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 immunoassayspecific 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 T₄ and T₃ 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-mustremain-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.

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immunoassay analyze	rs
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 Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Architect i2000/1999/U.S. U.S./U.S. 100+/600+ Batch, random access, cont. random access/floor-standing/rack 48 x 44 x 68 in./23 sq. ft.
Tests available on instrument in U.S.	β hCG, 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 Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays	AFP, glycated Hb AFP, glycated Hb AFP, CA 19-9, fPSA, tPSA, testost., anti-HBc, anti-HBs, anti-HCV, HBsAg & confirm., B ₁₂ , ferr. None UPplath, UPpAg, and UPp, and UANAD, IsM, anti-HANAD, T, untaka
Tests in development	HBclgM, 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, myogI., theoph., phenobarb., phenytoin, vancomycin, DHEAS, dPD, SCC
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	None Glycated Hb
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	No n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection Auto detection / adequate reagent or specimen Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	Chemiluminescence w/ flexible protocols/magnetic microparticle 25 per module, max. 4 modules=100 assays max. 100+ 0 25/100-test & 500-test kits 30 d/30 d/yes (2–5°C) Yes Yes Yes/2D bar code, lot. no., no. tests, calib. data No/0.3 ppm 300/250/1,000 No/inquid Yes/1,200 No 150 µL/50 µL Yes/no No/ 60–65 decibels No Yes (2 of 5 interl., codabar, codes 39 & 128)/yes Yes Yes Yes Yes Yes Yes/yes Yes Yes/yes Yes/yes Seconds Yes 2–6 pt. curve No/30 d Yes/yes 3 levels every 24 h Yes/yes
Automatic shutdown/startup is programmable/startup time Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	No/no/10 mm. 28 min. Every 18 sec. from positive sample ID 67/200 per module (aspir. to result: 28 min.) Yes/yes Onboard/no All major LIS vendors

Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results

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cast download & host query) s le/not available nin., weekly: <10 min., monthly: none udit trail of who replaced parts)/yes
le/not available nin., weekly: <10 min., monthly: none
le/not available nin., weekly: <10 min., monthly: none
le/not available nin., weekly: <10 min., monthly: none
nin., weekly: <10 min., monthly: none
nin., weekly: <10 min., monthly: none
nin., weekly: <10 min., monthly: none
udit trail of who replaced parts)/yes
00 immunoassays per d
t price)
or offices/yes (5 d on-site integration)
advanced, patented chemiluminescence detection w/ flexible protocols delivers superior assay æ; modularity: seamlessly integrate multiple instruments orkstation, throughput from 200–800 tests/h; flexibility: TLA, as workcell or standalone unit.

All major LIS vendors

Yes

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FUNENTS 54 / CAP TODAY RUNNERTS SA / CAP TODAY	nated immunoassay ar	nalyzers
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, β hCG, 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, Sci 70, ENA scr., TPO, antithyroglob. mitochond. M2, histone, ssDNA, MPO (p-ANCA), PR3 (C-ANCA), RF IgM, IgA), rubella Ig&Ig&IgM, rubeola IgG & IgM, VZV IgG&IgM, mumj & IgM, HSV I/II IgG&IgM, EB VCA IgG&IgM, EBNA G, EA, syph. IgG&I (Ab&Ag), Lyme IgG & IgM, EB VCA IgG&IgM, EBNA G, EA, syph. IgG, IgG & IgM, HSC ore IgG & IgM, HBe (Ag&Ab), HBsAb, HbsAg, C. diff ti cand. (IgG/IgM.IgA), mycoplas. IgG & IgM, E. histolytica, prot. C Ag VWF Ag, anticardiolip.(IgG/IgM/IgA) &. scr., amph., barbit., benzod cotinine, LSD, metham., morph., opiates, PCP, THC, DHEAS, estrad. testost., CRP, and adaptable to all standard ELISA test kits, all mar and all types of kits
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	Homocysteine, 3rd-gen. TSH HCV, cyclosporine, fPSA, tPSA Hepatitis, retrovirus, fPSA, tPSA, β -2 microgl., insulin, cyclosporine, CA 19-9, CMV IgM None Hepatitis, retrovirus, fPSA, tPSA, testost., cyclosporine, anti-TPO, anti-TG, PTH, CMV IgM, cortisol	Completely open system Completely open system for use by all manufacturers and all types Completely open system for use by all manufacturers and all types Completely open system for use by all manufacturers and all types Completely open system for use by all manufacturers and all types
User-defined methods implemented for what analytes	None	Completely open system for use by all manufacturers and all types
Tests not available on other manufacturers' analyzers	Drugs of abuse and congenitals	Completely open system for use by all manufacturers and all types
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 No. of user-definable (open) channels	20 0 0	18 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 manufac
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 $\mu\text{L}/\text{50}$ 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 pediatric 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	No/no	No/no
out-of-linear range high/low results 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/ves	Yes/ves
Unboard realtime UC/support multiple UC 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 B-hCG test	13 min. 20 ago, from standby	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	68–126 tests/flexible platform—load list dependent (assay dependent)	Between 15–50 tests per h/depends on protocol
each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	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/
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 Avg. time to complete maintenance by lab personnel	Yes Daily: 5 min., weekly: 30 min., monthly: 30 min.	Yes Daily: 5 min., weekly: 10 min., monthly: 10 min. Vec (incl. quilit trail of who are lead to the lung
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, programm

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FUNENTS 58 / CAP TODAY RUNNERTS S8 / CAP TODAY	nated immunoassay ai	halyzers
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 Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Advia Centaur/1998/U.S. U.S./U.S. >500/>1,200 Cont. random access/floor-standing/rack or direct track sampling 51.5 x 72.5 x 41.5 in./21 sq. ft.	ACS: 180 SE/1997/U.S. U.S./U.S. >1,200/>4,000 Cont. random access/benchtop/ring 24 x 59 x 23 in./9.5 sq. ft.
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. serum cortisol, deoxypyrid., hCG, FSH, LH, prolac., progest., estr PSA, equimolar PSA, cPSA, anti-TPO, anti-TG, CEA, AFP, BR 27.2 myogl., digitoxin, digoxin, theoph., phenobarb., phenytoin, vance gentamicin, carbamazep., tobramycin
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	Phenytoin, aTPO, gentamicin Rubella IgG & IgM, toxo IgG & IgM Specific allergens, rubella IgG & IgM, toxo IgG & IgM OV, CA 19-9 Theoph., valp. acid, vanc., homocyst., Her2/ <i>neu</i> , PTH, NAPA, procain., quinidine, anti- TG, insulin, C-peptide, CA 125, high-sens. E2, BNP, high-sens. CRP, HBsAg, HBsAb, free estriol, Gigb/A1c; cyclosporine, FK 506, B2/M, DHEAS, HBcAb IgM, HBcAb,	None None Gl, OV Homocyst., valp. acid, NAPA, procain., quinidine, HER2/ <i>neu</i> , DHE C-peptide, CA 125
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	HBeAb, HBeAg, HAV, HAV-IgM, CMV IgG, CMV IgM None BR 27.29	None BR 27.29
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	No n/a n/a	No n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels	Chemiluminescence/magnetic particle 30 30 0	Chemiluminescence/magnetic particle 13 13 0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use	30/50–100 96 h/28 d/yes (4°C) Yes Yes	13/50 40 h/1.7 d/no Yes Yes
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryove Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	Yes/assay name, lot no., expir., pack ID er n/a/zero carryover 230/180/840 No/liquid	Yes/assay name, lot no., expir., pack ID n/a/— 150/60/450 No/liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated	Yes/1,000 No 10 µL/50 µL Yes/no No/~2.5 L per h —	Yes/450 No 10 µL/50 µL No/no No/-1.8 L per h —
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	No Yes/multiple/no Yes (2 of 5 interl., codabar, codes 39 & 128)/yes Yes Yes	No Yes/multiple/no Yes (2 of 5 interl., codabar, codes 39 & 128)/yes Yes Yes
Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	Yes/yes Yes Yes/yes No/no Yes/yes	Yes/yes Yes Yes/no No/no Yes/yes
Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	No/no 15 sec. minimum No	No/no 20 sec. No
No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required Onboard realtime QC/support multiple QC lot nos. per analyte	2 No/varies, avg. 21 d Yes/yes 24 h Yes/yes	2 No/varies by assay, generally 28 d Yes/yes 24 h Yes/yes
Automatic shutdown/startup is programmable/startup time Stat time to completion of B-hCG test	No/no/none	No/no/<5 min, generally remains on
Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface	15 sec. 80/240 (15 sec.) Yes/yes Onboard/—	<60 sec. 60/180 (20 sec.) Yes/yes 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, Healthcare (all major vendors)
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	Yes — Yes (broadcast download & host query) Yes Yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T)	Yes Yes Yes (broadcast download & host query) Yes Yes
Modem servicing/can diagnose own malfunctions/determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures	Yes/yes/yes No 4 h TBD/3 h	No/no/no No 4 h 4 mos./3 h
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	Yes Yes Daily: 3 min., weekly: 20 min., monthly: 30 min. Yes/yes	4 mos./3 n Yes Daily: 15 min., weekly: 15 min., monthly: 15 min. Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$220,000, STS model \$225,000/300+ beds or ≥400 tests per d \$17,000 Varies on site, 4 d at vendor offices/yes	\$130,000/≥50 immunoassays per d \$13,000 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	Automatic dilutions, repeats performed onboard; clot detection a CD-ROM offers online operators manual & help

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Auton	nated immunoassay ai	nalyzers
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.SFrance
Country where manufactured/where reagents manufactured	Ireland/U.S., U.K.	U.S./U.SFrance
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 sg. 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, β 2-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/ <i>neu</i>	CEA, T ₃ , T ₄ , T-uptake, hypersens. 3rd-gen. TSH, FT ₄ , FT ₃ , β hCG, projest., estrad., unconj. estriol, B ₁₂ , fol., RBC fol., ferr., CK-MB, cortisol, urine cortisol, insulin, AFP-open neural tube defect, tot theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo lg Hybritech PSA & fPSA, testosterone, ostase, toxo lgM
Tests cleared but not clinically released	None	Hypersensitive human growth hormone, thyroglobulin
Tests not available in U.S. but submitted for clearance	None	Accu Tnl
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, antithyrog
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	cPSA, HER-2/ <i>neu</i>	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 No. of different measured assays onboard simultaneously	EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle 22	Chemiluminescence/magnetic particle 24
No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	22 0 22/50–200, assay dependent	24 O 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	Voo (f. 16 partice) require oney probandling /grop)	Voc
Reagents bar-coded/information in bar code Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays	437/78/875	Yes Yes/assay no., lot no., expir., unique reag. pack ID no. No/≤3 ppm 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 Requires dedicated water system/water consumption Noise generated	Yes/no No/n/a	No/no No/n/a <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	No/no	No/no
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	30 sec. No	n/a 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 B-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 Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	Yes/yes Onboard/no Cerner, Sunquest, Meditech, HBOC, Citation, Soft, Dawning, Antrim, Dynamic Healthcare, Data Innovations (all major vendors)	Yes/yes Onboard/yes (incl. or addt'l cost—negotiable) 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 Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes (Advia LabCell, Lab Interlink) No/—/—	No No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures		No 24 h max., usually w/in 6 h Not avail./not avail.
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	4 mos./2 n Yes No daily maintenance No/no	Not avail./not avail. Yes Daily: 15 min., weekly: 30 min., monthly: none 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

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INSTRUCT OF

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 No. of units in clinical use in U.S./outside U.S.	U.S./U.S. & France —/—	U.S.A./U.K. <10/>40
Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Cont. random access/benchtop/rack 18.5 x 39 x 24 in./8 sq. ft.	Batch/benchtop/rack 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, ScI-70, dsDNA, GBM, MPO, PR3, Tg, TPO, cardiolipin IgG, IgA, IgM and screen, B2GP1 IgG, IgA, IgM an 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 Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	Same as Access Same as Access Same as Access	None None Open system—any ELISA
Research-use-only assays Tests in development	None Same as Access	Open system Phosphatidyl serine IgG, IgA, IgM, mitochondrial M2, SMA, LKM
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	None Same as Access	Open system Open system
Fully automated microplate system	No	Yes
No. of each analyte performed in separate disposable unit No. of wells in microplate	n/a n/a	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 No. of different assays programmed, calibrated at once	24 24	12 assays per plate 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 Reagent container placed directly on system for use	Yes Yes	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 Walkaway capacity in min./specimens/tests-assays	No/≤ 3 ppm 180/60/300	Yes/0 Assau demondent/02/Assau demondent
walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	No/liquid	Assay dependent/92/Assay dependent Yes/liquid
Uses disposable cuvettes/max. no. stored	Yes/294	No
Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol.	Νο 5 μL/100 μL	No 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 Noise generated	No <70 decibels within 1 meter	No
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/100 µL Yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no	Yes/50 µL Yes/various/no
		Vec (0 of 5 interl, codebox, codes 20.8 100)/
Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	Yes (2 of 5 interl., codabar, code 39 & 128)/yes Yes	Yes (2 of 5 interl., codabar, codes 39 & 128)/— Yes
Onboard test auto inventory (determines vol. in container)	Yes	No
Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen	Yes/yes Yes	No/yes Yes
Clot detection/reflex testing capability	No/yes	Yes/no
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	No/no Yes/yes	No/no Yes/no
Sample vol. can be reduced/increased to rerun	No/no	No/no
out-of-linear range high/low results	1 0 and	
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	36 sec. No	n/a No
No. of calibrators required for each analyte	6	Assay specific
Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay	No/28 d Yes/yes	Yes/once per analyte per plate Yes/yes
How often QC required	24 h	Per plate
Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	Yes/yes No/no/remains in ready mode	Yes/no Yes/—/1–2 min.
Automatic shutuown/startup is programmable/startup time	NO/110/1611allis in feauy mode	Tes/—/ 1-2 IIIII.
Stat time to completion of ß-hCG test Time delay from ordering stat test to aspir. of sample	15 min. 36 sec.	n/a n/a
Throughput per hr for three analytes on	30 sec. 33/100 (36 sec.)	n/a
each specimen, in no. of specimens/no. of tests (cycle time)	Verburg	 Vas hus
Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface	Yes/yes Onboard/yes (included or additional cost—negotiable)	Yes/yes 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 Vac (breadcast download & bast quari)	No Xoo (heet guera)
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	Yes (broadcast download & host query) Yes	Yes (host query) Yes
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes/yes	No/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer Mean time between failures/to repair failures	24 h max, usually within 6 h TBD/TBD	Within 24 h n/a/<24 h
Onboard error codes to facilitate troubleshooting	Yes	Yes
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	Daily: 15 min.; weekly: 30 min.; monthly: none Yes/no	Daily: 5 min/weekly: n/a/monthly: n/a 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) Training provided w/ purchase/advanced operator training	\$15,800 4 d at venor offices/yes	Varies 3 d on-site, 2–3 d at vendor offices/yes
Distinguishing features	The Access Immunoscenu Sustam plus the Access 9 affers the activistic	Fully onen true A. nieto evetam modular desire of reader weeker insub-terr
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 learned error recovery.

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RUNEN ¹⁵ 62 / CAP TODAY RUNE Auton	nated immunoassay ar	nalyzers
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.	300/3,000	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, Sci 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 G, EA, syph. IgG & IgM, chlam. (Ab&Ag), Lyme IgG & IgM, Legion. (Ab&Ag), <i>H. pylori</i> IgG, parvovirus IgG & IgM, HAV IgG & IgM, HBCore IgG & IgM, HBe (Ag&Ab), HBsAb, HBsAg, <i>C. diff.</i> tox A, giard., cand. (IgG, IgM, IgA), mycoplas. IgG & IgM, <i>E. histolytica</i> , 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.	ElA/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	r 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 Uses disposable cuvettes/max. no. stored	Yes/— Yes/288-3 plates	Yes/— 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 Noise generated	No/n/a	No/n/a
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	Yes/yes (mftr. & assay dependent)	Yes/yes (mftr. & assay dependent)
out-of-linear range high/low results		
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 B-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hr for three analytes on	n/a	n/a
each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC	Yes/yes	Yes/yes Onboard/yes (incl. in price)
	Onboard/yes (incl. in price)	· · · · · · · · · · · · · · · · · · ·

oadcast download & host query) s/yes 24 h ŀ h 5–10 min., weekly: 10 min., monthly: 15 min.	Yes Yes (broadcast download & host query) Yes No Yes/yes/yes No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
s/yes 24 h ! h 5–10 min., weekly: 10 min., monthly: 15 min.	Yes No Yes/yes/yes No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
s/yes 24 h ! h 5–10 min., weekly: 10 min., monthly: 15 min.	Yes No Yes/yes/yes No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
24 h ¦ h 5–10 min., weekly: 10 min., monthly: 15 min.	No Yes/yes/yes No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
24 h ¦ h 5–10 min., weekly: 10 min., monthly: 15 min.	Yes/yes/yes No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
24 h ¦ h 5–10 min., weekly: 10 min., monthly: 15 min.	No Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
⊧ h 5–10 min., weekly: 10 min., monthly: 15 min.	Within 24 h —/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
⊧ h 5–10 min., weekly: 10 min., monthly: 15 min.	—/<24 h Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
9–10 min., weekly: 10 min., monthly: 15 min.	Yes Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
	Daily: 6–10 min., weekly: 10 min., monthly: 15 min.
	Yes/no
0/>100 beds	\$38,000/>100 beds
ts on acquisition option	Depends on acquisition option
on-site/yes	3–5 d on-site/yes
latform; largest installed base of automated microplate analyzer in its proven performance and reliability; accommodates various sample tube ncluding 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
li li p	s on acquisition option n-site/yes atform; largest installed base of automated microplate analyzer in its roven performance and reliability; accommodates various sample tube

FUNENTS 64 / CAP TODAY Auton	nated immunoassay ar	nalyzers
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 No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system	U.S., Italy/U.S., France 1,500/>12,000 Batch, random access/benchtop/n/a	Japan/U.S., U.K., France, Korea, Australia —/— Batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint Tests available on instrument in U.S.	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 0.5.	Same for both instruments: <i>C. diff.</i> 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., <i>H. pylori</i> IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer	Newborn screening—contact Bio-Rad representative
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	None PSA	Contact Bio-Rad representative
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 Tests in development	None Amplified <i>C. trach.</i> , amplified <i>N. gonorr.</i> , combo. CT/NG, amplified <i>M. tuberc</i> .,	n/a
User-defined methods implemented for what analytes	quant. HIV-1 RNA, myoglobin, trop. I None	STC drugs of abuse, Ostex Ntx, DSL assays—contact companies rep
Tests not available on other manufacturers' analyzers	Quant. D-dimer, <i>C. difficile</i> toxin A, Lyme IgG/IgM, VZG, mumps IgG, measles IgG	-
Fully automated microplate system No. of each analyte performed in separate disposable unit	No One test per strip	Yes
No. of wells in microplate	n/a	— Min. strip: 1 sample; max. full plate, 96
Methods supported/separation methods No. of different measured assays onboard simultaneously	Fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device Vidas: 30, MiniVidas: 12	EIA/Coated microwell & noncoated microwell 9
No. of different assays programmed, calibrated at once No. of user-definable (open) channels	Total menu O	9 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 Multiple reagent configurations supported	n/a/n/a No	n/a/n/a/no Yes
Reagent container placed directly on system for use Reagents bar-coded/information in bar code	Yes Yes/assay name, lot no., sequence no., expir.	Requires operator prehandling/preparation No
Same capabilities when 3rd-party reagents used/susceptibility to carryove		No/reduced w/software version 4.0 & updated firmware. Depends on washing
Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	Assay dependent/12-30/12-30 No/dry	Varies by assay/90-270/up to 9 Yes/liquid, reconst. onboard
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	No No	No (yes for dils.) No
Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	100 µL/n/a Yes/no	10 μL/200 μL, 130 μL in microtubes Optional/no
Requires dedicated water system/water consumption Noise generated	No/no	No/— n/a
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	No No/n/a/no	Yes/130 μL Not claimed, but some users have validated for their own use/—
Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes n/a	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes No
Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection	n/a No/no	NO No No/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	No	No
Hemolysis/turbidity detection-quantitation	No/no No/no	No/no No/no Yac/no
Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun	No/no No/no	Yes/no No/no
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	n/a	The second secon
Autocalibration or autocalibration alert No. of calibrators required for each analyte	Yes 1	No 1–6 Na (analyzania and its and its and
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 updates
Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	No (mftrdetermined calib. curves)/yes Shortest interval: 8 h, longest: 24 h	Yes/yes Shortest interval: user determined, longest: w/in run recommended
Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	Yes/yes No/no/remains ready	Yes/yes (late 2000 through Unity QC program) For hardware/6 min.
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample	30 min. No delay	n/a 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)/(prote
Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface	Yes/yes Onboard/yes (addt'l cost)	Yes/yes (not yet tested) Onboard/customer acquires through LIS company, can be added to d
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 developm
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	Yes No Voc (hundrast damplest)	Not possible on batch analyzer No Voe (heredeet develoet)
Bidirectional interface capability Results transmitted to LIS as soon as test time complete	Yes (broadcast download) Yes	Yes (broadcast download) Yes V
Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine	No No/yes/yes	No No/no/no
malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer	No w/in 24 h	No 24 b
Mean time between failures/to repair failures	Vidas: 350 d, MiniVidas: 1,000 d/<2 h	24 h /4 h Ves
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	Yes Daily: 10–15 min., weekly: 10–15 min., monthly: 30 min. Yes/yes	Yes Daily: 5 min., weekly: 20 min., monthly: 20 min. No/no
List price/targeted bed size or daily volume Annual service contract cost (24h/7d)	Vidas: \$50,300, MiniVidas: \$27,300/≤400 beds \$2,340–\$4,680 (Mini–Vidas 30)	\$48,000/50–350 beds, 4–6 plates per d \$4,800
Training provided w/ purchase/advanced operator training Distinguishing features	As needed on-site, 3 d at vendor offices/yes Unique dual-function combination solid phase & pipetting device (SPR); ability to	As needed on-site, 3 d at vendor offices/— Coda 4.0 adds powerful, new fluidic controls, dilution capabilities, a
	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	alarms, and new wash parameters; able to perform pretreatment of (pipette, incubate, transfer to coated well); 5 methods for creating s dilutions; easy-to-operate programming

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Automa	ted immunoassay ana	CAP TODAY / 65
art 8 of 17	Dade Behring Inc. Christine Larriva P.O. Box 6101 Newark, DE 19714-6101 302-631-0440	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 www.dadebehring.com
lame of instrument/first year sold/where designed Country where manufactured/where reagents manufactured Io. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	www.dadebehring.com Opus Plus/1992/U.S. U.S./U.S. 2,000/300 Batch, random access, cont. random access/benchtop/rectangular tray 16.6 x 34.5 x 23 in./5.5 sq. ft.	Stratus CS Stat Fluorometric Analyzer/1998/U.S. U.S./U.S. 395/200 Random access/benchtop/whole blood collection tube 18 x 27 x 22 in./4.1 sq. ft.
ests 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, $\beta\text{-hCG}$
ests cleared but not clinically released	None	None
ests not available in U.S. but submitted for clearance	None	None
ests 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
Iser-defined methods implemented for what analytes	None	None
fests not available on other manufacturers' analyzers	None	None
ully automated microplate system	No	No
lo. of each analyte performed in separate disposable unit	1 test per test module	n/a
lo. of wells in microplate	n/a	n/a
Nethods supported/separation methods	Fluorescence, EIA/none (all assays homogeneous)	Fluorescence, EIA, dendrimer technology/fiber matrix filter
lo. of different measured assays onboard simultaneously	23	Up to 4
lo. of different assays programmed, calibrated at once	23	1
lo. of user-definable (open) channels	0	0
lo. of different analytes for which system accommodates reagent	20/50 per box	n/a/unit dose test packs
containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code	n/a/n/a/no No Yes Yes/lot no.	n/a/n/a/no Yes Yes
Same capabilities when 3rd-party reagents used/susceptibility to carryover Nalkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Jses disposable cuvettes/max. no. stored	No/zero carryover-new tip for each pipetting Assay dependent/20/20 No/dry No	Yes/assay ID, lot no., expir., calib. param. No/zero carryover 13 min. to 1st result, subsequent results in 4 min. intervals/1/up to 4 No/liquid No
Uses washable cuvettes/replacement frequency	Νο	No
Min. sample vol. aspirated precisely at once/min. dead vol.	10 μL/80 μL	/
Supplied with UPS (backup power)/requires floor drain	Νο/πο	No/no
Requires dedicated water system/water consumption	Νο/π/a	No/n/a
Noise generated	π/a	<65 decibels
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A	No No/n/a/no Yes w/ optional bar-code wand (2 of 5 interl., codabar, codes 39 & 128)/yes —	No No Yes/4 or 5 mL/yes Yes (2 of 5 interl., codabar, codes 39 & 128)/yes Yes
Onboard test auto inventory (determines vol. in container)	No	No
Measures no. of tests remaining/short sample detection	No/yes	No/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Clot detection/reflex testing capability	No/no	Yes/yes
lemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	No/no Yes/no No/no	No/no Yes/no No/no 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
Doboard 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 B-hCG test	17 min.	n/a
Fime delay from ordering stat test to aspir. of sample	Assay dependent	Instantly
Fhroughput per hr for three analytes on	Assay dependent	—/9 (—)
each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	Yes/no No/no —	Yes/yes No/yes (incl. in price) Cerner, Sunquest
IS interface operates simultaneously w/ running assays	Yes	Yes
Ises LOINC to transmit orders and results	No	No
Bidirectional interface capability	Yes (broadcast download & host query)	No
esults transmitted to LIS as soon as test time complete nterface available (or will be) to auto specimen handling system lodem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes No No/yes/yes	Yes No No/yes/yes
an order (via modem) malfunctioning part(s) w/o operator	No	No
n-site response time of service engineer	24 h	
ean time between failures/to repair failures	15 mos./4 h once field svc. rep. on site	/
nboard 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.
Duboard 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
Fraining 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

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Pail to Billion Pail to Bi	b. b. b. toth. uman, K. 1972 Hold 370 Wilds D. L. in Apple, C. 1005 597 are decigned. Base Advancement of the analysis	Part 9 of 17	•	
Canady yourse manufactured with an angel of an antibuland sequence and sequence of the	segente manufactored de la Sala Sala Sala Sala Sala Sala Sala		P.O. Box 6101, Newark, DE 19714-6101 302-631-0433	5700 W. 96th St., Los Angeles, CA 90045-5597
Automation (P ar P ar Diplatament happen) And Automation (P ar P ar Diplatament happen) And P ar Diplat	whed Her Her def 44 2 2 3 3 is in 123 4 9, it. 10 12 4 12 1 20 (it. it. it. it. it. it. it. it. it. it.	Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S.	U.S./U.S. 600/300	U.S./U.S., U.K. 5,000 worldwide
reg., shate, developing interms, developing interms, provided interms, interms,	wetter upf. sing d. gr. dim. 2. data. 2	Dimensions (H x W x D)/instrument footprint		16 x 42 x 24.75 in. (w/o computer)/7.2 sq. ft.
Tets as transition in 15. Surf admitted for detranse tests of admitted in tests of admitted for detranse tests of admitted for detranse	de for elemanne in el lie lie		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	specific IgE, total IgE, EPO, ferr., fol. acid, B ₁₂ , intact PTH, Pyrilinks-D, c cocaine metab., carbamazep., phenytoin, valp. acid, phenobarb., CMV Ig II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO ₄ , estrad., unconj. es LH, progest., prolac., sex horm. binding glob., testost., digitox., digox., tl Ab, anti-TPO Ab, FT ₃ , FT ₄ , rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT ₃ , AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT ₄ & TSH, C-pep., ir myogl., trop. I, ACTH, 82-microgl., cortisol, HsCRP, hGH. Turbo menu: CK myoglob., intact PTH, trop. I, hCG, albumin, <i>H. pylori</i>
Tacks in exception CSA, 50, 4, 6, 4, 600, 80, 100, 100, 100, 100, 100, 100, 10	CSA, C3, C4, dipton, B5, bandarma, equinable PSA Adv.org. a, dif. adv.binn, Daips, CMP (BA), Bold PA, Bold	Tests not available in U.S. but submitted for clearance	Amphet., barb., benz., cocaine, metham., opiates, PCP, THC	None Animal & grass allergy, ECP, mold, tree & weed allergy, osteocalcin, c nicotine metab., anti-HBc (& IgM), anti-HBs, HBsAg & confirm., rubella IgM, free β hCG, BR-MA, cytoker. 18, GI-MA, fPSA, TPS, andost., EBV, c
Torts in valuable on thir manufactures' analyzes Sector Strategies Sector Strategies Sector Strategies Sector Strategies Sector Strategies Ruy activated micropies performed in segarated inpussion Bale in micropies Bale in m	ndres' analyzers and yzers in analyzers in	Tests in development	CSA, C3, C4, digitox., IBC, transferrin., equimolar PSA	None ANA scr., <i>C. diff.,</i> calcitonin, chagas, CMV IgM, dsDNA Ab, bladder tu fibronec., anti-HBe, HBeAg, hep. A, IGF BP3, IGF-1, Lyme IgG & IgG/I
No. of example performant expande disponsible unitn°n°No. of direct ansacted says onbard dimulances:All cap units unidirects, dest tubidirect (intergresson, may not arbitonSentimative exceleds (addition)No. of direct ansacted says onbard dimulances:Set Sing biologic line tubidirect (set tubidirect)Set Sing biologic line tubication)No. of direct ansacted says onbard dimulances:Set Sing biologic line tubicationSet Sing biologic line tubicationNo. of direct as set containes of direct and set on containes of direct and set on containes of direct and set on table (Sing biologic line)Set Sing biologic line)No. of direct as set on containes of direct and set on table (Sing biologic line)Hop onel-30 dispond rang/2 hop well, 3d is directed set, tubication of the set on table (Sing biologic line)Set set set on table (Sing biologic line)Fill opps well, 3d is directed set on table (Sing biologic line)Set set set on table (Sing biologic line)No. of Sing biologic line)Set set set on table (Sing biologic line)No. of Sing biologic line)Set set set on table (Sing biologic line)No. of Sing biologic line)No. of Sing biologic line)No. of Sing biologic line)Set set set on table (Sing biologic line)No. of Sing bi	nik disposable unit via via 19 19 19 19 19 19 19 19		Only system to perform heterogeneous immunoassays & general assays on a	3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, latex-
b. of different measure assay contant simultaneously 40 (with prime inserver measure states of the inserver	particles of sinutfance.uky 46 (5% with optional inventory management system) 12. Turbo: 5 with inventors of the second of the	No. of each analyte performed in separate disposable unit	n/a	n/a
No. of Spring sprogrammed, Splatisk and a none in the splatisk and a splatisk a	ard simulaneously 40 (50 with spinned regroup management system) 12; Turke 5 10 10 10 10 12; Turke 5 10 10 10 10 10 10 10 10 10 10 10 10 10	Methods supported/separation methods		Chemiluminescence/bead, centrifugation
No. of different advect sector share advect soft advect advect soft advect soft advect soft advect advect soft	1001/2 for starts to for lutset PIN onlyrootainer set24 hopen well-30 d unopenedrys (2-8° C)n/a/30 d/ys (15° C)riseYesYesrootainer setYesYesrootainer setYesYesrootainer setYesYesrootainer setYesYesrootainer setYesYesrootaine setYesYesrootaine setYesYesrootaine setYesYesrootaine setYesYesrootainer yYesYesrootainer y <td></td> <td>48 (95 with optional inventory management system)</td> <td></td>		48 (95 with optional inventory management system)	
containers onload at once: tests per container setSortest: media once argent configuration support21 h open well-30 d unspender (sp. 72 h open well, 30 d u	r container set information and a set of the set of th	No. of user-definable (open) channels	10	0
Multiple respont configurations supportedYisYesRequent container placed directory on support field or you on you on you of you you with the support of you	rtedYesYesyesYes/ample ID no., patient name, medical record no., testsYes/lest, 14, explr.r codeYes/ample ID no., patient name, medical record no., testsYes/lest, 14, explr.r codeYes/nample ID no., patient name, medical record no., testsYes/lest, 14, explr.r/lests-essays	containers onboard at once/tests per container set		
Respire bisodd/information in bar oddYes/sample ID, aptiont nam, nedical roord no, bestsYes/sample V, appired N, appir	re ode versible versi	Multiple reagent configurations supported		Yes
Walkaway capacity in min./pacimani/htabis-assays	//det_sessors//det_//det_//det_det_det_det_det_det_det_det_det_det_	Reagents bar-coded/information in bar code		Yes/test, lot #, expir.
Use as space wetter spreasement frequencyYes/1200Yes/in aMin. sample vol. spirated precisely at once/min. deat vol.2 µ/-Spirated Min Sample vol. Spirated Precisely at once/min. deat vol.2 µ/-Min. sample vol. spirated precisely at once/min. deat vol.2 µ/-Spirated Min Sample vol. Spirated Precisely at once/min. deat vol.2 µ/-Requires dodicated vater system/water consumptionYes/2 µ sr hNo.5 1 µr hNo.5 1 µr hRequires dodicated vater system/water consumptionYes/2 µ sr hNo.5 1 µr hNo.5 1 µr hPrimary tube sampling/fue sizes/pierces caps on primary tubesYes/5 /1 0 µ/onNo.4 µr hNo.4 µr hBar code placement per WCDS standard Aut22AYesYes (2 d 5 linet, codebar, codes 39 a 128)/neYes (2 d 5 linet, codebar, codes 39 a 128)/neBar code placement per WCDS standard Aut22AYesYesNo.6 µr hMeasures n. of tasts remaining/short sample dretectionYes/YesYesHendynsylvahrdidity defection-quantifianYes /YesNo.6 µr hMeasures n. of tasts remaining/short sample dretectionYes/YesNo.6 µr hSample Va, can be reduced/noreased to rennYes /YesNo.6 µr hTime between initial result (respiration of sample for renuYes/YesNo.6 µr hNo docalizators required for each analyteYes/YesNo.6 µr hNo docalizators require	red non with the second	Walkaway capacity in min./specimens/tests-assays		100/—/ 70
Min. sample vol. sapirately precisely at once/min. dead vol.2µ/—5µ//Requires dedicated vater system/water consumptionYes/32 (pr hNo 51 per hNoise generatedYes/32 (pr hNo 51 per hNoise generatedYes/32 (pr hNo 51 per hNoise generatedYes/32 (pr hNo 51 per hSample dedicated vater system/water consumptionYes/32 (pr hNo 10/12Sample bar-oote reading rapability/statiodic:riminationYes (2 4 5 intel., codator, codes 38 4 120)/yesYesSample bar-oote reading rapability/statiodic:riminationYes (2 4 5 intel., codator, codes 38 4 120)/yesYesNo code patient reading rapability/statiodic:riminationYes (2 4 5 intel., codator, codes 38 4 120)/yesYesNo code patient reading rapability/statiodic:riminationYes (YesNoNo code patient samples onboard/stationatic rerun capabilityYes/yesNoNo code patient rapability/station framponeYes/yesNoNo code patient reading rapability/station framponeYes/yesNoNo code patient rapability frame rapability frameNoNoNo code patient rapability frameYes/yesNoNo code patient rapability frameYes/yesNoNo code patient rapability frameYes/yesNoNo code patient rapability frame rapability frame <td< td=""><td>to one of min. dead vol. 2 µ/— 5 µ/F S 5 def bits in the set of th</td><td>Uses disposable cuvettes/max. no. stored</td><td>Yes/12,000</td><td>Yes/n/a</td></td<>	to one of min. dead vol. 2 µ/— 5 µ/F S 5 def bits in the set of th	Uses disposable cuvettes/max. no. stored	Yes/12,000	Yes/n/a
Requires dedicated water system/water consumption Yen32 Lpr h Mol 51 per h Noise generated 470 doubles 56 ecbels min, max. 68 56 ecbels min, max. 68 Has dedicated polishir sample cup/dead vol. Yen10 JL-2 µL No No Sample bar-code reading capability/autodiscrimination Yes (24 5 intert, oxdabar, codes 38 2 128)/yes Yes (24 5 intert, oxdabar, codes 38 2 128)/yes Bar code placement per NCO.5 standard Auto2A Yes Yes Yes Auto docted on or document area Yes (24 5 intert, oxdabar, codes 38 2 128)/yes Yes Auto docted on or document area Yes Yes Yes Cold docted on or document area Yes Yes Yes Cold docted on or document area Yes Yes Yes Cold docted on or documentation Yes/yes Nono Dilution of patient samples onobard/automatic rerun capability Yes/yes Nono Auto alloration or auto alloration of annyle for rerun Immediately aller is result No Auto alloration or auto alloration of annyle for rerun Yes/yes No Auto alloration or annyle Yes/yes No No	r consumption 'res/22 µer h 'of decibe' 55 decibes min.max.68 cord decibe' 55 decibes min.max.69 rord decibe' 55 decibes min.max.69 see cage ao primar fubes 'res/5, 71 0m.1/no totofiscrimination 'res (2 of 5 interl, codebar, codes 39 & 129)/yes 'res (2 of 5 interl, codebar, codes 39 & 128)/no res vol. in container) 'res 'res 'res sonic in container) 'res 'res 'res 'res 'res 'res 'res 'res	Min. sample vol. aspirated precisely at once/min. dead vol.		
Noise generated </td <td>c70 decibis57 decibis min.mar. 68adv vi.Yes/10 µ-20 µLNores case on primary tubesYes/2 n 10 mL/noNo/n/2/Yes (2 of 5 interl., codabar, codes 39 & 128)/yesYes (2 of 5 interl., codabar, codes 39 & 128)/yesNord Auto2AYesYes (2 of 5 interl., codabar, codes 39 & 128)/yesNosample detectionYes/yesYesYesyes vol. in container)Yes/yesYesspecimenYes/yesYesspecimenYes/yesNotionMo/noMo/noto menu capabilityYes/yesNoto rerunImmediately after 1st resultu/ato rerunYes/yesNoalty to rerunYes/yesNo<!--</td--><td></td><td></td><td></td></td>	c70 decibis57 decibis min.mar. 68adv vi.Yes/10 µ-20 µLNores case on primary tubesYes/2 n 10 mL/noNo/n/2/Yes (2 of 5 interl., codabar, codes 39 & 128)/yesYes (2 of 5 interl., codabar, codes 39 & 128)/yesNord Auto2AYesYes (2 of 5 interl., codabar, codes 39 & 128)/yesNosample detectionYes/yesYesYesyes vol. in container)Yes/yesYesspecimenYes/yesYesspecimenYes/yesNotionMo/noMo/noto menu capabilityYes/yesNoto rerunImmediately after 1st resultu/ato rerunYes/yesNoalty to rerunYes/yesNo </td <td></td> <td></td> <td></td>			
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Bar iode placement per IVCIS standard AutCA Yes — Mobard test at university (deturmines vol. in container) Yes No Measures no. of tests remaining/short sample detuction Yes/yes Yes/yes Auto detection of adequate reagent or specime Yes Yes Cht detection/reflex testing capability Yes/yes Na/no Hompiss/trubitity detection-quantitation No/no Na/no Dilution of patient samples onboard/automatic rerun capability Yes/yes Na/no Not. Na/no Na/no Out-of-linear range high/low results mmediately after 1st result n/a No. of calibratoria cequided for each analyte Yes/yes Na/no Autocalibration after Yes Na/no Autocalibration cautocalibration after Yes/yes Na/no Autocalibration cautocalibration after Yes/yes Na/no Autocalibration cautocalibration after Yes/yes Na/no Autocalibration after Yes/yes Na/no Autoralibration after Yes/yes Na/no Autoralibration after <td>rid Auto2A 'yes'</td> <td>Primary tube sampling/tube sizes/pierces caps on primary tubes</td> <td>Yes/5, 7, 10 mL/no</td> <td>No/n/a/—</td>	rid Auto2A 'yes'	Primary tube sampling/tube sizes/pierces caps on primary tubes	Yes/5, 7, 10 mL/no	No/n/a/—
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		Annual service contract cost (24h/7d)	\$16,790	\$7,500
Distinguishing features Only instrument available that integrates heterogeneous immunoassays onboard System performance reliability; worldwide user satisfaction; bre			· · ·	<i>,</i> 1

Dimensions (H x W x D)/instrument footprint 79 x 60 x 30/12.5 sq. ft. 28 x 48 x 26 in.47.8 q. ft., incl. onboard computer, reage Tests available on instrument in U.S. AP, PC EX, 0M-MA, PSA, 3rd-gen. PSA, Frg., Trg., Frg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Trg., Frg., Trg., Frg.	TO / CAP TODAY		
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Requires dedicated valer system/valer consumption No/15 per h No/16 Noise generated 22 decibels — Has dedicated pediatric sample cup/dead vol. Yes/70 µL Possible-can use 1.5 mL vial/100 µL Finany tube sample cup/dead vol. Yes/2 7.5 % 100 mm/no Yes/2 0 f5 intel., codabar, codes 39 & 128/yes Yes (2 f5 intel., codabar, codes 39 & 128/yes Bar code picaement per NCCL standard Auto2A Yes Yes Yes Yes Alto detection of adequate regent or specimen Yes (2 f5 intel., codabar, codes 39 & 128/yes Yes Auto adtection of adequate regent or specimen Yes yes Noino Noino Sample Nut, can be reduced/increased to rorun Noino Noino Noino Sample Nut, can be reduced/increased to rorun Noino Noino Noino Sample Nut, can be reduced/increased to rorun Noino Noino Noino Auto-calibration or autocalibration ader Yes Yes Noino Auto-calibration or autocalibration ader Yes Noino Noino Auto-calibration or autocalibration ader Yes/yes Yes/yes Noino Calibratis can be			
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Bar odde placement per VICUS standard Auto2A Yes — Onborard test auto inventory (deturmines vol. in container) Yes Yes Measures no. of tests remaining/short sample detection Yes/yes Yes Auto detection of adequate reagent or specimen Yes Yes Clot detection/reflex testing capability Yes/yes No/no Nomon No/no No/no Dilution of patient samples onboard/automatic rerun capability Yes/yes Yes/no No/no No/no No/no No/no out-of-linear range high/low results No/no No/no nuto calibration alert Yes No No o of alibration alert Yes No No o of alibration required for each analyte 2 level algustors, supplex of analyte Yes/res Obeard to C raquired Dialibration requerency No/1-4 weeks (assay dependent) Yes/res Nord calibration alert Yes No No No Calibratis can be stared onboard/aug, calibration frequency No/1-4 weeks (assay dependent) Yes/res Calibratis can be stared onboard/aug, calibration frequency No/1-4 weeks (assay dependent) Yes/res Calibratis can be stared onboard/aug, calibration frequency No/1 Weeks (assay dependent) Orbeard	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
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Uses LOINC to transmit orders and resultsNoYesBidirectional interface capabilityYes (broadcast download & host query)Yes (broadcast download & host query)Results transmitted to LIS as soon as test time completeYesYesInterface available (or will be) to auto specimen handling systemYes (universal interface)NoModem servicing/can diagnose own malfunctions/determineYes/yes/noNo/yes/yesmalfunctioning componentYes/yes/noNoCan order (via modern) malfunctioning part(s) w/o operatorNoNoOn-site response time of service engineer6 hWin 24 hMean time between failures/to repair failures2 mos/5 h-/Onboard error codes to facilitate troubleshootingYesYesAvg. time to complete maintenance by lab personnelDaily: 5-10 min., weekly: none, monthly: 20-30 min.Daily: 3 min., weekly: 5 min., monthly: noneNo/yesNo/yesS55,000/all bed sizes, all test vols.\$124,500/>\$2,000 tests per month\$55,000/all bed sizes, all test vols.List price/targeted bed size or daily volume\$124,500/>\$12,500\$12,500Incl. in reagent rental	Interfaces up and running in active user sites with	Sunquest, Cerner, HBOC, CCA, ALG	Cerner
Bidirectional interface capabilityYes (broadcast download & host query)Yes (broadcast download & host query)Results transmitted to LIS as soon as test time completeYesYesInterface available (or will be) to auto specimen handling systemYes (universal interface)NoModem servicing/can diagnose own malfunctions/determineYes/yes/noNo/yes/yesmalfunctioning componentCan order (via modem) malfunctioning part(s) w/o operatorNoOn-site response time of service engineer6 hw/in 24 hMean time between failures/to repair failures2 mos/5 h-/Onboard error codes to facilitate troubleshootingYesYesAvg. time to complete maintenance by lab personnelDaily: 5-10 min., weekly: none, monthly: 20-30 min.Daily: 3 min., weekly: 5 min., monthly: noneNo/noNo/noNo/noNo/no			
Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning componentYes (universal interface) Yes/yes/noNoCan order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineerNoNoOn-site response time of service engineer6 hw/in 24 hMean time between failures/to repair failures2 mos/5 h/Onboard error codes to facilitate troubleshooting VesYesYesAvg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo moduleDaily: 5-10 min., weekly: none, monthly: 20-30 min. No/yesDaily: 3 min., weekly: 5 min., monthly: none No/noList price/targeted bed size or daily volume Annual service contract cost (24h/7d)\$124,500/>2,000 tests per month \$12,500\$55,000/all bed sizes, all test vols. Incl. in reagent rental	Bidirectional interface capability	Yes (broadcast download & host query)	Yes (broadcast download & host query)
Modem servicing/can diagnose own malfunctions/determine malfunctioning componentYes/yes/noNo/yes/yesCan order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineerNoNoOn-site response time of service engineer6 hw/in 24 hMean time between failures/to repair failures2 mos./5 h/Onboard error codes to facilitate troubleshooting VesYesYesAvg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo moduleDaily: 5-10 min., weekly: none, monthly: 20-30 min. No/yesDaily: 3 min., weekly: 5 min., monthly: none No/noList price/targeted bed size or daily volume Annual service contract cost (24h/7d)\$124,500/>2,000 tests per month \$12,500\$55,000/all bed sizes, all test vols. Incl. in reagent rental			
Can order (via modem) malfunctioning part(s) w/o operatorNoNoOn-site response time of service engineer6 hw/in 24 hMean time between failures/to repair failures2 mos./5 h/Onboard error codes to facilitate troubleshootingYesYesAvg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo moduleDaily: 5-10 min., weekly: none, monthly: 20-30 min. No/yesDaily: 3 min., weekly: 5 min., monthly: none No/noList price/targeted bed size or daily volume Annual service contract cost (24h/7d)\$124,500/>2,000 tests per month \$12,500\$55,000/all bed sizes, all test vols. Incl. in reagent rental	Modem servicing/can diagnose own malfunctions/determine		
On-site response time of service engineer6 hw/in 24 hMean time between failures/to repair failures2 mos./5 h/Onboard error codes to facilitate troubleshootingYesYesAvg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo moduleDaily: 5-10 min., weekly: none, monthly: 20-30 min. No/yesDaily: 3 min., weekly: 5 min., monthly: none No/noList price/targeted bed size or daily volume Annual service contract cost (24h/7d)\$124,500/>2,000 tests per month \$12,500\$55,000/all bed sizes, all test vols. Incl. in reagent rental		No	No
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo moduleYes Daily: 5–10 min., weekly: none, monthly: 20–30 min. No/yesYes Daily: 3 min., weekly: 5 min., monthly: none No/noList price/targeted bed size or daily volume Annual service contract cost (24h/7d)\$124,500/>2,000 tests per month \$12,500\$55,000/all bed sizes, all test vols. Incl. in reagent rental	On-site response time of service engineer	6 h	w/in 24 h
Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module Daily: 5–10 min., weekly: none, monthly: 20–30 min. Daily: 3 min., weekly: 5 min., monthly: none No/yes List price/targeted bed size or daily volume Annual service contract cost (24h/7d) \$124,500/>2,000 tests per month \$12,500 \$55,000/all bed sizes, all test vols. Incl. in reagent rental			
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	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
Annual service contract cost (24h/7d) \$12,500 Incl. in reagent rental	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
			Immunosimplicity reagent manufactured & 510(k) cleared specif

Interfaces up and running in active user sites with

THUNENTS 72 / CAP TODAY Auton	nated immunoassay ai	nalyzers
		·
Part 11 of 17	DiaSorin Inc. Gary Tremain (gary.tremain@diasorin.com)	DiaSorin Inc. Gary Tremain (gary.tremain@diasorin.com)
	1990 Industrial Blvd. Stillwater, MN 55082	1990 Industrial Blvd. Stillwater, MN 55082
	800-328-1482 www.diasorin.com	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. Operational type/model type/sample handling system	60/550 Batch/benchtop/rack	35/70 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,	HBsAg, anti-HBs, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-H HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-
	CMV-IgM, HSV I-IgG, HSV II-IgG, HSV I/II-IgG, rubeola-IgG, mumps-IgG, VZV IgG,	CMV-IgM, HSV I-IgG, HSV II-IgG, HSV I/II-IgG, rubeola-IgG, mumps-
	MP IgG, <i>H. pylori</i> IgG, Lyme IgG & IgM, syphilis IgG, syphilis IgM, ANA scr., anti- dsDNA, anti-SSA, anti-SSB, anti-Sm, anti-RNP/Sm, anti-ScI-70, anti-Jo-1, anti- biotece anti-corriction	MP IgG, <i>H. pylori</i> IgG, Lyme IgG & IgM, syphilis IgG, syphilis IgM, A dsDNA, anti-SSA, anti-SSB, anti-Sm, anti-RNP/Sm, anti-ScI-70, an biotece anti-activities
Tests cleared but not clinically released	histone, anti-cardiolipin None	histone, anti-cardiolipin
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	None	None None
Tests not available in U.S. but available in other countries	None	None
Research-use-only assays Tests in development	None None	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 No. of each analyte performed in separate disposable unit	Yes —	Yes
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 No. of different assays programmed, calibrated at once	6	11 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 Reagent container placed directly on system for use	Yes No, requires operator prehandling/prep.	Yes Yes
Reagents bar-coded/information in bar code	No	Yes/reagent type
Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays	No/0 w/ disposable tips, wash volume dependent w/ washable tip Per batch	Yes/1 ppm 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 Uses washable cuvettes/replacement frequency	No No	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 Requires dedicated water system/water consumption	Yes/no No/< 1 L per h	Yes/no No/< 1 L per h
Noise generated		
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes	No Yes/10 mm, 14 mm/—	No 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	
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 Hemolysis/turbidity detection-quantitation	No/no No/no	Yes/no No/no
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be 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. of calibrators required for each analyte	No	No Variable
Calibrants can be stored onboard/avg. calibration frequency	—/ —	No/per batch
Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	—/— Each batch	Yes/no Each batch
Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	Yes/no No/—/15 min.	Yes/no No/—/15 min.
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample	n/a —	n/a —
Throughput per hr for three analytes on	Varies by assay, up to 90 specimens per microtiter plate	Varies by assay, up to 90 specimens per microtiter plate
each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC	No/yes	No/yes
	Onboard/yes (incl. in price)	Onboard/no

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

NSTRUEL OK

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	Fully automated allergy & autoimmune testing; >900 allergens; user-definable software
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
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
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
malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	No	No
Interface available (or will be) to auto specimen handling system	No	No
Modem servicing/can diagnose own malfunctions/determine	No/yes/yes	Yes/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
IS interface operates simultaneously w/ running assays Ises LOINC to transmit orders and results	Yes	No No
nterfaces up and running in active user sites with	All major LISs	-
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
Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	Depends on reagent methodology	n/a
Stat time to completion of B-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
Automatic shutdown/startup is programmable/startup time	Yes/no/1–2 min	Yes/no/2–3 min.
How often QC required	Each run	Every assay
Doboard realtime QC/support multiple QC lot nos. per analyte	No/no	Yes/yes
Calibrants can be stored onboard/avg. calibration frequency	Vorna	No/monthly
Multipoint calib. supported/multiple calibs. stored for same assay	Yes/no	Yes/yes
Autocalibration or autocalibration alert	No	Yes
No. of calibrators required for each analyte	1–14	1–5
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	n/a	n/a
Dilution of patient samples onboard/automatic rerun capability	Yes/no	Yes/no
Sample vol. can be reduced/increased to rerun	No/no	No/no
Clot detection/reflex testing capability	Yes/yes	Yes/no
Hemolysis/turbidity detection-quantitation	No/no	No/no
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen	Yes	Yes
Bar code placement per NCCLS standard Auto2A	Yes	No
Onboard test auto inventory (determines vol. in container)	Yes	Yes
Sample bar-code reading capability/autodiscrimination	Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes (2 of 5 interl., codabar, codes 39 & 128)/n/a
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
Requires dedicated water system/water consumption Noise generated	No/	No/
Vin. 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
Jses disposable cuvettes/max. no. stored	No	No
Jses washable cuvettes/replacement frequency	No	No
System is open (home-brew methods can be used)/liquid or dry system	Yes/liquid	Yes/liquid
Same capabilities when 3rd-party reagents used/susceptibility to carryover Nalkaway capacity in min./specimens/tests-assays		No/<1 part in 10,000 Assay dependent/100/288
Reagent container placed directly on system for use	Requires operator prehandling/preparation	Yes
Reagents bar-coded/information in bar code	No	No
Shortest/median onboard reagent stability/refrigerated onboard	n/a/n/a/no	8 h/12 h/no
Multiple reagent configurations supported	Yes	Yes
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
No. of user-definable (open) channels	Unlimited	Multiple
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
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
-	time	
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	96–min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells
Fully automated microplate system	Yes	Yes
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
Research-use-only assays	n/a	lgG
Tests in development	n/a	None
Tests not available in U.S. but available in other countries	n/a	IgG, Basophil Histamine Release, cardiolipin IgA, cardiolipin IgA, IgG, IgM, ssD HPO p-ANCA, mitochondrial, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM, CIC Clq, CIC C3d
Tests cleared but not clinically released	n/a	None
Tests not available in U.S. but submitted for clearance	n/a	RF IgA
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, IgG, RF IgM, PR-3 ANCA, ENA-6 profile, ENA-6 scr., SS-A, SS-B, gliadin IgG & I Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, cardiolipin scr.; u definable software
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.
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
lame of instrument/first year sold/where designed	Triturus/1999/Spain	Hy+Tec 288/ex U.S. 1998, U.S. 1999/Netherlands
	8880 NW 18th Terr. Miami, FL 33172 800-379-0957 www.grifols.com	7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com

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FUNEN ⁵ 74 / CAP TODAY April 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 Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Hy•Tec 480/1994/Switzerland Switzerland/U.S., Germany, Scotland 8/57 Batch, random access/benchtop/rack-robotics 19.7 x 55 x 28 in./10.6 sq. ft.	CL System ID/1993/Sweden U.S./U.S. 60+/— Batch/benchtop/rack Processor: 17 x 48 x 26 in.; washer: 15 x 27 x 20 in.; luminometer: 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, ScI-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, cardiolipin scr.; <i>H. pylori;</i> user-definable software	hGH, prolac., FT ₄ , ferr., FSH, TT ₄ , TSH, LH, intact PTH, cortisol, and ACTH, TT ₃ , erythropoietin., T ₃ -uptake, DHEAS, calcitonin, thyroglo
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	None Rf IgA 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 Clq, CIC C3d	None None None
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	lgG, Basophil Histamine Release None <i>H. pylori</i> Allergy & autoimmune testing on fully automated system, BHR	None None None IgF I
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	Yes 8 96-min. strip: 8 wells/1 strip, max. full plate: 12 strips/96 wells	No n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar-coded/information in bar code	EIA, tube-based & microplate-based assays/cellulose disc & coated well Varies by assay, up to 480 Multiple Multiple 1/200-allergy, 96-autoimmune 8 h/12 h/no Yes No, requires oper. prehandling/prep. No	Chemiluminescence/bead 1 1 0 1/100 8 h/1 d/no Yes No, requires oper. prehandling/prep. No
Same capabilities when 3rd-party reagents used/susceptibility to carryover Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated	No/<1 part in 10,000 Assay dependent/100/480 Yes/liquid No No 10 μL-50 μL, assay dependent//300 μL Yes/no No/	—/ —/256/1 Yes/liquid No No 25 µL/150 µL No/no No/ —
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	No Yes/—/no Yes (2 of 5 interl., codabar, codes 39 & 128)/n/a No Yes Yes/yes Yes No/no	No Yes/10 x 75/no Yes (2 of 5 interl., codabar, codes 39 & 128)/yes No No No/no Yes Yes
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	No/no Yes/no No/no n/a Yes	No/no Yes/no No/no
No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency Multipoint calib. supported/multiple calibs. stored for same assay How often QC required Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	1–5 No/monthly Yes/yes Every assay Yes/yes Yes/no/5 min.	2 Yes/once per run Yes/no Shortest interval: 4 h, longest: 8 h No/no No/no/10 min.
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time)	n/a n/a n/a	n/a — —/— (—)

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

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Frunt ⁵ 76 / CAP TODAY Auton	nated immunoassay ar	halyzers
Devis 1.4 of 17	Nichols Institute Diagnostics	Olympus America Inc.
Part 14 of 17	Bill Wilson (wilsonb@nicholsdiag.com)	Susan Watanabe (watans@olympus.com)
	33051 Calle Aviador San Juan Capistrano, CA 92675	Two Corporate Center Dr. Melville, NY 11747
	800-286-4643 x 5212 nicholsdiag.com	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. Operational type/model type/sample handling system	>120/>160 Batch, cont. random access/benchtop/rack	>300/>800 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 0, apolipo. A1 & B, microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 & C4 com ferr., haptoglobin, immunogl. A, G, M, microalbumin, myogl., prealb., rheu transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyrami ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobar phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethar methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox uptake, T ₄ thyrox. Also, general chemistries, enzymes, HDL
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	None None	Ceruloplasmin 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 Tests in development	Osteocalcin, pepsinogen I 25 hydroxy vit D, 1,25 dihydroxy vit D, IGFBP-3, Sangtec 100, direct renin,	None LDL
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	aldosterone, <i>H. pylori</i> None IGF-1, calcitonin, pepsinogen	HbA1c, fructosamine None
Fully automated microplate system	No	No
No. of each analyte performed in separate disposable unit No. of wells in microplate	n/a n/a	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 No. of different assays programmed, calibrated at once	15 15	>40 99
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 15/varies, typically 100	95 76/100–6,160
containers onboard at once/tests per container set 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 Same capabilities when 3rd-party reagents used/susceptibility to carryover	Yes/assay ID, lot no., serial no., expir. r_No/<5x10 ⁻⁵	Yes/reag. ID, lot no., bottle no., expir. 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 Uses washable cuvettes/replacement frequency	Yes/120 No	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 Requires dedicated water system/water consumption	Yes/no No/—	Optional/yes 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 Sample bar-code reading capability/autodiscrimination	Yes/10 x 75, 16 x 100 mm/no Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes/pediatric, 5 mL, 7 mL, 10 mL/no 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 Auto detection of adequate reagent or specimen	Yes/yes Yes	Yes/yes Yes
Clot detection/reflex testing capability	Yes/no	Yes/yes
Hemolysis/turbidity detection-quantitation Dilution of nations samples onboard/automatic rerun canability	No/no Yas/no	Yes/yes Yes/yes
Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun	Yes/no No/no	Yes/yes Yes/yes
out-of-linear range high/low results	27 min	Varias bu run siza
Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert	37 min. No	Varies by run size Yes
No. of calibrators required for each analyte	2	1–6
Calibrants can be stored onboard/avg. calibration frequency Multinoint calib, supported/multiple calibs, stored for same assay	No/7 d Yes/no	Yes/14 d Yes/no
Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	res/no Shortest interval: 4 h, longest: 8 h	Yes/no Lab-defined
Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	No/no No/no/10 min.	Yes/yes Yes/yes/24 h availability
Stat time to completion of B-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 Interfaces up and running in active user sites with	Onboard/yes (incl. in price) All commercially available LISs	Onboard/yes (addt'l cost) Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, A SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Orchard, Citation

LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes Yes Yes (broadcast download & host query) Yes No No/yes/yes	Yes No Yes (broadcast download & host query) Yes Yes (Olympus OLA 1500 Sorter, Labotix, Lab InterLink) Yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/to repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module	No 24 h 183 d/24 h Yes Daily: 10 min., weekly: 30–45 min., monthly: 5 min. No/no	No <24 h >20 weeks/<24 h Yes Daily: 3 min., weekly: 7 min., monthly: 45 min. Daily: 3 min., weekly: 7 min., monthly: 45 min. Yes (incl. audit trail of who replaced parts)/yes
List price/targeted bed size or daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$125,000/300+ beds Inquire 5 d at vendor offices/yes	\$130,000/200–2,000 tests per d (depending on menu) Inquire 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

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ET HENTS 80 / CAP TODAY FUNE AUTON	nated immunoassay ai	nalyzers
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	Roche Diagnostics Dale Knight (dale.knight@roche.com) 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074
	www.orthoclinical.com	www.roche.com/labsystems/us
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system	Vitros ECi Immunodiagnostic System/1997/U.S. U.S./U.K. >1,000 worldwide Cont. random access/floor-standing/universal sample racks (circular) accommodate primary & secondary tubes without need for adapters	Elecsys 2010/1996/— Japan/Germany >500/>3,500 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 &-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., MB, trop. T, myglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferr., RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β -hC anti-TPO
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	aHBs, B ₁₂ , folate, RBC folate, PSA HBsAg, aHCV CA 19-9, fβ–hCG, a-HBc IgM, a-HBc, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II	— HBsAg, HBsAg (conf) Osteocalcin, CA 19-9, anti-HBc, Cyfra 21-1, anti-HBs, anti HBc IgM, a HBeAq
Research-use-only assays Tests in development	None Myoglobin	
User-defined methods implemented for what analytes	None	None
Tests not available on other manufacturers' analyzers	Hepatitis, HIV	Trop. T, serum β Crosslaps, free PSA
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	No n/a n/a	No n/a n/a
Methods supported/separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	Chemiluminescence (enhanced)/coated microwell 20 —	Electrochemiluminescence/magnetic particle 15 60
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 20/100	0 15/100–200
containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported	—/60 d/yes (2°–8°C) Yes	56 d/56 d/yes (20°C) Yes
Reagent container placed directly on system for use Reagents bar-coded/information in bar code	Yes Yes/test ID, expir., lot no., pack ID	Yes Yes/calib. curve, application params., lot no., expir., reag. name
Same capabilities when 3rd-party reagents used/susceptibility to carryove		No/zero carryover (disposable sample tips)
Walkaway capacity in min./specimens/tests-assays System is open (home-brew methods can be used)/liquid or dry system	No/liquid	120/disk: 30, rack: 100/180 No/liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	Yes/2,000 No	Yes/— No
Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	10 µL/60 µL Yes/—	10 µL/100 µL —/no
Requires dedicated water system/water consumption	No/—	—/110 No/—
Noise generated Has dedicated pediatric sample cup/dead vol.	Not determined No	— No
Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination	Yes/multiple ped. cup capabilities/no Yes (2 of 5 interl., codabar, codes 39 & 128)/yes	Yes/13–16 mm diam./no 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) Measures no. of tests remaining/short sample detection	Yes Yes/yes	Yes Yes/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	Yes Yes/yes	Yes Yes/no
Hemolysis/turbidity detection-quantitation	Yes/yes	No/no
Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun	Yes/yes Yes/yes	Yes/no No/no
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	_	
Autocalibration or autocalibration alert	Yes	Yes
No. of calibrators required for each analyte Calibrants can be stored onboard/avg. calibration frequency	1–3 No/28 d	2 No/monthly
Multipoint calib. supported/multiple calibs. stored for same assay How often QC required	Yes/yes 1 per d	Yes/yes Once per 24 h
Onboard realtime QC/support multiple QC lot nos. per analyte	Yes/yes Yes/yes Yes/yes/5 min. from power off	Yes/yes
Automatic shutdown/startup is programmable/startup time	· .	No/no/4 min.
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample	24 min. —	9 min. 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 Data management capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with	Yes/yes Onboard/no Cerner, Sunquest, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, HBOC, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche	Yes/yes Onboard/yes (addt'l cost) All major LISs
LIS interface operates simultaneously w/ running assays	Yes Vac	Yes
Uses LOINC to transmit orders and results Bidirectional interface capability	Yes Yes (broadcast download)	No Yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system	Yes Yes (all systems)	Yes 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 «4 la (contrast dependent)	No
On-site response time of service engineer Mean time between failures/to repair failures	<4 h (contract dependent) —/dependent on corrective action	<24 h —/—
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	Yes Daily: <5 min., weekly: <30 min., monthly: <10 min.	Yes Daily: 1 min., weekly: 5 min., biweekly: 25 min., monthly: none
Onboard maintenance records/maintenance training demo module List price/targeted bed size or daily volume	No/yes \$140,000/daily volume to approx. 1,000 tests	No/no (training CD-ROM) Disk: \$120,000, rack: \$135,000/various
Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	Varies w/ service level choices As needed on-site, 4 d at vendor offices/yes	Incl. w/ reagent rental 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	Connectable to Clinical Lab Automation System; liquid ready-to-use r autocalib., autodil.; ECL technology for broad dynamic ranges, & fast time, stat interrupt; onboard reag. storage; minimal maintenance

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EN ENS 82 / CAP TODAY FRUNE IN BALLON	nated immunoassay ar	nalyzers
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 Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system Dimensions (H x W x D)/instrument footprint	Elecsys 1010/1997/— Switzerland/Germany >275/>2,500 Random access/benchtop/sample disk 25.6 x 37 x 25.2 in./6.5 sg. ft.	Aptus Automated EIA System/1998/— —/U.S. — Batch, random access/benchtop/rack 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 I capture, toxo rubella & CMV IgG quant., HSV-I IgG, HSV-II IgG, HSV I/I Ig EA IgG, EBV VCA IgG & IgM, EBV EBNA IgG, VZV IgG, mumps IgG, measle burgdorferi IgG/M, <i>H. pylori</i> IgG, <i>Legionella</i> IgG/M/A, mycoplasma IgG & ENA, & ANCA screens, SS-A/Ro, SS-B/La, Sm, Sm/RNP, ScI-70, Jo-1, ds IgM, gliadin IgA & IgG, anticardiolipin IgG, IgM, & IgA, MPO, PR-3, TPO,
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— — Osteocalcin, CA 19-9, HBsAg, anti-HBs, anti-HBc, Cyfra 21-1	None None Quant EBV EA, VCA, IgG & IgM, EBNA
Research-use-only assays Tests in development	 CA 72-4, NSE, anti-TG, TG, sHBG	None Syphilis, salivary ELISAs, HBA _{1C}
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	None Trop. T, serum β Crosslaps, fPSA	Implemented by end user–HBsAg, HIV, syphilis, coccidiodes, PSA None
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	No n/a n/a	Yes — Min. strip: break-away wells, max. full plate: 96 x 4 plates
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures no. of tests remaining/short sample detection Auto detection of adequate reagent or specimen Clot detection/reflex testing capability Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample vol. can be reduced/increased to rerun out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte	ECLIA electrochemiluminescence IA/ magnetic particle 6 	9 >100 20 9/96 12 h/7 d/no Yes Yes Yes/ot no. & expiration date Yes/zero carryover /120/9 Yes/liquid No No 10 μL/50 μL Yes/no No/n/a
Stat time to completion of ß-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in no. of specimens/no. of tests (cycle time) Can auto transfer QC results to LIS/onboard capability to review QC	No/no/5 min. 9 min. 65 sec. 20/55 (65 sec.) Yes/yes Onboard/yes (addt'l cost) All major LISs	Yes/<3 min. n/a n/a Depends on combination of assays No/yes Onboard/optional (addt'l cost) 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	—/—	<u> </u>	
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	

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FUNENTS 84 / CAP TODAY FUNENTS AUTON	nated immunoassay a	nalyzers
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	Tosoh Medics Inc. Jane Merschen (jane@tosohm.com) 347 Oyster Point Blvd., #201 S. San Francisco, CA 94080 650-615-4970
	www.tosohm.com	www.tosohm.com
Name of instrument/first year sold/where designed Country where manufactured/where reagents manufactured No. of units in clinical use in U.S./outside U.S. Operational type/model type/sample handling system	AIA Nex•IA/1997/Japan Japan/Japan 40/300 Cont. random access/floor-standing/rack, carrousel, TLA	AIA-600 II/2000/Japan Japan/Japan 60/300 Cont. random access/benchtop/chain
Dimensions (H x W x D)/instrument footprint Tests available on instrument in U.S.	47 x 35 x 26 in./6.3 sq. ft. TSH, 3rd-gen. TSH, FT ₄ , T ₃ , T ₄ , T-uptake, FT ₃ , TPO Ab, Tg Ab, β hCG, estradiol, FSH, hCG (intact), LH II, progesterone, prolactin, AFP, CEA, PSA, CA 125, β -2 microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin,	19.8 x 31.6 x 29.1 in./2.5 sq. ft. Same menu as for AIA-Nex+IA (see column at left)
Tests cleared but not clinically released	troponin I, ferritin, folate, B ₁₂ 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 Research-use-only assays Tests in development	HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa CA 19-9 Testost., CA 15-3, digox., type IV collagen, RBC fol.	HBsAg, HBsAb, HBeAg, toxo IgG & IgM, rubella IgG & SLa CA 19-9 Testost., CA 15-3, digox., type IV collagen, RBC fol.
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	None	None None
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	No n/a n/a	No n/a n/a
Methods supported/separation methods	Fluorescence, EIA/bead	Fluorescence. EIA/bead
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	234 Entire menu	≥34 Entire menu
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent	0 N/a/unitized test cup	0 N/a/unitized test cup
containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard	72 h/72 h/n/a	72 h/72 h/n/a
Multiple reagent configurations supported Reagent container placed directly on system for use	Yes Yes	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 Walkaway capacity in min./specimens/tests-assays	52/75–200/400 for the standard model	No/zero carryover 52/26/26
System is open (home-brew methods can be used)/liquid or dry system Uses disposable cuvettes/max. no. stored	No/dry n/a/unitized test cup	No/dry n/a/unitized test cup
Uses washable cuvettes/replacement frequency	n/a	n/a
Min. sample vol. aspirated precisely at once/min. dead vol. Supplied with UPS (backup power)/requires floor drain	10 µL/50 µL Yes/no	10 μL/100 μL Yes/no
Requires dedicated water system/water consumption Noise generated	No/n/a	No/n/a —
Has dedicated pediatric sample cup/dead vol. Primary tube sampling/tube sizes/pierces caps on primary tubes Sample bar-code reading capability/autodiscrimination	No Yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no Yes/yes	No Yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & Yes/yes
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container)	Yes Yes	Yes Yes
Measures no. of tests remaining/short sample detection	Yes/yes	Yes/yes
Auto detection of adequate reagent or specimen Clot detection/reflex testing capability	Yes Yes/no	Yes Yes/no
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	No/no Yes/no	No/no Yes/no
Sample vol. can be reduced/increased to rerun	No/yes	No/yes
out-of-linear range high/low results Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert No. of calibrators required for each analyte	No 2 or 6—analyte dependent	No 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 How often QC required	Yes/yes 24 h	Yes/yes 24 h
Onboard realtime QC/support multiple QC lot nos. per analyte Automatic shutdown/startup is programmable/startup time	Yes/yes No/no/5–8 min.	No/no No/no/5 min.
Stat time to completion of B-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 Data management capability/instrument vendor supplies LIS interface	Yes/yes Optional add-on (software mftr: Schuyler House, Sunquest, LabForce, HBOC, Antrim, Data Innovations)/yes (addt'l cost)	Yes/no Optional add-on (software mftr: Schuyler House, Sunquest, LabFor Antrim, Data Innovations)/yes (addt'l cost)
Interfaces up and running in active user sites with	Schuyler House, Fletcher Flora	Schuyler House, Fletcher Flora
LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results	Yes Yes	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 Interface available (or will be) to auto specimen handling system Modem servicing/can diagnose own malfunctions/determine malfunctioning component	Yes Yes (Hitachi, Panasonic, Sysmex) No/no/no	Yes No No/no/no
malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator	No	No
On-site response time of service engineer Mean time between failures/to repair failures	24 h —/—	24 h Unknown/—
Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel	Yes Daily: 5–8 min., weekly: none, monthly: none	Yes Daily: 5 min., weekly: 5 min., monthly: none
Onboard maintenance records/maintenance training demo module List price/targeted bed size or daily volume	Yes (incl. audit trail of who replaced parts)/no \$135.000/65+ beds 1.500-2.000 + tests	No/no \$70,000/500–2,500 tests per month
List price/targeted bed size of daily volume Annual service contract cost (24h/7d) Training provided w/ purchase/advanced operator training	\$135,000/65+ beds, 1,500–2,000 + tests \$10,800 4 d at vendor offices/no	\$70,000/500-2,500 tests per month \$5,600 3 d at vendor offices/no
Distinguishing features	3 sample loading options on single system: 200 sample rack loader, TLA adaptable, standard carrousel model; unitized test cups; primary tube sampling; no reagent prep.; dual clot detection; room temp. stability for 5 d; automated	Unitized test cups; primary tube sampling; no reagent prep.; dual o room temp. stability for 5 d; automated sample dilution & pretreatu generation TSH sensitivity; appropriate for stat & routine use