

A solution for any service challenge

Michael McNeely, MD
Raymond D. Aller, MD

Survey of
Instruments

The 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

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Automated immunoassay analyzers

Solution

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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 anti-animal 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. □

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. Z22, 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. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	hTSH II, TT ₃ , TT ₄ , FT ₃ , FT ₄ , T-uptake, βhCG, 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, opi- ates, PCP, acetamin., ethanol, salicylates, tricyc. (*currently not avail- able in U.S.) FDA cleared: 3rd-gen. TSH n/a n/a none 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 No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter 20 20 0 20/100 onboard reagent stability: 48, 112, 224, 336/no no yes yes/assay name, reag. lot no., expir., pack no. ID no/<1 ppm 60/90/90 no/liquid yes/90 reaction vessels no 10 μL/73 μL for sample cup, 450 μL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional no/— 52-68 decibels no yes/100 & 75 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes w/ AxSym Plus yes/no yes/yes no/no seconds no 6 pt. or 2 pt. w/ master calib., index calib. no/4 weeks yes/yes (up to 4 curves/analyte) shortest interval: 8 h, longest: 24 h yes/yes no/no/1 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 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 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	13 min. 30 sec from standby 68-120 tests/flexible platform—load list dependent (assay dependent) yes/yes onboard/no all major LIS vendors yes yes yes (broadcast download & host query) yes yes no/yes/yes no 12 h 5 mos/w/in 12 h per customer request 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

SURVEY
OF INSTRUMENTS

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Automated immunoassay analyzers

Part 2 of 20	Abbott Diagnostics Suzanne Macaitis suzanne.macaitis@abbott.com 100 Abbott Park Rd., Dept. ZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-936-3323 www.abbott.com	Awareness Technology Inc. Mary Freeman info@awaretech.com 1935 SW Martin Hwy. Palm City, FL 34990 772-283-6540 www.awaretech.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	Architect iSystem/1999/U.S. U.S./U.S. 100+/700+ batch, random access, cont. random access/floor-standing/rack 48 x 44 x 68 in/23 sq ft per module	ChemWell/1998/U.S. U.S./open system 3/170 batch, random access/benchtop/rack 16 x 34 x 20 in/4 sq ft
Tests available on instrument in U.S.	βhCG, FSH, LH, prolac., progest., CEA, 3rd-gen. TSH, Total T ₄ , FT ₄ , FT ₃ , TT ₃ , testost.*, estradiol, B ₁₂ , * ferr.* (*currently not available in U.S.)	unlimited—open system
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	n/a n/a	— unlimited—open system
Research-use-only assays Tests in development	none hepatitis, retrovirus, thyroid, metabolic, cancer, TDM, cardiac	unlimited—open system —
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	general biochemistries n/a
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a	yes up to 12 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 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	Chemiluminescence w/ flexible protocols/magnetic microparticle 25 per module*, max. 4 modules=100 assays max. (* for kits with ≤3 reagent bottles) 100+ 0 25 per module*/100-test & 500-test kits (* for kits with ≤3 reagent bottles) 30 d/30 d/yes (2–12°C) yes yes yes/2D bar code, lot. no., no. tests, calib. data no/0.3 ppm 300/250/1,000 no/liquid yes/1,200 no 150 µL/50 µL yes/no no/— 60–65 decibels no yes/10–16 mm, up to 75–100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/no no/no yes/no yes/yes seconds yes 2–6 pt. curve no/30 d yes/yes 3 levels every 24 h yes/yes n/a/no/10 min	EIA/coated microwell up to 12 unlimited unlimited 27/assay dependent assay dependent/assay dependent/yes (10°C below ambient) yes yes yes no no/none assay dependent/96/12 yes/liquid yes/96 yes/assay dependent 2µL/— no/no no — no yes/12 x 75 mm/no no/— — yes no/no yes no/yes no/no yes/no yes/yes assay dependent no assay dependent yes/assay dependent yes/yes shortest interval: each run; longest: daily yes/yes yes/yes/2 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 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 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	n/a every 18 sec from positive sample ID 67/200 per module (aspir. to result: 29 min) yes/yes onboard/no all major LIS vendors yes — yes (broadcast download & host query) yes yes yes/yes/yes no 12 h not available/not available yes daily: <15 min; weekly: <10 min; monthly: none yes (incl. audit trail of who replaced parts)/yes	assay dependent 30 sec assay dependent yes/yes onboard/yes (included) — no yes yes (broadcast download & host query) yes no yes/yes/yes no within 48 h —/— yes daily: <10 min; weekly: <10 min; monthly: <10 min no/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$169,500/500 immunoassays per day \$27,450 (list price) 5 d at vendor offices/yes (5 d on-site integration)	\$25,000/up to 500 tests per day \$4,000 3 d on-site/no
Distinguishing features	Chemiflex: advanced, patented chemiluminescence detection technology w/ 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 walk-away	ability to perform general biochemistries

Automated immunoassay analyzers

Part 3 of 20	Bayer Diagnostics John Talley john.talley.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040 www.bayerdiag.com	Bayer Diagnostics John Talley john.talley.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040 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, gentam-icin, 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, β2-microgl., deoxypyrid., AFP, CA 15-3, CA 125 II, CEA, complexed PSA, PSA, hCG, hCG/extended range-100,000 mIU/mL, LH, FSH, pro-lac., progest., estradiol, testost., unconj. estriol, HER-2/ <i>neu</i>
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/ <i>neu</i> , 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 Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	chemiluminescence/magnetic particle 13 13 0 13/50 40 h/1.7 d/no yes yes yes/assay name, lot no., expir., pack ID n/a/— 150/60/450 no/liquid yes/450 no 10 µL/50 µL no/no no/~1.8 L per h — no yes/multiple/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/no no/no yes/yes no/no 20 sec no 2 no/varies by assay, generally 28 d yes/yes 24 h yes/yes no/no/<5 min, generally remains on	EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle 22 22 0 22/50–200, assay dependent 21 h/30 d/yes (4°–11°C) yes yes (T ₃ & cortisol require oper. prehandling/prep.) yes/test name, expir., No. of tests, lot No., pack ID n/a/≤5 ppm 437/78/875 no/liquid no yes/24 h 2 µL/75 µL w/ 1 mL sample cup yes/no no/n/a — yes/30 µL yes/multiple/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes (auto countdown)/yes yes yes/no no/no no/no no/no 30 sec no 6 no/varies by assay, generally 60 d yes/yes shortest interval: each shift, longest: 24 h yes/yes no/no/3 min, generally remains on
Stat time to completion of β-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	15 min <60 sec 60/180 (20 sec) yes/yes onboard/no Cerner, Soft, Meditech, Antrim, Sunquest, HBOC, Citation, Triple G, Dynamic Healthcare (all major vendors)	38 min 30 sec 40/120 (30 sec) yes/yes 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 Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	yes yes yes (broadcast download & host query) yes yes no/no/no no 4 h 4 mos/3 h yes daily: 15 min, weekly: 15 min, monthly: 15 min yes (incl. audit trail of who replaced parts)/yes	yes yes yes (broadcast download & host query) yes yes (Advia LabCell, Lab Interlink) no/—/— — 4 h 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

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

**SURVEY
OF INSTRUMENTS**

Part 4 of 20

**SURVEY
OF INSTRUMENTS**

Part 4 of 20

Automated immunoassay analyzers



Access® AccuTnl™ Troponin I Assay

Raising The Standard Of Performance.



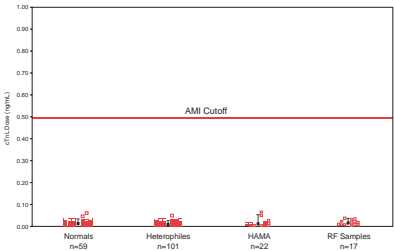
Time to results of 12 minutes allows laboratories to deliver results in less than 30 minutes from sample draw.

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



Part 5 of 20	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	Access 2 Immunoassay System/2001/U.S. U.S./U.S. & France 250/125 cont. random access/benchtop/rack 18.5 x 39 x 24 in/6.5 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	same as Access (see page 64) same as Access same as Access
Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	same as Access none
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none same as Access
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 No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	chemiluminescence/magnetic particle 24 24 0 24/100 tests per kit, 50 tests per cartridge 336 h/28 d/yes (4°C) yes yes yes/assay No., lot No., expir., unique reagent pack ID No. no/≤ 3 ppm 180/60/300 no/liquid yes/294 no 5 µL/100 µL yes (when networked)/no no <70 within 1 meter yes/100 µL yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes no/no yes/yes no/no 36 sec no 6 no/28 d yes/yes 24 h 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) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	15 min 36 sec 33/100 (36 sec) yes/yes onboard/yes (included or additional cost—negotiable) all major LIS vendors yes no yes (broadcast download & host query) yes no yes/yes/yes no 24 h max, usually within 6 h TBD/TBD 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	\$149,800/all volumes & hospital sizes \$15,800 4 d at venor offices/yes
Distinguishing features	the Access Immunoassay System, plus the Access 2, offers the network capability 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

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Automated immunoassay analyzers					
Part 6 of 20		Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com		The Binding Site Inc. Anne Grainger 5889 Oberlin Dr., #101 San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk	
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		Synchron LXi 725/2002/U.S. U.S./U.S. —/— cont. random access/floor-standing/rack-closed tube 60 x 134.5 x 48 in/44.8 sq ft		DSX Automated System/2000/Guernsey, U.K. U.S./U.K. >40/>100 (total) batch/benchtop/rack 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, Scl-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		—		none	
Tests not available in U.S. but submitted for clearance		CEA, T ₃ , T ₄ , TU, 3rd gen TSH, FT ₄ , FT ₃ , βhCG, prolac, FSH, LH, progest, estrad., unconj. estriol, B ₁₂ , 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, toxo IgM, rubella IgG, hybritech PSA, hybritech fPSA, testosterone, thyroglob., anti-thyroglob., human growth hormone, ostase, Accu Tnl, plus >100 Synchron chem tests, including critical care, general, esoteric, urine & CSF chemistries, all current Synchron DATs, TDMS, proteins, & serologies		none	
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 single platform using closed tube sampling		open system	
Fully automated microplate system		no		yes	
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		65		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 containers onboard at once/tests per container set		65/50 tests per cartridge, 100 tests per kit (immuno), 300 tests per container set (general)		25/96 per 4 plates	
Shortest/median onboard reagent stability/refrigerated onboard		336 h/28 d/yes (4°C)		24 h/n/a/no	
Multiple reagent configurations supported		yes		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		no	
Same capabilities when 3rd-party reagents used/susceptibility to carryover		no/≤ 3 ppm		yes/0	
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	
Uses disposable cuvettes/max. no. stored		yes/294		no	
Uses washable cuvettes/replacement frequency		yes, 2 yr warranty (general chem.)		no	
Min. sample vol. aspirated precisely at once/min. dead vol.		5 μL/100 μL		5 μL/200 μL (50 μL with microtubes)	
Supplied with UPS (backup power)/requires floor drain		—/yes		yes/no	
Requires dedicated water system/water consumption		yes/—		no	
Noise generated in decibels		—		—	
Has dedicated pediatric sample cup/dead vol.		no/—		yes/50 μL	
Primary tube sampling/tube sizes/pierces caps on primary tubes		yes/13x75 & 100, 16x75 & 100/yes		yes/various/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)/—	
Bar code placement per NCCLS standard Auto2A		yes		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/yes		yes/no	
Hemolysis/turbidity detection-quantitation		yes for general chemistry/yes for general chemistry		no/no	
Dilution of patient samples onboard/automatic rerun capability		yes/yes		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		36 sec		n/a	
Autocalibration or autocalibration alert		no		no	
No. of calibrators required for each analyte		6		assay specific	
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		36 sec		n/a	
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)		33/100 (36 sec)		assay dependent	
Can auto transfer QC results to LIS/onboard capability to review QC		yes/yes		yes/yes	
Data management capability/instrument vendor supplies LIS interface		onboard/yes (included or additional cost is negotiable)		onboard/yes (additional)	
Interfaces up and running in active user sites with		n/a		in development	
LIS interface operates simultaneously w/ running assays		yes		yes	
Uses LOINC to transmit orders and results		yes		no	
Bidirectional interface capability		yes (broadcast download & host query)		yes (host query)	
Results transmitted to LIS as soon as test time complete		yes		yes (manual transmission available)	
Interface available (or will be) to auto specimen handling system		no		no	
Modem servicing/can diagnose own malfunctions/determine malfunctioning component		yes/yes/yes		no/yes/yes	
Can order (via modem) malfunctioning part(s) w/o operator		no		no	
On-site response time of service engineer		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		yes		yes	
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		no/no	
List price/targeted bed size or daily volume		TBD/—		\$49,000 (dependent on modules)/200+ beds	
Annual service contract cost (24h/7d)		—		varies	
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 automation; single point-of-sample entry using closed tube sampling, dual scheduling, and parallel processing with full menu equivalence to the Synchron and Access product lines		fully open, true 4-plate system, modular design of reader, washer, incubators, bar-code reader and ambient drawer enables easy upgrades and express shipping of replacement modules reducing downtime; software can be trained for learned error recovery	

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 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 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	EIA/coated microplate, varies acc. to kit mfrt. 8 (3 plates) 500 500 8/96 (3 plates) mfrt. dependent/no yes no, requires operator prehandling/prep. no yes/zero carryover option —/96-8/8 yes/— yes/288-3 plates no 10 µL/200 µL yes/no no/n/a — no yes/11 x 55–16 x 100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/— — yes yes/yes yes no/yes no/no yes/no yes/yes (mfrt. & assay dependent) n/a n/a mfrt. & assay dependent —/mfrt. & assay dependent yes/— mfrt. & assay dependent yes/yes no/no/5 min	EIA/coated microplate, varies acc. to kit mfrt. 6 (2 plates) 500 500 6/96 (2 plates) mfrt. dependent/no yes no, requires operator prehandling/prep. no yes/zero carryover option —/96-6/6 yes/— yes/192-2 plates no 10 µL/200 µL yes/no no/n/a — no yes/16 x 100–11 x 55 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/— — yes yes/yes yes no/yes no/no yes/no yes/yes (mfrt. & assay dependent) n/a n/a mfrt. & assay dependent —/mfrt. & assay dependent yes/— mfrt. & assay dependent 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) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	n/a n/a n/a yes/yes onboard/yes (incl. in price) — yes — yes (broadcast download & host query) yes no yes/yes/yes no within 24 h —/<24 h yes daily: 6–10 min, weekly: 10 min, monthly: 15 min yes/no	n/a n/a n/a yes/yes onboard/yes (incl. in price) — yes — yes (broadcast download & host query) yes no yes/yes/yes no within 24 h —/<24 h yes 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

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 www.bio-rad.com	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
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	Coda/outside U.S. 1996; in U.S. 1997/Japan Japan/U.S., U.K., France, Korea, Australia —/— batch/benchtop/rack 21.6 x 39.5 x 26 in/7.13 sq ft	PhD System/2000/Belgium Belgium/U.S. 50/0 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	contact Bio-Rad representative	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	contact Bio-Rad representative	—
Research-use-only assays	n/a	—
Tests in development	—	anti-thyroglobulin, anti-TPO, anti-MPO, anti-PR3, anti-GBM, anti-Gliadin IgG, anti-gliadin IgA, ASCA IgG, ASCA IgA, aCL IgG/IgM, aCL IgA, aPS IgG/IgM, anti-β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPT IgG, aPT IgM
User-defined methods implemented for what analytes	STC drugs of abuse, Ostex Ntx, DSL assays—contact companies represented	—
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	—	1
No. of wells in microplate	min. strip: 1 sample; max. full plate, 96	min. strip: 1; max. full plate: 96
Methods supported/separation methods	EIA/coated microwell & noncoated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	9	8
No. of different assays programmed, calibrated at once	9	8
No. of user-definable (open) channels	unlimited	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	n/a/n/a/no	4 h/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	requires operator prehandling/preparation
Reagents bar-coded/information in bar code	no	no/n/a
Same capabilities when 3rd-party reagents used/susceptibility to carryover	no/reduced w/software version 4.0 & updated firmware, depends on amount of washing	yes/—
Walkaway capacity in min./specimens/tests-assays	varies by assay/90-270/up to 9	195/184/1
System is open (home-brew methods can be used)/liquid or dry system	yes/liquid, reconst. onboard	yes/liquid
Uses disposable cuvettes/max. no. stored	no (yes for dilts.)	no/n/a
Uses washable cuvettes/replacement frequency	no	no/n/a
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/200 µL, 130 µL in microtubes	1 µL/200 µL
Supplied with UPS (backup power)/requires floor drain	optional/no	yes/no
Requires dedicated water system/water consumption	no/—	no
Noise generated in decibels	n/a	—
Has dedicated pediatric sample cup/dead vol.	yes/130 µL	no
Primary tube sampling/tube sizes/pierces caps on primary tubes	not claimed, but some users have validated for their own use/—	no/—/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)/no
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	no	no
Measures no. of tests remaining/short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen	no	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	—	n/a
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	1–6	1–5
Calibrants can be stored onboard/avg. calibration frequency	no/most assays require calib. w/ each run, some as long as 2 weeks w/ 1 & 2 pt. updates	no/each run
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	shortest interval: user determined, longest: w/in run recommended	each run
Onboard real-time QC/support multiple QC lot nos. per analyte	yes/yes (late 2000 through Unity QC program)	no/no
Automatic shutdown/startup is programmable/startup time	for hardware/6 min.	no/no/5 min
Stat time to completion of B-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	~90 tests per h w/ all results in approx. 3 h (assay dependent)/(protocol specific)	n/a/n/a
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	onboard/customer acquires through LIS company, can be added to contract	onboard/yes (included)
Interfaces up and running in active user sites with	homegrown systems, Cerner, Dawning, & Sunquest under development	—
LIS interface operates simultaneously w/ running assays	not possible on batch analyzer	yes
Uses LOINC to transmit orders and results	no	no
Bidirectional interface capability	yes (broadcast download)	no
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/no/no	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 h	<24 h
Mean time between failures/to repair failures	—/4 h	6 mo/4 h
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 20 min; monthly: 20 min	daily: 15 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/maintenance training demo module	no/no	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)	\$4,800	\$6,000
Training provided w/ purchase/advanced operator training	As needed on-site, 3 d at vendor offices/—	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

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

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Automated immunoassay analyzers			
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 No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays	EIA/coated microwell 12 12 unlimited 12/96 —/—/no yes yes no no/no (disposable tips) varies by assay/180/unlimited	fluorescence, EIA, dendrimer technology/fiber matrix filter up to 4 1 0 n/a/unit dose test packs n/a/n/a/no yes yes 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 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 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 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	yes/liquid no no 10 µL/100 µL no/no no 60 dBA no yes/5, 7, 10 mL/no yes (2 of 5 interl., codabar, codes 39 & 128)/no no no/no no yes/no no/no yes/no no/no — no assay dependent no/with each run yes/no user determined yes/yes (through Unity QC program) no/no	no/liquid no no n/a no/no no/n/a <65 no yes/4 or 5 mL/yes yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes n/a no/yes yes yes/yes no/no yes/no no/no n/a yes 60–90 d same lot, new lot 60–90 d same lot, new lot yes/yes 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 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 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 Can order (via agent) 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	n/a n/a assay dependent yes/— onboard/yes — no no yes (broadcast download) yes no no/no/no no — —/— yes daily: 5 min; weekly: 10 min; monthly: 30 min no/no	14 min instantly 3/9 yes/yes no/yes (incl. in price) Cerner, Sunquest yes no no yes no no/yes/yes no — 6 mos or 180 d/2.99 h; 12 mos or 163 d/2.94 h yes 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	

Automated immunoassay analyzers

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 (HM)/1997/U.S.
Country where manufactured/where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	—/—	600/300
Operational type/model type/sample handling system	batch, random access, cont. random access/floor-standing/segmented sample wheel	batch, random access, cont. random access/floor-standing/segmented sample 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 amino-transferase, alkaline phosphatase, amylase, aspartate aminotransferase, CK, CK isoenzyme, glutamyl transferase, lactic dehydrogenase, lipase, pseudo-cholinesterase, 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 pro-tein, lactic acid, prealbum., carbamazep., digox., digitox., gentamicin, lithium, phenobarbital, phenytoin, theophy., tobramycin, vancomycin, valp. acid, aceta-minophen, 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, heteroge-neous immunoassays, specialty, immunology, TDM & toxicology. General chem-istry 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	CSA	CSA
Tests not available in U.S. but available in other countries	CSA	CSA
Research-use-only assays	—	none
Tests in development	fPSA, tPSA	fPSA, tPSA
User-defined methods implemented for what analytes	—	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
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	n/a
No. of wells in microplate	—	n/a
Methods supported/separation methods	EIA/magnetic particle	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles
No. of different measured assays onboard simultaneously	47	48 (95 with optional reagent management system)
No. of different assays programmed, calibrated at once	140	140
No. of user-definable (open) channels	10	10
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	47/avg. 80–120	44–88/max. 240
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	yes	—
Reagents bar-coded/information in bar code	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	yes/n/a due to probe washing	no/≤.130 ppm
Walkaway capacity in min./specimens/tests-assays	can be hours/60/>1,000	—
System is open (home-brew methods can be used)/liquid or dry system	yes/reconstitutes onboard	no/reconstitutes onboard
Uses disposable cuvettes/max. no. stored	yes/12,000	yes/12,000
Uses washable cuvettes/replacement frequency	no/—	no
Min. sample vol. aspirated precisely at once/min. dead vol.	2 µL/primary tube capable	2 µL/—
Supplied with UPS (backup power)/requires floor drain	yes/no	yes/yes
Requires dedicated water system/water consumption	yes/up to 3.5 L per h	yes/3.2 L per h
Noise generated in decibels	<70	<70
Has dedicated pediatric sample cup/dead vol.	no	yes/10 µL–20 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 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	yes
Clot detection/reflex testing capability	yes/yes	yes/yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample vol. can be reduced/increased to rerun	yes/no	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	3–5	varies—3 levels for most assays
Calibrants can be stored onboard/avg. calibration frequency	no/30–90 d	yes/15–90 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	no/no	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	24 sec	24 sec
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	83/250 (14.4 sec)	—
Can auto transfer QC results to LIS/onboard capability to review QC	yes/yes	yes/yes
Data management capability/instrument vendor supplies LIS interface	optional add-on/no (additional)	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	yes	yes
Uses LOINC to transmit orders and results	no	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	2–8 h	2–8 h
Mean time between failures/to repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <10 min; weekly: 5 min; monthly: 20–30 min	daily: 2 min, weekly: 2 min, monthly: 15 min
Onboard maintenance records/maintenance training demo module	yes/no	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)	\$15,000	\$17,500
Training provided w/ purchase/advanced operator training	5 d on-site; 4 d at vendor offices/no	5 d on-site, 4 d at vendor offices/yes
Distinguishing features	consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet over 95 percent of testing needs; eliminates sample splitting	analyzer integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests & immunoassays

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Automated immunoassay analyzers			
Part 12 of 20	Diagnostic Products Corp. Joe Kelly jkelly@dpconline.com 5700 W. 96th St., Los Angeles, CA 90045-5597 310-642-5180 www.dpcweb.com	Diagnostic Products Corp. Joe Kelly jkelly@dpconline.com 5700 W. 96th St., Los Angeles, CA 90045-5597 310-642-5180 www.dpcweb.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	Immulite/1993; Immulite Turbo/1999/U.S. U.S./U.S., U.K. 5,000 worldwide cont. random access/benchtop/loading platform 16 x 42 x 24.75 in (w/o computer)/7.2 sq ft	Immulite 2000/1998/U.S. U.S./U.S. 2,000 worldwide Cont. random access/floor-standing/rack 79 x 60 x 30/12.5 sq ft	
Tests available on instrument in U.S.	AlaTOP allergy scr., allergy food panel FP5E, total IgE, EPO, ferr., fol. acid, B ₁₂ , intact PTH, Pylilinks-D, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I & II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO ₄ , estrad., unconj. estriol, FSH, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT ₃ , FT ₄ , rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT ₃ , TT ₄ , thyrogl., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT ₄ & TSH, C-pep., insul., CK-MB, myogl., trop. I, ACTH, B2-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, urinary albumin, homocysteine, <i>H. pylori</i> IgG, AFP-NTD, THCA. Turbo menu: CK-MB, myoglob., intact PTH, trop. I, hCG	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, progest., prolac., total testost., β-2-microgl., cortisol, ferr., total IgE, intact PTH, C-pep., folic acid, B ₁₂ , insulin, unconj. estriol, carbamazep., phenytoin, valp. acid, HsCRP, hGH, ACTH, PAP, pheno, homocysteine, CMV IgG (qualit.), <i>H. pylori</i> IgG, rubella IgG, toxo IgG, troponin I, CK-MB, herpes I & II IgG, ALA top allergy screen, pylilinks-D, myoglobin, toxo IgM, canine TSH, rubella IgM, digoxin, GENT, allergy, tobramycin, theophylline, SHBG, AFT-NTD	
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	none HBsAg, a-HBs, aHBc, HBcIgM, HBsAg confirm, BRMA (CA 15-3) — GI-MA (CA 19-9), free PSA, TPS, Lyme screen, ECP osteocalcin, nicotine metabolite, cytokines, free βHCG	none HBsAg +confirm, aHBs, aHBc, HBc IgM, BR-MA (CA 19-9) — fPSA, Lyme screen, nicotine metabolite, CA 19-9 (GIMA)	
Tests in development	ANA scr., <i>C. diff.</i> , calcitonin, chagas, CMV IgM, dsDNA Ab, hep. A, IGF BP3, IGF-1, Lyme IgG & IgG/IgM, Hbe, Hbe IgM, androstenedione, cryptosporidium Ag, D-dimer, EBV, gastrin giardia Ag, <i>H. pylori</i> A, HSV IgM, ILIO, NMP 22, NSE, PAPP-A	anti-HBe, HBeAg, ANA screen, Chagas, CMV IgG avidity, dsDNA, EBV, HAV total, HAV IgM, <i>H. pylori</i> IgA, rubella IgG avidity, toxo IgG avidity, vancomycin, urinary 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 Tests not available on other manufacturers' analyzers	none 3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, SHBG, TBG, EPO, canine TSH, thyroglob., intact PTH, ACTH. Turbo: intact PTH	none TBG, thyrogl., SHBG, intact PTH, C-peptide, 3rd-gen. PSA	
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 Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	chemiluminescence/bead, centrifugation 12; Turbo: 5 unlimited; Turbo: 5 0 12/100 or 500; Turbo: 50 for intact PTH only n/a/30 d/yes (15°C) yes yes yes/test, lot No., expir. no/<10 ppm 100/—/70 no/liquid yes/n/a no 5 μL/100 μL yes/no no/0.5 L per h 55 min., max. 68 no no/n/a/— yes (2 of 5 interl., codabar, codes 39 & 128)/no — no yes/yes yes no/no no/no no/no no/no n/a no 2-level adjustors, supplied in kit no/1–4 weeks (assay dependent); Turbo: 2 wks no/yes customer determined no/yes no/no/5 min	chemiluminescence/bead, centrifugation 24 unlimited n/a 24/200 or 600 n/a/90 d/yes (4°C) yes yes yes/test, lot No., expir. no/<10 ppm cycle dependent/90/1,000 no/liquid yes/1,000 no 5 μL/50 μL yes/no no/1.5 L per h 52 yes/50 μL yes/12 x 75 & 100; 13 x 75 & 100; 16 x 75 & 100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no min. 18 sec yes 2 level adjustors, supplied in kit no/1–4 weeks (assay dependent) n/a/yes cutomer determined 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 each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	42 min; Turbo: 15 min 2.5 min 40/120 (—) no/yes onboard/yes (addt'l cost) Sunquest, Cerner, Citation, ALG, CHC, DynaMedix, Antrim, Antek, CSS yes no yes (broadcast download & host query) yes no no/yes/no no 4 h 8 mos/4 h yes daily: 5 min, weekly: 10 min, monthly: 20 min no/yes	35 min 18 sec 67/200 (—) yes/yes onboard/yes (addt'l cost) Sunquest, Cerner, HBOC, CCA, ALG yes no yes (broadcast download & host query) yes yes (universal interface) yes/yes/no no 6 h 2 mos/5 h yes daily: 5–10 min, weekly: none, monthly: 20–30 min no/yes	
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$75,000; Turbo: \$77,500/>1,000 tests per mo. \$7,500 3.5 d at vendor offices/no, in development	\$124,500/>4,000 tests per month \$12,500 3.5 d at vendor offices/no, in development	
Distinguishing features	system performance reliability; worldwide user satisfaction; breadth of immunoassay menu	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	

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SURVEY OF INSTRUMENTS			84 / CAP TODAY	April 2002
Automated immunoassay analyzers				
Part 15 of 20	Hycor Biomedical Inc. cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com		Hycor Biomedical Inc. 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, Scl-70, Jo-1, GPC, GBM, MPO p-ANCA, mitochondrial, 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, Scl-70, Jo-1, GPC, GBM, MPO p-ANCA, mitochondrial, cardiolipin IgG & IgM, cardiolipin scr.; <i>H. pylori</i> ; 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	<i>H. pylori</i> allergy & autoimmune testing on fully automated system		<i>H. pylori</i> 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 containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	varies by assay, up to 288 allergens or 8 autoimmune multiple multiple varies by assay, up to 288 allergens or 8 autoimmune 8 h/12 h/no yes yes no yes/<1 part in 10,000 assay dependent/100/288 yes/liquid no no 10 µL–50 µL, assay dependent//100 µL yes/no no/— — no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/n/a no yes yes/yes yes no/no no/no yes/no no/no n/a yes 1–5 no/monthly yes/yes every assay yes/yes yes/no/2–3 min		varies by assay, up to 480 multiple multiple 1/200-allergy, 96-autoimmune 8 h/12 h/no yes yes no yes/<1 part in 10,000 assay dependent/100/480 yes/liquid no no 10 µL–50 µL, assay dependent//300 µL yes/no no/— — no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/n/a no yes yes/yes yes no/no no/no yes/no no/no n/a yes 1–5 no/monthly yes/yes every assay yes/yes yes/no/5 min	
Stat time to completion of β-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 n/a yes/yes onboard/optional 25		n/a n/a n/a yes/yes onboard/no 30	
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 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 no yes optional no yes/yes/no no 48 h 6 mos/48 h yes daily: 10–15 min, weekly: 20–25 min, monthly: 20–25 min yes (incl. audit trail of who replaced parts)/yes		no no yes yes no no/yes/no no 48 h 6 mos/48 h yes daily: 10–15 min, weekly: 20–25 min, monthly: 20–25 min 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	

Automated immunoassay analyzers

Part 16 of 20	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 33051 Calle Aviator San Juan Capistrano, CA 92675* 800-286-4643 nicholsdiag.com	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 33051 Calle Aviator San Juan Capistrano, CA 92675* 800-286-4643 nicholsdiag.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	CLSystem ID/1993/Sweden U.S./U.S. 60+ /— batch/benchtop/rack processor: 17 x 48 x 26 in; washer: 15 x 27 x 20 in; luminometer: 16.5 x 32 x 25 in/15 sq ft	Nichols Advantage Specialty System/1997/Germany U.S./U.S. >120/>160 batch, cont. random access/benchtop/rack 44 x 45 x 26 in/8 sq ft
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 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 T ₃ , T ₄ , AFP, CEA, CA 15-3, NSE, TPA, CA 19-9, CA 125, prolac., total hCG
Research-use-only assays Tests in development	none none	osteocalcin, <i>H. pylori</i> IgG 1,25 dihydroxy vit D, IGFBP-3, Sangtec 100, aldosterone, <i>H. pylori</i>
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none —	none IGF-I, calcitonin, pepsinogen, Bio-Intact PTH (I-84), 25 hydroxy vit. D, direct renin
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 Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	chemiluminescence/bead 1 1 0 1/100 8 h/1 d/no yes no, requires oper. prehandling/prep. no — /— —/256/1 yes/liquid no no 25 µL/150 µL no/no no/— — no yes/10 x 75/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes no no no/no yes yes/no no/no yes/no no/no — no 2 yes/once per run yes/no shortest interval: 4 h, longest: 8 h no/no no/no/10 min	chemiluminescence/magnetic particle 15 15 0 15/varies, typically 100 8 h/—/yes (17°C) no no, requires oper. prehandling/prep. yes/assay ID, lot No., serial No., expir. no/≤5x10 ⁻⁵ up to 480/120/15 x 100=1,500 no/liquid yes/120 no 10 µL/200 µL yes/no no/— 67 yes/100 µL yes/10 x 75, 16 x 100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no yes/yes no/no 37 min no 2 no/7 d yes/no shortest interval: 4 h, longest: 8 h no/no no/no/10 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 — — /— (—) yes/yes no/yes —	n/a n/a up to 55/up to 165 (—) yes/yes onboard/yes (incl. in price) all commercially available 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 Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	— no yes (broadcast download) yes no no/yes/yes no 24 h 10 mos/48 h yes daily: 10 min, weekly: 30 min, monthly: 60 min no/no	yes yes yes (broadcast download & host query) yes no no/yes/yes no 24 h 90 d/24 h yes daily: 10 min, weekly: 30–45 min, monthly: 5 min no/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	component related/— — —	\$125,000/300+ beds inquire 4 d at vendor offices/yes
Distinguishing features	a chemiluminescence seq. batch analyzer designed to provide results for specialized and routine immunoassays; continuous sample loader, bidirectional communication, pos. sample ID; 1,200 patient samples per 8-h shift * Nichols Institute Diagnostics will have a new address May 15, 2002. It will be 1311 Calle Batido, San Clemente, CA 92673	the fully automated continuous random access chemiluminescence system that 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 & minimizes hands-on time; onboard refrigeration * Nichols Institute Diagnostics will have a new address May 15, 2002. It will be 1311 Calle Batido, San Clemente, CA 92673

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

SURVEY OF INSTRUMENTS			86 / CAP TODAY	April 2002
Automated immunoassay analyzers				
Part 17 of 20		Olympus America Inc. Susan Watanabe susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com		Ortho-Clinical Diagnostics, a Johnson & Johnson Company Tim Vesling tvesling@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 or 908-218-1300 www.orthoclinical.com
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint		AU400/1999/Japan Japan/U.S., Ireland >300/>1,100 cont. random access/floor-standing/rack & turntable 47.6 x 57.1 x 29.9 in/70 x 129 in		Vitros ECI Immunodiagnostic System/1997/U.S. U.S./U.K. >1,000 worldwide cont. random access/floor-standing/universal sample racks (circular) accommo- date primary & secondary containers without need for adapters 51 x 44 x 29 in/8.9 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers		α 1-acid glycoprotein, α 1-antitrypsin, anti-streptolysin O, apolipo. A1 & B, β -2-microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 & C4 complement, ferr., haptoglobin, immunogl. A, G, M, microalbumin, myogl., prealb., rheum. factor, transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, etho-sux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, van-comycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T-uptake, T ₄ thyrox. Also, general chemistries, enzymes, direct HDL & direct LDL ceruloplasmin none cotinine none none HbA1c, fructosamine none		3rd-gen. TSH, TT ₃ , TT ₄ , FT ₃ , FT ₄ , T ₃ -uptake, total β -hCG, estradiol, progesterone, LH, FSH, prolactin, N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, equimolar troponin I, aHBs, B ₁₂ , folate, RBC folate, equimolar PSA, HBsAg, aHCV none none CA 19-9, f β -hCG, a-HBc IgM, a-HBc, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II HCV antigen myoglobin, HAV total, HIV 1/11o, BNP none hepatitis, HIV
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 Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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		EIA, photometric, potentiometric, calc. results/none (all homogeneous) >40 99 95 76/100–6,160 168 h/60 d/yes (4–12°C) yes yes yes/reag. ID, lot No., bottle No., expir. yes/n/a variable/up to 102/8,058 yes/liquid no yes/permanent 2.0 μ L/25 μ L optional/yes yes/26 L per h @ peak consump. <65 no yes/pediatric, 5 mL, 7 mL, 10 mL/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes yes/yes yes/yes varies by run size yes 1–6 yes/14 d yes/no lab-defined yes/yes yes/yes/24 h availability		chemiluminescence (enhanced)/coated microwell 20 29 programmed & calibrated at once; up to 25 lots calibrated per assay 0 20/100 56 d/56 d/yes (2°–8°C) yes yes yes/test ID, expir., lot No., pack ID —/zero carryover 360/60/400 no/liquid yes/2,000 no 10 μ L/60 μ L no/— no/— not determined no yes/multiple ped. cup capabilities/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no assay dependent yes 1–3 no/28 d yes/yes 1 per d yes/yes yes/yes/5 min from power off
Stat time to completion of β -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 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 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		n/a <1 min 133.3/400 (9 sec) yes/yes onboard/yes (add'l cost) Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Orchard, Citation yes no yes (broadcast download & host query) yes yes (Olympus OLA 1500 Sorter, Labotix, Lab InterLink) yes/yes/yes no <24 h >20 weeks/<24 h yes daily: 3 min, weekly: 7 min, monthly: 45 min yes (incl. audit trail of who replaced parts)/yes		24 min. — 30/90 (40 sec) yes/yes onboard/no Cerner, Sunquest, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, HBOC, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, SMS, Dawning yes yes yes (broadcast download) yes yes (all systems) yes/yes/yes no <4 h (contract dependent) —/dependent on corrective action yes daily: <5 min, weekly: <30 min, monthly: <10 min no/yes
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training		\$130,000/200–2,000 tests per d (depending on menu) inquire 5 d on-site, 5 d at vendor offices/yes		\$140,000/daily volume to approx. 250–500 tests varies w/ service level choices 3.5 d at vendor offices/yes, as needed on-site
Distinguishing features		open reagent system; 120+ test menu incl. general chemistry & homogeneous immunoassay; onboard automation to repeat, reflex, or predilute samples; true random access & fast throughput; family of standardized analyzers including AU600, AU640, AU2700, & AU5400		immunoassay analyzer provides fast & easy fully automated, random access hepatitis testing along w/ thyroid, cardiac, anemia, endocrin, bone, & oncology assays; Intellichek on the Vitros ECI System performs, monitors, and verifies all sample and assay processing steps to reduce the possibility of an erroneous result being reported out

SURVEY OF INSTRUMENTS			92 / CAP TODAY	April 2002
Automated immunoassay analyzers				
Part 20 of 20	Tosoh Medics Inc. Jane Merschen jane@tosohm.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 650-615-4970 www.tosohm.com		Tosoh Medics Inc. Jane Merschen jane@tosohm.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 650-615-4970 www.tosohm.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	AIA Nex•IA/1997/Japan Japan/Japan 40/300 cont. random access/floor-standing/rack, carousel, TLA 47 x 35 x 26 in/6.3 sq ft		AIA-600 II/2000/Japan Japan/Japan 60/300 cont. random access/benchtop/chain 19.8 x 31.6 x 29.1 in/2.5 sq ft	
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, FT ₄ , T ₃ , T ₄ , T-uptake, FT ₃ , TPO Ab, Tg Ab, βhCG, estradiol, FSH, hCG (intact), LH II, progesterone, prolactin, ST-βHCG, ST-estradiol, ST-FSH, 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, B ₁₂		same menu as for AIA Nex•IA (see column at left)	
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	none CA 19-9		none CA 19-9	
Tests not available in U.S. but available in other countries	HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa		HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa	
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	CA 19-9 testosterone none none		CA 19-9 testosterone none none	
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 Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in 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 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 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	fluorescence, EIA/bead ≥34 entire menu 0 n/a/unitized test cup 72 h/72 h/n/a yes yes yes/lot No., test code no/zero carryover 52/75–200/400 for the standard model no/dry n/a/unitized test cup n/a 10 µL/50 µL yes/no no/n/a — no yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no yes/yes yes yes yes/yes yes yes/no no/no yes/no no/yes n/a no 2 or 6—analyte dependent no/60–90 d yes/yes 24 h yes/yes no/no/5–8 min		fluorescence, EIA/bead ≥34 entire menu 0 n/a/unitized test cup 72 h/72 h/n/a yes yes yes/lot No., test code no/zero carryover 52/26/26 no/dry n/a/unitized test cup n/a 10 µL/100 µL yes/no no/n/a — no yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no yes/yes yes yes yes/yes yes yes/no no/no yes/no no/yes n/a no 2 or 6—analyte dependent no/60–90 d yes/yes 24 h no/no no/no/5 min	
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per 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	~18 min 90 sec 40/120 (30 sec) yes/yes optional add-on (software mfr: Schuyler House, Sunquest, LabForce, HBOC, Antrim, Data Innovations)/yes (addt'l cost)		~18 min 60 sec 20/60 (1 min) yes/no optional add-on (software mfr: Schuyler House, Sunquest, LabForce, HBOC, 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 Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	yes yes yes (broadcast download & host query) yes yes (Hitachi, Panasonic, Sysmex) no/no/no no 24 h —/— yes daily: 5–8 min, weekly: none, monthly: none yes (incl. audit trail of who replaced parts)/no		yes yes yes (broadcast download & host query) yes no no/no/no no 24 h unknown/— Yes daily: 5 min, weekly: 5 min, monthly: none no/no	
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$135,000/65+ beds, 1,500–2,000+ tests \$10,800 4 d at vendor offices/no		\$70,000/500–2,500 tests per month \$5,600 3 d at vendor offices/no	
Distinguishing features	3 sample loading options on single system: 200 sample rack loader, TLA adaptable, standard carousel model; unitized test cups; primary tube sampling; no reagent prep.; dual clot detection; room temp. stability for 5 d; automated sample dilution & pretreatment; 3rd-generation TSH sensitivity; appropriate for stat & routine use		unitized test cups; primary tube sampling; no reagent prep.; dual clot detection; room temp. stability for 5 d; automated sample dilution & pretreatment; 3rd-generation TSH sensitivity; appropriate for stat & routine use	