Automated immunoassay analyzers

Picturing tomorrow's system

David Smalley, PhD
Raymond D. Aller, MD

CAP TODAY's lineup of immunoassay analyzers begins here and spans 17 pages, and could make it easy to forget that only a few years ago, laboratory professionals were clamoring for automation in this area of the lab. We were tired of the manual pipetting and manual washing. Today, we have auto-dispensers for serum, auto-reagent delivery systems, washers that are markedly improved over the manual methods, and built-in readers. Bringing us those conveniences are nearly three dozen analyzers manufactured by 20 vendors; the details on what they test for and how they operate are displayed on pages 53–84. The vendors supplied the data in response to CAP TODAY's questions. We encourage readers to verify the responses by talking to current users of this equipment.

Nearly every laboratory performing immunoassays can automate to some degree. The higher the test volume, the more sophistication required. Throughput of tests is important, but being able to test for multiple analytes simultaneously is paramount. Does the throughput the manufacturer claims correspond with reality? One laboratorian told of us a hybrid chemistry-immunoassay analyzer with a claimed immunoassay throughput of more than 150 tests per hour; it actually produced less than 50. Can your analyzer start a test when another has yet to finish? It sounds simple, but not all analyzers have that ability. Can the system multi-task? Some don't, and some labs don't need it. What is being tested? The analytes your laboratory wants to test may require an immunoassay-specific analyzer, or they may be available on your lab's chemistry analyzer.

We should consider which of the assays we provide today are obsolete. The most obvious examples are total T_4 and T_3 uptake, which should have been replaced with free T_4 assays a number of years ago. Other examples are hepatitis B e antigen and antibody; hepatitis B DNA quantitation provides much more clinically useful information. We owe it to our patients to be leaders in eliminating obsolete tests.

In forecasting the future of immunoassay testing, a crystal ball would be helpful. Can the immunoassay analyzer of the future read at multiple wavelengths, and does it have the flexibility to perform assays such as end-point molecular tests? Does the analyzer work in the same fashion as a high-throughput chemistry analyzer? Can it interface bidirectionally? Can it be set in a workflow that makes it possible for a single user to test chemistry and immunoassays simultaneously? Even more important, can the system adapt to your lab's needs rather than you having to change the lab to fit the system's functionality?

Let us develop a vision for the future of immunoassays. Let's not settle indefinitely for the antibody detection systems of the 1990s. We should think about how laboratories 10 years hence need to be structured. Let's abandon the this-is-the-way-we-have-always-done-it-so-it-must-remain-that-way mode of thinking. The current state of laboratory medicine calls for us to be proactive and visionary. If we don't make our labs more efficient, more automated, and less reliant on specialized skills, they may not survive the 21st century. Manufacturers appreciate the vision laboratorians have in the real world. If you make your vision known to the world of immunoassay, the whole blood throughput of tomorrow's immunoassay analyzer may match that of hematology and the speed may equal that of a high-volume chemistry analyzer. The manufacturers are our partners in this endeavor, and they appreciate the ideas we have. Share them.

Dr. Smalley is technical director, Memphis (Tenn.) Pathology Laboratories. Dr. Aller is vice president for medical affairs and informatics at MDS Laboratory Services (U.S.). He is based in California and Nashville, Tenn., and can be reached at raller@mdslabsus.com.

Part 1 of 17	Abbott Diagnostics Michele Case (michele.case@abbott.com) 100 Abbott Park Rd., Dept. 02LB, AP6C-5 Abbott Park, IL 60064-3500 847-938-6532
Name of instrument/first year sold/where designed	Architect i2000/1999/U.S.
Country where manufactured/where reagents manufactured	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	100+/600+
Operational type/model type/sample handling system	Batch, random access, cont. random access/floor-standing/rack
Dimensions (H x W x D)/instrument footprint	48 x 44 x 68 in./23 sq. ft.
Tests available on instrument in U.S.	βhCG, FSH, LH, prolac., progest., CEA, 3rd-gen. TSH, T_4, FT_4, FT_3, TT_3, testost.*, estradiol, B_{12},* ferr.* (* temporarily not available in U.S.)
Tests cleared but not clinically released	AFP, glycated Hb
Tests not available in U.S. but submitted for clearance	AFP, glycated Hb
Tests not available in U.S. but available in other countries	AFP, CA 19-9, fPSA, tPSA, testost., anti-HBc, anti-HBs, anti-HCV, HBsAg & confirm., B_{12}, ferr.
Research-use-only assays	None
Tests in development	HBcIgM, HBeAg, anti-HBe, anti-HAVAB-IgM, anti-HAVAB, T-uptake, homocyst., cortisol, digoxin, CA-125, CA 15-3, UE3, BAP, PTH, anti-TPO, anti-TG, rubella IgG & IgM, toxo IgG & IgM, CMV IgG & IgM, HSV-2, pepsinogen, syph. TP, HTLV I/II, tacrolimus, cyclosporine, CK-MB, trop. I, myogl., theoph., phenobarb., phenytoin, vancomycin, DHEAS, dPD, SCC
User-defined methods implemented for what analytes	None
Tests not available on other manufacturers' analyzers	Glycated Hb
Fully automated microplate system	No
No. of each analyte performed in separate disposable unit	n/a
No. of wells in microplate	n/a
Methods supported/separation methods	Chemiluminescence w/ flexible protocols/magnetic microparticle
No. of different measured assays onboard simultaneously	25 per module, max. 4 modules=100 assays max.
No. of different assays programmed, calibrated at once	100+
No. of user-definable (open) channels	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	25/100-test & 500-test kits
Shortest/median onboard reagent stability/refrigerated onboard	30 d/30 d/yes (2–5°C)
Multiple reagent configurations supported	Yes
Reagent container placed directly on system for use	Yes
Reagents bar-coded/information in bar code	Yes/2D bar code, lot. no., no. tests, calib. data
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/0.3 ppm
Walkaway capacity in min./specimens/tests-assays	300/250/1,000
System is open (home-brew methods can be used)/liquid or dry system	No/liquid
Uses disposable cuvettes/max. no. stored	Yes/1,200
Uses washable cuvettes/replacement frequency	No
Min. sample vol. aspirated precisely at once/min. dead vol.	150 µL/50 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no
Requires dedicated water system/water consumption	No/—
Noise generated	60–65 decibels
Has dedicated pediatric sample cup/dead vol.	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/10–16 mm, up to 75–100 mm/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A	Yes
Onboard test auto inventory (determines vol. in container)	Yes
Measures no. of tests remaining/short sample detection	Yes/yes
Auto detection of adequate reagent or specimen	Yes
Clot detection/reflex testing capability	Yes/yes
Hemolysis/turbidity detection-quantitation	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/yes
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	Yes/yes
Time between initial result & reaspiration of sample for rerun	Seconds
Autocalibration or autocalibration alert	Yes
No. of calibrators required for each analyte	2–6 pt. curve
Calibrants can be stored onboard/avg. calibration frequency	No/30 d
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes
How often QC required	3 levels every 24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/10 min.
Stat time to completion of ß-hCG test	28 min.
Time delay from ordering stat test to aspir. of sample	Every 18 sec. from positive sample ID
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	67/200 per module (aspir. to result: 28 min.)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/no
Interfaces up and running in active user sites with	All major LIS vendors
LIS interface operates simultaneously w/ running assays	Yes
Uses LOINC to transmit orders and results	—
Bidirectional interface capability	Yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	Yes
Interface available (or will be) to auto specimen handling system	Yes
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No
On-site response time of service engineer	12 h
Mean time between failures/to repair failures	Not available/not available
Onboard error codes to facilitate troubleshooting	Yes
Avg. time to complete maintenance by lab personnel	Daily: <15 min., weekly: <10 min., monthly: none
Onboard maintenance records/maintenance training demo module	Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume	$169,500/500 immunoassays per d
Annual service contract cost (24h/7d)	$27,450 (list price)
Training provided w/ purchase/advanced operator training	5 d at vendor offices/yes (5 d on-site integration)
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.

Automated immunoassay analyzers

Part 2 of 17	Abbott Diagnostics Michelle Accuso-Stevens (michelle.accuso-stevens@abbott.com) 100 Abbott Park Rd., Dept. 02LB, AP6C-5 Abbott Park, IL 60064-3500 847-937-0425	ACT Diagnostics George Mills (gmills@actdiagnostics.com) 4100 Avenida de la Plata, Ste. D Oceanside, CA 92056 888-770-4228 www.actdiagnostics.com
Name of instrument/first year sold/where designed	AxSym/1993 worldwide, 1994 U.S./U.S.	Alpha Prime/2000/France
Country where manufactured/where reagents manufactured	U.S./U.S.	France/open system
No. of units in clinical use in U.S./outside U.S.	4,000+/15,000+	10/50
Operational type/model type/sample handling system	Cont. random access/floor-standing/segment	Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	51 x 63 x 33.5 in./22 sq. ft.	100 x 48 x 70 in./—
Tests available on instrument in U.S.	hTSH II, TT_3, TT_4, FT_3, FT_4, T-uptake, βhCG, FSH, LH, estrad., prolac., progest., CK-MB, myogl., trop. I, B_{12}*, ferr.*, fol.*, PSA, CEA, CA 125, CA 15-3, AFP, CMV IgG, rubella IgG & IgM, toxo IgG & IgM, carbamazep., digitox., digox., gentamicin, NAPA, phenytoin, phenobarb., procain., quinidine, theoph., tobramycin, valp. acid, vanc., amph/meth, barbit., benzodiazep., cannab., cocaine, methadone, opiates, PCP, acetamin., ethanol, salicylates, tricyc. (*temporarily not available in U.S.)	Sm/RNP, Sm, SS-A & -B, Jo-1, Scl 70, ENA scr., TPO, antithyroglob., thyroglob., mitochond. M2, histone, ssDNA, MPO (p-ANCA), PR3 (C-ANCA), RF IgM, RF/3 (IgG, IgM, IgA), rubella IgG&IgM, rubeola IgG & IgM, VZV IgG&IgM, mumps G, CMV IgG & IgM, HSV I/II IgG&IgM, EB VCA IgG&IgM, EBNA G, EA, syph. IgG&IgM, chlam. (Ab&Ag), Lyme IgG & IgM, legion. (Ab&Ag), H. pylori IgG, parvovirus IgG&IgM, HAV IgG & IgM, HBCore IgG & IgM, HBe (Ag&Ab), HBsAb, HBsAg, C. diff toxA, giard., cand. (IgG/IgM.IgA), mycoplas. IgG & IgM, E. histolytica, prot. C Ag, prot. S total, VWF Ag, anticardiolip.(IgG/IgM/IgA) & scr., amph., barbit., benzodiazep., cocaine, cotinine, LSD, metham., morph., opiates, PCP, THC, DHEAS, estrad., progest., testost., CRP, and adaptable to all standard ELISA test kits, all manufacturers, and all types of kits
Tests cleared but not clinically released	Homocysteine, 3rd-gen. TSH	Completely open system
Tests not available in U.S. but submitted for clearance	HCV, cyclosporine, fPSA, tPSA	Completely open system for use by all manufacturers and all types of kits
Tests not available in U.S. but available in other countries	Hepatitis, retrovirus, fPSA, tPSA, β-2 microgl., insulin, cyclosporine, CA 19-9, CMV IgM	Completely open system for use by all manufacturers and all types of kits
Research-use-only assays	None	Completely open system for use by all manufacturers and all types of kits
Tests in development	Hepatitis, retrovirus, fPSA, tPSA, testost., cyclosporine, anti-TPO, anti-TG, PTH, CMV IgM, cortisol	Completely open system for use by all manufacturers and all types of kits
User-defined methods implemented for what analytes	None	Completely open system for use by all manufacturers and all types of kits
Tests not available on other manufacturers' analyzers	Drugs of abuse and congenitals	Completely open system for use by all manufacturers and all types of kits
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit	n/a	1
No. of wells in microplate	n/a	Min. strip: 1 well; max. full plate: 96 wells, 4 plates
Methods supported/separation methods	FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter	EIA/coated solid phase microplate varies acc. to kit mftr.
No. of different measured assays onboard simultaneously	20	18
No. of different assays programmed, calibrated at once	20	18
No. of user-definable (open) channels	0	18
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	20/100	18/up to 244
Shortest/median onboard reagent stability/refrigerated onboard	112 h/14 d/No	6 h/60 d/yes (4°C)
Multiple reagent configurations supported	No	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/assay name, reag. lot no., expir., pack no. ID	Yes/protocol no., batch no., validation criteria, calculates manufacturer's curve
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/<1 ppm	Yes/<1 ppm
Walkaway capacity in min./specimens/tests-assays	60/90/90	18 h total/4 x 96/4 x 96
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	Yes/90 reaction vessels	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	100 µL/50 µL for sample cup, 450 µL for aliquot, 4.5 mL for primary	6 µL/10µL
Supplied with UPS (backup power)/requires floor drain	Yes (soft close of files only)/optional	No/no
Requires dedicated water system/water consumption	No/—	No/1 L per h
Noise generated	52–68 decibels	54 decibels
Has dedicated sample cup/dead vol.	Yes/50 µL for sample cup	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/100 & 75 mm/no	Yes/11 x 55, 16 x 100 mm/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A	Yes	Yes
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/no
Auto detection of adequate reagent or specimen	Yes	No
Clot detection/reflex testing capability	Available July 2001/yes	No/no
Hemolysis/turbidity detection-quantitation	Yes/no	No/yes
Dilution of patient samples onboard/automatic rerun capability	Yes/yes	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	Seconds	n/a
Autocalibration or autocalibration alert	No	Yes
No. of calibrators required for each analyte	6 pt. or 2 pt. w/ master calib., index calib.	2–9 depending on kit used
Calibrants can be stored onboard/avg. calibration frequency	No/4 weeks	Yes/weekly
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes (up to 4 curves/analyte)	Yes/yes
How often QC required	Shortest interval: 8 h, longest: 24 h	Daily
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/1 min.	No/yes/—
Stat time to completion of ß-hCG test	13 min.	Depends on kit
Time delay from ordering stat test to aspir. of sample	30 sec. from standby	Depends on kit
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	68–126 tests/flexible platform—load list dependent (assay dependent)	Between 15–50 tests per h/depends on protocol
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	No/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/no	Onboard/no
Interfaces up and running in active user sites with	All major LIS vendors	All following ASTM standardization
LIS interface operates simultaneously w/ running assays	Yes	Yes
Uses LOINC to transmit orders and results	Yes	Yes
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	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/yes	Yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	Yes
On-site response time of service engineer	12 h	Max. 24 h per contract
Mean time between failures/to repair failures	5 mos./w/in 12 h per customer request	9 mos./24 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 5 min., weekly: 30 min., monthly: 30 min.	Daily: 5 min., weekly: 10 min., monthly: 10 min.
Onboard maintenance records/maintenance training demo module	No/no	Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume	$124,000/>100 patients tests per d	$44,000/between 100 and 600 wells per day
Annual service contract cost (24h/7d)	$16,800 extended hours coverage	$7,500
Training provided w/ purchase/advanced operator training	5 d on site, 5 d at vendor offices/yes	2 d on-site, 5 d at vendor office/yes
Distinguishing features	Menu, reliability, quality of result	Unique well-by-well management, onboard refrigeration, programmable dilution capability, open system, unsurpassed quality of results

Automated immunoassay analyzers

Part 3 of 17	Bayer Diagnostics Jean R. Onofrio (jean.onofrio.b@bayer.com) 511 Benedict Ave. Tarrytown, NY 10591 914-333-6014 www.bayer.com	Bayer Diagnostics Jean Metzar (jean.metzar.b@bayer.com) 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040 www.bayerdiag.com
Name of instrument/first year sold/where designed	Advia Centaur/1998/U.S.	ACS: 180 SE/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.	>500/>1,200	>1,200/>4,000
Operational type/model type/sample handling system	Cont. random access/floor-standing/rack or direct track sampling	Cont. random access/benchtop/ring
Dimensions (H x W x D)/instrument footprint	51.5 x 72.5 x 41.5 in./21 sq. ft.	24 x 59 x 23 in./9.5 sq. ft.
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, T_4, FT_4, T-uptake, T_3, FT_3, B_{12}, fol., RBC fol., ferr., LH, FSH, prolac., progest., testost., estradiol, hCG, CK-MB, myogl., trop. I, digoxin, digitoxin, urine & serum cortisol, IgE, equimolar PSA, CEA, AFP, BR 27.29, tobramycin, carbamazep., phenobarb., cPSA	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., PSA, equimolar PSA, cPSA, anti-TPO, anti-TG, CEA, AFP, BR 27.29, CK-MB, trop. I, myogl., digitoxin, digoxin, theoph., phenobarb., phenytoin, vancomycin, gentamicin, carbamazep., tobramycin
Tests cleared but not clinically released	Phenytoin, aTPO, gentamicin	None
Tests not available in U.S. but submitted for clearance	Rubella IgG & IgM, toxo IgG & IgM	None
Tests not available in U.S. but available in other countries	Specific allergens, rubella IgG & IgM, toxo IgG & IgM	None
Research-use-only assays	OV, CA 19-9	GI, OV
Tests in development	Theoph., valp. acid, vanc., homocyst., Her2/neu, PTH, NAPA, procain., quinidine, anti-TG, insulin, C-peptide, CA 125, high-sens. E2, BNP, high- sens. CRP, HBsAg, HBsAb, free estriol, Ghgb/A_{1c}, cyclosporine, FK 506, B_2M, DHEAS, HBcAb IgM, HBcAb, HBeAb, HBeAg, HAV, HAV-IgM, CMV IgG, CMV IgM	Homocyst., valp. acid, NAPA, procain., quinidine, HER2/neu, DHEAS, insulin, C-peptide, CA 125
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	BR 27.29	BR 27.29
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	Chemiluminescence/magnetic particle	Chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	30	13
No. of different assays programmed, calibrated at once	30	13
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	30/50–100	13/50
Shortest/median onboard reagent stability/refrigerated onboard	96 h/28 d/yes (4°C)	40 h/1.7 d/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/assay name, lot no., expir., pack ID	Yes/assay name, lot no., expir., pack ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	n/a/zero carryover	n/a/—
Walkaway capacity in min./specimens/tests-assays	230/180/840	150/60/450
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	No/liquid
Uses disposable cuvettes/max. no. stored	Yes/1,000	Yes/450
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/50 µL	10 µL/50 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	No/no
Requires dedicated water system/water consumption	No/~2.5 L per h	No/~1.8 L per h
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/multiple/no	Yes/multiple/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/no
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 out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	15 sec. minimum	20 sec.
Autocalibration or autocalibration alert	No	No
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/avg. calibration frequency	No/varies, avg. 21 d	No/varies by assay, generally 28 d
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/yes
How often QC required	24 h	24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/none	No/no/<5 min, generally remains on
Stat time to completion of ß-hCG test	18 min.	15 min.
Time delay from ordering stat test to aspir. of sample	15 sec.	<60 sec.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	80/240 (15 sec.)	60/180 (20 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	Onboard/—	Onboard/no
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, HBOC, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, HBOC, and most other major vendors	Cerner, Soft, Meditech, Antrim, Sunquest, HBOC, Citation, Triple G, Dynamic Healthcare (all major vendors)
LIS interface operates simultaneously w/ running assays	Yes	Yes
Uses LOINC to transmit orders and results	—	Yes
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 (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T)	Yes
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/yes	No/no/no
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	4 h	4 h
Mean time between failures/to repair failures	TBD/3 h	4 mos./3 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 3 min., weekly: 20 min., monthly: 30 min.	Daily: 15 min., weekly: 15 min., monthly: 15 min.
Onboard maintenance records/maintenance training demo module	Yes/yes	Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume	$220,000, STS model $225,000/300+ beds or ≥400 tests per d	$130,000/≥50 immunoassays per d
Annual service contract cost (24h/7d)	$17,000	$13,000
Training provided w/ purchase/advanced operator training	Varies on site, 4 d at vendor offices/yes	Varies on site, 4 d at vendor offices/yes
Distinguishing features	Ability to access/change solutions, waste, disposables & reag. at any time w/o pausing sampling or processing; onboard automatic dilutions, repeats, & cascade reflex testing; disposable tips; 240 results/h, compatible with Hitachi racks	Automatic dilutions, repeats performed onboard; clot detection & management; CD-ROM offers online operators manual & help

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Part 4 of 17	Bayer Diagnostics Jean Metzar (jean.metzar.b@bayer.com) 511 Benedict Ave. Tarrytown, NY 10591 914-333-6040 www.bayerdiag.com	Beckman Coulter Inc. Joel Greiner (jcgreiner@beckman.com) 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com
Name of instrument/first year sold/where designed	Bayer Immuno I Immunoassay System/1993/U.S.	Access Immunoassay System/1993/U.S.-France
Country where manufactured/where reagents manufactured	Ireland/U.S., U.K.	U.S./U.S.-France
No. of units in clinical use in U.S./outside U.S.	400/~400	1,500/2,500
Operational type/model type/sample handling system	Cont. random access/floor-standing/rack	Cont. random access/benchtop/rack
Dimensions (H x W x D)/instrument footprint	54 x 65 x 29 in./13.1 sq. ft.	18.5 x 39 x 24 in./8 sq. ft.
Tests available on instrument in U.S.	T_3, T_4, T-uptake, FT_4, FT_3, TSH, 3rd-gen. TSH, digoxin, theoph., gentamicin,, tobramycin, phenytoin, phenobarb., valp. acid, vancomycin, carbamazep., quinidine, 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, prolac., progest., estradiol, testost., unconj. estriol, HER-2/neu	CEA, T_3, T_4, T-uptake, hypersens. 3rd-gen. TSH, FT_4, FT_3, βhCG, prolac, FSH, LH, project., estrad., unconj. estriol, B_{12}, fol., RBC fol., ferr., CK-MB, myogl., trop. I, cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, Hybritech PSA & fPSA, testosterone, ostase, toxo IgM
Tests cleared but not clinically released	None	Hypersensitive human growth hormone, thyroglobulin
Tests not available in U.S. but submitted for clearance	None	Accu TnI
Tests not available in U.S. but available in other countries	CA 19-9, CA 72-4, rubella IgM	HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab
Research-use-only assays	None	None
Tests in development	CA 19-9, CA 72-4, rubella IgM	CMV IgG & IgM, CA 125, CA 15-3, µDPD, rubella IgM, antithyroglob., PTH, DHEAS
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	cPSA, HER-2/neu	Chlam. Ag & confirm., AFP-ONTD, hybritech PSA & fPSA
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle	Chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	22	24
No. of different assays programmed, calibrated at once	22	24
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	22/50–200, assay dependent	24/50 tests per cartridge, 100 tests per kit
Shortest/median onboard reagent stability/refrigerated onboard	21 h/30 d/yes (4°–11°C)	336 h/28 d/yes (4°C)
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes (T_3 & cortisol require oper. prehandling/prep.)	Yes
Reagents bar-coded/information in bar code	Yes/test name, expir., no. of tests, lot no., pack ID	Yes/assay no., lot no., expir., unique reag. pack ID no.
Same capabilities when 3rd-party reagents used/susceptibility to carryover	n/a/≤5 ppm	No/≤3 ppm
Walkaway capacity in min./specimens/tests-assays	437/78/875	180/60/300-31
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	No/liquid
Uses disposable cuvettes/max. no. stored	No	Yes/294
Uses washable cuvettes/replacement frequency	Yes/24 h	No
Min. sample vol. aspirated precisely at once/min. dead vol.	2 µL/75 µL w/ 1 mL sample cup	5 µL/100 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	No/no
Requires dedicated water system/water consumption	No/n/a	No/n/a
Noise generated	—	<70 decibels w/in 1 meter
Has dedicated pediatric sample cup/dead vol.	Yes/30 µL	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/multiple/no	Yes/13 x 75 & 100, 16 x 75 & 100, 2 mL & 3 mL sample cups/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes/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 (auto countdown)/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	Yes/no	No/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	No/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	30 sec.	n/a
Autocalibration or autocalibration alert	No	No
No. of calibrators required for each analyte	6	6
Calibrants can be stored onboard/avg. calibration frequency	No/varies by assay, generally 60 d	No/28 d
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/yes
How often QC required	Shortest interval: each shift, longest: 24 h	24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/3 min., generally remains on	No/no/remains in ready mode
Stat time to completion of ß-hCG test	38 min.	15 min.
Time delay from ordering stat test to aspir. of sample	30 sec.	36 sec.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	40/120 (30 sec.)	33/100 (36 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	Onboard/no	Onboard/yes (incl. or addt'l cost—negotiable)
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, HBOC, Citation, Soft, Dawning, Antrim, Dynamic Healthcare, Data Innovations (all major vendors)	All major LISs
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
Interface available (or will be) to auto specimen handling system	Yes (Advia LabCell, Lab Interlink)	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/—/—	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	—	No
On-site response time of service engineer	4 h	24 h max., usually w/in 6 h
Mean time between failures/time to repair failures	4 mos./2 h	Not avail./not avail.
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	No daily maintenance	Daily: 15 min., weekly: 30 min., monthly: none
Onboard maintenance records/maintenance training demo module	No/no	Yes/no
List price/targeted bed size or daily volume	$139,000/≥50 tests per d	$129,800/all vols. & hospital sizes
Annual service contract cost (24h/7d)	—	$14, 800
Training provided w/ purchase/advanced operator training	Varies on site, 5 d at vendor offices/yes	4 d at vendor offices/yes
Distinguishing features	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	Cont. random access benchtop analyzer; state-of-the-art chemiluminescence methodology; ease of use: any test, any tech, any time; superior assays: TSH, FT_4, UE_3, Hybritech PSA, fPSA, trop. I, B_{12}, fol.

Automated immunoassay analyzers

Part 5 of 17	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	Access 2 Immunoassay System/2001/U.S.	DSX Automated System/2000/Guernsey, U.K.
Country where manufactured/where reagents manufactured	U.S./U.S. & France	U.S.A./U.K.
No. of units in clinical use in U.S./outside U.S.	—/—	<10/>40
Operational type/model type/sample handling system	Cont. random access/benchtop/rack	Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	18.5 x 39 x 24 in./8 sq. ft.	32 x 42 x 36 in./7 sq. ft.
Tests available on instrument in U.S.	Same as Access	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	Same as Access	None
Tests not available in U.S. but submitted for clearance	Same as Access	None
Tests not available in U.S. but available in other countries	Same as Access	Open system—any ELISA
Research-use-only assays	None	Open system
Tests in development	Same as Access	Phosphatidyl serine IgG, IgA, IgM, mitochondrial M2, SMA, LKM
User-defined methods implemented for what analytes	None	Open system
Tests not available on other manufacturers' analyzers	Same as Access	Open system
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	Min. 1 x 8; max. full plate 96 x 4 plates
Methods supported/separation methods	Chemiluminescence/magnetic particle	Enzyme immunoassay/coated microwell
No. of different measured assays onboard simultaneously	24	12 assays per plate
No. of different assays programmed, calibrated at once	24	Unlimited
No. of user-definable (open) channels	0	Unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	24/100 tests per kit, 50 tests per cartridge	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.	No
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/≤ 3 ppm	Yes/0
Walkaway capacity in min./specimens/tests-assays	180/60/300	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	No	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 (when networked)/no	Yes/no
Requires dedicated water system/water consumption	No	No
Noise generated	<70 decibels within 1 meter	—
Has dedicated pediatric sample cup/dead vol.	Yes/100 µL	Yes/50 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no	Yes/various/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, code 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	No/yes	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/yes	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
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 realtime 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 ß-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.)	n/a —
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—negotiable)	Onboard/yes (additional)
Interfaces up and running in active user sites with	All major LIS vendors	In development
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 (host query)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/yes	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	24 h max, usually within 6 h	Within 24 h
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	Daily: 15 min.; weekly: 30 min.; monthly: none	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	$149,800/all volumes & hospital sizes	$45,000/200+ beds
Annual service contract cost (24h/7d)	$15,800	Varies
Training provided w/ purchase/advanced operator training	4 d at venor offices/yes	3 d on-site, 2–3 d at vendor 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.	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.

Automated immunoassay analyzers

Part 6 of 17	BioChem ImmunoSystems (U.S.) Inc. Elaine Soltes (biochemUS3@aol.com) 754 Roble Rd., Ste. 70 Allentown, PA 18103 610-264-0885 www.biochem-pharma.com	BioChem ImmunoSystems (U.S.) Inc. Elaine Soltes (biochemUS3@aol.com) 754 Roble Rd., Ste. 70 Allentown, PA 18103 610-264-0885 www.biochem-pharma.com
Name of instrument/first year sold/where designed	Labotech/1996/Italy	PersonalLAB/1998/Italy
Country where manufactured/where reagents manufactured	Italy/n/a (open system)	Italy/n/a (open system)
No. of units in clinical use in U.S./outside U.S.	300/3,400	200/>400 worldwide
Operational type/model type/sample handling system	Batch/benchtop/rack	Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	20 x 34.5 x 20 in./4.8 sq. ft.	24 x 26 x 25.6 in./4.6 sq. ft.
Tests available on instrument in U.S.	Sm/RNP, Sm, SS-A & -B, Jo-1, Scl 70, ENA scr., TPO, antithyroglob., thyroglob., mitochond. M2, histone, ssDNA, dsDNA, MPO (p-ANCA), PR3 (C-ANCA), RF IgM, RF/3 (IgG, IgM, IgA), rubella IgG & IgM, rubeola IgG & IgM, toxo IgG & IgM, VZV IgG & IgM, mumps G, CMV IgG & IgM, HSV I/II IgG & IgM, EB VCA IgG & IgM, EBNA IgG, EA, syph. IgG & IgM, chlam. (Ab&Ag), Lyme IgG & IgM, Legion. (Ab&Ag), *H. pylori* IgG, parvovirus IgG & IgM, HAV IgG & IgM, HBCore IgG & IgM, HBe (Ag&Ab), HBsAb, HBsAg, *C. diff.* tox A, giard., cand. (IgG, IgM, IgA), mycoplas. IgG & IgM, *E. histolytica*, prot. C Ag, prot. S total, VWF Ag, anticardiolip. (IgG, IgM, IgA) & scr., amph., barbit., benzodiazep., cocaine, cotinine, LSD, metham., morph., opiates, PCP, THC, DHEAS, estrad., progest., testost., CRP	Same as Labotech
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	None	None
Tests not available in U.S. but available in other countries	None	None
Research-use-only assays	None	None
Tests in development	None	None
User-defined methods implemented for what analytes	Open platform	Open platform
Tests not available on other manufacturers' analyzers	n/a (open platform)	n/a (open platform)
Fully automated microplate system	Yes	Yes
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	Min. strip: 8; max. full plate: 96	Min. strip: 8; max. full plate: 96
Methods supported/separation methods	EIA/coated microplate, varies acc. to kit mftr.	EIA/coated microplate, varies acc. to kit mftr.
No. of different measured assays onboard simultaneously	8 (3 plates)	6 (2 plates)
No. of different assays programmed, calibrated at once	500	500
No. of user-definable (open) channels	500	500
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	8/96 (3 plates)	6/96 (2 plates)
Shortest/median onboard reagent stability/refrigerated onboard	Mftr. dependent/no	Mftr. dependent/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	No, requires operator prehandling/prep.	No, requires operator prehandling/prep.
Reagents bar-coded/information in bar code	No	No
Same capabilities when 3rd-party reagents used/susceptibility to carryover	Yes/zero carryover option	Yes/zero carryover option
Walkaway capacity in min./specimens/tests-assays	—/96-8/8	—/96-6/6
System is open (home-brew methods can be used)/liquid or dry system	Yes/—	Yes/—
Uses disposable cuvettes/max. no. stored	Yes/288-3 plates	Yes/192-2 plates
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/200 µL	10 µL/200 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	Yes/no
Requires dedicated water system/water consumption	No/n/a	No/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/11 x 55–16 x 100 mm/no	Yes/16 x 100–11 x 55 mm/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/—	Yes (2 of 5 interl., codabar, codes 39 & 128)/—
Bar code placement per NCCLS standard Auto2A	—	—
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	No/yes	No/yes
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	Yes/yes (mftr. & assay dependent)	Yes/yes (mftr. & assay dependent)
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	n/a	n/a
No. of calibrators required for each analyte	Mftr. & assay dependent	Mftr. & assay dependent
Calibrants can be stored onboard/avg. calibration frequency	—/mftr. & assay dependent	—/mftr. & assay dependent
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/—	Yes/—
How often QC required	Mftr. & assay dependent	Mftr. & assay dependent
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	No/n/a
Automatic shutdown/startup is programmable/startup time	No/no/5 min.	No/no/5 min.
Stat time to completion of ß-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)	n/a	n/a
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 (incl. in price)	Onboard/yes (incl. in price)
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/ running assays	Yes	Yes
Uses LOINC to transmit orders and results	—	—
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	No	No
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	Within 24 h	Within 24 h
Mean time between failures/to repair failures	—/<24 h	—/<24 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 6–10 min., weekly: 10 min., monthly: 15 min.	Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
Onboard maintenance records/maintenance training demo module	Yes/no	Yes/no
List price/targeted bed size or daily volume	$64,500/>100 beds	$38,000/>100 beds
Annual service contract cost (24h/7d)	Depends on acquisition option	Depends on acquisition option
Training provided w/ purchase/advanced operator training	3–5 d on-site/yes	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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 7 of 17	bioMérieux Inc. Jean-Christophe Daniel (jean-christophe_daniel@na.biomerieux.com) 595 Anglum Rd. Hazelwood, MO 63042-2320 314-506-8087 or 800-638-4835 ext. 8087 www.biomerieux.com	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
Name of instrument/first year sold/where designed	Vidas & MiniVidas/1989/U.S.	Coda/ex U.S. late 1996, U.S. 1997/Japan
Country where manufactured/where reagents manufactured	U.S., Italy/U.S., France	Japan/U.S., U.K., France, Korea, Australia
No. of units in clinical use in U.S./outside U.S.	1,500/>12,000	—/—
Operational type/model type/sample handling system	Batch, random access/benchtop/n/a	Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	Vidas: 16 x 32 x 21 in.; MiniVidas: 21 x 21 x 17 in./Vidas 4.5, MiniVidas 4 sq. ft.	21.6 x 39.5 x 26 in./7.13 sq. ft.
Tests available on instrument in U.S.	Same for both instruments: *C. diff.* toxin A, chlam. Ag, chlam. blocking, RSV, rotavirus, rubella IgG, toxo competition (IgG/IgM), measles IgG, mumps IgG, varicella IgG, Lyme (IgG/IgM), TSH, FT_4, T_4, T-uptake, T_3, hCG, estradiol, FSH, LH, prolac., progest., ferr., cortisol (serum & urine), total IgE, CK-MB, digoxin, theoph., *H. pylori* IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer	Newborn screening—contact Bio-Rad representative
Tests cleared but not clinically released	None	Contact Bio-Rad representative
Tests not available in U.S. but submitted for clearance	PSA	—
Tests not available in U.S. but available in other countries	HBsAg, anti-HBs total, anti-HBc IgM, anti-HBc total, HBeAg, anti-HBe, HAV IgM, anti-HAV total, HIV 1/2, HIV P24II, HIV DVO, tox IgG avidity, testosterone	Contact Bio-Rad representative
Research-use-only assays	None	n/a
Tests in development	Amplified *C. trach.*, amplified *N. gonorr.*, combo. CT/NG, amplified *M. tuberc.*, quant. HIV-1 RNA, myoglobin, trop. I	—
User-defined methods implemented for what analytes	None	STC drugs of abuse, Ostex Ntx, DSL assays—contact companies represented
Tests not available on other manufacturers' analyzers	Quant. D-dimer, *C. difficile* toxin A, Lyme IgG/IgM, VZG, mumps IgG, measles IgG	—
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit	One test per strip	—
No. of wells in microplate	n/a	Min. strip: 1 sample; max. full plate, 96
Methods supported/separation methods	Fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device	EIA/Coated microwell & noncoated microwell
No. of different measured assays onboard simultaneously	Vidas: 30, MiniVidas: 12	9
No. of different assays programmed, calibrated at once	Total menu	9
No. of user-definable (open) channels	0	Unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	Unit dose format/30 or 60	9 assays, 24 containers/288 tests
Shortest/median onboard reagent stability/refrigerated onboard	n/a/n/a/no	n/a/n/a/no
Multiple reagent configurations supported	No	Yes
Reagent container placed directly on system for use	Yes	Requires operator prehandling/preparation
Reagents bar-coded/information in bar code	Yes/assay name, lot no., sequence no., expir.	No
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/zero carryover	No/reduced w/software version 4.0 & updated firmware. Depends on amount of washing
Walkaway capacity in min./specimens/tests-assays	Assay dependent/12-30/12-30	Varies by assay/90-270/up to 9
System is open (home-brew methods can be used)/liquid or dry system	No/dry	Yes/liquid, reconst. onboard
Uses disposable cuvettes/max. no. stored	No	No (yes for dils.)
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	100 µL/n/a	10 µL/200 µL, 130 µL in microtubes
Supplied with UPS (backup power)/requires floor drain	Yes/no	Optional/no
Requires dedicated water system/water consumption	No/no	No/—
Noise generated	—	n/a
Has dedicated pediatric sample cup/dead vol.	No	Yes/130 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	No/n/a/no	Not claimed, but some users have validated for their own use/—
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	n/a	No
Onboard test auto inventory (determines vol. in container)	n/a	No
Measures no. of tests remaining/short sample detection	No/no	No/yes
Auto detection of adequate reagent or specimen	No	No
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	No/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	n/a	—
Autocalibration or autocalibration alert	Yes	No
No. of calibrators required for each analyte	1	1–6
Calibrants can be stored onboard/avg. calibration frequency	No/14 d	No/most assays require calib. w/ each run, some as long as 2 weeks w/ 1 & 2 pt. updates
Multipoint calib. supported/multiple calibs. stored for same assay	No (mftr.-determined calib. curves)/yes	Yes/yes
How often QC required	Shortest interval: 8 h, longest: 24 h	Shortest interval: user determined, longest: w/in run recommended
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes (late 2000 through Unity QC program)
Automatic shutdown/startup is programmable/startup time	No/no/remains ready	For hardware/6 min.
Stat time to completion of ß-hCG test	30 min.	n/a
Time delay from ordering stat test to aspir. of sample	No delay	n/a
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	Vidas: 20, MiniVidas: 8/Vidas: 60, MiniVidas: 24 (—)	~90 tests per h w/ all results in approx. 3 h (assay dependent)/(protocol specific)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	Yes/yes (not yet tested)
Data management capability/instrument vendor supplies LIS interface	Onboard/yes (addt'l cost)	Onboard/customer acquires through LIS company, can be added to contract
Interfaces up and running in active user sites with	Sunquest, Meditech, HBOC (Saint), Advanced Lab Systems (Path Lab), Cerner, Citation, SCC, SMS, SAIC/CHCS, CompuLab, Antrim, Dawning, Genesys (Dynamedix), Data-Innovations, call technical support for others	Homegrown systems, Cerner, Dawning, & Sunquest under development
LIS interface operates simultaneously w/ running assays	Yes	Not possible on batch analyzer
Uses LOINC to transmit orders and results	No	No
Bidirectional interface capability	Yes (broadcast download)	Yes (broadcast download)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/yes	No/no/no
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	w/in 24 h	24 h
Mean time between failures/to repair failures	Vidas: 350 d, MiniVidas: 1,000 d/<2 h	—/4 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 10–15 min., weekly: 10–15 min., monthly: 30 min.	Daily: 5 min., weekly: 20 min., monthly: 20 min.
Onboard maintenance records/maintenance training demo module	Yes/yes	No/no
List price/targeted bed size or daily volume	Vidas: $50,300, MiniVidas: $27,300/≤400 beds	$48,000/50–350 beds, 4–6 plates per d
Annual service contract cost (24h/7d)	$2,340–$4,680 (Mini–Vidas 30)	$4,800
Training provided w/ purchase/advanced operator training	As needed on-site, 3 d at vendor offices/yes	As needed on-site, 3 d at vendor offices/—
Distinguishing features	Unique dual-function combination solid phase & pipetting device (SPR); ability to perform immunoassay & amplified probe assay (in development) on same platform; assay menu mix (antigen detection, serology, fertility, thyroid, endocrine, coagulation) makes Vidas the ideal instrument for routine batch testing as well as emergency stat testing	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

Automated immunoassay analyzers

Part 8 of 17	Dade Behring Inc. Christine Larriva P.O. Box 6101 Newark, DE 19714-6101 302-631-0440 www.dadebehring.com	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 www.dadebehring.com
Name of instrument/first year sold/where designed	Opus Plus/1992/U.S.	Stratus CS Stat Fluorometric Analyzer/1998/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.	2,000/300	395/200
Operational type/model type/sample handling system	Batch, random access, cont. random access/benchtop/rectangular tray	Random access/benchtop/whole blood collection tube
Dimensions (H x W x D)/instrument footprint	16.6 x 34.5 x 23 in./5.5 sq. ft.	18 x 27 x 22 in./4.1 sq. ft.
Tests available on instrument in U.S.	Digoxin, digitoxin, theoph., gentamicin, tobramycin, vancomycin, phenobarb., phenytoin, valp. acid, carbamazep., T_4, TSH, T-uptake, FT_4, TT_3, hCG, β-hCG, myogl., CK-MB, trop. I, CEA, PSA, ferr.	Mass CK-MB, trop. I, myoglobin, β-hCG
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	None	None
Tests not available in U.S. but available in other countries	None	None
Research-use-only assays	None	None
Tests in development	None	High-sensitivity CRP, D-dimer
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	None	None
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	1 test per test module	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	Fluorescence, EIA/none (all assays homogeneous)	Fluorescence, EIA, dendrimer technology/fiber matrix filter
No. of different measured assays onboard simultaneously	23	Up to 4
No. of different assays programmed, calibrated at once	23	1
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	20/50 per box	n/a/unit dose test packs
Shortest/median onboard reagent stability/refrigerated onboard	n/a/n/a/no	n/a/n/a/no
Multiple reagent configurations supported	No	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/lot no.	Yes/assay ID, lot no., expir., calib. param.
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/zero carryover–new tip for each pipetting	No/zero carryover
Walkaway capacity in min./specimens/tests-assays	Assay dependent/20/20	13 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	No/dry	No/liquid
Uses disposable cuvettes/max. no. stored	No	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/80 µL	—/—
Supplied with UPS (backup power)/requires floor drain	No/no	No/no
Requires dedicated water system/water consumption	No/n/a	No/n/a
Noise generated	n/a	<65 decibels
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	No/n/a/no	Yes/4 or 5 mL/yes
Sample bar-code reading capability/autodiscrimination	Yes w/ optional bar-code wand (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
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	Yes	Yes
Clot detection/reflex testing capability	No/no	Yes/yes
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	—	n/a
Autocalibration or autocalibration alert	No	Yes
No. of calibrators required for each analyte	6 for most assays, 5 for digox., 3 for T-uptake	1 Calpak
Calibrants can be stored onboard/avg. calibration frequency	No/assay dependent, recalibrate when QC on	No/every 60 d—same lot, new lot
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/no	Yes/yes
How often QC required	Every 24 h	Shortest interval: daily system check, longest: every 60 d for liquid controls
Onboard realtime QC/support multiple QC lot nos. per analyte	—/—	Yes/no
Automatic shutdown/startup is programmable/startup time	No/no/remains on	No/no/30 min. to warm up
Stat time to completion of ß-hCG test	17 min.	n/a
Time delay from ordering stat test to aspir. of sample	Assay dependent	Instantly
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	Assay dependent	—/9 (—)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/no	Yes/yes
Data management capability/instrument vendor supplies LIS interface	No/no	No/yes (incl. in price)
Interfaces up and running in active user sites with	—	Cerner, Sunquest
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)	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/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	—
Mean time between failures/to repair failures	15 mos./4 h once field svc. rep. on site	—/—
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 5 min., weekly: 15 min., monthly: 5 min.	Daily: 5 min., weekly: none, monthly: 10 min.
Onboard maintenance records/maintenance training demo module	No/no	No/—
List price/targeted bed size or daily volume	$50,000/≤1,000 beds	$50,000/stat locations
Annual service contract cost (24h/7d)	$4,700 (8–5, M/F)	$6,094
Training provided w/ purchase/advanced operator training	Training on-site at install./no	3 d on-site/no
Distinguishing features	Low maintenance; no liquid waste; self-contained tests allow different analytes to be tested 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 9 of 17	Dade Behring Inc. Suzanne Carrillo P.O. Box 6101, Newark, DE 19714-6101 302-631-0433 www.dadebehring.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	Dimension RxL Chemistry System with Heterogeneous Module (HM)/1997/U.S.	IMMULITE/1993, IMMULITE Turbo/1999/U.S.
Country where manufactured/where reagents manufactured	U.S./U.S.	U.S./U.S., U.K.
No. of units in clinical use in U.S./outside U.S.	600/300	5,000 worldwide
Operational type/model type/sample handling system	Batch, random access, cont. random access/floor-standing/segmented sample wheel	Cont. random access/benchtop/loading platform
Dimensions (H x W x D)/instrument footprint	44 x 62.5 x 30.5 in./13.2 sq. ft.	16 x 42 x 24.75 in. (w/o computer)/7.2 sq. ft.
Tests available on instrument in U.S.	TSH, T-uptake, T_4, ß2 microglob., CRP, hCG, FSH, LH, prolac., PSA, no pretreatment digox., amikacin, carbamazep., digox., ethosuximide, gentamicin, lidocaine, methotrexate, NAPA, phenobarb., phenytoin, primidone, procainamide, quinidine, theoph., tobramycin, valp. acid, vancomycin, acetamin., ethyl alcohol, salicylate, serum & urine barbit., serum & urine benzodiazep., serum tricyc. antidepress., urine amphet., cannab., cocaine metab., methadone, opiate, phencyclidine, carbon dioxide, chloride, FT_4, ferr., IgG, IgM, IgA, no pretreat. HDL. Also coagulation, enzymes, general chemistry tests, CK-MB, trop. I, myoglobin, high-sens. CRP	AlaTOP allergy scr., allergy food panel FP5E, cat- & dog-specific IgE, latex- & mite-specific IgE, total IgE, EPO, ferr., fol. acid, B_{12}, intact PTH, Pyrilinks-D, cannab., cocaine metab., 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., sex horm. binding glob., 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, ß2-microgl., cortisol, HsCRP, hGH. Turbo menu: CK-MB, myoglob., intact PTH, trop. I, hCG, albumin, *H. pylori*
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	Amphet., barb., benz., cocaine, metham., opiates, PCP, THC	None
Tests not available in U.S. but available in other countries	None	Animal & grass allergy, ECP, mold, tree & weed allergy, osteocalcin, cytokines, nicotine metab., anti-HBc (& IgM), anti-HBs, HBsAg & confirm., rubella IgM, toxo IgM, free βhCG, BR-MA, cytoker. 18, GI-MA, fPSA, TPS, andost., EBV, cytokeratin 19, gastrin, NSE, *H. pylori* IgA
Research-use-only assays	None	None
Tests in development	CSA, C3, C4, digitox., IBC, transferrin., equimolar PSA	ANA scr., *C. diff.*, calcitonin, chagas, CMV IgM, dsDNA Ab, bladder tumor fibronec., anti-HBe, HBeAg, hep. A, IGF BP3, IGF-1, Lyme IgG & IgG/IgM
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	Only system to perform heterogeneous immunoassays & general assays on a single platform	3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, latex-specific IgE, SHBG, TBG, EPO, canine TSH, thyroglob., intact PTH, ACTH. Turbo: intact PTH
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles	Chemiluminescence/bead, centrifugation
No. of different measured assays onboard simultaneously	48 (95 with optional inventory management system)	12; Turbo: 5
No. of different assays programmed, calibrated at once	67	Unlimited; Turbo: 5
No. of user-definable (open) channels	10	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	44–88/max. 240	12/100 or 500; Turbo: 50 for intact PTH only
Shortest/median onboard reagent stability/refrigerated onboard	24 h open well–30 d unopened reag./72 h open well, 30 d unopened/yes (2–8°C)	n/a/30 d/yes (15°C)
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	—	Yes
Reagents bar-coded/information in bar code	Yes/sample ID no., patient name, medical record no., tests	Yes/test, lot #, expir.
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/≤.130 ppm	No/<10 ppm
Walkaway capacity in min./specimens/tests-assays	—	100/—/ 70
System is open (home-brew methods can be used)/liquid or dry system	No/reconstitutes onboard	No/liquid
Uses disposable cuvettes/max. no. stored	Yes/12,000	Yes/n/a
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	2 µL/—	5µL/100µL
Supplied with UPS (backup power)/requires floor drain	Yes/yes	Yes/no
Requires dedicated water system/water consumption	Yes/3.2 L per h	No/0.5 L per h
Noise generated	<70 decibels	55 decibels min., max. 68
Has dedicated pediatric sample cup/dead vol.	Yes/10 µL–20 µL	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/5, 7, 10 mL/no	No/n/a/—
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	—
Onboard test auto inventory (determines vol. in container)	Yes	No
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	No/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/yes	No/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	Yes/yes	No/no
Time between initial result & reaspiration of sample for rerun	Immediately after 1st result	n/a
Autocalibration or autocalibration alert	Yes	No
No. of calibrators required for each analyte	Varies—3 levels for most assays	2-level adjustors, supplied in kit
Calibrants can be stored onboard/avg. calibration frequency	Yes/15–90 d	No/1–4 weeks (assay dependent); Turbo: 2 wks
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	No/yes
How often QC required	24 h	Customer determined
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	No/yes
Automatic shutdown/startup is programmable/startup time	No/no/2 min. tech time, 5 min. instrument time	No/no/5 min.
Stat time to completion of ß-hCG test	16 min.	42 min; Turbo: 15 min.
Time delay from ordering stat test to aspir. of sample	24 sec.	2.5 min.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	—	40/120 (—)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	No/yes
Data management capability/instrument vendor supplies LIS interface	Optional add-on (DataFusion System Integrator–Dade Behring)/yes (addt'l cost)	Onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	Sunquest, Cerner, LabNet, HBOC, SMS, Meditech	Sunquest, Cerner, Citation, ALG, CHC, DynaMedix, Antrim, Antek, CSS
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 (Lab Track)	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/yes	No/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	2–8 h	4 h
Mean time between failures/to repair failures	—/—	8 mos./4 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 2 min., weekly: 2 min., monthly: 15 min.	Daily: 5 min., weekly: 10 min., monthly: 20 min.
Onboard maintenance records/maintenance training demo module	Yes/no	No/yes
List price/targeted bed size or daily volume	$239,400 with HM—$209,500 without/400+ beds	$75,000; Turbo: $77,500/>1,000 tests per mo.
Annual service contract cost (24h/7d)	$16,790	$7,500
Training provided w/ purchase/advanced operator training	2 d on-site, 4 d at vendor offices/yes	3.5 d at vendor offices/no, in development
Distinguishing features	Only instrument available that integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95% of most requested tests; eliminates sample splitting between general tests & immunoassays	System performance reliability; worldwide user satisfaction; breadth of immunoassay menu

Automated immunoassay analyzers

Part 10 of 17	Diagnostic Products Corp. Joe Kelly (jkelly@dpconline.com) 5700 W. 96th St., Los Angeles, CA 90045-5597 310-642-5180 www.dpcweb.com	Diamedix Corp. Pat Ahmad (pat_ahmad@ivax.com) 2140 North Miami Ave., Miami, FL 33127 305-324-2300 or 800-327-4565
Name of instrument/first year sold/where designed	Immulite 2000/1998/U.S.	Mago Plus Automated EIA Analyzer/1997/Italy
Country where manufactured/where reagents manufactured	U.S./U.S.	Italy/U.S.
No. of units in clinical use in U.S./outside U.S.	650 worldwide	—/—
Operational type/model type/sample handling system	Cont. random access/floor-standing/rack	Batch, random access/benchtop/2 racks, 120 samples total
Dimensions (H x W x D)/instrument footprint	79 x 60 x 30/12.5 sq. ft.	28 x 48 x 26 in./8.7 sq. ft., incl. onboard computer, reagents, spectrophotometer
Tests available on instrument in U.S.	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., sex horm. binding glob., 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)., *H. pylori* IgG, rubella IgG, toxo IgG, troponin I, CK-MB PAP	Toxo IgG, toxo IgM capture, rubella IgG, rubella IgM capture, CMV IgG, CMV IgM capture, HSV I & II IgG & IgM, measles IgG, VZV IgG, EBV-VCA IgG & IgM, EBNA-1 IgG & IgM, EBV-EA-D IgG & IgM, anti-*B. burgdorferi* IgG/IgM & IgM, mumps IgG, *H. pylori* IgG, mycoplasma IgG, anti-SSA/Ro, anti-SSB/La, anti-Sm, anti-Sm/RNP, anti-Scl-70, anti-Jo-1, anti-dsDNA, RF, ENA-6 scr., ANA ELISA scr., anti-MPO, anti-PR-3, anti-TPO, anti-TG
Tests cleared but not clinically released		None
Tests not available in U.S. but submitted for clearance	Herpes I & II IgG	None
Tests not available in U.S. but available in other countries	Anti-HBc (& IgM), anti-HBs, HBsAg & confirm., rubella IgM, BR-MA, fPSA, toxo IgM, GI-MA	Toxo IgA, CMV scr., herp. simpl. 1 IgG, 2 IgG, syph. scr., IgG & IgM, *H. pylori* IgA, VZV IgM cap., measles & mumps IgM cap., AMA-M2, anti-ribosomal, β2-microgl., α1-microgl., microalbum., anti-insul., ferr., IC-C1q, anti-LKM-1, anti-PCA/intrinsic factor, anti-RNA, anti-glom. basement memb., anti-cardio. scr., IgG or IgM, IgA, anti-β glycopr. 1 IgG or IgM, anti-ssDNA, anti-histone anti-BPI, anti-elastase, anti-cathepsin, anti-lysozyme, anti-lactoferrin, anti-gliadin IgG & IgA, anti-β-lactogl., anti-α-lactalbumin, anti-soya, centromere, transglutaminase IgA, RF(IgA), adenovirus IgG/IgM, brucella IgA, IgG, IgM, chlamydia pneu. IgA, IgM, IgG, mycop. IgM, IgG/IgM, RSV IgG/IgM, tetanus IgG, and others
Research-use-only assays	None	None
Tests in development	Digox., gentamycin, anti-HBe, HBeAg, allergen-specific IgE, tobramycin, ANA screen, Chagas, CMV IgG avidity, dsDNA, EBV, HAV total, HAV IgM, *H. pylori* IgA, Lyme screen, rubella IgG avidity, theophylline, toxo IgG avidity, vancomycin	Anti-cardio. scr., anti-cardio. IgG, IgM, IgA, anti-β-2-glycopr. scr., anti-β-2-glycopr. IgG, IgM, IgA, anti-gliadin IgG & IgA, mycoplasma IgG
User-defined methods implemented for what analytes	None	Programmed by customer at customer location
Tests not available on other manufacturers' analyzers	TBG, thyrogl., SHBG, intact PTH, C-peptide, 3rd-gen. PSA	Assays designed/FDA cleared for this analyzer; tests can be validated on other anals.
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit	n/a	Usually 1 analyte per well; multiple analytes per well in screen tests
No. of wells in microplate	n/a	Min. strip: 8 or less (breakapart wells), max. full plate: 96, up to 4 plates simul.
Methods supported/separation methods	Chemiluminescence/bead, centrifugation	EIA/microtiter
No. of different measured assays onboard simultaneously	24	9
No. of different assays programmed, calibrated at once	Unlimited	35 tests preprogrammed, ready for use
No. of user-definable (open) channels	n/a	20
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	24/200 or 600	9/96
Shortest/median onboard reagent stability/refrigerated onboard	n/a/90 d/yes (4°C)	>16 h/6 d/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/test, lot no., expir.	Available/kit lot no., exp. date
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/<10 ppm	Yes/not susceptible to carryover, has continuous internal cleaning
Walkaway capacity in min./specimens/tests-assays	Cycle dependent/90/500	Varies from 150 min.–240 min./9 tests & 384 results per run
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	Yes/1,000	Yes/120
Uses washable cuvettes/replacement frequency	No	No/n/a
Min. sample vol. aspirated precisely at once/min. dead vol.	5μL/50μL	4 μL/100 μL
Supplied with UPS (backup power)/requires floor drain	Yes/no	Yes/no
Requires dedicated water system/water consumption	No/1.5 L per h	No/n/a
Noise generated	52 decibels	—
Has dedicated pediatric sample cup/dead vol.	Yes/50 μL	Possible–can use 1.5 mL vial/100 μL
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/12 x 75 & 100; 13 x 75 & 100; 16 x 75 & 100 mm/no	Yes/up to 16 x 100/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	—
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	No/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/yes	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	Min. 18 sec.	n/a
Autocalibration or autocalibration alert	Yes	No
No. of calibrators required for each analyte	2 level adjustors, supplied in kit	Varies: 2 (single point curve tests), 6 (6 pt. curve tests), 3 (3 pt. curve tests)
Calibrants can be stored onboard/avg. calibration frequency	No/1–4 weeks (assay dependent)	Yes/every run
Multipoint calib. supported/multiple calibs. stored for same assay	No/yes	Yes/no
How often QC required	Cutomer determined	Each run
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/5 min.	Yes/yes/<5 min.
Stat time to completion of ß-hCG test	35 min.	n/a
Time delay from ordering stat test to aspir. of sample	18 sec.	< 15 min. set-up time
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	67/200 (—)	120/360 (~4 h)
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 (addt'l cost)	Onboard/yes (addt'l cost)
Interfaces up and running in active user sites	Sunquest, Cerner, HBOC, CCA, ALG	Cerner
LIS interface operates simultaneously w/ running assays	Yes	No
Uses LOINC to transmit orders and results	No	Yes
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 (universal interface)	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/no	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	6 h	w/in 24 h
Mean time between failures/to repair failures	2 mos./5 h	—/—
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 5–10 min., weekly: none, monthly: 20–30 min.	Daily: 3 min., weekly: 5 min., monthly: none
Onboard maintenance records/maintenance training demo module	No/yes	No/no
List price/targeted bed size or daily volume	$124,500/>2,000 tests per month	$55,000/all bed sizes, all test vols.
Annual service contract cost (24h/7d)	$12,500	Incl. in reagent rental
Training provided w/ purchase/advanced operator training	3.5 d at vendor offices/no, in development	1–2 d on site/as needed
Distinguishing features	Reflex testing; programmable out-of-range autodil.; sample-saver clot detection; customized, icon-driven, Windows-based SW; remote diag.; training-onboard, animated tutorial & interactive training CD; multirule QC SW with graphing capability; max. onboard reag. capacity for walkaway effic.; min. waste; uninterrupted test processing when replacing or changing system reag., fluids, consumables	Immunosimplicity reagent manufactured & 510(k) cleared specifically on MAGO Plus; can test 120 samples in 9 simultaneous assays on 4 microplates; reag. color-coded for ease in ID; containers ready-to-use; sample rack holds 120 samples & 120 dil. cups; user-friendly SW allows for rapid training; continual on-screen display; personalized reports by single test or profile

Automated immunoassay analyzers

Part 11 of 17	DiaSorin Inc. Gary Tremain (gary.tremain@diasorin.com) 1990 Industrial Blvd. Stillwater, MN 55082 800-328-1482 www.diasorin.com	DiaSorin Inc. Gary Tremain (gary.tremain@diasorin.com) 1990 Industrial Blvd. Stillwater, MN 55082 800-328-1482 www.diasorin.com
Name of instrument/first year sold/where designed	ETI-Lab/1996/Italy	Omni/1996/U.S
Country where manufactured/where reagents manufactured	Italy/U.S., Italy	U.S./U.S., Italy
No. of units in clinical use in U.S./outside U.S.	60/550	35/70
Operational type/model type/sample handling system	Batch/benchtop/rack	Batch/benchtop/pipetting station
Dimensions (H x W x D)/instrument footprint	24 x 34.5 x 20 in./4.8 sq. ft. + computer	24 x 56 x 25 in./9.7 sq. ft. + pipetting station + 2 computers
Tests available on instrument in U.S.	HBsAg, anti-HBs, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anti-HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-IgG, CMV-IgG, CMV-IgM, HSV I-IgG, HSV II-IgG, HSV I/II-IgG, rubeola-IgG, mumps-IgG, VZV IgG, MP IgG, *H. pylori* IgG, Lyme IgG & IgM, syphilis IgG, syphilis IgM, ANA scr., anti-dsDNA, anti-SSA, anti-SSB, anti-Sm, anti-RNP/Sm, anti-Scl-70, anti-Jo-1, anti-histone, anti-cardiolipin	HBsAg, anti-HBs, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anti-HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-IgG, CMV-IgG, CMV-IgM, HSV I-IgG, HSV II-IgG, HSV I/II-IgG, rubeola-IgG, mumps-IgG, VZV IgG, MP IgG, *H. pylori* IgG, Lyme IgG & IgM, syphilis IgG, syphilis IgM, ANA scr., anti-dsDNA, anti-SSA, anti-SSB, anti-Sm, anti-RNP/Sm, anti-Scl-70, anti-Jo-1, anti-histone, anti-cardiolipin
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	None	None
Tests not available in U.S. but available in other countries	None	None
Research-use-only assays	None	None
Tests in development	None	None
User-defined methods implemented for what analytes	n/a	n/a
Tests not available on other manufacturers' analyzers	n/a	n/a
Fully automated microplate system	Yes	Yes
No. of each analyte performed in separate disposable unit		
No. of wells in microplate	Min. strip: 8 wells in strip, 12 strips in plate; max. full plate: 96	Min. strip: 8 wells in strip, 12 strips in plate; max. full plate: 96
Methods supported/separation methods	EIA/coated microplate	EIA/coated microplate
No. of different measured assays onboard simultaneously	6	11
No. of different assays programmed, calibrated at once	6	11
No. of user-definable (open) channels	50	24
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	6/96	—/96
Shortest/median onboard reagent stability/refrigerated onboard	1/2 h/1 d/no	4 h/1 d/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	No, requires operator prehandling/prep.	Yes
Reagents bar-coded/information in bar code	No	Yes/reagent type
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/0 w/ disposable tips, wash volume dependent w/ washable tip	Yes/1 ppm
Walkaway capacity in min./specimens/tests-assays	Per batch	Per batch
System is open (home-brew methods can be used)/liquid or dry system	Yes/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	No	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/200 µL	10 µL/200 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	Yes/no
Requires dedicated water system/water consumption	No/< 1 L per h	No/< 1 L per h
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/10 mm, 14 mm/—	Yes/—/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/—	Yes (2 of 5 interl., codabar, codes 39 & 128)/—
Bar code placement per NCCLS standard Auto2A	—	—
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	No/no	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	No	No
No. of calibrators required for each analyte	—	Variable
Calibrants can be stored onboard/avg. calibration frequency	—/—	No/per batch
Multipoint calib. supported/multiple calibs. stored for same assay	—/—	Yes/no
How often QC required	Each batch	Each batch
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/no	Yes/no
Automatic shutdown/startup is programmable/startup time	No/—/15 min.	No/—/15 min.
Stat time to completion of ß-hCG test	n/a	n/a
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)	Varies by assay, up to 90 specimens per microtiter plate	Varies by assay, up to 90 specimens per microtiter plate
Can auto transfer QC results to LIS/onboard capability to review QC	No/yes	No/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/yes (incl. in price)	Onboard/no
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/ running assays	No	—
Uses LOINC to transmit orders and results	No	No
Bidirectional interface capability	No	Yes (broadcast download)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	—
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/no/no	No/no/no
Can order (via modem) malfunctioning part(s) w/o operator	No	—
On-site response time of service engineer	24 h	24 h
Mean time between failures/to repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	Yes	
Avg. time to complete maintenance by lab personnel	Daily: —, weekly: —, monthly: —	Daily: 20 min., weekly: 20 min., monthly: 1 h
Onboard maintenance records/maintenance training demo module	—/—	No/no
List price/targeted bed size or daily volume	$65,000/60–270 specimens per d	$70,000/≥250 specimens per d
Annual service contract cost (24h/7d)	n/a	n/a
Training provided w/ purchase/advanced operator training	5 d on-site/—	5 d on-site/5 d at vendor offices/—
Distinguishing features	Customized workflow analysis; complete service & support	Customized workflow analysis; complete service & support; supports 11 different microtiter plates simultaneously

Automated immunoassay analyzers

Part 12 of 17	Grifols-Quest Inc. John Medders (john.medders@grifols.com) 8880 NW 18th Terr. Miami, FL 33172 800-379-0957 www.grifols.com	Hycor Biomedical Inc. Dick Geiszler (dgeiszler@hycorbiomedical.com) 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com
Name of instrument/first year sold/where designed	Triturus/1999/Spain	Hy•Tec 288/ex U.S. 1998, U.S. 1999/Netherlands
Country where manufactured/where reagents manufactured	Spain/n/a	Netherlands/U.S., Germany, Scotland
No. of units in clinical use in U.S./outside U.S.	20/120	5/68
Operational type/model type/sample handling system	Batch/random access & cont. random access/benchtop/carrousel	Batch, random access/benchtop/rack-robotics
Dimensions (H x W x D)/instrument footprint	28.3 x 41.3 x 34.3 in./10 sq. ft.	29.5 x 42.5 x 27.5 in./8 sq. ft.
Tests available on instrument in U.S.	System is completely open, any EIA procedure can be programmed. Infectious diseases, autoimmune diseases, endocrinology, oncology markers, hepatitis and HIV profiles.	Specific IgE, total IgE, specific IgG, >900 allergens; ANA scr., TG, TPO, dsDNA, RF IgG, RF IgM, PR-3 ANCA, ENA-6 profile, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, cardiolipin scr.; user-definable software
Tests cleared but not clinically released	n/a	None
Tests not available in U.S. but submitted for clearance	n/a	RF IgA
Tests not available in U.S. but available in other countries	n/a	IgG, Basophil Histamine Release, cardiolipin IgA, cardiolipin IgA, IgG, IgM, ssDNA, HPO p-ANCA, mitochondrial, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM, CIC CIq, CIC C3d
Research-use-only assays	n/a	IgG
Tests in development	n/a	None
User-defined methods implemented for what analytes	n/a	*H. pylori*
Tests not available on other manufacturers' analyzers	n/a	Allergy & autoimmune testing on fully automated system, BHR
Fully automated microplate system	Yes	Yes
No. of each analyte performed in separate disposable unit	8	8
No. of wells in microplate	Min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time	96–min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells
Methods supported/separation methods	Enzyme immunoassay/coated microwell, onboard shaker, 4 individually temperature-controlled incubators	EIA, tube-based & microplate-based assays/cellulose disc & coated well
No. of different measured assays onboard simultaneously	1–8 tests on 1–4 plates	Varies by assay, up to 288 allergy or 8 autoimmune
No. of different assays programmed, calibrated at once	8 assays	Multiple
No. of user-definable (open) channels	Unlimited	Multiple
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	8/96	Varies, up to 8/200-allergy, 96-autoimmune
Shortest/median onboard reagent stability/refrigerated onboard	n/a/n/a/no	8 h/12 h/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Requires operator prehandling/preparation	Yes
Reagents bar-coded/information in bar code	No	No
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/<5 ppm	No/<1 part in 10,000
Walkaway capacity in min./specimens/tests-assays	180/92/8	Assay dependent/100/288
System is open (home-brew methods can be used)/liquid or dry system	Yes/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	No	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	2 µL/300 µL	10 µL–50 µL, assay dependent//100 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no but has external waste port to drain into sink or floor drain	Yes/no
Requires dedicated water system/water consumption	No/—	No/—
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	Yes/200 µL	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/12 x 75 mm, 13 x 85 mm/no	Yes/—/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)/n/a
Bar code placement per NCCLS standard Auto2A	Yes	No
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	Yes/yes	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	No	Yes
No. of calibrators required for each analyte	1–14	1–5
Calibrants can be stored onboard/avg. calibration frequency	No/n/a	No/monthly
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/no	Yes/yes
How often QC required	Each run	Every assay
Onboard realtime QC/support multiple QC lot nos. per analyte	No/no	Yes/yes
Automatic shutdown/startup is programmable/startup time	Yes/no/1–2 min	Yes/no/2–3 min.
Stat time to completion of ß-hCG test	System is open, depends on reagent methodology	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)	Depends on reagent methodology	n/a
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	Yes/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/yes (included)	Onboard/no
Interfaces up and running in active user sites with	All major LISs	—
LIS interface operates simultaneously w/ running assays	Yes	No
Uses LOINC to transmit orders and results	Yes	No
Bidirectional interface capability	Yes (broadcast download)	Yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/yes	Yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	24–48 h	48 h
Mean time between failures/to repair failures	—/depends on corrective action	6 mos./48 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 5–20 min.; weekly: n/a; monthly: n/a	Daily: 10–15 min., weekly: 20–25 min., monthly: 20–25 min.
Onboard maintenance records/maintenance training demo module	Yes (includes audit trail of who replaced parts)/yes	Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume	$79,000/300+ or higher	$55,000/all sites, variable test vols.
Annual service contract cost (24h/7d)	$11,000	—
Training provided w/ purchase/advanced operator training	4 d on-site/yes	3 d on-site/yes
Distinguishing features	Multibatch or continuous throughput EIA analyzer; user-defined menu, completely open system; easy color-coded worksheet and set up for operator; 2 probes for high-speed processing; unique cross-well washing; able to use fixed probes or disposable tips.	Fully automated allergy & autoimmune testing; >900 allergens; user-definable software

Automated immunoassay analyzers

Part 13 of 17	Hycor Biomedical Inc. Dick Geiszler (dgeiszler@hycorbiomedical.com) 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com	Nichols Institute Diagnostics Bill Wilson (wilsonb@nicholsdiag.com) 33051 Calle Aviador San Juan Capistrano, CA 92675 800-286-4643 x 5212 nicholsdiag.com
Name of instrument/first year sold/where designed	Hy•Tec 480/1994/Switzerland	CL System ID/1993/Sweden
Country where manufactured/where reagents manufactured	Switzerland/U.S., Germany, Scotland	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	8/57	60+/—
Operational type/model type/sample handling system	Batch, random access/benchtop/rack-robotics	Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	19.7 x 55 x 28 in./10.6 sq. ft.	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.
Tests available on instrument in U.S.	Specific IgE, total IgE, specific IgG, >900 allergens; ANA scr., TG, TPO, dsDNA, RFIgG & IgM, PR-3 c-ANCA, ENA-6 profile, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, cardiolipin scr.; *H. pylori;* user-definable software	hGH, prolac., FT_4, ferr., FSH, TT_4, TSH, LH, intact PTH, cortisol, anti-TPO, anti-TG, ACTH, TT_3, erythropoietin., T_3-uptake, DHEAS, calcitonin, thyroglob., osteocalcin
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	Rf IgA	None
Tests not available in U.S. but available in other countries	IgG, Basophil Histamine Release, cardiolipin IgA, cardiolipin IgA, IgG, IgM, ssDNA, MPO p-ANCA, mitochondrial, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG & IgM, CIC CIq, CIC C3d	None
Research-use-only assays	IgG, Basophil Histamine Release	None
Tests in development	None	None
User-defined methods implemented for what analytes	*H. pylori*	None
Tests not available on other manufacturers' analyzers	Allergy & autoimmune testing on fully automated system, BHR	IgF I
Fully automated microplate system	Yes	No
No. of each analyte performed in separate disposable unit	8	n/a
No. of wells in microplate	96-min. strip: 8 wells/1 strip, max. full plate: 12 strips/96 wells	n/a
Methods supported/separation methods	EIA, tube-based & microplate-based assays/cellulose disc & coated well	Chemiluminescence/bead
No. of different measured assays onboard simultaneously	Varies by assay, up to 480	1
No. of different assays programmed, calibrated at once	Multiple	1
No. of user-definable (open) channels	Multiple	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	1/200-allergy, 96-autoimmune	1/100
Shortest/median onboard reagent stability/refrigerated onboard	8 h/12 h/no	8 h/1 d/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	No, requires oper. prehandling/prep.	No, requires oper. prehandling/prep.
Reagents bar-coded/information in bar code	No	No
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/<1 part in 10,000	—/—
Walkaway capacity in min./specimens/tests-assays	Assay dependent/100/480	—/256/1
System is open (home-brew methods can be used)/liquid or dry system	Yes/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	No	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 μL–50 μL, assay dependent//300 μL	25 μL/150 μL
Supplied with UPS (backup power)/requires floor drain	Yes/no	No/no
Requires dedicated water system/water consumption	No/—	No/—
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/—/no	Yes/10 x 75/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/n/a	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A	No	No
Onboard test auto inventory (determines vol. in container)	Yes	No
Measures no. of tests remaining/short sample detection	Yes/yes	No/no
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	No/no	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	No/no
Time between initial result & reaspiration of sample for rerun	n/a	—
Autocalibration or autocalibration alert	Yes	No
No. of calibrators required for each analyte	1–5	2
Calibrants can be stored onboard/avg. calibration frequency	No/monthly	Yes/once per run
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/no
How often QC required	Every assay	Shortest interval: 4 h, longest: 8 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	No/no
Automatic shutdown/startup is programmable/startup time	Yes/no/5 min.	No/no/10 min.
Stat time to completion of ß–hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	—
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	n/a	—/— (—)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	Yes/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/no	No/yes
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/ running assays	No	—
Uses LOINC to transmit orders and results	No	No
Bidirectional interface capability	Yes (broadcast download & host query)	Yes (broadcast download)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/no	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	48 h	24 h
Mean time between failures/to repair failures	6 mos./48 h	10 mos./48 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 10–15 min., weekly: 20–25 min., monthly: 20–25 min.	Daily: 10 min., weekly: 30 min., monthly: 60 min.
Onboard maintenance records/maintenance training demo module	No/no	No/no
List price/targeted bed size or daily volume	$75,000/all sites, variable test vols.	Component related/—
Annual service contract cost (24h/7d)	—	—
Training provided w/ purchase/advanced operator training	3 d on site, 3 d at vendor offices/yes	—
Distinguishing features	Fully automated allergy & autoimmune testing; >900 allergens; open software	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

Automated immunoassay analyzers

Part 14 of 17	Nichols Institute Diagnostics Bill Wilson (wilsonb@nicholsdiag.com) 33051 Calle Aviador San Juan Capistrano, CA 92675 800-286-4643 x 5212 nicholsdiag.com	Olympus America Inc. Susan Watanabe (watans@olympus.com) Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com
Name of instrument/first year sold/where designed	Nichols Advantage Specialty System/1997/Germany	AU400/1999/Japan
Country where manufactured/where reagents manufactured	U.S./U.S.	Japan/U.S., Ireland
No. of units in clinical use in U.S./outside U.S.	>120/>160	>300/>800
Operational type/model type/sample handling system	Batch, cont. random access/benchtop/rack	Cont. random access/floor-standing/rack & turntable
Dimensions (H x W x D)/instrument footprint	44 x 45 x 26 in./8 sq. ft.	47.6 x 57.1 x 29.9 in./70 x 129 in.
Tests available on instrument in U.S.	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	α1-acid glycoprotein, α1-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, ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T-uptake, T_4 thyrox. Also, general chemistries, enzymes, HDL
Tests cleared but not clinically released	None	Ceruloplasmin
Tests not available in U.S. but submitted for clearance	None	None
Tests not available in U.S. but available in other countries	T3, T4, AFP, CEA, CA 15-3, NSE, TPA, CA 19-9, CA 125, prolac., total hCG	Cotinine
Research-use-only assays	Osteocalcin, pepsinogen I	None
Tests in development	25 hydroxy vit D, 1,25 dihydroxy vit D, IGFBP-3, Sangtec 100, direct renin, aldosterone, *H. pylori*	LDL
User-defined methods implemented for what analytes	None	HbA1c, fructosamine
Tests not available on other manufacturers' analyzers	IGF-I, calcitonin, pepsinogen	None
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	Chemiluminescence/magnetic particle	EIA, photometric, potentiometric, calc. results/none (all homogeneous)
No. of different measured assays onboard simultaneously	15	>40
No. of different assays programmed, calibrated at once	15	99
No. of user-definable (open) channels	0	95
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	15/varies, typically 100	76/100–6,160
Shortest/median onboard reagent stability/refrigerated onboard	8 h/—/yes (17°C)	168 h/60 d/yes (4–12°C)
Multiple reagent configurations supported	No	Yes
Reagent container placed directly on system for use	No, requires oper. prehandling/prep.	Yes
Reagents bar-coded/information in bar code	Yes/assay ID, lot no., serial no., expir.	Yes/reag. ID, lot no., bottle no., expir.
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/$\leq 5 \times 10^{-5}$	Yes/n/a
Walkaway capacity in min./specimens/tests-assays	Up to 480/120/15 x 100=1,500	Variable/up to 102/8,058
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	Yes/120	No
Uses washable cuvettes/replacement frequency	No	Yes/permanent
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/200 µL	2.0 µL/25 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	Optional/yes
Requires dedicated water system/water consumption	No/—	Yes/26 L per h @ peak consump.
Noise generated	67 decibels	<65 decibels
Has dedicated pediatric sample cup/dead vol.	In development	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/10 x 75, 16 x 100 mm/no	Yes/pediatric, 5 mL, 7 mL, 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	No	Yes
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	Yes/no	Yes/yes
Hemolysis/turbidity detection-quantitation	No/no	Yes/yes
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/yes
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/no	Yes/yes
Time between initial result & reaspiration of sample for rerun	37 min.	Varies by run size
Autocalibration or autocalibration alert	No	Yes
No. of calibrators required for each analyte	2	1–6
Calibrants can be stored onboard/avg. calibration frequency	No/7 d	Yes/14 d
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/no	Yes/no
How often QC required	Shortest interval: 4 h, longest: 8 h	Lab-defined
Onboard realtime QC/support multiple QC lot nos. per analyte	No/no	Yes/yes
Automatic shutdown/startup is programmable/startup time	No/no/10 min.	Yes/yes/24 h availability
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	<1 min.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	Up to 55/up to 165 (—)	133.3/400 (9 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	Onboard/yes (incl. in price)	Onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	All commercially available LISs	Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Orchard, Citation
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 (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	No	Yes (Olympus OLA 1500 Sorter, Labotix, Lab InterLink)
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/yes	Yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	24 h	<24 h
Mean time between failures/to repair failures	183 d/24 h	>20 weeks/<24 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 10 min., weekly: 30–45 min., monthly: 5 min.	Daily: 3 min., weekly: 7 min., monthly: 45 min.
Onboard maintenance records/maintenance training demo module	No/no	Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume	$125,000/300+ beds	$130,000/200–2,000 tests per d (depending on menu)
Annual service contract cost (24h/7d)	Inquire	Inquire
Training provided w/ purchase/advanced operator training	5 d at vendor offices/yes	5 d on site, 5 d at vendor offices/yes
Distinguishing features	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	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

Automated immunoassay analyzers

Part 15 of 17	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	Roche Diagnostics Dale Knight (dale.knight@roche.com) 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
Name of instrument/first year sold/where designed	Vitros ECi Immunodiagnostic System/1997/U.S.	Elecsys 2010/1996/—
Country where manufactured/where reagents manufactured	U.S./U.K.	Japan/Germany
No. of units in clinical use in U.S./outside U.S.	>1,000 worldwide	>500/>3,500
Operational type/model type/sample handling system	Cont. random access/floor-standing/universal sample racks (circular) accommodate primary & secondary tubes without need for adapters	Cont. random access/benchtop/rack or disk
Dimensions (H x W x D)/instrument footprint	51 x 44 x 29 in./8.9 sq. ft.	22.1 x 47.2 x 28.7 in./9.4 sq. ft.
Tests available on instrument in U.S.	3rd-gen. TSH, TT_3, TT_4, FT_3, FT_4, T_3-uptake, total ß-hCG, estradiol, progest., LH, FSH, prolac., N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, trop. I	TSH, FT_4, T_4, T_3, FT_3, T-uptake, LH, FSH, progest., estradiol, prolac., testost., CK-MB, trop. T, myglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferr., B_{12}, fol., RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, ß–hCG, CA 15-3, anti-TPO
Tests cleared but not clinically released	aHBs, B_{12}, folate, RBC folate, PSA	—
Tests not available in U.S. but submitted for clearance	HBsAg, aHCV	HBsAg, HBsAg (conf)
Tests not available in U.S. but available in other countries	CA 19-9, fß–hCG, a-HBc IgM, a-HBc, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II	Osteocalcin, CA 19-9, anti-HBc, Cyfra 21-1, anti-HBs, anti HBc IgM, anti-HBe, HBeAg
Research-use-only assays	None	—
Tests in development	Myoglobin	CA 72-4, NSE, anti-TG, SHBG, infec. diseases, TG
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	Hepatitis, HIV	Trop. T, serum ß Crosslaps, free PSA
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	Chemiluminescence (enhanced)/coated microwell	Electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	20	15
No. of different assays programmed, calibrated at once	—	60
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	20/100	15/100–200
Shortest/median onboard reagent stability/refrigerated onboard	—/60 d/yes (2°–8°C)	56 d/56 d/yes (20°C)
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/test ID, expir., lot no., pack ID	Yes/calib. curve, application params., lot no., expir., reag. name
Same capabilities when 3rd-party reagents used/susceptibility to carryover	—/zero carryover	No/zero carryover (disposable sample tips)
Walkaway capacity in min./specimens/tests-assays	60/500/—	120/disk: 30, rack: 100/180
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	No/liquid
Uses disposable cuvettes/max. no. stored	Yes/2,000	Yes/—
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/60 µL	10 µL/100 µL
Supplied with UPS (backup power)/requires floor drain	Yes/—	—/no
Requires dedicated water system/water consumption	No/—	No/—
Noise generated	Not determined	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/multiple ped. cup capabilities/no	Yes/13–16 mm diam./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	—
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/no
Hemolysis/turbidity detection-quantitation	Yes/yes	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/yes	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	Yes/yes	No/no
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	Yes	Yes
No. of calibrators required for each analyte	1–3	2
Calibrants can be stored onboard/avg. calibration frequency	No/28 d	No/monthly
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/yes
How often QC required	1 per d	Once per 24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/yes
Automatic shutdown/startup is programmable/startup time	Yes/yes/5 min. from power off	No/no/4 min.
Stat time to completion of ß-hCG test	24 min.	9 min.
Time delay from ordering stat test to aspir. of sample	—	42 sec.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	30/90 (40 sec.)	30/88 (42 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	Onboard/no	Onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, HBOC, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche	All major LISs
LIS interface operates simultaneously w/ running assays	Yes	Yes
Uses LOINC to transmit orders and results	Yes	No
Bidirectional interface capability	Yes (broadcast download)	Yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	Yes	Yes
Interface available (or will be) to auto specimen handling system	Yes (all systems)	Yes (CLAS & Roche task targeted automation)
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes/yes	No/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	<4 h (contract dependent)	<24 h
Mean time between failures/to repair failures	—/dependent on corrective action	—/—
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: <5 min., weekly: <30 min., monthly: <10 min.	Daily: 1 min., weekly: 5 min., biweekly: 25 min., monthly: none
Onboard maintenance records/maintenance training demo module	No/yes	No/no (training CD-ROM)
List price/targeted bed size or daily volume	$140,000/daily volume to approx. 1,000 tests	Disk: $120,000, rack: $135,000/various
Annual service contract cost (24h/7d)	Varies w/ service level choices	Incl. w/ reagent rental
Training provided w/ purchase/advanced operator training	As needed on-site, 4 d at vendor offices/yes	3 d Indianapolis based/yes
Distinguishing features	Enhanced chemiluminescence enables ultrasensitive and expanded-range assays; sample handling: smart-metering with save-the-sample clot management, disposable tips, & AutoFlex testing ensures accurate sample checking and integrity; random access assay processing: bidirectional, dual-ring incubator provides for optimized test methods & unlimited method expansion including HIV & hepatitis random access testing.	Connectable to Clinical Lab Automation System; liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, & fast turnaround time, stat interrupt; onboard reag. storage; minimal maintenance

Automated immunoassay analyzers

Part 16 of 17	Roche Diagnostics Dale Knight (dale.knight@roche.com) 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Sigma Diagnostics 545 S. Ewing Ave. St. Louis, MO 63103 314-771-5765 or 800-325-3424 www.sigma-aldrich.com
Name of instrument/first year sold/where designed	Elecsys 1010/1997/—	Aptus Automated EIA System/1998/—
Country where manufactured/where reagents manufactured	Switzerland/Germany	—/U.S.
No. of units in clinical use in U.S./outside U.S.	>275/>2,500	—
Operational type/model type/sample handling system	Random access/benchtop/sample disk	Batch, random access/benchtop/rack
Dimensions (H x W x D)/instrument footprint	25.6 x 37 x 25.2 in./6.5 sq. ft.	27.5 x 26 x 47.25 in./8.5 sq. ft.
Tests available on instrument in U.S.	TSH, T_3, T_4, T-uptake, FT_3, FT_4, FSH, LH, prolac., progest., estradiol, testost., CK-MB, trop. T, myogl., digoxin, CEA, AFP, PSA (screen), CA 125, ferr., IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β-hCG, CA 15-3, anti-TPO	Toxo IgG & IgM, rubella IgG & IgM, CMV IgG & IgM, toxo rubella & CMV IgM capture, toxo rubella & CMV IgG quant., HSV-I IgG, HSV-II IgG, HSV I/II IgM, EBV EA IgG, EBV VCA IgG & IgM, EBV EBNA IgG, VZV IgG, mumps IgG, measles IgG, B. burgdorferi IgM/G, *H. pylori* IgG, *Legionella* IgG/M/A, mycoplasma IgG & IgM, ANA, ENA, & ANCA screens, SS-A/Ro, SS-B/La, Sm, Sm/RNP, Scl-70, Jo-1, dsDNA, RF IgM, gliadin IgA & IgG, anticardiolipin IgG, IgM, & IgA, MPO, PR-3, TPO, TG
Tests cleared but not clinically released	—	None
Tests not available in U.S. but submitted for clearance	—	None
Tests not available in U.S. but available in other countries	Osteocalcin, CA 19-9, HBsAg, anti-HBs, anti-HBc, Cyfra 21-1	Quant EBV EA, VCA, IgG & IgM, EBNA
Research-use-only assays	—	None
Tests in development	CA 72-4, NSE, anti-TG, TG, sHBG	Syphilis, salivary ELISAs, HBA_{1c}
User-defined methods implemented for what analytes	None	Implemented by end user–HBsAg, HIV, syphilis, coccidiodes, PSA
Tests not available on other manufacturers' analyzers	Trop. T, serum β Crosslaps, fPSA	None
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	Min. strip: break-away wells, max. full plate: 96 x 4 plates
Methods supported/separation methods	ECLIA electrochemiluminescence IA/ magnetic particle	EIA/microtiter
No. of different measured assays onboard simultaneously	6	9
No. of different assays programmed, calibrated at once	—	>100
No. of user-definable (open) channels	0	20
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	6/100–200	9/96
Shortest/median onboard reagent stability/refrigerated onboard	28 d/28 d/no	12 h/7 d/no
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/calib. curve, application params., lot no., expir., reag. name	Yes/lot no. & expiration date
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/<8 ppm	Yes/zero carryover
Walkaway capacity in min./specimens/tests-assays	150/42 1° tube + 24 sample cups/128	—/120/9
System is open (home-brew methods can be used)/liquid or dry system	No/liquid	Yes/liquid
Uses disposable cuvettes/max. no. stored	Yes/128	No
Uses washable cuvettes/replacement frequency	No	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/100 µL	10 µL/50 µL
Supplied with UPS (backup power)/requires floor drain	No/no	Yes/no
Requires dedicated water system/water consumption	No/—	No/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	Yes/—	Yes/50 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/13–16 mm diam./no	No/direct tubes accepted (12 x 75, 13 x 85 mm)/no
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar code placement per NCCLS standard Auto2A	—	—
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Measures no. of tests remaining/short sample detection	Yes/yes	No/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	Yes/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 out-of-linear range high/low results	No/no	n/a
Time between initial result & reaspiration of sample for rerun	—	n/a
Autocalibration or autocalibration alert	Yes	No
No. of calibrators required for each analyte	2	Varies
Calibrants can be stored onboard/avg. calibration frequency	No/7 d	No/each run
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/no
How often QC required	Once per 24 h	Each run
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	Yes/no
Automatic shutdown/startup is programmable/startup time	No/no/5 min.	Yes/<3 min.
Stat time to completion of ß-hCG test	9 min.	n/a
Time delay from ordering stat test to aspir. of sample	65 sec.	n/a
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	20/55 (65 sec.)	Depends on combination of assays
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	No/yes
Data management capability/instrument vendor supplies LIS interface	Onboard/yes (addt'l cost)	Onboard/optional (addt'l cost)
Interfaces up and running in active user sites with	All major LISs	ClinLab, CompTron, Cerner, Sunquest, MEDITECH, Progimed
LIS interface operates simultaneously w/ running assays	Yes	No
Uses LOINC to transmit orders and results	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, after QC reviewed
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	No/yes/no	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer	<24 h	w/in 24 h
Mean time between failures/to repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 1 min., biweekly: 5 min., monthly: 5 min.	Daily: 2 min., weekly: 5 min., monthly: none
Onboard maintenance records/maintenance training demo module	No/—	No/not needed
List price/targeted bed size or daily volume	$59,000/various	Contact vendor/all bed sizes & test vols.
Annual service contract cost (24h/7d)	Incl. w/ reagent rental	Contact vendor
Training provided w/ purchase/advanced operator training	3 d Indianapolis based/yes	5 d on-site/yes
Distinguishing features	Liquid ready-to-use reagents; autocalib., autodil.; ECL detection system provides broad measuring range & short TAT; stat interrupt; onboard reagent storage; minimal maintenance; small footprint	Chauffeur-driven software–easy to use; all Sigma assays FDA cleared for system-specific reagent packaging, CLIA moderate complexity, automation

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 17 of 17	Tosoh Medics Inc. Jane Merschen (jane@tosohm.com) 347 Oyster Point Blvd., #201 S. San Francisco, CA 94080 650-615-4970 www.tosohm.com	Tosoh Medics Inc. Jane Merschen (jane@tosohm.com) 347 Oyster Point Blvd., #201 S. San Francisco, CA 94080 650-615-4970 www.tosohm.com
Name of instrument/first year sold/where designed	AIA Nex•IA/1997/Japan	AIA-600 II/2000/Japan
Country where manufactured/where reagents manufactured	Japan/Japan	Japan/Japan
No. of units in clinical use in U.S./outside U.S.	40/300	60/300
Operational type/model type/sample handling system	Cont. random access/floor-standing/rack, carrousel, TLA	Cont. random access/benchtop/chain
Dimensions (H x W x D)/instrument footprint	47 x 35 x 26 in./6.3 sq. ft.	19.8 x 31.6 x 29.1 in./2.5 sq. ft.
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, AFP, CEA, PSA, CA 125, β-2 microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I, ferritin, folate, B_{12}	Same menu as for AIA-Nex•IA (see column at left)
Tests cleared but not clinically released	None	None
Tests not available in U.S. but submitted for clearance	BRCA (27.29)	BRCA (27.29)
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	CA 19-9	CA 19-9
Tests in development	Testost., CA 15-3, digox., type IV collagen, RBC fol.	Testost., CA 15-3, digox., type IV collagen, RBC fol.
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	None	None
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/separation methods	Fluorescence, EIA/bead	Fluorescence, EIA/bead
No. of different measured assays onboard simultaneously	≥34	≥34
No. of different assays programmed, calibrated at once	Entire menu	Entire menu
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	N/a/unitized test cup	N/a/unitized test cup
Shortest/median onboard reagent stability/refrigerated onboard	72 h/72 h/n/a	72 h/72 h/n/a
Multiple reagent configurations supported	Yes	Yes
Reagent container placed directly on system for use	Yes	Yes
Reagents bar-coded/information in bar code	Yes/lot no., test code	Yes/lot no., test code
Same capabilities when 3rd-party reagents used/susceptibility to carryover	No/zero carryover	No/zero carryover
Walkaway capacity in min./specimens/tests-assays	52/75–200/400 for the standard model	52/26/26
System is open (home-brew methods can be used)/liquid or dry system	No/dry	No/dry
Uses disposable cuvettes/max. no. stored	n/a/unitized test cup	n/a/unitized test cup
Uses washable cuvettes/replacement frequency	n/a	n/a
Min. sample vol. aspirated precisely at once/min. dead vol.	10 µL/50 µL	10 µL/100 µL
Supplied with UPS (backup power)/requires floor drain	Yes/no	Yes/no
Requires dedicated water system/water consumption	No/n/a	No/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	No	No
Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no	Yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no
Sample bar-code reading capability/autodiscrimination	Yes/yes	Yes/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/no	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results	No/yes	No/yes
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	No	No
No. of calibrators required for each analyte	2 or 6—analyte dependent	2 or 6—analyte dependent
Calibrants can be stored onboard/avg. calibration frequency	No/60–90 d	No/60–90 d
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/yes	Yes/yes
How often QC required	24 h	24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes	No/no
Automatic shutdown/startup is programmable/startup time	No/no/5–8 min.	No/no/5 min.
Stat time to completion of ß-hCG test	~18 min.	~18 min.
Time delay from ordering stat test to aspir. of sample	90 sec.	60 sec.
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	40/120 (30 sec.)	20/60 (1 min.)
Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	Yes/no
Data management capability/instrument vendor supplies LIS interface	Optional add-on (software mftr: Schuyler House, Sunquest, LabForce, HBOC, Antrim, Data Innovations)/yes (addt'l cost)	Optional add-on (software mftr: 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	Yes	Yes
Uses LOINC to transmit orders and results	Yes	Yes
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 (Hitachi, Panasonic, Sysmex)	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	—/—	Unknown/—
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel	Daily: 5–8 min., weekly: none, monthly: none	Daily: 5 min., weekly: 5 min., monthly: none
Onboard maintenance records/maintenance training demo module	Yes (incl. audit trail of who replaced parts)/no	No/no
List price/targeted bed size or daily volume	$135,000/65+ beds, 1,500–2,000 + tests	$70,000/500–2,500 tests per month
Annual service contract cost (24h/7d)	$10,800	$5,600
Training provided w/ purchase/advanced operator training	4 d at vendor offices/no	3 d at vendor offices/no
Distinguishing features	3 sample loading options on single system: 200 sample rack loader, TLA adaptable, standard carrousel 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