A solution for any service challenge

Michael McNeely, MD Raymond D. Aller, MD

he first automated immunoassay analyzers became available in the 1990s and were widely adopted into routine laboratory practice. In the mid-1990s we began to hear of the next generation of instruments that would provide broader menus and higher throughput, or be designed for smaller or specialized laboratories. The second generation experienced a prolonged gestation, and instruments were released with inadequate menus and, occasionally, engineering flaws. On pages 60–92, in CAP TODAY's

annual lineup of immunoassay analyzers, we list 38 instruments from 20 manufacturers. The specifications of these instruments are not substantially different from those published in the April 2001 issue. The major change is that most of the instruments and their test lists are now a reality. We urge would be purchasers to study actual user experience in appropriate settings.

The instruments profiled here can be classified further as closed systems or open systems. The closed systems are generally designed for routine work and selected specialized tests, and the manufacturer's reagents must be used. Chemiluminescence is the dominant detection system and is capable of high analytical sensitivity. High-volume versions can now generate 200 tests per hour and they cost in excess of \$200,000. Smaller instruments for niche applications and lower-volume settings have throughputs of 60–120 tests per hour and cost \$100,000–\$130,000.

The open systems are usually automated pipetting stations with readers that accept a variety of manufacturers' reagents. EIA is the standard analytical application. Open systems are often used for serology and esoteric testing, but an expanding list of routine assays is emerging within the sensitivity constraints imposed by EIA.

Thus, this generation of immunoassay instruments provides a solution for virtually any service

continued on page 60

Automated immunoassay analyzers

Solution

continued from page 59

challenge. Many laboratories are now exploring how to provide troponin assays around-the-clock and the practicality of an instrument that offers only part of a testing panel (for example, hepatitis).

This diversity is fostering several trends that conflict with one another:

- High-volume analyzers are encouraging centralized processing.
- Low-volume and niche analyzers are able to counter the trend to centralize.
- Expanded test menus make manual radioisotope techniques obsolete, except in referral centers.
- We are now capable of running vast numbers of assays with a rapid turnaround time. This has caused us to be less critical of why we are performing these tests. What is the real diagnostic application of a serum estradiol? How many cases of folate deficiency do we diagnose and what is the case-finding cost? Should cancer markers be used for screening? Is total testosterone a meaningful assay without a measure of SHBG?
- ❖ A few years ago most instruments provided a standard repertoire of tests. Today these menus have been extended to develop one or two specialty areas such as hormones, TDMs, allergy testing, autoimmunity antibodies, cancer markers, or infectious disease serology. For this reason, the choice of instrument may be dictated by a special service requirement. The evolution over the next few years will see a broad menu of tests on most instruments, but it is difficult to assess when a manufacturer's projections will become reality.

Automation has provided clinical medicine with reliable and precise assays. In the early days of immunoassay, clinicians would consider results as a support or confirmation of their clinical impression, and analytical problems were an accepted part of the picture. However, the more we have come to rely on immunoassays and trust the results they provide, the more dangerous are their frailties. This was dramatically played out when a court awarded a young Seattle woman \$16 million for being subjected to a hysterectomy and chemotherapy because of a heterophile antibody false-positive serum hCG. It is now recognized that any two-site immunoassay is susceptible to heterophile antibody interference (for example, HAAA or human antianimal antibodies).

Other analytical problems, known for several years, have gained higher profile recently. For example, all manufacturers' prolactin assays will detect macroprolactin to a variable degree, and this may cause a pituitary adenoma to be misdiagnosed. We have come to appreciate the nonspecificity of steroid determinations such as urinary and serum cortisol assays and estradiol. Parathyroid hormone has come under greater scrutiny because it is now recognized that almost all intact assays for this hormone detect both PTH(1-84), the active molecule, as well as PTH(7-84), which is a PTH antagonist.

Those laboratories that are considering the purchase of new immunoassay analyzers must think strategically to merge their changing workloads with the analyzers' evolving menus. But keep in mind that a new paradigm in analysis is probably only one instrument life away. \square Bibliography

Ismail AA, Barth JH. Wrong biochemistry results. *Br Med J.* 2001;323:705–706.

Ward G, McKinnon L, Badrick T, et al. Heterophile antibodies remain a problem for the immunoassay laboratory. *Am J Clin Pathol.* 1997;108:417–421.

Dr. McNeely is director of chemistry and medical director of informatics, MDS Metro Laboratory Services, Vancouver, BC, Canada. Dr. Aller is based in Vista, Calif., and can be reached at raller@earthlink.net.

Part 1 of 20	Abbott Diagnostics Troy Henry troy.henry@abbott.com 100 Abbott Park Rd., Dept. ZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-937-9785 www.abbott.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 (H x W x D)/instrument footprint	AxSym/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 4,000+/15,000+ cont. random access/floor-standing/segment 59 x 63 x 33.5 in/22 sq ft
Tests available on instrument in U.S.	hTSH II, TT $_3$, TT $_4$, FT $_3$, FT $_4$, T-uptake, β hCG, FSH, LH, estrad., prolac., progest., CK-MB, homocysteine, myogl., trop. I, B $_{12}^*$, ferr.*, fol.*, PSA, CEA, CA 125, CA-19-9, CA 15-3, AFP, CMV IgG, rubella IgG & IgM, toxo IgG & IgM, carbamazep., digitox., digox., gentamicin, NAPA, phenytoin, phenobarb., procain., quinidine, theoph., tobramycin, valp. acid, vanc., amph/meth, barbit., benzodiazep., cannab., cocaine, methadone, opiates, PCP, acetamin., ethanol, salicylates, tricyc. (*currently not available 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	FDA cleared: 3rd-gen. TSH n/a n/a n/a none hopetitic retroiting metabolic feetility.
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	hepatitis, retrovirus, metabolic, fertility none drugs of abuse and congenitals
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously	FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels	20 20 0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	20/100
Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported	onboard reagent stability: 48, 112, 224, 336/no
Reagent container placed directly on system for use Reagents bar-coded/information in bar code	yes yes/assay name, reag. lot no., expir., pack no. ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	
Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	no/liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	yes/90 reaction vessels no
Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption	10 μL/73 μL for sample cup, 450 μL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional no/—
Noise generated in decibels Has dedicated pediatric sample cup/dead vol.	52–68 decibels no
Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	yes/100 & 75 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection	yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	yes yes w/ AxSym Plus
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	yes/no yes/yes
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	seconds no
No. of calibrators required for each analyte	6 pt. or 2 pt. w/ master calib., index calib.
Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	no/4 weeks yes/yes (up to 4 curves/analyte) shortest interval: 8 h, longest: 24 h
Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	yes/yes no/no/1 min.
Stat time to completion of B-hCG test	13 min.
Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	30 sec from standby 68–120 tests/flexible platform—load list dependent (assay dependent
Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface	yes/yes onboard/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays	all major LIS vendors yes
Uses LOINC to transmit orders and results Bidirectional interface capability	yes yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component	yes yes no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no 12 h
Mean time between failures/to repair failures	5 mos/w/in 12 h per customer request
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	yes daily: 5 min; weekly: 30 min; monthly: 30 min no/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$124,000/>100 patients tests per d \$16,800 extended hours coverage 5 d on-site, 5 d at vendor offices/yes
Distinguishing features	menu, reliability

Automated immunoassay analyzers

Abbott Diagnostics Awareness Technology Inc. Suzanne Macaitis suzanne.macaitis@abbott.com Mary Freeman info@awaretech.com Part 2 of 20 100 Abbott Park Rd., Dept. ZZ2, AP6C-5 1935 SW Martin Hwy. Abbott Park, IL 60064-3500 Palm City, FL 34990 847-936-3323 772-283-6540 www.abbott.com www.awaretech.com Name of instrument/first year sold/where designed Architect iSystem/1999/U.S. ChemWell/1998/U.S. Country where manufactured/where reagents manufactured U.S./U.S. U.S./open system No. of units in clinical use in U.S./outside U.S. 100+/700+ 3/170 Operational type/model type/sample handling system batch, random access, cont. random access/floor-standing/rack batch, random access/benchtop/rack 48 x 44 x 68 in/23 sq ft per module Dimensions (H x W x D)/instrument footprint 16 x 34 x 20 in/4 sq ft βhCG, FSH, LH, prolac., progest., CEA, 3rd-gen. TSH, Total T₄, FT₄, FT₃, TT₃, Tests available on instrument in U.S. unlimited-open system testost.*, estradiol, B₁₂,* ferr.* (*currently not available in U.S.) Tests cleared but not clinically released none Tests not available in U.S. but submitted for clearance n/a Tests not available in U.S. but available in other countries n/a unlimited—open system Research-use-only assays unlimited—open system Tests in development hepatitis, retrovirus, thyroid, metabolic, cancer, TDM, cardiac User-defined methods implemented for what analytes none general biochemistries Tests not available on other manufacturers' analyzers none Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a up to 12 No. of wells in microplate min. strip, 8; max. full plate, 96 n/a Methods supported/separation methods Chemiluminescence w/ flexible protocols/magnetic microparticle EIA/coated microwell 25 per module*, max. 4 modules=100 assays max. (* for kits with ≤3 reagent No. of different measured assays onboard simultaneously up to 12 No. of different assays programmed, calibrated at once 100+ unlimited No. of user-definable (open) channels unlimited No. of different analytes for which system accommodates reagent 25 per module*/100-test & 500-test kits (* for kits with ≤3 reagent bottles) 27/assay dependent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard assay dependent/assay dependent/yes (10°C below ambient) 30 d/30 d/yes (2-12°C) Multiple reagent configurations supported yes Reagent container placed directly on system for use yes yes Reagents bar-coded/information in bar code yes/2D bar code, lot. no., no. tests, calib. data Same capabilities when 3rd-party reagents used/susceptibility to carryover no/0.3 ppm no/none Walkaway capacity in min./specimens/tests-assays 300/250/1,000 assay dependent/96/12 System is open (home-brew methods can be used)/liquid or dry system no/liquid yes/liquid Uses disposable cuvettes/max. no. stored yes/1,200 yes/96 Uses washable cuvettes/replacement frequency yes/assay dependent Min. sample vol. aspirated precisely at once/min. dead vol. 150 uL/50 uL 2μL/— Supplied with UPS (backup power)/requires floor drain yes/no no/no Requires dedicated water system/water consumption no Noise generated in decibels 60-65 decibels Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes yes/10-16 mm, up to 75-100 mm/no yes/12 x 75 mm/no Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes no/-Bar code placement per NCCLS standard Auto2A yes Onboard test auto inventory (determines vol. in container) yes yes Measures no. of tests remaining/short sample detection no/no yes/yes Auto detection of adequate reagent or specimen yes yes Clot detection/reflex testing capability yes/no no/yes Hemolysis/turbidity detection-quantitation no/no no/no Dilution of patient samples onboard/automatic rerun capability yes/no yes/no Sample vol. can be reduced/increased to rerun yes/yes yes/yes out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun seconds assay dependent Autocalibration or autocalibration alert No. of calibrators required for each analyte 2-6 pt. curve assay dependent Calibrants can be stored onboard/avg. calibration frequency no/30 d yes/assay dependent Multipoint calib. supported/multiple calibs. stored for same assay yes/yes How often QC required 3 levels every 24 h shortest interval: each run; longest: daily Onboard real-time QC/support multiple QC lot nos. per analyte yes/yes yes/yes Automatic shutdown/startup is programmable/startup time n/a/no/10 min yes/yes/2 min Stat time to completion of B-hCG test assay dependent Time delay from ordering stat test to aspir. of sample every 18 sec from positive sample ID 30 sec Throughput per hr for three analytes on 67/200 per module (aspir. to result: 29 min) assay dependent each specimen, in no. of specimens/no. of tests (cycle time)
Can auto transfer QC results to LIS/onboard capability to review QC yes/yes Data management capability/instrument vendor supplies LIS interface onboard/yes (included) onboard/no Interfaces up and running in active user sites with all major LIS vendors LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results yes (broadcast download & host query) yes (broadcast download & host query) Bidirectional interface capability Results transmitted to LIS as soon as test time complete yes Interface available (or will be) to auto specimen handling system yes Modem servicing/can diagnose own malfunctions/determine yes/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator no within 48 h On-site response time of service engineer 12 h Mean time between failures/to repair failures not available/not available _/_ Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel daily: <15 min; weekly: <10 min; monthly: none daily: <10 min; weekly: <10 min; monthly: <10 min yes (incl. audit trail of who replaced parts)/yes Onboard maintenance records/maintenance training demo module no/no List price/targeted bed size or daily volume \$169,500/500 immunoassays per day \$25,000/up to 500 tests per day \$27,450 (list price) Annual service contract cost (24h/7d) \$4,000 Training provided w/ purchase/advanced operator training 5 d at vendor offices/yes (5 d on-site integration) 3 d on-site/no Distinguishing features Chemiflex: advanced, patented chemiluminescence detection technology w/ ability to perform general biochemistries flexible protocols delivers superior assay performance; modularity: seamlessly integrate multiple instruments to single workstation, throughput from 200-800 tests/h; flexibility: integrate to TLA, as workcell or standalone unit; 5-hour walkApril 2002 CAP TODAY / **63**

Part 3 of 20	Bayer Diagnostics John Talley john.talley.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040	Bayer Diagnostics John Talley john.talley.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040
	www.bayerdiag.com	www.bayerdiag.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 (H x W x D)/instrument footprint	ACS: 180 SE/1997/U.S. U.S./U.S. >1,200/>4,000 cont. random access/benchtop/ring 24 x 59 x 23 in/9.5 sq ft	Bayer Immuno I Immunoassay System/1993/U.S. Ireland/U.S., U.K. 400/~400 cont. random access/floor-standing/rack 54 x 65 x 29 in/13.1 sq ft
Tests available on instrument in U.S.	T ₃ , T ₄ , FT ₄ , FT ₃ , T-uptake, TSH, 3rd-gen. TSH, B ₁₂ , fol., RBC fol., ferr., IgE, urine & serum cortisol, deoxypyrid., hCG, FSH, LH, prolac., progest., estradiol, testost., equimolar PSA, cPSA, anti-TPO, anti-TG, CEA, AFP, BR 27.29, CK-MB, trop. I, myogl., digitoxin, digoxin, theoph., phenobarb., phenytoin, vancomycin, gentamicin, carbamazep., tobramycin, valporic acid	T ₃ , T ₄ , T-uptake, FT ₄ , FT ₃ , TSH, 3rd-gen. TSH, digoxin, theoph., gentamicin, tobramycin, phenytoin, phenobarb., valp. acid, vancomycin, carbamazep., quini dine, NAPA, procain., ferr., B ₁₂ , fol., RBC fol., CK-MB, myogl., trop. I, rubella IgG toxo IgG & IgM, cortisol, B2-microgl., deoxypyrid., AFP, CA 15-3, CA 125 II, CEA, complexed PSA, PSA, hCG, hCG/extended range-100,000 mIU/mL, LH, FSH, prolac., progest., estradiol, testost., unconj. estriol, HER-2/neu
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	C-peptide, insulin, homocyst., PTH none none	none none CA 19-9, CA 72-4, rubella IgM
Research-use-only assays Tests in development	CA 19-9 (RUO), OV (RUO) HER2/neu, BNP	CA 19-9 (RUO) —
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	none cPSA, HER-2/ <i>neu</i>
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a	no n/a n/a
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	chemiluminescence/magnetic particle 13 13 0 13/50	EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle 22 22 0 22/50–200, assay dependent
Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	40 h/1.7 d/no yes yes	21 h/30 d/yes (4°-11°C) yes yes (T ₃ & cortisol require oper. prehandling/prep.)
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored	150/60/450 no/liquid yes/450	yes/test name, expir., No. of tests, lot No., pack ID n/a/≤5 ppm 437/78/875 no/liquid no
Uses washable cuvettes/replacement frequency Min. 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 in decibels	no 10 μL/50 μL no/no -1.8 L per h	yes/24 h 2 μL/75 μL w/ 1 mL sample cup yes/no no/n/a —
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 NCCLS standard Auto2A	no yes/multiple/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes	yes/30 µL yes/multiple/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes
Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation	yes yes/yes yes yes/no no/no	yes yes (auto countdown)/yes yes yes/no no/no
Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	yes/yes no/no 20 sec no	no/no no/no 30 sec no
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	no/varies by assay, generally 28 d yes/yes 24 h	6 no/varies by assay, generally 60 d yes/yes shortest interval: each shift, longest: 24 h
Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	yes/yes no/no/<5 min, generally remains on	yes/yes no/no/3 min, generally remains on
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr 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	15 min <60 sec 60/180 (20 sec) yes/yes	38 min 30 sec 40/120 (30 sec) yes/yes
Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/no Cerner, Soft, Meditech, Antrim, Sunquest, HBOC, Citation, Triple G, Dynamic Healthcare (all major vendors)	onboard/no Cerner, Sunquest, Meditech, HBOC, Citation, Soft, Dawning, Antrim, Dynamic Healthcare, Data Innovations (all major vendors)
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes yes yes (broadcast download & host query) yes yes	yes yes yes (broadcast download & host query) yes yes (Advia LabCell, Lab Interlink)
Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no/no/no no 4 h	no/—/— 4 h
Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	4 mos/3 h yes daily: 15 min, weekly: 15 min, monthly: 15 min yes (incl. audit trail of who replaced parts)/yes	4 mos/2 h yes no daily maintenance no/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$130,000/≥50 immunoassays per d \$13,000 varies on-site, 4 d at vendor offices/yes	\$139,000/≥50 tests per d — varies on-site, 5 d at vendor offices/yes
Distinguishing features	automatic dilutions, repeats performed onboard; clot detection & management; CD-ROM offers online operators manual & help	broad menu includes unique oncology testing; unparalleled accuracy, precision universal solid phase for all assays; clot detection & management; true onboard reag, refrigeration extends calib. & reagent stability

Part 4 of 20	Bayer Diagnostics Nancy McLean nancy.mclean.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6014 www.bayer.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Advia Centaur/1998/U.S. U.S./U.S. >500/>1,200 cont. random access/floor-standing/rack or direct track sampling 51.5 x 72.5 x 41.5 in/21 sq ft	Access Immunoassay System/1993/U.SFrance U.S./U.SFrance 1,500/2,500 Cont. random access/benchtop/rack 18.5 x 39 x 24 in/6.5 sq ft
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, T ₄ , FT ₄ , T-uptake, T ₃ , FT ₃ , B ₁₂ , fol., RBC fol., ferr., LH, FSH, prolac., progest., testost., estradiol, hCG, CK-MB, myogl., trop. I, digoxin, digitoxin, urine & serum cortisol, IgE, equimolar PSA, CEA, AFP, BR 27.29, tobramycin, carbamazep., phenobarb., cPSA, phenytoin, aTPO, gentamicin, theophylline, vancomycin, anti-TG, rubella IgG & IgM, toxo IgG & IgM, valporic acid, CA 15-3	CEA, T ₃ , T ₄ , T-uptake, hypersens. 3rd-gen. TSH, FT ₄ , FT ₃ , βhCG, prolac, FSH, LH, progest., estrad., unconj. estriol, B ₁₂ , fol., RBC fol., ferr., CK-MB, myogl., cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithyroglob., hypersensitive human growth hormone, thyroglobulin, Accu TnI
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	homocyst., insulin, C-peptide, PTH CA 125 specific allergens	— — HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab
Research-use-only assays Tests in development	CA 19-9 HER2/ <i>neu,</i> BNP, HBsAg, HBsAb, HBcAb IgM, HBcAb, HBeAb, HBeAg, HAV, HAV-IgM, CMV IgG, CMV IgM	none CMV IgG & IgM, CA 125, CA 15-3, rubella IgM, PTH, DHEAS, BNP
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	none chlam. Ag & confirm., AFP-ONTD, hybritech PSA & fPSA
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a	no n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	chemiluminescence/magnetic particle 30 30 0	chemiluminescence/magnetic particle 24 24
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	30/50–100	24/50 tests per cartridge, 100 tests per kit
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	96 h/28 d/yes (4°C) yes yes yes yes/assay name, lot no., expir., pack ID	336 h/28 d/yes (4°C) yes yes yes yes/assay No., lot No., expir., unique reag. pack ID No.
Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored	n/a/zero carryover 230/180/840	no/≤3 ppm 180/60/300-31 no/liquid yes/294
Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	no 10 μL/50 μL yes/no	no 5 μL/100 μL no/no
Requires dedicated water system/water consumption Noise generated in decibels Has dedicated pediatric sample cup/dead vol.	no/~2.5 L per h — no	no/n/a <70 within 1 meter no
Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	yes/multiple/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes	yes/13 x 75 & 100, 16 x 75 & 100, 2 mL & 3 mL sample cups/no yes/yes yes
Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen	yes/yes yes	yes yes/yes yes
Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	yes/yes no/no yes/yes no/no	no/no no/no yes/no no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte	15 sec minimum no 2	n/a no 6
Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	no/varies, avg. 21 d yes/yes 24 h	no/28 d yes/yes 24 h
Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	yes/yes no/no/none	yes/yes no/no/remains in ready mode
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	18 min 15 sec 80/240 (15 sec)	15 min 36 sec 33/100 (36 sec)
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/— Cerner, Sunquest, Meditech, HBOC, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, HBOC, and most other major vendors	yes/yes onboard/yes (incl. or addt'l cost—negotiable) all major LISs
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability	yes	yes no
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component	yes (broadcast download & host query) yes yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T) yes/yes/yes	yes (host query) yes no no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures	no 4 h TBD/3 h	no 24 h max., usually w/in 6 h not avail./not avail.
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	yes daily: 3 min, weekly: 20 min, monthly: 30 min yes/yes	yes daily: 15 min, weekly: 30 min, monthly: none yes/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$220,000, STS model \$225,000/300+ beds or ≥400 tests per d \$17,000 varies on-site, 4 d at vendor offices/yes	\$129,800/all vols. & hospital sizes \$14, 800 4 d at vendor offices/yes
Distinguishing features	ability to access/change solutions, waste, disposables & reag. at any time w/o pausing sampling or processing; onboard automatic dilutions, repeats, & cascade reflex testing; disposable tips; 240 results/h, compatible with Hitachi racks	cont. random access benchtop analyzer; state-of-the-art chemiluminescence methodology; ease of use: any test, any tech, any time; superior assays: TSH, FT ₄ , UE ₃ , hybritech PSA, fPSA, B ₁₂ , fol., Accu TnI

Automated immunoassay analyzers

Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com Part 5 of 20 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com Name of instrument/first year sold/where designed Access 2 Immunoassay System/2001/U.S. Country where manufactured/where reagents manufactured U.S./U.S. & France No. of units in clinical use in U.S./outside U.S. 250/125 Operational type/model type/sample handling system cont. random access/benchtop/rack 18.5 x 39 x 24 in/6.5 sq ft Dimensions (H x W x D)/instrument footprint Tests available on instrument in U.S. same as Access (see page 64) Tests cleared but not clinically released same as Access Tests not available in U.S. but submitted for clearance same as Access Tests not available in U.S. but available in other countries same as Access Research-use-only assays Tests in development User-defined methods implemented for what analytes none Tests not available on other manufacturers' analyzers same as Access Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a No. of wells in microplate Methods supported/separation methods chemiluminescence/magnetic particle 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 24/100 tests per kit, 50 tests per cartridge containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard 336 h/28 d/yes (4°C) Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code yes/assay No., lot No., expir., unique reagent pack ID No. Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays 180/60/300 System is open (home-brew methods can be used)/liquid or dry system no/liquid yes/294 Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. $5 \mu L/100 \mu L$ Supplied with UPS (backup power)/requires floor drain yes (when networked)/no Requires dedicated water system/water consumption Noise generated in decibels <70 within 1 meter Has dedicated pediatric sample cup/dead vol. yes/100 μL Primary tube sampling/tube sizes/pierces caps on primary tubes yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection yes/yes Auto detection of adequate reagent or specimen Clot detection/reflex testing capability no/ves Hemolysis/turbidity detection-quantitation no/no Dilution of patient samples onboard/automatic rerun capability yes/yes Sample vol. can be reduced/increased to rerun no/no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun 36 sec Autocalibration or autocalibration alert no No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency no/28 d Multipoint calib. supported/multiple calibs. stored for same assay yes/yes How often QC required Onboard real-time QC/support multiple QC lot nos. per analyte yes/yes Automatic shutdown/startup is programmable/startup time no/no/remains in ready mode Stat time to completion of B-hCG test 15 min Time delay from ordering stat test to aspir. of sample 36 sec Throughput per hr for three analytes on 33/100 (36 sec) each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC onboard/yes (included or additional cost-negotiable) Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with all major LIS vendors LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability yes (broadcast download & host query) Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine yes/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 24 h max, usually within 6 h Mean time between failures/to repair failures TBD/TBD Onboard error codes to facilitate troubleshooting daily: 15 min; weekly: 30 min; monthly: none Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module yes/no List price/targeted bed size or daily volume \$149,800/all volumes & hospital sizes Annual service contract cost (24h/7d) \$15,800 Training provided w/ purchase/advanced operator training 4 d at venor offices/yes the Access Immunoassay System, plus the Access 2, offers the network capabili-Distinguishing features



Access® AccuTnl® Troponin I Assay

Raising The Standard Of Performance.



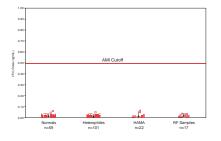
Time to results of 12 minutes allows laboratories to deliver results in less than 30 minutes from sample draw.

The assay uses heparinized plasma, the preferred sample type for rapid sample processing.

No common sample interference from bilirubin, serum albumin, hemoglobin, triolein, sodium heparin or fibrinogen.

Improved specificity with cross-reactivity below 0.1% when conjoint skeletal and cardiac muscle injury is present.

Studies show that response to heterophiles, human anti-mouse antibodies and rheumatoid factor is far below AMI Cutoff.



Visit www.beckmancoulter/accutni



ty of up to 4 Access 2s using a single LIS interface with remote diagnostics, fully automated user-defined reflex testing; onboard context sensitive help, and

aliquot tube capability

© Copyright 2001 Beckman Coulter, Inc.

Automated immunoassay analyzers

The Binding Site Inc. Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com Anne Grainger Part 6 of 20 200 S. Kraemer Blvd. 5889 Oberlin Dr., #101 Brea, CA 92822 San Diego, CA 92121 800-633-4484 714-993-8329 www.beckmancoulter.com www.bindingsite.co.uk Name of instrument/first year sold/where designed Synchron LXi 725/2002/U.S. DSX Automated System/2000/Guernsey, U.K. Country where manufactured/where reagents manufactured U.S./U.S. U.S./U.K. No. of units in clinical use in U.S./outside U.S. >40/>100 (total) Operational type/model type/sample handling system cont. random access/floor-standing/rack-closed tube batch/benchtop/rack Dimensions (H x W x D)/instrument footprint 60 x 134.5 x 48 in/44.8 sq ft 32 x 42 x 36 in/7 sq ft Tests available on instrument in U.S. ANA screen, ENA screen, SS-A, SS-B, Sm, Sm/RNP, Jo-1, ScI-70, dsDNA, GBM, MPO, PR3, Tg, TPO, cardiolipin IgG, IgA, IgM and screen, B2GP1 IgG, IgA, IgM and screen, gliadin IgG, IgA and screen, tissue transglutaminase IgA-all preprogrammed, plus system is totally open for any assay Tests cleared but not clinically released CEA, T $_3$, T $_4$, TU, 3rd gen TSH, FT $_4$, FT $_3$, β hCG, prolac, FSH, LH, progest, estrad., unconj. estriol, B $_{12}$, fol., ferr., CK-MB, myogl., cortisol, urine cortisol, insulin, Tests not available in U.S. but submitted for clearance AFP-open neural tube defect, total IgE, digox., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm, toxo IgG, toxo IgM, rubella IgG, hybritech PSA, hybritech fPSA, testosterone, thyroglob., anti-thyroglob., human growth hormone, ostase, Accu TnI, plus >100 Synchron chem tests, including critical care, general, esoteric, urine & CSF chemistries, all current Synchron DATs, TDMs, proteins, & Tests not available in U.S. but available in other countries open system—any ELISA Research-use-only assays open system Tests in development same as Access/same as Synchron phosphatidyl serine IgG, IgA, IgM, mitochondrial M2, SMA, LKM User-defined methods implemented for what analytes open system Tests not available on other manufacturers' analyzers only system to perform heterogeneous immunoassays & general chemistry on a open system single platform using closed tube sampling Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a No. of wells in microplate min. strip 1 x 8; max. full plate 96 x 4 plates Methods supported/separation methods chemiluminescence/magnetic particle EIA/coated microwell No. of different measured assays onboard simultaneously 12 assays per plate No. of different assays programmed, calibrated at once 65 unlimited No. of user-definable (open) channels 100 unlimited No. of different analytes for which system accommodates reagent 65/50 tests per cartridge, 100 tests per kit (immuno), 300 tests per container set 25/96 per 4 plates containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard 336 h/28 d/yes (4°C) 24 h/n/a/no Multiple reagent configurations supported yes Reagent container placed directly on system for use yes requires operator prehandling/preparation Reagents bar-coded/information in bar code yes/assay No., lot No., expir., unique reagent pack ID Same capabilities when 3rd-party reagents used/susceptibility to carryover no/≤ 3 ppm Walkaway capacity in min./specimens/tests-assays 180/132/5,280 assay dependent/92/assay dependent System is open (home-brew methods can be used)/liquid or dry system no/liquid yes/liquid yes/294 Uses disposable cuvettes/max. no. stored no Uses washable cuvettes/replacement frequency yes, 2 yr warranty (general chem.) 5 μL/100 μL Min. sample vol. aspirated precisely at once/min. dead vol. 5 μL/200 μL (50 μL with microtubes) Supplied with UPS (backup power)/requires floor drain —/yes Requires dedicated water system/water consumption yes/— Noise generated in decibels Has dedicated pediatric sample cup/dead vol. yes/50 µL Primary tube sampling/tube sizes/pierces caps on primary tubes yes/13x75 & 100, 16x75 & 100/yes Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes (2 of 5 interl., codabar, codes 39 & 128)/-Bar code placement per NCCLS standard Auto2A yes 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/no yes/yes Hemolysis/turbidity detection-quantitation yes for general chemistry/yes for general chemistry no/no yes/no yes/yes Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun no/no no/no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun 36 sec n/a Autocalibration or autocalibration alert assay specific No. of calibrators required for each analyte 6 Calibrants can be stored onboard/avg. calibration frequency no/28 d yes/once per analyte per plate Multipoint calib. supported/multiple calibs. stored for same assay yes/yes yes/yes How often QC required 24 h per plate Onboard real-time QC/support multiple QC lot nos. per analyte yes/yes yes/no Automatic shutdown/startup is programmable/startup time no/no/remains in ready mode yes/--/1-2 min Stat time to completion of B-hCG test 15 min n/a Time delay from ordering stat test to aspir. of sample n/a 36 sec Throughput per hr for three analytes on 33/100 (36 sec) each specimen, in no. of specimens/no. of tests (cycle time) assay dependent Can auto transfer QC results to LIS/onboard capability to review QC yes/yes Data management capability/instrument vendor supplies LIS interface onboard/yes (included or additional cost is negotiable) onboard/yes (additional) Interfaces up and running in active user sites with in development LIS interface operates simultaneously w/ running assays yes yes Uses LOINC to transmit orders and results Bidirectional interface capability yes (broadcast download & host query) yes (host query) Results transmitted to LIS as soon as test time complete yes yes (manuai transmission available) Interface available (or will be) to auto specimen handling system no Modem servicing/can diagnose own malfunctions/determine yes/yes/yes no/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 24 h max, usually within 6 h within 24-72 h, dependent on service contract Mean time between failures/to repair failures TBD/TBD n/a/<24 h Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel TBD daily: 5 min; weekly: n/a; monthly: n/a Onboard maintenance records/maintenance training demo module yes/no \$49,000 (dependent on modules)/200+ beds List price/targeted bed size or daily volume TBD/— Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training TBD/— 3 d on-site, 2 d at vendor offices/yes Distinguishing features workstation consolidation without compromise through the use of innovative fully open, true 4-plate system, modular design of reader, washer, incubators, automation; single point-of-sample entry using closed tube sampling, dual bar-code reader and ambient drawer enables easy upgrades and express shipscheduling, and parallel processing with full menu equivalence to the Synchron ping of replacement modules reducing downtime; software can be trained for and Access product lines learned error recovery

Part 7 of 20	BioChem ImmunoSystems (U.S.) Inc. Elaine Soltes biochemUS3@aol.com 754 Roble Rd., Ste. 70 Allentown, PA 18109 610-264-0885 www.biochemimmunosystems.com	BioChem ImmunoSystems (U.S.) Inc. Elaine Soltes biochemUS3@aol.com 754 Roble Rd., Ste. 70 Allentown, PA 18109 610-264-0885 www.biochemimmunosystems.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 (H x W x D)/instrument footprint	Labotech/1996/Italy Italy/n/a (open system) 300/3,000 Batch/benchtop/carousel 20 x 34.5 x 20 in/4.8 sq ft	PersonalLab/1998/Italy Italy/n/a (open system) 200/>400 worldwide batch/benchtop/rack 24 x 26 x 25.6 in/4.6 sq ft
Tests available on instrument in U.S.	open system	open system
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 none	none none
Research-use-only assays Tests in development	none none	none none
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	open platform n/a (open platform)	open platform n/a (open platform)
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes n/a min. strip: 8; max. full plate: 96	yes n/a min. strip: 8; 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	EIA/coated microplate, varies acc. to kit mftr. 8 (3 plates) 500 500 8/96 (3 plates)	EIA/coated microplate, varies acc. to kit mftr. 6 (2 plates) 500 500 6/96 (2 plates)
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	mftr. dependent/no yes no, requires operator prehandling/prep.	mftr. dependent/no yes no, requires operator prehandling/prep.
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	no yes/zero carryover option —/96-8/8 yes/—	no yes/zero carryover option —/96-6/6 yes/—
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	yes/288-3 plates no 10 μL/200 μL yes/no	yes/192-2 plates no 10 µL/200 µL yes/no
Requires dedicated water system/water consumption Noise generated in decibels Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	no/n/a	no/n/a — no yes/16 x 100–11 x 55 mm/no
Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection	yes (2 of 5 interl., codabar, codes 39 & 128)/— yes yes/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/— yes yes/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	yes no/yes no/no yes/no	yes no/yes no/no yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	yes/yes (mftr. & assay dependent) n/a n/a	yes/yes (mftr. & assay dependent) n/a n/a
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	mftr. & assay dependent —/mftr. & assay dependent yes/— mftr. & assay dependent	mftr. & assay dependent —/mftr. & assay dependent yes/— mftr. & assay dependent
Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	yes/yes no/no/5 min	no/n/a no/no/5 min
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	n/a n/a n/a	n/a n/a n/a
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	yes/yes onboard/yes (incl. in price) — yes	yes/yes onboard/yes (incl. in price) — yes
Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete	yes (broadcast download & host query) yes	yes (broadcast download & host query) yes
Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	no yes/yes/yes no	no yes/yes/yes no
On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting	within 24 h —/<24 h yes	within 24 h —/<24 h yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	daily: 6–10 min, weekly: 10 min, monthly: 15 min yes/no	daily: 6–10 min, weekly: 10 min, monthly: 15 min yes/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$64,500/>100 beds depends on acquisition option 3–5 d on-site/yes	\$38,000/>100 beds depends on acquisition option 3–5 d on-site/yes
Distinguishing features	open platform; largest installed base of automated microplate analyzer in its class; proven performance and reliability; accommodates various sample tube sizes including primary tubes within same run	open platform; 2 sample aspir. options: metal needle or disposable plastic tips; proven performance & reliability; accommodates various sample tube sizes including primary tubes within same run

Automated immunoassay analyzers

hioMérieux Inc. BioChem ImmunoSystems (U.S.) Inc. Elaine Soltes biochemUS3@aol.com Jean-Christophe Daniel jean-christophe.daniel@na.biomerieux.com Part 8 of 20 754 Roble Rd., Ste. 70 595 Analum Rd. Allentown, PA 18109 Hazelwood, MO 63042-2320 610-264-0885 314-506-8087 or 800-638-4835 ext. 8087 www.biochemimmunosystems.com www.biomerieux.com Name of instrument/first year sold/where designed PersonalLab Junior/2002/Italy Vidas & MiniVidas/1989/U.S. Country where manufactured/where reagents manufactured Italy/U.S. & Italy & Ireland & Germany U.S., Italy/U.S., France <10/— No. of units in clinical use in U.S./outside U.S. 1,500/>14,000 Operational type/model type/sample handling system -/benchtop/rack batch, random access/benchtop/n/a Vidas: 16 x 32 x 21 in; MiniVidas: 21 x 21 x 17 in/Vidas 4.5, MiniVidas 4 sq ft Dimensions (H x W x D)/instrument footprint 25 x 26 x 25.6 in/-Tests available on instrument in U.S. same for both instruments: C. diff. toxin A, chlam. Ag, chlam. blocking, RSV, open system—any microplate assay rotavirus, rubella IgG, toxo competition (IgG/IgM), measles IgG, mumps IgG, varicella IgG, Lyme (IgG/IgM), TSH, FT₄, T₄, T₃, hCG, estradiol, FSH, LH, prolac., progest., ferr., cortisol (serum & urine), total IgE, CK-MB, digoxin, theoph., *H. pylori* IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer, tPSA Tests cleared but not clinically released open system Tests not available in U.S. but submitted for clearance open system testosterone, myoglobin, trop. I HBsAg, anti-HBs total, anti-HBc IgM, anti-HBc total, HBeAg, anti-HBe, HAV IgM, Tests not available in U.S. but available in other countries open system anti-HAV total, HIV 1/2, HIV P24II, HIV DVO, tox IgG avidity, testosterone, Research-use-only assays open system Tests in development amplified C. trach., amplified N. gonorr., amplified M. tuberc., quant. HIV-1 RNA open system User-defined methods implemented for what analytes open system Tests not available on other manufacturers' analyzers open system quant. D-dimer, C. difficile toxin A, Lyme IgG/IgM, VZG, mumps IgG, measles IgG Fully automated microplate system yes No. of each analyte performed in separate disposable unit 1 test per strip No. of wells in microplate min. strip: 1; max. full plate: 12 n/a EIA/— Methods supported/separation methods fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device Vidas: 30, MiniVidas: 12 No. of different measured assays onboard simultaneously 500 No. of different assays programmed, calibrated at once 500 total menu No. of user-definable (open) channels unit dose format/30 or 60 No. of different analytes for which system accommodates reagent 6/manufacturer defined containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard n/a/n/a/no Multiple reagent configurations supported yes Reagent container placed directly on system for use requires operator prehandling & preparation Reagents bar-coded/information in bar code yes/assay name, lot No., sequence No., expir Same capabilities when 3rd-party reagents used/susceptibility to carryover yes/zero carryover—disposable tips no/zero carryover Walkaway capacity in min./specimens/tests-assays assay dependent/12-30/12-30 System is open (home-brew methods can be used)/liquid or dry system yes/liquid no/dry Uses disposable cuvettes/max. no. stored yes/no yes (reagents)/-Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. 10 μL/200 μL 100 µL/n/a yes (optional)/no Supplied with UPS (backup power)/requires floor drain yes/no Requires dedicated water system/water consumption no/n/a no/no Noise generated in decibels Has dedicated pediatric sample cup/dead vol. no yes/11-12.5 mm/no Primary tube sampling/tube sizes/pierces caps on primary tubes yes (2 of 5 interl., codabar, codes 39 & 128)/yes Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes Bar code placement per NCCLS standard Auto2A yes Onboard test auto inventory (determines vol. in container) no n/a Measures no. of tests remaining/short sample detection no/no yes/yes Auto detection of adequate reagent or specimen yes no Clot detection/reflex testing capability yes/yes (not automatic) no/no Hemolysis/turbidity detection-quantitation no/no Dilution of patient samples onboard/automatic rerun capability no/no Sample vol. can be reduced/increased to rerun manufacturer dependent/manufacturer dependent no/no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun n/a Autocalibration or autocalibration alert yes No. of calibrators required for each analyte manufacturer dependent Calibrants can be stored onboard/avg. calibration frequency yes/manufacturer dependent no/14 d Multipoint calib. supported/multiple calibs. stored for same assay no (mftr.-determined calib. curves)/yes yes/yes How often QC required manufacturer dependent shortest interval: 8 h, longest: 24 h Onboard real-time QC/support multiple QC lot nos. per analyte no/yes yes/yes Automatic shutdown/startup is programmable/startup time no/no/5 min no/no/remains ready Stat time to completion of B-hCG test n/a Time delay from ordering stat test to aspir. of sample n/a no delay Throughput per hr for three analytes on manufacturer dependent Vidas: 20, MiniVidas: 8/Vidas: 60, MiniVidas: 24 (--) each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC yes/yes Data management capability/instrument vendor supplies LIS interface no/yes (optional) onboard/yes (addt'l cost) Sunquest, Meditech, HBOC (Saint), Advanced Lab Systems (Path Lab), Cerner, Interfaces up and running in active user sites with Citation, SCC, SMS, SAIC/CHCS, CompuLab, Antrim, Dawning, Genesys (Dynamedix), Data-Innovations, call technical support for others LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability yes (broadcast download) 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 yes/no/yes no/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 12-24 h w/in 24 h Mean time between failures/to repair failures Vidas: 350 d, MiniVidas: 1,000 d/<2 h Onboard error codes to facilitate troubleshooting daily: 10-15 min, weekly: 10-15 min, monthly: 30 min Avg. time to complete maintenance by lab personnel daily: 5 min; weekly: 10 min; monthly: 15 min Onboard maintenance records/maintenance training demo module yes/no List price/targeted bed size or daily volume Vidas: \$51,800, MiniVidas: \$28,100/≤400 beds \$2,340-\$4,680 (Mini-Vidas 30) Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training 3 d on-site/yes (w/additional fee) as needed on-site, 3 d at vendor offices/yes Distinguishing features unique dual-function combination solid phase & pipetting device (SPR); ability to perform immunoassay & amplified probe assay (in development) on same platform; assay menu mix (antigen detection, serology, fertility, thyroid, endocrine, coagulation) makes Vidas the ideal instrument for routine batch testing as well as emergency stat testing

April 2002 CAP TODAY / **73**

Part 9 of 20	Bio-Rad Laboratories Clinical Diagnostics Group David Hagebush david_hagebush@bio-rad.com 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000	Bio-Rad Laboratories Clinical Diagnostics Group Tom Williamson tom_williamson@bio-rad.com 4000 Alfred Nobel Dr. Hercules, CA 94547 510-741-4611
	www.bio-rad.com	www.bio-rad.com
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S.	Coda/outside U.S. 1996; in U.S. 1997/Japan Japan/U.S., U.K., France, Korea, Australia —/—	PhD System/2000/Belgium Belgium/U.S. 50/0
Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	batch/benchtop/rack 21.6 x 39.5 x 26 in/7.13 sq ft	batch/benchtop/rack 35 x 66 x 35 in/16 sq ft
Tests available on instrument in U.S.	newborn screening—contact Bio-Rad representative	ANA (EIA), anti-Centvomere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (EIA), anti-SS-B (EIA), anti-scl-70 (EIA), anti-Sm (EIA), anti-SmRNP (EIA), anti-ssDNA (EIA)
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	contact Bio-Rad representative	=
Tests not available in U.S. but available in other countries	contact Bio-Rad representative	_
Research-use-only assays Tests in development	n/a 	anti-thyroglobulin, anti-TPO, anti-MPO, anti-PR3, anti-GBM, anti-Gliadin IgG, anti-gliadin IgA, ASCA IgA, ASCA IgA, aCL IgG/IgM, aCL IgA, aPS IgG/IgM, anti-
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	STC drugs of abuse, Ostex Ntx, DSL assays—contact companies represented —	β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPT IgG, aPT IgM — —
Fully automated microplate system	yes	no 1
No. of each analyte performed in separate disposable unit No. of wells in microplate	min. strip: 1 sample; max. full plate, 96	min. strip: 1; max. full plate: 96
Methods supported/separation methods No. of different measured assays onboard simultaneously	EIA/coated microwell & noncoated microwell	EIA/coated microwell
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	9 unlimited	8 no limit
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	9 assays, 24 containers/288 tests	8/192
Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported	n/a/n/a/no	4 h/—/no
Reagent container placed directly on system for use	yes requires operator prehandling/preparation	yes requires operator prehandling/preparation
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover	no no/reduced w/software version 4.0 & updated firmware, depends on amount of	no/n/a yes/—
Walkaway capacity in min./specimens/tests-assays	washing varies by assay/90-270/up to 9	195/184/1
System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored	yes/liquid, reconst. onboard no (yes for dils.)	yes/liquid no/n/a
Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol.	no 10 μL/200 μL, 130 μL in microtubes	no/n/a 1 μL/200 μL
Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption	optional/no no/—	yes/no no
Noise generated in decibels Has dedicated pediatric sample cup/dead vol.	n/a yes/130 μL	no
Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination	not claimed, but some users have validated for their own use/— yes (2 of 5 interl., codabar, codes 39 & 128)/yes	no/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/no
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	yes no	yes no
Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen	no/yes no	no/yes
Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation	no/no no/no	yes no/no no/no
Dilution of patient samples onboard/automatic rerun capability	yes/no	yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	no	n/a no
No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency	1-6 no/most assays require calib. w/ each run, some as long as 2 weeks w/ 1 & 2 pt.	1–5 no/each run
Multipoint calib. supported/multiple calibs. stored for same assay	updates yes/yes	yes/no
How often QC required Onboard real-time QC/support multiple QC lot nos. per analyte	shortest interval: user determined, longest: w/in run recommended yes/yes (late 2000 through Unity QC program)	each run no/no
Automatic shutdown/startup is programmable/startup time	for hardware/6 min.	no/no/5 min
Stat time to completion of ß-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on	n/a n/a ~90 tests per h w/ all results in approx. 3 h (assay dependent)/(protocol specific)	n/a n/a n/a/n/a
each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC	yes/yes (not yet tested)	no/yes
Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/customer acquires through LIS company, can be added to contract homegrown systems, Cerner, Dawning, & Sunguest under development	onboard/yes (included)
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	not possible on batch analyzer	yes
Bidirectional interface capability	no yes (broadcast download)	no no
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes no	yes no
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/no/no	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no 24 h	no <24 h
Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting	—/4 h yes	6 mo/4 h yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	daily: 5 min; weekly: 20 min; monthly: 20 min no/no	daily: 15 min; weekly: 15 min; monthly: 30 min no/no
List price/targeted bed size or daily volume	\$48,000/50-350 beds, 4-6 plates per d	\$35,000/>50 tests per day
Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$4,800 As needed on-site, 3 d at vendor offices/—	\$6,000 2 d on-site/no
Distinguishing features	Coda 4.0 adds powerful, new fluidic controls, dilution capabilities, audible alarms, and new wash parameters; able to perform pretreatment of sample (pipette, incubate, transfer to coated well); 5 methods for creating sample dilutions; easy-to-operate programming	accurate pipetting at 1 μL ; connection of 1–10 pipetting stations together through an ethernet hub, graphical user interface

	Part 10 of 20	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 800-224-6723 www.bio-rad.com	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.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 (H x W x D)/instrument footprint	Evolis/2001/Germany Germany/U.S. & France 0/90 batch/benchtop/rack 37 x 44 x 30 in/10 sq ft	Stratus CS Stat Fluorometric Analyzer/1998/U.S. U.S./U.S. 500/400 random access/benchtop/whole blood collection tube 18 x 27 x 22 in./4.1 sq. ft.
	Tests available on instrument in U.S.	contact Bio-Rad representative	mass CK-MB, trop. I, myoglobin, β-hCG
	Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	contact Bio-Rad representative —	none none
	Tests not available in U.S. but available in other countries	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBc Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, syphilis total Ab, CMV total Ab	none
	Research-use-only assays Tests in development	=	none D-dimer
	User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	=	none none
	Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip, 1; max. full plate, 96	no n/a n/a
	Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	EIA/coated microwell 12 12	fluorescence, EIA, dendrimer technology/fiber matrix filter up to 4 1
	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	unlimited 12/96 —/—/no	0 n/a/unit dose test packs
	Multiple reagent configurations supported Reagent container placed directly on system for use	yes yes	n/a/n/a/no yes yes
	Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays	no no/no (disposable tips) varies by assay/180/unlimited	yes/assay ID, lot No., expir., calib. param. no/zero carryover 14 min to 1st result, subsequent results in 4 min intervals/1/up to 4
	System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	yes/liquid no no	no/liquid no no
	Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	10 μL/100 μL no/no	n/a no/no
	Requires dedicated water system/water consumption Noise generated in decibels	no 60 dBA	no/n/a <65
	Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	no yes/5, 7, 10 mL/no	no yes/4 or 5 mL/yes
	Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	yes (2 of 5 interl., codabar, codes 39 & 128)/no no	yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes
	Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection	no no/no	n/a no/yes
	Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	no yes/no	yes yes/yes
	Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	no/no yes/no	no/no yes/no
	Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	no/no	no/no
	Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	no	n/a yes
	No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency	assay dependent no/with each run	60–90 d same lot, new lot 60–90 d same lot, new lot
	Multipoint calib. supported/multiple calibs. stored for same assay	yes/no	yes/yes
	How often QC required Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	user determined yes/yes (through Unity QC program) no/no	shortest interval: daily system check, longest: every 60 d for liquid controls yes/no no/no/30 min. to warm up
	Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample	n/a n/a	14 min instantly
	Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	assay dependent	3/9
l	Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface	yes/— onboard/yes	yes/yes no/yes (incl. in price)
l	Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays	no	cerner, Sunquest yes
١	Uses LOINC to transmit orders and results Bidirectional interface capability	no yes (broadcast download)	no no
	Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes no	yes no
	Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/no/no	no/yes/yes
	Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no —	no
	Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting	_/_ yes	6 mos or 180 d/2.99 h; 12 mos or 163 d/2.94 h yes
	Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	daily: 5 min; weekly: 10 min; monthly: 30 min no/no	daily: 5 min, weekly: none, monthly: 10 min no/—
	List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	—/50-400 tests per day — —/—	\$50,000/stat locations \$6,094 3 d on-site/no
	Distinguishing features	Evolis is a fully automated microplate system that meets the highest level of safety (positive identification of samples, reagents, microplates, clot detection, no contamination), flexibility (continuous loading of samples, reagents, and microplates), and productivity (4 plates, 180 samples, 12 different assays can be processed simultaneously)	whole blood collection tubes (heparin) or precentrifuged plasma (heparin); onboard centrifugation; unit-dose testpaks; color-coded calibrators packaged on Calpaks; diluent paks for dilutions; self-contained system (no waste lines, etc.); closed container sampling; electronic QC

April 2002 CAP TODAY / **75**

Part 11 of 20	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com
Name of instrument/first year sold/where designed	Dimension Xpand Integrated Chemistry Analyzer/2001/U.S.	Dimension RxL Integrated Chemistry System with Heterogeneous Module
Country where manufactured/where reagents manufactured	U.S./U.S.	(HM)/1997/U.S. U.S./U.S.
No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system	—/— batch, random access, cont. random access/floor-standing/segmented sample	600/300 batch, random access, cont. random access/floor-standing/segmented sample
	wheel	wheel
Dimensions (H x W x D)/instrument footprint	45 x 51 x 31 in (without monitor)/—	44 x 62.5 x 30.5 in./13.2 sq. ft.
Tests available on instrument in U.S.	thyrox. uptake, total thyrox., hemoglobin A1c, acid phosphat., alanine aminotransferase, alkaline phosphatase, amylase, aspartate aminotransferase, CK, CK isoenzyme, glutamyl transferase, lactic dehydrogenase, lipase, pseudocholinesterase, ferr., free thyrox., HCG, mass CK-MB, myoglob., PSA, TSH, trop. I, C3, C4, CRP, hish-sens. CRP, IgA, IgG, IgM, transferr., ammonia, urine CSF protein, lactic acid, prealbum., carbamazep., digox., digitox., gentamicin, lithium, phenobarbital, phenytoin, theophy., tobramycin, vancomycin, valp. acid, acetaminophen, ethyl alcohol, salicylate; urine screens: amph., barbit., benzo., cannab., cocaine metab., methad., opiates, phencyc. (see Dimension RxL at right for full general chemistry menu)	See Dimension Xpand test menu at left for endocrinology, enzymes, heterogeneous immunoassays, specialty, immunology, TDM & toxicology. General chemistry test menu: album., calcium, cholest., creatinine, dir. & total bili., glucose, HDLC, auto. HDL, iron, magnes., phosphorus, total iron-binding capacity (& no pretreat), total protein, triglyc., urea nitrogen, uric acid, carbon dioxide, chloride potassium, sodium
Tests cleared but not clinically released	-	none
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	CSA CSA	CSA CSA
Research-use-only assays	_	none
Tests in development User-defined methods implemented for what analytes	fPSA, tPSA	fPSA, tPSA none
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on single platform	system performs heterogeneous immunoassays & general assays on a single platform
	<u>'</u>	
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no 	no n/a n/a
Methods supported/separation methods	EIA/magnetic particle	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic
No. of different measured assays onboard simultaneously	47	particles 48 (95 with optional reagent management system)
No. of different assays programmed, calibrated at once	140	140
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	10 47/avg. 80–120	10 44–88/max. 240
containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard	72 h/30 d/yes (2–8°C)	24 h open well-30 d unopened reag./72 h open well, 30 d unopened/yes (2-8°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use Reagents bar-coded/information in bar code	yes yes/lot No., unique flex ID, stability	yes/sample ID No., patient name, medical record No., tests
Same capabilities when 3rd-party reagents used/susceptibility to carryover		no/≤.130 ppm
Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	can be hours/60/>1,000 ves/reconstitutes onboard	no/reconstitutes onboard
Uses disposable cuvettes/max. no. stored	yes/12,000	yes/12,000
Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol.	no/— 2 µL/primary tube capable	no 2 μL/—
Supplied with UPS (backup power)/requires floor drain	yes/no	yes/yes
Requires dedicated water system/water consumption Noise generated in decibels	yes/up to 3.5 L per h <70	yes/3.2 L per h <70
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	no yes/5, 7, 10 mL/no	yes/10 µL-20 µL yes/5, 7, 10 mL/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	yes yes	yes yes
Measures no. of tests remaining/short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	yes yes/yes	yes yes/yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun	yes/yes yes/no	yes/yes yes/yes
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	<20 sec	immediately after 1st result
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency	3–5 no/30–90 d	varies—3 levels for most assays yes/15-90 d
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required Onboard real-time QC/support multiple QC lot nos. per analyte	24 h no/no	24 h yes/yes
Automatic shutdown/startup is programmable/startup time	_/_/_	no/no/2 min tech time, 5 min instrument time
Stat time to completion of B-hCG test	16 min	16 min
Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on	24 sec 83/250 (14.4 sec)	24 sec
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	yes/yes optional add-on/no (additional)	yes/yes optional add-on (DataFusion System Integrator–Dade Behring)/yes (addt'l cost)
Interfaces up and running in active user sites with	all major LIS vendors	Sunquest, Cerner, LabNet, HBOC, SMS, Meditech
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	yes no	yes no
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes yes	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 3.0 h	no
On-site response time of service engineer Mean time between failures/to repair failures	2–8 h —/—	2–8 h —/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	daily: <10 min; weekly: 5 min; monthly: 20–30 min yes/no	daily: 2 min, weekly: 2 min, monthly: 15 min yes/no
List price/targeted bed size or daily volume	\$165,000/50,000–200,000 tests per year	\$249,000/—
Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$15,000 5 d on-site; 4 d at vendor offices/no	\$17,500 5 d on-site, 4 d at vendor offices/yes
rrunning provided w/ purchase/advanced operator training		·
Distinguishing features	consolidated low-volume workstation that integrates immunoassays onboard	analyzer integrates heterogeneous immunoassays onboard with other

Diagnostic Products Corp.

Automated immunoassay analyzers

Diagnostic Products Corp.

Joe Kelly jkelly@dpconline.com Joe Kelly jkelly@dpconline.com Part 12 of 20 5700 W. 96th St., Los Angeles, CA 90045-5597 5700 W. 96th St., Los Angeles, CA 90045-5597 310-642-5180 www.dpcweb.com 310-642-5180 www.dpcweb.com Name of instrument/first year sold/where designed Immulite 2000/1998/U.S. Immulite/1993; Immulite Turbo/1999/U.S. Country where manufactured/where reagents manufactured U.S./U.S., U.K. U.S./U.S. No. of units in clinical use in U.S./outside U.S. 5,000 worldwide 2,000 worldwide Cont. random access/floor-standing/rack Operational type/model type/sample handling system cont. random access/benchtop/loading platform Dimensions (H x W x D)/instrument footprint 16 x 42 x 24.75 in (w/o computer)/7.2 sq ft 79 x 60 x 30/12.5 sq ft AFP, CEA, OM-MA, PSA, 3rd-gen. PSA, FT $_3$, TT $_3$, FT $_4$, TT $_4$ TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen. TSH, DHEA-SO $_4$, estrad., FSH, hCG, LH, AlaTOP allergy scr., allergy food panel FP5E, total IgE, EPO, ferr., fol. acid, B₁₂, intact Tests available on instrument in U.S. PTH, Pyrilinks-D, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I & II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO₄, estrad., unconj. estriol, FSH, progest., prolac., total testost., β-2-microgl., cortisol, ferr., total IgE, intact PTH, C-pep., folic acid, B₁₂, insulin, unconj. estriol, carbamazep., phenytoin, valp. acid, HsCRP, hGH, ACTH, PAP, pheno, homocysteine, CMV IgG (qualit)., *H. pylori* IgG, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT₃, FT₄, rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT₃, TT₄, thyrogl., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT₄ & TSH, C-pep., insul., CK-MB, myogl., trop. I, ACTH, B2-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, urinary alburubella IgG, toxo IgG, troponin I, CK-MB, herpes I & II IgG, ALA top allergy screen, pyrilinks-D, myoglobin, toxo IgM, canine TSH, rubella IgM, digoxin, GENT, allergy, min, homocysteine, H. pylori IgG, AFP-NTD, THCA. Turbo menu: CK-MB, myoglob., tobramycin, theophylline, SHBG, AFT-NTD intact PTH, trop. I, hCG Tests cleared but not clinically released HBsAg, a-HBs, aHBc, HBclgM, HBsAg confirm, BRMA (CA 15-3) HBsAg +confirm, aHBs, aHBc, HBc IgM, BR-MA (CA 19-9) Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries GI-MA (CA 19-9), free PSA, TPS, Lyme screen, ECP osteocalcin, nicotine metabo-Research-use-only assays fPSA, Lyme screen, nicotine metabolite, CA 19-9 (GIMA) lite, cytokines, free βHCG Tests in development ANA scr., C. diff., calcitonin, chagas, CMV IgM, dsDNA Ab, hep. A, IGF BP3, IGF-1, anti-HBe, HBeAg, ANA screen, Chagas, CMV IgG avidity, dsDNA, EBV, HAV total, Lyme IgG & IgG/IgM, Hbe, Hbe IgM, androstenedione, cryptosporidium Ag, D-HAV IgM, H. pylori IgA, rubella IgG avidity, toxo IgG avidity, vancomycin, urinary dimer, EBV, gastrin giardia Ag, H. pylori A, HSV IgM, ILIO, NMP 22, NSE, PAPP-A albumin, androstendione, calcitonin, D-dimer, ECP, free βHCG, gastrin, HSV IgM, IGF1, IGF BP3, NMP22, NSE, PAPP-A, CMV IgM User-defined methods implemented for what analytes TBG, thyrogl., SHBG, intact PTH, C-peptide, 3rd-gen. PSA Tests not available on other manufacturers' analyzers 3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, SHBG, TBG, EPO, canine TSH, thyroglob., intact PTH, ACTH. Turbo: intact PTH Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a n/a No. of wells in microplate n/a n/a Methods supported/separation methods chemiluminescence/bead, centrifugation chemiluminescence/bead, centrifugation No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once unlimited; Turbo: 5 unlimited No. of user-definable (open) channels No. of different analytes for which system accommodates reagent 12/100 or 500; Turbo: 50 for intact PTH only 24/200 or 600 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard n/a/30 d/yes (15°C) n/a/90 d/yes (4°C) Multiple reagent configurations supported yes yes Reagent container placed directly on system for use yes yes yes/test, lot No., expir. yes/test, lot No., expir. Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover no/<10 ppm no/<10 ppm Walkaway capacity in min./specimens/tests-assays
System is open (home-brew methods can be used)/liquid or dry system cycle dependent/90/1,000 100/—/70 no/liquid no/liquid Uses disposable cuvettes/max. no. stored yes/n/a yes/1,000 Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. 5 μL/100 μL 5 μL/50 μL Supplied with UPS (backup power)/requires floor drain yes/no Requires dedicated water system/water consumption no/0.5 L per h no/1.5 L per h Noise generated in decibels 55 min., max. 68 Has dedicated pediatric sample cup/dead vol. yes/12 x 75 & 100; 13 x 75 & 100; 16 x 75 & 100 mm/no Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) no yes Measures no. of tests remaining/short sample detection yes/yes yes/yes Auto detection of adequate reagent or specimen Clot detection/reflex testing capability yes no/no yes/yes Hemolysis/turbidity detection-quantitation no/no no/no Dilution of patient samples onboard/automatic rerun capability no/no yes/yes Sample vol. can be reduced/increased to rerun no/no no/no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun n/a min. 18 sec Autocalibration or autocalibration alert No. of calibrators required for each analyte 2-level adjustors, supplied in kit 2 level adjustors, supplied in kit no/1-4 weeks (assay dependent); Turbo: 2 wks no/1-4 weeks (assay dependent) Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay no/yes n/a/yes How often QC required customer determined cutomer determined Onboard real-time QC/support multiple QC lot nos. per analyte no/yes yes/yes Automatic shutdown/startup is programmable/startup time no/no/5 min no/no/5 min Stat time to completion of B-hCG test 42 min; Turbo: 15 min 35 min Time delay from ordering stat test to aspir. of sample 18 sec 2.5 min Throughput per hr for three analytes on 40/120 (--) 67/200 (--) each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC no/yes Data management capability/instrument vendor supplies LIS interface onboard/yes (addt'l cost) onboard/yes (addt'l cost) Sunquest, Cerner, Citation, ALG, CHC, DynaMedix, Antrim, Antek, CSS Sunquest, Cerner, HBOC, CCA, ALG Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results yes (broadcast download & host query) Bidirectional interface capability yes (broadcast download & host query) Results transmitted to LIS as soon as test time complete yes Interface available (or will be) to auto specimen handling system yes (universal interface) no Modem servicing/can diagnose own malfunctions/determine no/yes/no yes/yes/no malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer 4 h 6 h 8 mos/4 h Mean time between failures/to repair failures 2 mos/5 h Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel daily: 5 min, weekly: 10 min, monthly: 20 min daily: 5-10 min, weekly: none, monthly: 20-30 min Onboard maintenance records/maintenance training demo module List price/targeted bed size or daily volume \$75,000; Turbo: \$77,500/>1,000 tests per mo. \$124,500/>4,000 tests per month Annual service contract cost (24h/7d) \$7,500 \$12,500 Training provided w/ purchase/advanced operator training 3.5 d at vendor offices/no, in development 3.5 d at vendor offices/no, in development Distinguishing features system performance reliability; worldwide user satisfaction; breadth of high throughput system with Windows-based, fully multitasking software, integrated training via tutorial & interactive training CD series, clot detection, sample/reagent level detection, auto dilutions and auto reflex testing, remote diagnostics, unrivaled service, support and menu

Automated immunoassay analyzers

Diamedix Corp. DiaSorin Inc. Pat Ahmad pat ahmad@ivax.com Trish Kilbo trish.kilbo@diasorin.com Part 13 of 20 2140 North Miami Ave. 1951 Northwestern Ave. Miami, FL 33127 Stillwater, MN 55082 305-324-2300 or 800-327-4565 800-328-1482 www.diasorin.com Name of instrument/first year sold/where designed ETI-Lab/1996/Italy Mago Plus Automated EIA Analyzer/1997/Italy Country where manufactured/where reagents manufactured Italy/U.S., Italy No. of units in clinical use in U.S./outside U.S. 60/550 Operational type/model type/sample handling system Batch, random access/benchtop/2 racks, 120 samples total batch/benchtop/rack Dimensions (H x W x D)/instrument footprint 28 x 48 x 26 in/8.7 sq ft, incl. onboard computer, reagents, spectrophotometer 24 x 34.5 x 20 in/4.8 sq ft + computer Tests available on instrument in U.S. toxo IgG, toxo IgM capture, rubella IgG, rubella IgM capture, CMV IgG, CMV IgM HBsAg, anti-HBs, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anticapture, HSV I & II IgG & IgM, measles IgG, VZV IgG, EBV-VCA IgG & IgM, EBNA-1 HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-IgG, CMV-IgG, CMV-IqM, HSV I-IqG, HSV II-IqG, HSV I/II-IqG, rubeola-IqG, mumps-IqG, VZV IqG, IgG & IgM, EBV-EA-D IgG & IgM, anti-B. burgdorferi IgG/IgM & IgM, mumps IgG, MP IgG, H. pylori IgG, Lyme IgG & IgM, syphilis IgG, syphilis IgM, ANA scr., anti-H. pylori IgG, mycoplasma IgG, anti-SSA/Ro, anti-SSB/La, anti-Sm, anti-Sm/RNP, dsDNA, anti-SSA, anti-SSB, anti-Sm, anti-RNP/Sm, anti-ScI-70, anti-Jo-1, antianti-ScI-70, anti-Jo-1, anti-dsDNA, RF, ENA-6 scr., ANA ELISA scr., anti-MPO, anti-PR-3, anti-TPO, anti-TG, anti-cardio. scr., anti-cardio. lgG, lgM, lgA, anti-βhistone, anti-cardiolipin 2-glycopr. scr., anti-β-2-glycopr. lgG, lgM, anti-gliadin lgG & lgA Tests cleared but not clinically released none Tests not available in U.S. but submitted for clearance none toxo lgA, CMV scr., herp. simpl. 1 & 2 lgG, syph. scr., lgG & lgM, $\it H. pylori$ lgA, VZV lgM Tests not available in U.S. but available in other countries cap., measles & mumps IgM cap., AMA-M2, anti-ribosomal, β 2-microgl., α 1-microgl., microalbum., anti-insul., ferr., IC-C1q, anti-LKM-1, anti-PCA/intrinsic factor, anti-RNA, anti-glom. basement memb., anti-ssDNA, anti-histone anti-BPI, anti-elastase, anti-cathepsin, anti-lysozyme, anti-lactoferrin, anti- β -lactogl., anti- α -lactalbumin, anti-soya, centromere, transglutaminase IgA, RF(IgA), adenovirus IgG/IgM, brucella IgA, IgG, IgM, chlamydia pneu. IgA, IgM, IgG, mycop. IgM, IgG/IgM, RSV IgG/IgM, tetanus IgG, and others Research-use-only assays none anti-β2 glycoprotein IgA Tests in development none programmed by customer at customer location User-defined methods implemented for what analytes n/a Tests not available on other manufacturers' analyzers assays designed/FDA cleared for this analyzer; tests can be validated on other anals. n/a Fully automated microplate system yes No. of each analyte performed in separate disposable unit usually 1 analyte per well; multiple analytes per well in screen tests No. of wells in microplate min. strip: 8 or less (breakapart wells), max. full plate: 96, up to 4 plates simul. min. strip: 8 wells in strip, 12 strips in plate; max. full plate: 96 Methods supported/separation methods EIA/coated microplate No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once 40 tests preprogrammed, ready for use 6 No. of user-definable (open) channels 50 No. of different analytes for which system accommodates reagent 9/96 6/96 containers onboard at once/tests per container set >16 h/6 d/no Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported yes no, requires operator prehandling/prep. Reagent container placed directly on system for use Reagents bar-coded/information in bar code available/kit lot No., exp. date yes/not susceptible to carryover, has continuous internal cleaning Same capabilities when 3rd-party reagents used/susceptibility to carryover no/0 with disposable tips, wash volume dependent with washable tip Walkaway capacity in min./specimens/tests-assays varies from 150 min-240 min/9 tests & 384 results per run per batch yes/liquid System is open (home-brew methods can be used)/liquid or dry system yes/liquid yes/120 Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency no/n/a Min. sample vol. aspirated precisely at once/min. dead vol. $4 \mu L/100 \mu L$ 10 µL/200 µL Supplied with UPS (backup power)/requires floor drain yes/no Requires dedicated water system/water consumption no/< 1 L per h Noise generated in decibels possible-can use 1.5 mL vial/100 μL Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes yes/up to 16 x 100/no yes/10 mm, 14 mm/-Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes (2 of 5 interl., codabar, codes 39 & 128)/-Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) yes yes Measures no. of tests remaining/short sample detection yes/yes yes/yes Auto detection of adequate reagent or specimen yes yes Clot detection/reflex testing capability no/no no/no Hemolysis/turbidity detection-quantitation no/no no/no Dilution of patient samples onboard/automatic rerun capability yes/no yes/no Sample vol. can be reduced/increased to rerun no/no no/no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert no No. of calibrators required for each analyte varies: 2 (single point curve tests), 6 (6 pt. curve tests), 3 (3 pt. curve tests) Calibrants can be stored onboard/avg. calibration frequency yes/every run Multipoint calib. supported/multiple calibs. stored for same assay yes/no How often QC required each run each batch Onboard real-time QC/support multiple QC lot nos. per analyte yes/yes yes/no Automatic shutdown/startup is programmable/startup time yes/yes/<5 min no/—/15 min. Stat time to completion of B-hCG test n/a n/a Time delay from ordering stat test to aspir. of sample < 15 min set-up time Throughput per hr for three analytes on 120/360 (~4 h) varies by assay, up to 90 specimens per microtiter plate each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC onboard/yes (incl. in price) Data management capability/instrument vendor supplies LIS interface onboard/yes (addt'l cost) Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results yes yes (broadcast download & host query) Bidirectional interface capability no Results transmitted to LIS as soon as test time complete yes yes Interface available (or will be) to auto specimen handling system no Modem servicing/can diagnose own malfunctions/determine yes/no/no no/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer w/in 24 h 24 h Mean time between failures/to repair failures —/— -/-Onboard error codes to facilitate troubleshooting yes daily: 3 min, weekly: 5 min, monthly: none Avg. time to complete maintenance by lab personnel _/_ Onboard maintenance records/maintenance training demo module List price/targeted bed size or daily volume \$55,000/all bed sizes, all test vols. \$65,000/60-270 specimens per d Annual service contract cost (24h/7d) incl. in reagent rental Training provided w/ purchase/advanced operator training 1-2 d at vendor's facility or on-site/as needed 5 d on-site/-**Distinguishing features** immunosimplicity reagent manufactured & 510(k) cleared specifically on Mago customized workflow analysis; complete service & support Plus; can test 120 samples in 9 simultaneous assays on 4 microplates; reag. colorcoded for ease in ID; containers ready-to-use; sample rack holds 120 samples & 120 dil. cups; user-friendly SW allows for rapid training; continual on-screen dis-

play; personalized reports by single test or profile

Part 14 of 20	DiaSorin Inc. Trish Kilbo trish.kilbo@diasorin.com 1951 Northwestern Ave. Stillwater, MN 55082 800-328-1482 www.diasorin.com	Grifols-Quest Inc. John Medders john.medders@grifols.com 8880 NW 18th Terr. Miami, FL 33172 800-379-0957 www.grifols-quest.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 (H x W x D)/instrument footprint	ETI-Max/2002/Germany Germany/U.S. & Italy —/— batch/benchtop/rack 47 x 53 x 31 in/20 sq ft	Triturus/1999/Spain Spain/n/a 35/280 batch/random access & cont. random access/benchtop/carousel
Tests available on instrument in U.S.	HBsAg, anti-HBs, HCV, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anti-HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-IgG, CMV-IgG, CMV-IgM, HSV I-IgG, HSV II-IgG, rub-IgG, rub-IgG, will-IgG, rub-IgG, will-IgG, rub-IgG, WZV IgC, MP IgG, H. pylori IgG, Lyme IgG & IgM, syphilis IgG, ENA scr., ANA scr., anti-dsDNA, anti-Sm, anti-RNP/Sm, anti-SSB, anti-SSA, anti-Sc1-70, anti-Jo-1, anti-histone, anti-cardiolipin IgG & IgM, total anti-cardiolipin, CAE	28.3 x 41.3 x 34.3 in/10 sq ft system is completely open, any EIA procedure can be programmed. Infectious diseases, autoimmune diseases, endocrinology, oncology markers, hepatitis and HIV profiles
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 none	n/a n/a n/a
Research-use-only assays Tests in development	none none	n/a n/a
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	n/a n/a	n/a n/a
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time	yes 8 min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time
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	EIA/coated microplate n/a open open n/a/— —/—/no yes yes, placed directly on system	EIA/coated microwell, onboard shaker, 4 individually temperature-controlled incubators 1-8 tests on 1-4 plates 8 assays unlimited 8/96 n/a/n/a/no yes requires operator prehandling/preparation
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./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 Min. 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 in decibels	yes/part Nos. no/n/a 300/160/open no/liquid no no 10 μL/100 μL —/no no	no no/<5 ppm 180/92/8 yes/liquid no no $2 \mu L/300 \mu L$ yes/no but has external waste port to drain into sink or floor drain no/n/a
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 NCCLS 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/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes — yes yes/yes yes/-/no no/no yes/no	yes/200 µL yes/12 x 75 mm, 13 x 85 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes yes/yes yes/yes yes/yos no/no yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/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	-/-/- no varies per kit no/ yes/no per run -/- yes/yes/5 min	no/no n/a no 1–14 no/n/a yes/yes each run no/no yes/no/1–2 min
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr 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	n/a — n/a yes/no no/yes —	system is open, depends on reagent methodology n/a depends on reagent methodology yes/yes onboard/yes (included) all major LISs
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results 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	yes yes (broadcast download) yes no no/—/—	yes yes (broadcast download) yes no no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module		no 24–48 h —/depends on corrective action yes daily: 5–20 min; weekly: n/a; monthly: n/a yes (includes audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$75,000/medium-sized hospital — 3 d on-site/no	\$79,000/300+ or higher \$16,000 4 d on-site/yes
Distinguishing features	instrument is easy to set up, continuous loading of patient samples	multibatch or continuous throughput EIA analyzer; user-defined menu, completely open system; easy color-coded worksheet and set up for operator; 2 probes for high-speed processing; unique cross-well washing; able to use fixed probes or disposable tips

	cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com	cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.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 (H x W x D)/instrument footprint	Hy•Tec 288/outside U.S. 1998, U.S. 1999/Netherlands Netherlands/U.S., Scotland 12/77 random batches/benchtop/rack-robotics 29.5 x 42.5 x 27.5 in/8 sq ft	Hy•Tec 480/1994/Switzerland Switzerland/U.S., Scotland 7/57 random batches/benchtop/rack-robotics 19.7 x 55 x 28 in/10.6 sq ft
Tests available on instrument in U.S.	specific IgE, total IgE, >950 allergens; ANA scr., TG, TPO, dsDNA, RF IgG, RF IgM, PR-3 c-ANCA, MPO p-ANCA & anti-mitochondrial, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, ScI-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, cardiolipin scr.; user-definable software	specific IgE, total IgE, >950 allergens; ANA scr., TG, TPO, dsDNA, RFIGG & IgM, PR-3 c-ANCA, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, ScI-70, Jo 1, GPC, GBM, MPO p-ANCA, mitochondrial, cardiolipin IgG & IgM, cardiolipin scr.; H. pylori; user-definable software
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 specific IgG, cardiolipin IgA, cardiolipin IgA, IgG, IgM, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM	none none IgG, basophil histamine release, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG & IgM
Research-use-only assays Tests in development	none anti- β -2 GPI, anti-tissue transglutaminase	none anti- β -2 GPI, anti-tissue transglutaminase
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	H. pylori allergy & autoimmune testing on fully automated system	H. pylori allergy & autoimmune testing on fully automated system, basophil histamine release
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes 8 96-min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells	yes 8 96-min. strip: 8 wells/1 strip; max. full plate: 12 strips/96 wells
Methods supported/separation methods	EIA, tube-based & microplate-based assays/cellulose disc & coated well	EIA, tube-based & microplate-based assays/cellulose disc & coated well
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	varies by assay, up to 288 allergens or 8 autoimmune multiple multiple varies by assay, up to 288 allergens or 8 autoimmune	varies by assay, up to 480 multiple multiple 1/200-allergy, 96-autoimmune
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	8 h/12 h/no yes yes	8 h/12 h/no yes yes
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored	no yes/<1 part in 10,000 assay dependent/100/288	no yes/<1 part in 10,000 assay dependent/100/480 yes/liquid no
Uses washable cuvettes/replacement frequency Min. 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 in decibels	no 10 μL-50 μL, assay dependent//100 μL yes/no no/—	no 10 μL-50 μL, assay dependent//300 μL yes/no no/—
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/n/a no	no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/n/a no
Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen	yes yes/yes yes	yes yes/yes yes
Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	no/no no/no yes/no no/no	no/no no/no yes/no no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte	n/a yes 1-5	n/a yes 1-5
Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	no/monthly yes/yes every assay	no/monthly yes/yes every assay
Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	yes/yes yes/no/2–3 min	yes/yes yes/no/5 min
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on	n/a n/a n/a	n/a n/a n/a
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/optional 25	yes/yes onboard/no 30
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability	no no yes	no no yes
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	optional no yes/yes/no	yes no no/yes/no
malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	no 48 h	no 48 h
Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	6 mos/48 h yes daily: 10–15 min, weekly: 20–25 min, monthly: 20–25 min	6 mos/48 h yes daily: 10–15 min, weekly: 20–25 min, monthly: 20–25 min
Onboard maintenance records/maintenance training demo module	yes (incl. audit trail of who replaced parts)/yes	no/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$55,000/all sites, variable test vols. \$5,500 3 d on-site/yes	\$75,000/all sites, variable test vols. 3 d on-site, 3 d at vendor offices/yes
Distinguishing features	fully automated allergy & autoimmune testing; >950 allergens; user-definable software	fully automated allergy & autoimmune testing; >950 allergens; open software

April 2002 CAP TODAY / 85

Part 16 of 20	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 33051 Calle Aviador San Juan Capistrano, CA 92675* 800-286-4643 nicholsdiag.com	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 33051 Calle Aviador San Juan Capistrano, CA 92675* 800-286-4643 nicholsdiag.com
Name of instrument/first year sold/where designed	CLSystem ID/1993/Sweden	Nichols Advantage Specialty System/1997/Germany
Country where manufactured/where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	60+/— batch/benchtop/rack	>120/>160 batch, cont. random access/benchtop/rack
Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	processor: 17 x 48 x 26 in; washer: 15 x 27 x 20 in; luminometer: 16.5 x 32 x	44 x 45 x 26 in/8 sq ft
billiensions (if x w x b)/instrument tootprint	25 in/15 sq ft	44 X 43 X 20 III/0 34 It
Tests available on instrument in U.S.	hGH, prolactin, ferr., TSH, intact PTH, cortisol, anti-TPO, anti-TG, ACTH, calcitonin, thyroglob.	ACTH, cortisol, urinary cortisol, EPO, ferritin, sTfR, CT, intact PTH, hGH, IGF-1, FT ₃ , FT ₄ , 3rd-gen. TSH, TG, anti-TG, anti-TPO, DHEAS, Bio-Intact PTH (I-84), 25 hydroxy vit D, direct renin
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	none none	none T ₃ , T ₄ , AFP, CEA, CA 15-3, NSE, TPA, CA 19-9, CA 125, prolac., total hCG
rests not available in 0.3. but available in other countries	none	13, 14, NTT, OLN, ON 13-3, NOL, 11 N, ON 17-7, ON 123, PIOIGE, ICIGITIO
Research-use-only assays	none	osteocalcin, H. pylori IgG
Tests in development	none	1,25 dihydroxy vit D, IGFBP-3, Sangtec 100, aldosterone, H. pylori
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	_	IGF-I, calcitonin, pepsinogen, Bio-Intact PTH (I-84), 25 hydroxy vit. D, direct renin
·		
Fully automated microplate system	no 	no n/a
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	chemiluminescence/bead	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	1	15
No. of different assays programmed, calibrated at once	1	15
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent	1/100	15/varies, typically 100
containers onboard at once/tests per container set	8 h/1 d/no	8 h/_/vos (17°C)
Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported		8 h/—/yes (17°C) no
Reagent container placed directly on system for use	yes no, requires oper. prehandling/prep.	no, requires oper. prehandling/prep.
Reagents bar-coded/information in bar code	no	yes/assay ID, lot No., serial No., expir.
Same capabilities when 3rd-party reagents used/susceptibility to carryover		no/≤5x10-5
Walkaway capacity in min./specimens/tests-assays	—/256/1	up to 480/120/15 x 100=1,500
System is open (home-brew methods can be used)/liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/max. no. stored	no	yes/120
Uses washable cuvettes/replacement frequency	no	no
Min. sample vol. aspirated precisely at once/min. dead vol.	25 μL/150 μL	10 μL/200 μL
Supplied with UPS (backup power)/requires floor drain	no/no	yes/no
Requires dedicated water system/water consumption Noise generated in decibels	no/—	no/— 67
Has dedicated pediatric sample cup/dead vol.	no	yes/100 μL
Primary tube sampling/tube sizes/pierces caps on primary tubes	ves/10 x 75/no	yes/10 x 75, 16 x 100 mm/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A	no	no
Onboard test auto inventory (determines vol. in container)	no _	yes
Measures no. of tests remaining/short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	yes /ra	yes
Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation	yes/no no/no	yes/yes no/no
Dilution of patient samples onboard/automatic rerun capability	yes/no	yes/yes
Sample vol. can be reduced/increased to rerun	no/no	no/no
out-of-linear range high/low results		
Time between initial result & reaspiration of sample for rerun	_	37 min
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/avg. calibration frequency	yes/once per run	no/7 d
Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	yes/no shortest interval: 4 h, longest: 8 h	yes/no shortest interval: 4 h, longest: 8 h
Onboard real-time QC/support multiple QC lot nos. per analyte	no/no	no/no
Automatic shutdown/startup is programmable/startup time	no/no/10 min	no/no/10 min
· · · · · ·	,	,
Stat time to completion of B-hCG test Time delay from ordering stat test to espir, of cample	n/a	n/a
Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on	 _/_ (_)	n/a up to 55/up to 165 (—)
each specimen, in no. of specimens/no. of tests (cycle time)	. ()	ap to our up to 100 ()
Can auto transfer QC results to LIS/onboard capability to review QC	yes/yes	yes/yes
Data management capability/instrument vendor supplies LIS interface	no/yes	onboard/yes (incl. in price)
Interfaces up and running in active user sites with	-	all commercially available LISs
IIS interface apprates simultaneously w/ rupping assesse		201
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	no	yes yes
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/can diagnose own malfunctions/determine	no/yes/yes	no/yes/yes
malfunctioning component		
Can order (via modem) malfunctioning part(s) w/o operator	NO 24 h	no 24 b
On-site response time of service engineer Mean time between failures/to repair failures	24 h 10 mos/48 h	24 h 90 d/24 h
Onboard error codes to facilitate troubleshooting	yes	90 0/24 n Yes
Avg. time to complete maintenance by lab personnel	daily: 10 min, weekly: 30 min, monthly: 60 min	daily: 10 min, weekly: 30–45 min, monthly: 5 min
Onboard maintenance records/maintenance training demo module	no/no	no/no
List price/targeted bed size or daily volume	component related/—	\$125,000/300+ beds
Annual service contract cost (24h/7d)	-	inquire
Training provided w/ purchase/advanced operator training	-	4 d at vendor offices/yes
Distinguishing features	a chamiluminaceance are batch analysis declared to the Co.	the fully outerwated continuous and law and the state of
Distinguishing features	a chemiluminescence seq. batch analyzer designed to provide results for spe- cialized and routine immunoassays; continuous sample loader, bidirectional	the fully automated continuous random access chemiluminescence system that will run specialty assays as if they were routine; has coding of primary sample.
	communication, pos. sample ID; 1,200 patient samples per 8-h shift	will run specialty assays as if they were routine; bar coding of primary sample tubes, reagents, stored master curve & 2 pt. calib.; assures ease of use & mini-
	communication, pos. sample io, 1,200 patient samples per 8-11 SMIT	
		mizes usuas-on time; onnosia retrineration
		mizes hands-on time; onboard refrigeration
	* Nichols Institute Diagnostics will have a new address May 15, 2002. It will be	* Nichols Institute Diagnostics will have a new address May 15, 2002. It will be
	* Nichols Institute Diagnostics will have a new address May 15, 2002. It will be 1311 Calle Batido, San Clemente, CA 92673	•

Automated immunoassay analyzers

Ortho-Clinical Diagnostics, a Johnson & Johnson Company Olympus America Inc. Susan Watanabe susan.watanabe@olympus.com Tim Vesling tvesling@ocdus.jnj.com Part 17 of 20 1001 U.S. Highway 202 Two Corporate Center Dr. Melville, NY 11747 Raritan, NJ 08869 800-223-0125 800-828-6316 or 908-218-1300 www.olympus.com www.orthoclinical.com Name of instrument/first year sold/where designed AU400/1999/Japan Vitros ECi Immunodiagnostic System/1997/U.S. Country where manufactured/where reagents manufactured Japan/U.S., Ireland U.S./U.K. No. of units in clinical use in U.S./outside U.S. >300/>1,100 >1,000 worldwide Operational type/model type/sample handling system cont. random access/floor-standing/rack & turntable cont. random access/floor-standing/universal sample racks (circular) accommodate primary & secondary containers without need for adapters Dimensions (H x W x D)/instrument footprint 51 x 44 x 29 in/8.9 sq ft 47.6 x 57.1 x 29.9 in/70 x 129 in α1-acid glycoprotein, α1-antitrypsin, anti-streptolysin 0, apolipo. A1 & B, β-2-3rd-gen. TSH, TT₃, TT₄, FT₃, FT₄, T₃-uptake, total ß-hCG, estradiol, progesterone, Tests available on instrument in U.S. microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 & C4 complement, LH, FSH, prolactin, N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, equimolar troponin I, aHBs, B₁₂, folate, RBC folate, ferr., haptoglobin, immunogl. A, G, M, microalbumin, myogl., prealb., rheum. factor, transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, ethoequimolar PSA, HBsAq, aHCV sux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T-uptake, T₄ thyrox. Also, general chemistries, enzymes, direct HDL & direct LDL 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 cotinine CA 19-9, f β -hCG, a-HBc IgM, a-HBc, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II Research-use-only assays none myoglobin, HAV total, HIV 1/11o, BNP Tests in development none User-defined methods implemented for what analytes HbA1c, fructosamine none Tests not available on other manufacturers' analyzers hepatitis, HIV none Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a n/a No. of wells in microplate n/a n/a EIA, photometric, potentiometric, calc. results/none (all homogeneous) Methods supported/separation methods chemiluminescence (enhanced)/coated microwell No. of different measured assays onboard simultaneously >40 No. of different assays programmed, calibrated at once 29 programmed & calibrated at once; up to 25 lots calibrated per assay No. of user-definable (open) channels No. of different analytes for which system accommodates reagent 76/100-6,160 20/100 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard 168 h/60 d/yes (4-12°C) 56 d/56 d/yes (2°-8°C) Multiple reagent configurations supported yes yes Reagent container placed directly on system for use yes yes/test ID, expir., lot No., pack ID Reagents bar-coded/information in bar code yes/reag. ID, lot No., bottle No., expir. Same capabilities when 3rd-party reagents used/susceptibility to carryover yes/n/a —/zero carryover variable/up to 102/8,058 Walkaway capacity in min./specimens/tests-assays 360/60/400 System is open (home-brew methods can be used)/liquid or dry system yes/liquid no/liquid Uses disposable cuvettes/max. no. stored yes/2,000 yes/permanent Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. 2.0 µL/25 µL 10 μL/60 μL optional/yes Supplied with UPS (backup power)/requires floor drain no/— Requires dedicated water system/water consumption yes/26 L per h @ peak consump. Noise generated in decibels not determined Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes yes/pediatric, 5 mL, 7 mL, 10 mL/no yes/multiple ped. cup capabilities/no Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes (2 of 5 interl., codabar, codes 39 & 128)/yes Bar code placement per NCCLS 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 Clot detection/reflex testing capability yes/yes yes/yes Hemolysis/turbidity detection-quantitation yes/yes no/no Dilution of patient samples onboard/automatic rerun capability yes/yes yes/yes Sample vol. can be reduced/increased to rerun yes/yes no out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun varies by run size assay dependent Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency no/28 d yes/14 d Multipoint calib. supported/multiple calibs. stored for same assay yes/no yes/yes How often QC required lab-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/24 h availability yes/yes/5 min from power off Stat time to completion of B-hCG test 24 min. n/a Time delay from ordering stat test to aspir. of sample <1 min Throughput per hr for three analytes on 133.3/400 (9 sec) 30/90 (40 sec) each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC yes/yes Data management capability/instrument vendor supplies LIS interface onboard/yes (addt'l cost) onboard/no Cerner, Sunquest, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Interfaces up and running in active user sites with Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, Unisys, HBOC, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Orchard, Citation PHCP, INS, SMS, Dawning LIS interface operates simultaneously w/ running assays yes yes Uses LOINC to transmit orders and results no yes yes (broadcast download & host query) yes (broadcast download) Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system yes (Olympus OLA 1500 Sorter, Labotix, Lab InterLink) yes (all systems) Modem servicing/can diagnose own malfunctions/determine yes/yes/yes yes/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer <4 h (contract dependent) <24 h Mean time between failures/to repair failures —/dependent on corrective action >20 weeks/<24 h Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel daily: 3 min, weekly: 7 min, monthly: 45 min daily: <5 min, weekly: <30 min, monthly: <10 min Onboard maintenance records/maintenance training demo module yes (incl. audit trail of who replaced parts)/yes \$130,000/200-2,000 tests per d (depending on menu) List price/targeted bed size or daily volume \$140,000/daily volume to approx. 250-500 tests Annual service contract cost (24h/7d) varies w/ service level choices Training provided w/ purchase/advanced operator training 5 d on-site, 5 d at vendor offices/yes 3.5 d at vendor offices/yes, as needed on-site Distinguishing features open reagent system; 120+ test menu incl. general chemistry & homogeneous immunoassay analyzer provides fast & easy fully automated, random access immunoassay; onboard automation to repeat, reflex, or predilute samples; true hepatitis testing along w/ thyroid, cardiac, anemia, endocrin, bone, & oncology random access & fast throughput; family of standardized analyzers including assays; Intellichek on the Vitros ECi System performs, monitors, and verifies all AU600, AU640, AU2700, & AU5400 sample and assay processing steps to reduce the possibility of an erroneous

result being reported out

Part 18 of 20	Roche Diagnostics Doug Felten doug.felten@roche.com; Michael Leuther michael.leuther@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Doug Felten doug.felten@roche.com; Michael Leuther michael.leuther@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Elecsys 2010/1996/— Japan/Germany >500/>3,500 cont. random access/benchtop/rack or disk 22.1 x 47.2 x 28.7 in/9.4 sq ft	Elecsys 1010/1997/— Switzerland/Germany >275/>2,500 random access/benchtop/sample disk 25.6 x 37 x 25.2 in/6.5 sq ft
Tests available on instrument in U.S.	TSH, FT ₄ , T ₄ , T ₃ , FT ₃ , T-uptake, LH, FSH, progest., estradiol, prolac., testost., CK-MB, trop. T, myglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferr., B ₁₂ , fol., RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β -hCG, CA 15-3, anti-TPO, serum β Crosslaps, free PSA, HBsAg, HBsAg (conf), anti-HBs	TSH, T ₃ , T ₄ , T-uptake, FT ₃ , FT ₄ , FSH, LH, prolac., progest., estradiol, testost., CK. MB, trop. T, myogl., digoxin, CEA, AFP, PSA (screen), CA 125, ferr., IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β-hCG, CA 15-3, anti-TPO
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 — osteocalcin, CA 19-9, anti-HBc, cyfra 21-1, anti-HBs, anti HBc IgM, anti-HBe, HBeAg, CA 72-4, NSE, anti-TG, SHBG, infec. diseases, TG, CA 19-9, pro BNP	— — osteocalcin, CA 19-9, HBsAg, anti-HBs, anti-HBc, Cyfra 21-1
Research-use-only assays Tests in development	osteocalcin, CA 19-9, anti-HBc, anti-HBc IgM, anti HBe, HBcAg, SHBG, TG, anti-TG, NSE, cyfra 21-1, cortisol urine	CA 72-4, NSE, anti-TG, TG, sHBG
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none trop. T	none trop. T, serum β Crosslaps, fPSA
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a	no n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	electrochemiluminescence/magnetic particle 15 60	ECLIA electrochemiluminescence IA/ magnetic particle 6 —
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	0 15/100–200	0 6/100–200
Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	56 d/56 d/yes (20°C) yes	28 d/28 d/no yes
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	120/disk: 30, rack: 100/180	yes yes/calib. curve, application params., lot No., expir., reag. name no/<8 ppm 150/42 1° tube + 24 sample cups/128 no/liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	yes/— no 10 μL/100 μL —/no	yes/128 no 10 μL/100 μL no/no
Requires dedicated water system/water consumption Noise generated in decibels Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	no/— — no yes/13–16 mm diam./no	no/— — yes/— ves/13-16 mm diam./no
Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes — yes
Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	yes/yes yes	yes/yes yes
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	yes/no no/no yes/no no/no	yes/no no/no yes/no no/no
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte	yes 2	— yes 2
Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay	no/monthly yes/yes	no/7 d yes/yes
How often QC required Onboard real-time QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	once per 24 h yes/yes no/no/4 min	once per 24 h yes/yes no/no/5 min
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on	9 min 42 sec 30/88 (42 sec)	9 min 65 sec 20/55 (65 sec)
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 (addt'l cost) all major LISs	yes/yes onboard/yes (addt'l cost) all major LISs
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	yes no	yes no
Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	yes (broadcast download & host query) yes yes (CLAS & Roche task targeted automation)	yes (broadcast download & host query) yes no
Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	no/yes/no no	no/yes/no no
On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting	<24 h —/— yes	<24 h —/— yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	daily: 1 min, weekly: 5 min, biweekly: 25 min, monthly: none no/no (training CD-ROM)	daily: 1 min, biweekly: 5 min, monthly: 5 min no/—
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	disk: \$120,000, rack: \$135,000/various incl. w/ reagent rental 3 d Indianapolis based/yes	\$59,000/various incl. w/ reagent rental 3 d Indianapolis based/yes
Distinguishing features	connectable to Clinical Lab Automation System; liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, & fast turnaround time, stat interrupt; onboard reag. storage; minimal maintenance	liquid ready-to-use reagents; autocalib., autodil.; ECL detection system provide broad measuring range & short TAT; stat interrupt; onboard reagent storage; minimal maintenance; small footprint

Automated immunoassay analyzers

Roche Diagnostics Sigma Diagnostics Doug Felten doug.felten@roche.com; Michael Leuther michael.leuther@roche.com Linda Schwartz | Ischwartz@sial.com Part 19 of 20 9115 Hague Rd. 545 S. Ewing Ave. Indianapolis, IN 46250 St. Louis, MO 63103 800-428-5074 314-771-5765 or 800-325-3424 www.roche.com/labsystems/us www.sigma-aldrich.com Name of instrument/first year sold/where designed Modular Analytics E170/2001/Japan Aptus Automated EIA System/1998/— —/U.S. Country where manufactured/where reagents manufactured Japan/Germany No. of units in clinical use in U.S./outside U.S. 32/166 (combination of E and EE systems) Operational type/model type/sample handling system continuous random access/floor-standing/rack Batch, random access/benchtop/rack Dimensions (H x W x D)/instrument footprint 96.25 (W) x 43.25 (D) in (Modular E configuration)/approx. 60 sq ft (one module sys-27.5 x 26 x 47.25 in/8.5 sq ft Tests available on instrument in U.S. TNT, CK-MB, digoxin, myoglobin, T₄, T-uptake, TSH 3rd gen, FT₄, T₃, FT₃, ATPO, toxo IgG & IgM, rubella IgG & IgM, CMV IgG & IgM, toxo rubella & CMV IgM capture, toxo rubella & CMV IgG quant., HSV-I IgG, HSV-II IgG, HSV I/II IgM, EBV EA HCG, β-hCG, FSH, LH, progesterone, prolactin, estradiol, DHEA-S, testosterone, CEA, AFP, PSA (screen), fPSA, CA 125, CA 15-3, ferritin, B₁₂, folate, RBC folate, IgG, EBV VCA IgG & IgM, EBV EBNA IgG, VZV IgG, mumps IgG, measles IgG, B. intact PTH, & Crosslaps, HBsAg, HBsAg (conf.), cortisol, insulin, IGE burgdorferi IgG/M, H. pylori IgG, Legionella IgG/M/A, mycoplasma IgG & IgM, ANA, ENA, & ANCA screens, SS-A/Ro, SS-B/La, Sm, Sm/RNP, ScI-70, Jo-1, dsDNA, RF IgM, gliadin IgA & IgG, anticardiolipin IgG, IgM, & IgA, MPO, PR-3, TPO, TG, syphilis Trep-Chek Tests cleared but not clinically released none Tests not available in U.S. but submitted for clearance anti-HBs Tests not available in U.S. but available in other countries osteocalcin, pro BNP, CA 19-9, CA 72-4, cyfra 21-1, NSE, anti-HBc, anti-HBc IgM, quant EBV EA, VCA, IgG & IgM, EBNA, syphilis screen IgG/IgM anti-HBe, HBeAg, TG, anti-TG, digitoxin Research-use-only assays osteocalcin, CA 19-9, pro BNP, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, SHBG, Tests in development syphilis, salivary ELISAs, HBA_{1c} NSE, cyfra 21-1, cortisol urine, TG, anti-TG User-defined methods implemented for what analytes implemented by end user-HBsAg, HIV, syphilis, coccidiodes, PSA none Tests not available on other manufacturers' analyzers Fully automated microplate system no yes No. of each analyte performed in separate disposable unit No. of wells in microplate min. strip: break-away wells; max. full plate: 96 x 4 plates Methods supported/separation methods FIA/microtiter electrochemiluminescence/magnetic particle, electrochemiluminescence No. of different measured assays onboard simultaneously 25 per E module, maximum of 60 No. of different assays programmed, calibrated at once 25 per module >100 No. of user-definable (open) channels 20 No. of different analytes for which system accommodates reagent 25 per moduule/100-200 9/96 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard 12 h/7 d/no 56 d/56 d/yes (20°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/calib. curve, application params., lot No., expir., reag. name yes/lot No. & expiration date Same capabilities when 3rd-party reagents used/susceptibility to carryover yes/zero carryover n/a/zero, uses disposable sample tips Walkaway capacity in min./specimens/tests-assays 360/—/1,006 —/120/9 System is open (home-brew methods can be used)/liquid or dry system no/liquid yes/liquid Uses disposable cuvettes/max. no. stored yes/ no Uses washable cuvettes/replacement frequency no Min. sample vol. aspirated precisely at once/min. dead vol. $--/100 \mu L$ 10 μL/50 μL Supplied with UPS (backup power)/requires floor drain no/no yes/no Requires dedicated water system/water consumption yes/18 per module in full operation no/n/a Noise generated in decibels Has dedicated pediatric sample cup/dead vol. yes/50 µL Primary tube sampling/tube sizes/pierces caps on primary tubes yes/13 x 75 to 16 x 100/no no/direct tubes accepted (12 x 75, 13 x 85 mm)/no Sample bar-code reading capability/autodiscrimination yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes (2 of 5 interl., codabar, codes 39 & 128)/yes Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) yes yes Measures no. of tests remaining/short sample detection no/yes yes/yes Auto detection of adequate reagent or specimen yes yes Clot detection/reflex testing capability no/no yes/-Hemolysis/turbidity detection-quantitation no/no no/no Dilution of patient samples onboard/automatic rerun capability yes/yes yes/no Sample vol. can be reduced/increased to rerun yes/yes n/a out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun n/a Autocalibration or autocalibration alert yes No. of calibrators required for each analyte varies Calibrants can be stored onboard/avg. calibration frequency no/monthly no/each run Multipoint calib. supported/multiple calibs. stored for same assay yes/yes yes/no How often QC required each run Onboard real-time QC/support multiple QC lot nos. per analyte yes/no yes/yes Automatic shutdown/startup is programmable/startup time yes/yes/11 min yes/<3 min Stat time to completion of B-hCG test 18 min Time delay from ordering stat test to aspir. of sample n/a Throughput per hr for three analytes on 56/176 (21 sec) depends on combination of assays each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC yes/yes Data management capability/instrument vendor supplies LIS interface onboard/yes (addt'l cost) onboard/optional (addt'l cost) ClinLab, CompTron, Cerner, Sunquest, Meditech, Progimed Interfaces up and running in active user sites with all major LISs LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results **Bidirectional interface capability** yes (broadcast download & host query) yes (broadcast download & host guery) Results transmitted to LIS as soon as test time complete yes, after QC reviewed yes (Roche Modular Pre-Analytical Systems and task targeted automation) Interface available (or will be) to auto specimen handling system no Modem servicing/can diagnose own malfunctions/determine yes/yes/no no/yes/yes malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer ≤24 h w/in 24 h Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel daily: 5 min, weekly: 10 min, monthly: 15 min daily: 2 min, weekly: 5 min, monthly: none no/not needed Onboard maintenance records/maintenance training demo module List price/targeted bed size or daily volume \$295,000 Modular E; \$470,000 Modular EE; \$645,000 Modular EEE/various contact vendor/all bed sizes & test vols. Annual service contract cost (24h/7d) incl. w/ reagent rental contact vendor Training provided w/ purchase/advanced operator training 5 d at vendor offices/yes 5 d on-site/yes Distinguishing features expandable liquid ready-to-use reagents that are compatible with other Elecsys chauffeur-driven software-easy to use; all Sigma assays FDA cleared for syssystems, compatible with Pre-Analytic Automation; ECL technology provides tem-specific reagent packaging, CLIA moderate complexity, automation broad measuring range and market, best low-end sensitivity, troponin T, auto-

Automated immunoassay analyzers

Tosoh Medics Inc. Tosoh Medics Inc. Jane Merschen jane@tosohm.com Jane Merschen jane@tosohm.com Part 20 of 20 347 Oyster Point Blvd., #201 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 South San Francisco, CA 94080 650-615-4970 650-615-4970 www.tosohm.com www.tosohm.com Name of instrument/first year sold/where designed AIA Nex • IA/1997/Japan AIA-600 II/2000/Japan Country where manufactured/where reagents manufactured Japan/Japan Japan/Japan No. of units in clinical use in U.S./outside U.S. 60/300 Operational type/model type/sample handling system cont. random access/floor-standing/rack, carousel, TLA cont. random access/benchtop/chain Dimensions (H x W x D)/instrument footprint 47 x 35 x 26 in/6.3 sq ft 19.8 x 31.6 x 29.1 in/2.5 sq ft TSH, 3rd-gen. TSH, FT $_4$, T $_3$, T $_4$, T-uptake, FT $_3$, TPO Ab, Tg Ab, β hCG, estradiol, FSH, hCG (intact), LH II, progesterone, prolactin, ST- β HCG, ST-estradiol, ST-FSH, Tests available on instrument in U.S. same menu as for AIA Nex+IA (see column at left) ST-HCG (intact), ST-LHII, ST-progesterone, ST-prolactin AFP, CEA, PSA, CA 125, 27.29, ST-27.29, β-2 microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B₁₂ Tests cleared but not clinically released none none CA 19-9 Tests not available in U.S. but submitted for clearance CA 19-9 HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa Tests not available in U.S. but available in other countries HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa Research-use-only assays CA 19-9 CA 19-9 Tests in development testosterone testosterone User-defined methods implemented for what analytes none Tests not available on other manufacturers' analyzers none none Fully automated microplate system no No. of each analyte performed in separate disposable unit n/a n/a No. of wells in microplate n/a n/a Methods supported/separation methods fluorescence, EIA/bead fluorescence, EIA/bead No. of different measured assays onboard simultaneously ≥34 ≥34 No. of different assays programmed, calibrated at once entire menu entire menu No. of user-definable (open) channels No. of different analytes for which system accommodates reagent n/a/unitized test cup n/a/unitized test cup containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard 72 h/72 h/n/a 72 h/72 h/n/a 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., test code yes/lot No., test code Same capabilities when 3rd-party reagents used/susceptibility to carryover no/zero carryover no/zero carryover Walkaway capacity in min./specimens/tests-assays 52/75-200/400 for the standard model 52/26/26 System is open (home-brew methods can be used)/liquid or dry system no/dry Uses disposable cuvettes/max. no. stored n/a/unitized test cup n/a/unitized test cup Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. 10 μL/50 μL 10 μL/100 μL Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption yes/no yes/no no/n/a no/n/a Noise generated in decibels Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A yes yes Onboard test auto inventory (determines vol. in container) yes yes Measures no. of tests remaining/short sample detection yes/yes yes/yes Auto detection of adequate reagent or specimen yes yes Clot detection/reflex testing capability yes/no yes/no Hemolysis/turbidity detection-quantitation no/no no/no Dilution of patient samples onboard/automatic rerun capability yes/no yes/no Sample vol. can be reduced/increased to rerun no/yes no/yes out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun n/a n/a Autocalibration or autocalibration alert No. of calibrators required for each analyte 2 or 6—analyte dependent 2 or 6—analyte dependent Calibrants can be stored onboard/avg. calibration frequency no/60-90 d no/60-90 d Multipoint calib. supported/multiple calibs. stored for same assay yes/yes yes/yes How often QC required 24 h 24 h Onboard real-time QC/support multiple QC lot nos. per analyte yes/yes no/no Automatic shutdown/startup is programmable/startup time no/no/5-8 min no/no/5 min Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample 90 sec 60 sec Throughput per hr for three analytes on 40/120 (30 sec) 20/60 (1 min) each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC optional add-on (software mftr: Schuyler House, Sunquest, LabForce, HBOC, Data management capability/instrument vendor supplies LIS interface optional add-on (software mftr: Schuyler House, Sunguest, LabForce, HBOC, Antrim, Data Innovations)/yes (addt'l cost) Antrim, Data Innovations)/yes (addt'l cost) Interfaces up and running in active user sites with Schuyler House, Fletcher Flora Schuyler House, Fletcher Flora LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability yes (broadcast download & host query) yes (broadcast download & host query) Results transmitted to LIS as soon as test time complete yes Interface available (or will be) to auto specimen handling system yes (Hitachi, Panasonic, Sysmex) Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator no On-site response time of service engineer 24 h 24 h Mean time between failures/to repair failures unknown/-Onboard error codes to facilitate troubleshooting Yes Avg. time to complete maintenance by lab personnel daily: 5-8 min, weekly: none, monthly: none daily: 5 min, weekly: 5 min, monthly: none Onboard maintenance records/maintenance training demo module yes (incl. audit trail of who replaced parts)/no List price/targeted bed size or daily volume \$135,000/65+ beds, 1,500-2,000+ tests \$70,000/500-2,500 tests per month Annual service contract cost (24h/7d) \$10,800 \$5,600 Training provided w/ purchase/advanced operator training 3 d at vendor offices/no 4 d at vendor offices/no Distinguishing features 3 sample loading options on single system: 200 sample rack loader, TLA adaptunitized test cups; primary tube sampling; no reagent prep.; dual clot detection; able, standard carousel model; unitized test cups; primary tube sampling; no room temp. stability for 5 d; automated sample dilution & pretreatment; 3rd-generation TSH sensitivity; appropriate for stat & routine use reagent prep.; dual clot detection; room temp. stability for 5 d; automated sample dilution & pretreatment; 3rd-generation TSH sensitivity; appropriate for stat &