with lot change no/yes no/no/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 Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 16 minutes 24 seconds up to 146/437 (7.2 seconds) yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost) all major LIS vendors yes no — yes (broadcast download, host query) yes yes yes/yes/yes no 2-8 hours —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes no/no | 16 minutes 24 seconds up to 146/437 (7.2 seconds) yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost) all major LIS vendors yes no — yes (broadcast download, host query) yes yes yes/yes/yes no 2-8 hours —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes no/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | — multiple types yes (5 days on site, 4 days at vendor offices)/no | — multiple types yes (5 days on site, 4 days at vendor offices)/no |
| Distinguishing features (supplied by vendor) | analyzer integrates heterogeneous immunoassays onboard with other chemistries; upgradeable with LOCI module; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays | analyzer integrates homogeneous LOCI and heterogeneous immunoassays onboard with other chemistries; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays |

Automated immunoassay analyzers

| Part 27 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 Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3828 www.siemens.com/diagnostics |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | IMMULITE 1000/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S. U.S./U.S., U.K. >7,000 worldwide continuous random access/benchtop/loading platform 19 x 46 x 26/7.98 | IMMULITE 2000/1998/U.S. U.S./U.S., U.K. >5,500 worldwide continuous random access/floor-standing/rack 47 x 60 x 30/12.5 |
| 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, CMV IgG, cortisol, C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori 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, 3gTSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma quant. IgG, Troponin I, Unconjugated Estriol, Valproic Acid, Vitamin B12; Turbo STAT menu: CKMB, HCG, Intact PTH, Myoglobin, Troponin I, others | 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. pylori 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, 3g TSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma quant. IgG, troponin I, unconjugated estriol, valproic acid, vitamin B12, others |
| 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, ECP, cannabinoids (THC), D-dimer | 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 |
| Research-use-only assays 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, syphilis, HBsAb 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. pylori 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 No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/bead, centrifugation 12 unlimited 0 12; 5 for Turbo/100; 50 for Turbo i-PTH —/30 days/yes (15°C) yes yes yes/test, lot No., expir. no/<10 ppm 100/—/70 no/liquid yes/— no 5 μ L 5 μ L/100 μ L yes/no no/0.5 L per hour 55-68 decibels no/— no/—/— yes — yes yes/yes yes no/no no/no yes/no no/no — yes 2-level adjustors, supplied in kit no/1-4 weeks (assay dependent); 2 weeks for Turbo no/yes customer determined no/yes no/no/5 minutes | chemiluminescence/bead, centrifugation 24 unlimited — 24/200 —/90 days/yes (4°C) yes yes yes/test, lot No., expir. no/<3 ppm 300/90/1,300 no/liquid yes/1,300 no/— 5 μ L to 100 μ L sample 5 μ L/50 μ L yes/no no/— 52 decibels yes/50 μ L yes/75-100 mm height; 12-16 mm width/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes —/— yes/yes no/no min. 18 seconds yes 2-level adjustors, supplied in kit no/1-4 weeks (assay dependent) yes/yes customer determined yes/yes yes/no/4 minutes |
| Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 42 minutes; 15 minutes for Turbo (total hCG) 2.5 minutes 120/120 (—) no/yes onboard/yes (additional cost) CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, others yes no — yes (broadcast download & host query) yes no yes/yes/no no 4 hours 10 months/4 hours yes daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes —/yes | 35 minutes (total HCG) 18 seconds 200/200 (18 seconds) yes/yes onboard/yes (additional cost) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others yes no — yes (broadcast download & host query) yes yes (universal interface) yes/yes/yes no 4 hours 3 months/5 hours yes daily: 5-10 minutes; weekly: 20 minutes; monthly: 20-30 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 | \$75,000; Turbo: \$77,500/>1,000 tests per month \$8,000 3.5 days at vendor offices/yes | \$124,500/>6,000 tests per month \$16,500 (RealTime Solutions) varies on site, 5 days at vendor offices/yes |
| Distinguishing features (supplied by vendor) | system reliability and performance; large test menu | high-throughput system, combines specific allergens & routine esoteric testing on one platform; clot detection; sample/reagent level detection; autodilution & autoreflex testing; remote diagnostics; QM & logistics reports |

Automated immunoassay analyzers

| 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | IMMULITE 2500 SMS/2004/U.S. U.S./U.S., U.K. >600 worldwide continuous random access/floor standing/rack 79 x 112 x 40/30.69 | Stratus CS Acute Care Diagnostic System/1998/U.S. U.S./U.S. —/— random access/benchttop/whole blood collection tube 18 x 27 x 22/4.1 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 3gAllergy specific IgE, ACTH, AFP, androstenedione, Anti-TG Ab, Anti-TPO Ab, beta-2 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. pylori IgG, HCG, herpes I & II IgG, high sensitivity CRP, IGFBP-3, IGF-1, insulin, intact PTH, LH, microalbumin, myoglobin, OM-MA (CA125), phenobarbital, phenytoin, progesterone, prolactin, PSA, Pylilinks-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 — 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 — D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, syphilis, HBsAb, Quantitative none 3gPSA, IGF-1, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH | mass CK-MB, myoglobin, β -hCG, D-dimer, NT-proBNP, high sensitivity troponin I, CardioPhase hsCRP — — — — — — — |
| 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/bead, centrifugation 24 unlimited — 24/200 —/90 days/yes (4°C) yes yes yes/test, lot No., expiration no/<3 ppm 300/275/1,300 no/liquid yes/1,300 no/— 5 μ L to 100 μ L sample 5 μ L/50 μ L yes/no no/— 52 decibels yes/50 μ L yes/75–100 mm height; 12–16 mm width/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes/yes —/— yes/yes no/no min. 18 seconds yes 2-level adjustors, supplied in kit no/1–4 weeks (assay dependent) yes/yes customer determined yes/yes yes/no/4 minutes | fluorescence, EIA, dendrimer technology/fiber matrix filter up to 4 1 0 up to 4 TestPaks/unit dose TestPak — yes yes yes/assay ID, lot No., expir., calib. param. no/zero carryover 14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4 no/liquid no no 2.5 mL whole blood 50-90 μ L/— optional/no no/— <65 decibels no yes/4 or 5 mL/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes — —/yes yes yes/no not affected yes/no no/no — yes 1 Calpak no/30–90 days same lot, new lot yes/yes shortest interval: daily electronic QC, longest: every 30 days for liquid controls 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 specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 15 minutes (total HCG) 18 seconds 200/200 (18 seconds) yes/yes onboard/yes (additional cost) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others yes no — yes (broadcast download & host query) yes yes (universal interface) yes/yes/yes no 4 hours 3 months/5 hours yes daily: 5–10 minutes; weekly: 20 minutes; monthly: 20–30 minutes no/yes | 14 minutes immediately 3/9 yes/yes yes/yes (additional cost) all major LIS vendors yes no — no yes no no/yes/yes no 2–8 hours >225 days/2.9 hours yes daily: none; weekly: none; 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 | \$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 handling, user-definable testing; runs specific allergen testing, alongside routine IAs; flexible connectivity to automation via SMS; autoreflex, autodilute; QM & logistics reports | whole blood collection tubes or precentrifuged plasma; onboard centrifugation; unit-dose 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 stand-alone workstation featuring its own cart, refrigerator, & uninterruptible power supply |

Automated immunoassay analyzers

| 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | 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 × 59.1 × 35.7/14.66 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 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-S04, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori 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 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 D-dimer, CMV IgM, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, syphilis, HBsAb quantitative, procalcitonin none 3gPSA, IGF-I, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH | 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, IgE, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen, ferritin, folate, B12, testosterone, CA 19-9, intact PTH — RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnI 3rd gen, PSA II, cystatin C. — HbA1c — — |
| 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 Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | chemiluminescence/— 24 unlimited — —/— —/—/— — — —/— —/— 300/90/1,300 no/liquid no/— —/— 5 µL to 100 µL 5 µL/50 µL yes/— no/— — yes/uses specialized racks yes/75–100 mm/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes no/no — yes 2 level adjusters, supplied in kit no/1–4 weeks (assay dependent) yes/yes customer determined —/— yes/yes/15 minutes | fluorescence/bead 48 48 0 48/— (this is a unitized test cup) 72 hours/72 hours/no yes yes yes/lot No., test code no/zero 172/200/960 no/dry no/— no/— 500 µL tube, 100 µL cup 10 µL/500 µL tube, 100 µL cup yes/no no/— — no/— yes/ 7mL and 10 mL or 15 × 75 & 100, 13 × 75 & 100/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no varies no 2 or 6 (analyte dependent) no/30–90 days yes/yes 24 hours yes/yes no/no/5 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | 35 minutes 18 seconds 200/200 (18 seconds) yes/yes onboard (\$2,000 QC software only, Siemens)/yes — yes no — yes (broadcast download & host query) yes yes, universal interface yes/yes/yes no 4 hours 3 months/5 hours yes daily: 5–10 min; weekly: 20 min; monthly: 20–30 min no/yes | approx. 18 minutes 40 seconds 66/200 (18 seconds) yes/yes —/no — yes yes package insert yes (broadcast download & host query) yes yes (Hitachi, A&T, Bayer, Thermo, iLAS) no/no/no no 24 hours 5 months/24 hours yes daily: 5 min; weekly: 5 min yes, includes audit trail/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | under development/>6,000 per months under development —/— | \$185,000/65+ beds, 1,500–2,000 tests depends on acquisition option 4 days at vendor's office/no |
| 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 |

Automated immunoassay analyzers

| 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 |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet | AIA-360/2004/Japan Japan/Japan 525/1,825 continuous random access/benchtop/carousel 21 x 19 x 16/2.1 | AIA-1800/2003/Japan Japan/Japan 64/486 continuous random access/floor standing/rack, sort drawer, standard and LA 65 x 50 x 37/12.8 |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | 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 — RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., cystatin C, PSA II — HbA1c — — | TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO 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 — RBC folate BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., cystatin C, PSA II — HbA1c — — |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | — — — | — — — |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | fluorescence, EIA/beam 25 entire menu 0 —/unitized test cup 72hours/72hours/— yes yes yes/lot No., test code no/zero carryover 58/25/25 no/dry no no 500 μ L tube, 100 μ L cup 10 μ L/500 μ L tube, 100 μ L cup no/no no/— — no yes/primary draw tubes: 13 x 75 & 100; 16 x 75 & 100/no yes/yes yes yes yes/yes yes yes/no no/no no/no no/no — no 2 or 6-analyte dependent no/30–90 days yes/yes 24 hours no/no no/no/5 minutes | fluorescence, EIA/beam 31 trays entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 58/170/640 no/dry —/unitized test cup — 500 μ L tube, 100 μ L cup 10 μ L/500 μ L tube, 100 μ L cup yes/no no/— — no yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100; 13 x 75 & 100/no yes/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no varies no 2 or 6-analyte dependent no/30–90 days yes/yes 24 hours yes/yes 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) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface | ~18 minutes 60 seconds 12/36 (1 minutes) yes/no Antek, Schuyler House, more | ~18 minutes 40 seconds 60/180 (20 seconds) yes/yes 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 How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | — — yes package insert no yes no no/no/no no — >6 months/24 hours yes daily: 5 minutes no/no | yes yes yes package insert yes (broadcast download & host query) yes yes (Hitachi, Siemens, Thermo, iLAS) no/no/no no 24 hours 5 months/24 hours yes daily: 5–8 minutes; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$25,000/200–1,000 tests per month \$2,050–\$3,500 training DVD; on-site install | \$175,000/65+ beds, 1,500–2,000 tests \$11,458 4 days at vendor offices/no |
| Distinguishing features (supplied by vendor) | unitized test cups; primary tube sampling; no reagent preparation, room temp. stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use; compact size; four tests per sample; random access | two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use |

Automated immunoassay analyzers

| Part 31 of 31 | 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 | Trinity Biotech Marlene Jinks marlene.jinks@trinityusa.com 4 Connell Drive, Ste. 7100, Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com |
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| Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet | AIA-600 II/2000/Japan Japan/Japan 495/1,085 cont. random access/benchtop/chain 19.8 × 31.6 × 29.1/6.4 | Nexgen Four/2003/Italy Italy/U.S., Italy, Ireland —/— batch, random access, continuous random access/benchtop/ring (carousel) 28 × 53.2 × 29.5 (includes carousel)/— |
| Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers | TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO 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, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, intact PTH — RBC folate HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP, cTnI 3rd gen., cystatin C, PSA II — HbA1c none none | 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 open system—any microplate assay open system—any microplate assay |
| Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate | no — — | yes — min. strip: 1; max. full plate: 96 × 4 plates |
| Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to 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 | fluorescence, EIA/ bead 26 entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 52/26/26 no/dry —/unitized test cup — 500 μL tube, 100 μL cup 10 μL/500 μL tube, 100 μL cup yes/no no/— — no yes/primary draw tubes: 7 mL & 10 mL or 15 × 75 & 100, 13 × 75 & 100/no yes/yes yes yes yes/yes yes yes/no no/no yes/no no/yes — no 2 or 6—analyte dependent no/60–90 days yes/yes 24 hours no/no no/no/5 minutes | EIA/coated microwell 500+ 500+ 500+ 16/manufacturer defined —/—/no yes requires operator prehandling, preparation yes/— yes/zero carryover with plastic tips varies/varies/varies yes/liquid yes/— yes/— 200 μL dead vol. plus amount required by test 10 μL/200 μL yes/no no/— — no/— yes/—/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/— yes yes no/yes yes yes/yes no/no yes/no no/no — — manufacturer dependent manufacturer dependent/manufacturer dependent yes/manufacturer dependent manufacturer dependent —/— no/no/10 minutes |
| Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module | ~18 minutes 60 seconds 20/60 (1 minute) yes/no optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (additional cost) Schuyler House, Fletcher Flora yes yes package insert yes (broadcast download & host query) yes no no/no/no no 24 hours 98% uptime/— yes daily: 5 minutes; weekly: 5 minutes; monthly: none no/no | manufacturer dependent — —/open system—depends on kit yes/yes onboard/yes — — — yes yes no yes/yes/yes no by contract —/— yes daily: 5 minutes; weekly: 5–10 minutes; monthly: 10–15 minutes —/no |
| List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training | \$70,000/500–2,500 tests per month \$5,941 3 days at vendor offices/no | \$72,900/>100 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 |