22 / CAP TODAY October 2008

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	Abaxis Inc.	Abbott Point of Care
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Part 1 of 11	800-822-2947 www.abaxis.com	800-827-7828 www.abbottpointofcare.com
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Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007	Piccolo Xpress/2006 18,000/—	i-Stat 1 analyzer/2000 —/—
No. units in clinical use in U.S./Outside U.S.	2,500/4,000	/ 30,000+ worldwide
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./Canada
Operational type/Reagent type	self-contained disk with multi-test reagent panel	—/self-contained single-use cartridges packages-slides
Sample handling system/Model type	disk loaded directly into instrument/benchtop	na/handheld
Dimensions in inches (H \times W \times D)/Instrument footprint	12.75 × 6 × 8/1 sq ft	9.25 × 3.0 × 2.85/< 1 sq ft
Tests available on instrument in U.S.	ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN,	tropinin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium,
	creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase,	potassium, chloride, hematocrit, pH, PCO2, PO2, TCO2, ACTc, ACTk, PT/INR;
	potassium, TCO2, chloride, cholesterol, HDL ratio, HDL, LDL, triglycerides-VLDL,	hemoglobin, HCO3, BEecf, SO2, anion gap, BNP
Tests alcoyed but not alinically released	phosphorus, direct bilirubin, magnesium, LD, C reactive protein	
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance	-	Ξ
Tests not available in U.S. but available in other countries	none	Ξ
Research-use-only assays/Tests in development	-/-	—/—
User-defined methods implemented for what analytes	none	
Methods supported/Immunoassay methods	enzymatic/—	potentiometry, amperometric, conductometric/—
No. of direct ion selective electrode channels	_	10
Must load separate reag. pack for each specimen/No. of diff.	no, self-contained discs with multi-test reagent panel/up to 14 tests per disc with 13 available discs	yes/up to 13
assays in pack • Separate reag. pack for each test run	with 13 available discs	yes
No. of different measured assays onboard simultaneously	CLIA waived CMP has 14 analytes	—
No. of different assays programmed, calibrated at once	14	18
No. of user-definable (open) channels/No. active simultaneously	0/—	_/_ /:
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	self-contained reagent discs have from 2 to 14 tests per disc	—/unit use
Shortest/Median onboard reag. stability/Refrigerated onboard	—/—/—	—/14 days/no
Multiple reag. configurations supported	yes	no
Reag. container placed directly on system for use	yes	-
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/		— based on volume/—/based on volume
Therapeutic drugs/Special analytes	\$0.57/—/—	Dased on volume/—/Dased on volume
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	approximately 12/1/14	2/1/up to 18
System is liquid, dry, or reconstituted onboard	reconstitutes onboard	<u> </u>
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	no/— requires 80 to 100 μL of whole blood, serum, or plasma	no/— 16 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/—
Noise generated in decibels	none	none
Dedicated pediatric sample cup/Dead volume	no no/	no/— no/no
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	no/— yes/—	yes, shortly before sample is aspirated, by handheld scanner as tubes are
dampie bai code reading dapability. Tattodiocini	y631—	loaded, at the bedside (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/	— —/yes/yes	— —/yes/yes
Clot detection	—/ yes/ yes	—/ yes/ yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high	yes/no —/—	no/no no/no
results/Increased to rerun out-of-linear-range low results	<i>-</i> -	no/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of	self-calibrated onboard/disk/—/—	each test/each test/—/—
abuse Automatic shutdown/Startup programmable	yes/yes	yes/yes
	, jour jou	300/300
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine	10–12 min, 2–14 tests 10–12 min, 2–14 tests	2 min, — 2 min, —
Solidini, potassidin, cinoride, 1002, glucose, drea, creatinine Album., direct & total bili., AST, ALT, ALP	10–12 min, 2–14 tests 10–12 min, 2–14 tests	
Typical time delay from ordering stat test to aspir. of sample	_	none
How often QC required/Onboard SW capability to review QC	automatic QC onboard/yes	shortest interval: 24 hr; longest interval: each new lot or reagent/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes ves	yes/yes yes
QU results transieneu automaticany to Elo	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	optional add-on (<\$30,000, SW mftr: Abbott Point of Care)/yes (add'l cost)
Lab information systems with which interfaces up and running in	hundreds of LIS and EMR systems	all systems
active user sites Bidirectional interface capability		(bysedeset download 9 heat grow)
Test results transmitted to LIS as soon as chem. time complete	yes yes	yes (broadcast download & host query) yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	_	customized on site
Lab can control analyzer remotely	no	yes
Interface avail. (or will be) to automated specimen handling system	-	
Marten convicing available/Can diagnose own maltunations/		······································
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for	24-hr loaner/yes	replacement within 24 hr/yes
troubleshooting		
Mean time between failures/To repair failures	3 years/—	not determined/replacement within 24 hr
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: none; weekly: none; monthly: none —/yes	daily: none; weekly: none; monthly: none —/—
Training provided with purchase/Advanced oper. training avail.	yes/yes	/ /yes
Annual service contract cost (24 h/7 d)	1-year warranty, extended warranty—\$1,200	\$750
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Distinguishing features (supplied by company)	provides comprehensive CLIA-waived menu of tests; 13 available discs (9 CLIA waived) represent most commonly ordered chemistry panels; works with three	handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests on two drops of whole blood or plasma
	simple steps, as easy to operate as a CD player; provides lab-accurate results	Calulate Illainel, alle coagulation tosts on two grops of miloto stock of piece
	on site, in minutes, using 100 µL sample of whole blood, serum, or plasma;	
	intranet connectivity helps labs extend their reach to the point-of-care, while	
	maintaining centralized control of test data	

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Part 2 of 11	800-220-4488 www.alfawassermannus.com	800-220-4488 www.alfawassermannus.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ACE/1993; ACE Alera Clinical Chemistry System/2004 \$69,995/— 1,200/700+ U.S./U.S./U.S. batch, random access, discrete, continuous random access/stat & closed	Alfa S40/2008 \$32,500/200 0/400 Japan/Japan/Japan batch, random access, discrete, continuous random access/self-contained
Sample handling system/Model type Dimensions in inches (H \times W \times D)/Instrument footprint	reagent system with open reagent system channel ring with up to 5 segments (15 samples per segment)/benchtop ACE: $15.75 \times 27.25 \times 22.50$; ACE Alera: $18 \times 27.5 \times 22.5/4.3$ sq ft	single-use cartridges-packages-slides single patient rack with multiple sample types/benchtop $17.6\times21.1\times23.4/3~\text{sq ft}$
Tests available on instrument in U.S.	albumin, gamma GT, bilirubin direct & total, calcium, creatinine, glucose, inorganic phosphorus, total iron, magnesium, total protein, BUN, uric acid, amylase, AST (GOT), alkaline phosphatase, ALT (GPT), CK, LDH, cholesterol, HDL-C, LDL-C, triglycerides, sodium, potassium, chloride, CO2, digoxin, T4, T-uptake, HbA1c, lipase, direct TIBC, ferritin, homocystein, Lp(a), microalbumin, apo A1, apo B, transferrin	ALP, ALB, ALT, amylase, AST, Tbili, BUN, Ca, chol, creat, GGT, GLU, HDL, IP, LDH, TRIG, TP, UA, CO2
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	none UIBC	CK, CRP HbA1c, LDL-C, DIG, THEO (No. 1) The control of the control
Research-use-only assays/Tests in development User-defined methods implemented for what analytes	open-channel bottles are available for user-derived or third-party reagents	—/HbA1c, LDL, digoxin, theophylline, magnesium —
Methods supported/Immunoassay methods	photometry, potentiometry (ion selective electrode), turbidimetric/ homogeneous EIA	photometry
No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff. assays in pack	3 no/—	0 no/—
Separate reag. pack for each test run	no	yes
No. of different measured assays onboard simultaneously	40	0
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag.	200 15/15 40/30–250 tests per bottle	40 0/0 40/1 test per container set
containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard	5 days/30 days/yes (10° to 14°C)	—/—/no
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	no yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	yes \$0.16/\$3.50/\$3.50	no \$0.95–\$3.50 (bundled instrument/reagent/maintenance cost per reportable
Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays	75/75/248	result: \$1.05-\$3.60)/—/— 20/1/11
System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	liquid yes/248 no/—	liquid yes/included in test cartridge no/—
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	3 μL	3 μL no/no
Requires dedicated water system/Water consumption in L per hour	yes/no no/	no/.4
Noise generated in decibels Dedicated pediatric sample cup/Dead volume	55 no/—	25 yes/20 μL
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/yes yes, as sample is being aspirated (2 of 5 interleaved, UPC, Codabar, code 39, code 128 set B & C)/yes	yes/no —/—
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A	yes, proprietary dot coding no	yes no
Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/	yes yes/yes/no	no —/yes/no
Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high	yes/yes	no/no no/no —/—
results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert	yes/no yes	
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of	no/yes 3 hr/30 days/45 days with 48 hr updates/—	—/yes —/reagent cartridges are factory calibrated/—/—
abuse Automatic shutdown/Startup programmable	_/_	no/no
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine	4 min, 35 specimens 7 min, 20 specimens	<u> </u>
Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	10 min, 12 specimens immediate response, as soon as 10 seconds	15 min/4 specimens 30 seconds
How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	daily/yes yes/yes	daily/no no/—
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites	onboard/no Schuyler House, Antek, LabPak, Apex, others	optional add-on (various manufacturers)/no —
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download) yes, when requisition is done	no yes
LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes no	yes no
How labs get LOINC codes for reagent kits Lab can control analyzer remotely	_	_
Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	no/yes/yes 24 hr/yes	no/no/no will use depot repair/yes
Mean time between failures/To repair failures	2 per yr/1 hr	less than one per year/<24 hrs
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oney training avail	daily: 15 min; weekly: 30 min; monthly: 60 min yes/no 4.5 days at manufacturer's facility/yes	daily: <5 min; weekly: <10 min; monthly: <10 min no/no
Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	4.5 days at manufacturer's facility/yes varies, several programs available	1 day on site/yes \$1,800 year
Distinguishing features (supplied by company)	easy-to-use, multitasking software; closed-tube sampling; stat interrupt capability; extensive test menu; onboard sample and reagent refrigeration; onboard reagent inventory management; liquid, ready-to-use reagents; integrated ISE module; dedicated field service organization; self-contained analyzer; no external water source or waste drainage	self-contained reagent cartridge/optical cuvette system with all test parameters encoded on 2D bar code; virtually unlimited test menu; true operator walk-away time
Tabulation does not represent an endorsement by the College of American		

Orieniisti	ry analyzers (for low-volume la	aboratories)
	Beckman Coulter Inc.	The Binding Site
Part 3 of 11	200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Maureen ZetImeisl info@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.thebindingsite.com
Name of instrument/First year sold in U.S.	Synchron CX5 Pro/2001	SPAPLUS (Serum Protein Analyzer)/2007
List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S.	\$193,500/— —/—	\$57,000/— —/—
Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	U.S./U.S. & Ireland continuous random access/open reagent system	Japan/Japan/United Kingdom batch, random access, discrete/self-contained single-use cartridges- packages-slides
Sample handling system/Model type	sectors, centrifugable/floor-standing	2 sample carousels that can each hold 45 samples: 30 primary tubes, 10 non- bar-coded sample tubes/cups and 5 stat samples/benchtop
Dimensions in inches (H $ imes$ W $ imes$ D)/Instrument footprint	$69 \times 61 \times 30/12.7$ sq ft	20.5 × 31.5 × 25.2/14 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released	alb, ALP, ALT, amylase, AST, BUN, calc., CO2, chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, Mg, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, microalbumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin O, IgA, IgM, IgG, rheumatoid factor, transferrin; thyroids: thyroxine, T-up, P-amylase, C-reactive protein, creatine kinase	serum-free kappa, serum-free lambda, cystatin C, lgG, lgG1, lgG2, lgG3, lgG4
Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	Ξ	IgA, IgM, Beta-2-Microglobulin —
Research-use-only assays/Tests in development	—/—	tetanus toxoid/lgD, B2M, lgA subclasses, lgA high sensitivity, hevylite lgG, hevylite lgA, hevylite lgM, hevylite lgD
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine, lithium, ecstacy, barbiturate serum tox, benzodiazepine serum tox, tricyclics serum tox, amikacin, quinidine	_
Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	turbidimetry/—
No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff. assays in pack	5 (indirect) no/—	_ _/_
Separate reag. pack for each test run No. of different measured assays onboard simultaneously	no 29	no 24
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	50 100/29	 _/77
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	29/2,900–69,600 (100–2,400 tests per container)	24/100
Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use	168 hr/30 days/yes (2° to 8°C) yes	30 days/assay dependent/yes (9° to 12°C) yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	yes yes assay dependent/—/—	yes no —/—/—
Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays	400/63/1,827	~60/45/2–3
System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored	liquid no/—	liquid no/60
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	yes/permanent–2-yr warranty (80 stored on instrument) 3 μL	yes/once cuvettes reach OD threshold (0.33) 3 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	yes/no yes/7 70	yes/no no/3.5 —
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	yes/40 µL yes/no	
Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes	yes, on sample transport, shortly before sample is aspirated (codes 39 & 128)/— yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container)	yes yes	yes no
Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes yes	yes/yes/no yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/no	no/no yes/yes
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert	yes/no	yes/yes
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes no/yes 24 hr/up to 90 days/60 days/14 days	yes no/yes —/—/—
Automatic shutdown/Startup programmable	none required/—	no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	_
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., direct & total bili., AST, ALT, ALP Trained time delay from ordering stat test to capit of comple	8 min, 75 specimens 10 min, 32 specimens	=
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	45 sec 24 hr/yes	—/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes yes	user defined/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability	onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes (add'I cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, others	no (optional add-on in Europe)/yes (additional) CyberLab
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes (broadcast download & host query) yes yes	yes yes yes
Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	no —	no —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no yes	no yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/no	no/no/no
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day; rural: same or next day/yes	24 hrs/yes
Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	—/— daily: 5 min; weekly: 15 min; monthly: 20 min	—/24 hrs daily: 9 min; weekly: 20 min
Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/no 1 day on site, 5 days at vendor offices/no —	no/no 5 days, including installation and training \$8,950
Distinguishing features (supplied by company)	serum indices; centrifugable sectors; clot detection; bar-coded calibrators and controls; host query; reagent load while running; ready-to-use liquid reagents; Peltier thermal ring; ISE system; pulsed xenon light source; polychromatic correction; semipermanent glass cuvettes	low maintenance, prozone detection, autodilution, the combination of air-mixing system, dual-compartment reaction cuvettes, and a hot water wash make it ideal for Binding Site latex assays

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Part 4 of 11	391 Technology Way, Suite 2, Winston Salem, NC 27101 877-722-8910 www.carolinachemistries.com	34 Bunsen Dr., Irvine, CA 92618 888-903-5001 www.horiba-abx.com/us
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Name of instrument/First year sold in U.S.	BioLis 24i/2008	ABX Pentra 400/2006
List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S.	\$45,000/0 10/3,000	\$89,000/80 153/585
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/USA	France/France & U.S.
Operational type/Reagent type	batch, random access, continuous random access/open reagent system	batch, random access, discrete, continuous random access/self-contained
Sample handling system/Model type	sample ring/benchtop	single-use cartridges-packages-slides, open reagent system rack/benchtop
Dimensions in inches $(H \times W \times D)$ /Instrument footprint	20 × 31 × 25/5 sq ft	25 × 40 × 28 in/7.7 sq ft
T	400	H
Tests available on instrument in U.S.	100	albumin, calcium, sodium, alk phos, ALT, carbon dioxide, glucose (PAP), lipase, total protein, chloride, glucose (hexokinase), magnesium, triglycerides, amy-
		lase, cholesterol, nitrogen, iron, myoglobin, uric acid, total bilirubin, creatinine,
		lactic acid, phosphorus, direct dilirubin, potassium, HDL, CK, CRP, GGT, LDH,
Tests cleared but not clinically released	Lp-PLA2	LDL, urea nitrogen, micro Alb, urinary protein —
Tests not available in U.S. but submitted for FDA 510(k) clearance	vitamin D	_
Tests not available in U.S. but available in other countries	_	Alpha 1 antitypsin, C3, C4, ceruloplamin, orosomucoid, heparin, kappa chains, lambda chains
Research-use-only assays/Tests in development	—/vitamin D	—/TDMs, DAUs
User-defined methods implemented for what analytes	_	alcohol, apolipoprotein A1, apolipoprotien B, beta 2, microglobulin, ferritin,
		fructosamine, glyco mark, haptoglobin, Hgb A1c, homocysteine, HS CRP, IgA, IgG, IgM, pre albumin, rheumatoid factor, TIBC, transferrin, UIBC
		iga, igin, pre albumini, meumatoia factor, mbc, transfermi, oldo
Methods supported/Immunoassay methods	photometry, potentiometry/—	photometry, potentiometry (ion selective electrode), turbidimetric/—
No. of direct ion selective electrode channels	3	3 no/
Must load separate reag. pack for each specimen/No. of diff. assays in pack	no/—	no/—
Separate reag. pack for each test run	no	no
No. of different measured assays onboard simultaneously	39	55 55
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	39 39/39	55 15/15
No. of different analytes for which system accommodates reag.	39/3×300	55/100 to 400
containers onboard at once/Tests per container set	7 days/1/4 days/yes/(/20 to 000)	9 hours/20 days/yes (45° to 20°0)
Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported	7 days/14 days/yes (2° to 8°C) yes	8 hours/30 days/yes (15° to 32°C) yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes , ,
Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes	-/-/-	<i>- - -</i>
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	4 hrs/40/39	2 hrs/60/—
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/— yes/—	yes/432 no/—
Minimum sample volume aspirated precisely at one time	_	2 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	yes, water system provided with instrument/— —	no/avg. 0.5 <66
Dedicated pediatric sample cup/Dead volume	yes/30 µL	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (on sample transport, shortly before sample is aspirated, codes 39 & 128)/ yes	yes/no
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection	yes yes/yes	yes yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high	yes/yes yes/yes	yes/yes yes/yes
results/Increased to rerun out-of-linear-range low results	jour jour	, o.s., yee
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes/yes 24 hrs/14 days/14 days/14 days	yes/yes 2 hrs/14 days/—/—
Automatic shutdown/Startup programmable	yes/yes	no/yes
Stat time to completion of all analytes throughout and the		
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	12 min, 160 specimens	<5 min, —
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	1 hr, 60 specimens	7.5 min, 35 specimens
Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	14 min, 240 specimens 5 min	<11 min, 23 specimens 1–2 min
How often QC required/Onboard SW capability to review QC	8–24 hrs/yes	1–2 min 8 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/no
Lab information systems with which interfaces up and running in	Fletcher Flora, Lab Track, and several other common systems	Antek, Fletcher Flora, Meditech, Orchard, Schuyler House, Sunquest, Technidata
active user sites Bidirectional interface capability	yes (broadcast download, host query)	VPS
Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download, nost query) yes	yes yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits		no
1104 IUDO GOL LOTINO GOUGO TOT TEAGETIL NILO		
Lab can control analyzer remotely	no	no
Interface avail. (or will be) to automated specimen handling system	00	10
Modem servicing available/Can diagnose own malfunctions/	no/yes/yes	yes/yes/yes
Determine malfunctioning component		
On-site time of svc. engineer/Onboard error codes for troubleshooting	24 hrs/yes	<24 hrs/yes
Mean time between failures/To repair failures	_/_	—/<24 hrs
Average time to complete maintenance by lab personnel	daily: visual; weekly: 20 min; monthly: visual inspections <5 min	daily: 5 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail.	yes (includes audit trail)/no 5 days on site/yes	yes/yes 4 days at corporate office in California/yes
Annual service contract cost (24 h/7 d)	— — — — — — — — — — — — — — — — — — —	— Canada de Compositio de la Campionia Jud
	Hardson de la	handles destroy off and the second se
Distinguishing features (supplied by company)	Use of a water system eliminates the need to purchase, ship, and store cubes of water; HbA1c can be performed directly onboard with results equivalent	benchtop design offers the flexibility to run more than 53 assays with room for 55 onboard tests operated by a user-friendly, color-coded touchscreen
	to HPLC, no need to purchase a separate HbA1c analyzer; small size and	validation station; high throughput up to 420 tests/hr; clot level and crash
	large menu, 39 onboard chemistries; can run general chemistries and special	protection; auto rerun, autocalibration, and autodilution; ability to run up to
	chemistries from CMPs to D-dimer, cystatin C, insulin, and more	three reagents on a single assay; most reagents in plug-and-play cassettes

Part 5 of 11	Medica Corporation Charlene Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 781-275-7425 www.medicacorp.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S.	Easy RA/— —/— —/—	Stat Profile Critical Care Xpress/2002 \$25,000–\$59,000/— —/—
Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	U.S./U.S./ batch, random access, discrete, continuous random access/self-contained multi-use cartridge-packages-slides	U.S./U.S./U.S. discrete/self-contained multi-use cartridges
Sample handling system/Model type Dimensions in inches (H \times W \times D)/Instrument footprint	—/benchtop 15 × 40 × 26/7.2 sq ft	sample automatically drawn from syringe, capillary, or open tube/benchtop 17.2 \times 17.3 \times 22.3/2.7 sq ft
Tests available on instrument in U.S.	albumin, alk phos, alanine aminotransferase (ALT, SGPT), aspartate aminotransperase (AST, SGOT), calicum, chloride, cholesterol, CK, creatinine (serum & urine), GGT, glucose-trinder, HDL cholesterol, LDH, lithium, potassium,	pH, PCO2, PO2, SO2%, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, bilirubin, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance	sodium, total protein none blood urea nitrogen, GLU-H, direct bilirubin, total bilirubin, triglycerides, uric acid, phosphorus, magnesium, CO2, CK, amylase, iron	none none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays/Tests in development		none
User-defined methods implemented for what analytes	_	none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff. assays in pack	photometry, potentiometry 4 no/—	potentiometry (ISE), optical, reflectance/— 12 no/—
Separate reag. pack for each test run No. of different measured assays onboard simultaneously	no 28	no 20
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	28 0/—	20 0/—
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	28/80 to 250	20/200-500 samples (2,600-6,500 tests), depending on lab
Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported	168 hrs/30 days/yes yes	45 days/45 days/no —
Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	yes	requires operator prehandling, preparation — C. C
Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays	\$0.16/—/— 36/24/28	\$.06-\$.28 per test (cost varies with volume); bundled instr. reag. maint. cost per result \$.07-\$.31 per test (5-yr reagent rental)/—/— —/—/—
System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored	liquid yes/72	ISE no/—
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	no/— 2 μL	no/— 60 µL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour	no/no no/—	no (optional)/no no/—
Noise generated in decibels Dedicated pediatric sample cup/Dead volume	minimal no/—	minimal no/—
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/no yes	yes/no yes (optional), by handheld scanner as tubes are loaded onto instrument
Reagent bar-code reading capability	—; RFID	(2 of 5 interleaved, UPC, Codabar, codes 39 &128)/yes yes
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container)	yes	no yes
Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes/no yes	yes/yes yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	no/no yes/yes	yes (on co-oximeter module)/yes (on co-oximeter module) yes (on co-oximeter module)/no
Sample volume can be reduced to rerun out-of-linear-range high results/increased to rerun out-of-linear-range low results	yes/no	no/no
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes no/yes	yes yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	8 hrs/30 days/—/— no/no	30–120 min/30–120 min/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	3 min, 200 specimens	50 sec, 26-36, depending on use mode
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., direct & total bili., AST, ALT, ALP	8 min, 100 specimens 9 min, —	123 sec, 21-24, depending on use mode
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	41 min CLIA minimum/yes	—, — <2 sec 8 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	no/yes yes	yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in	onboard/yes —	onboard/no —
active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes	yes yes
How labs get LOINC codes for reagent kits	<u>no</u>	no —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	yes no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures	1 year/—	<8 business hr/yes —/—
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: 20 min; weekly: —; monthly: 30 min no/no	daily: none; weekly: <5 min; monthly: <15 min yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	_/_ _	1 day on site/yes \$3,750-\$7,685
Distinguishing features (supplied by company)	simplified user interface accessed through a touchscreen display; RFID-tagged reagents allow for reading and writing capability; all reagent parameters programmed on the wedge, no data entry; easy-to-replace components all located in a slide-out drawer; comprehensive inventories of all system components	comprehensive 20-test critical care profile, including ionized Mg, BUN, and creatinine; color touchscreen; integrated co-oximeter; open software architecture; onboard data management; automated onboard quality control; sealed waste system; auto-monitoring of QC and reagent packs; tankless gas calibration; automated maintenance

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Part 6 of 11	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Stat Profile pH0x series/1998 \$12,000-\$32,000/— —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges-packages-slides	Nova 16/1995 \$22,500-\$25,500/— —/— U.S./U.S. batch, random access/self-contained multiuse cartridges
Sample handling system/Model type Dimensions in inches (H \times W \times D)/Instrument footprint	sample automatically drawn from syringe, capillary, or open tube/benchtop 15 \times 15 \times 18/1.9 sq ft	40-position tray, stat sampling directly from sample container/benchtop $20.5\times19.2\times20.7/2.75$ sq ft
Tests available on instrument in U.S.	pH, PC02, P02, S02%, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, glucose, lactate	sodium, potassium, chloride, total CO2, glucose, BUN, creatinine, Hct
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	none none	none none
Research-use-only assays/Tests in development	none	none/none
User-defined methods implemented for what analytes	none	none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff.	potentiometry (ISE), optical, reflectance/— 5 no/—	potentiometry/— 8 no/—
assays in pack • Separate reag. pack for each test run No. of different measured assays onboard simultaneously	no 11	no 8
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	11 0/— 11/varies by analyzer and laboratory use pattern	8 0/— 8/(@ 8,000 tests/mo): 2,700 tests
Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use	45 days/45 days/no — requires operator prehandling, preparation	21 days/21 days/no — no, requires prehandling (remove clip from sealed bag & mix)
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes	varies by model/—/—	standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reag., maint. cost per result: \$0.92 (8-test panel)/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored	—/—/— ISE no/—	60 per tray/40 per tray/280 per tray — no/—
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	no/— 45 μL no (optional)/no	—/— 50 µL no/no
Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume	no/— minimal no/—	no/— minimal — .
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability	yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 &128)/yes yes	yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes alternate method
Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection		yes no/yes/yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high	yes yes*/yes* yes*/no no/no	yes no/no yes/yes no/no
results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes yes/yes	yes ves/—
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable		2 hr/2 hr/—/— —/—
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine	50 sec, 44 —, —	52 sec, 69 specimens 85 sec, 45 specimens
Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	-, - <2 sec 8 hr (CLIA)/yes	9 sec CLIA minimum/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface	yes/yes yes no/no	no/yes yes onboard & optional add-on (\$9,225, SW mftr: Nova)/no
Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability	virtually all yes (broadcast download & host query)	most LIS vendors including Cerner, Misys, McKesson, Soft, others yes
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes yes no	yes no no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	yes no	yes no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	—/— daily: none; weekly: <5 min; monthly: <15 min	<8 business hr/yes —/— daily: <2 min; weekly: <5 min; monthly: <5 min
Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes 1 day on site/yes varies by analyzer configuration & geographic location; discounts for multiple- year contract or 5-year reagent rental or lease	no/no 2 days on site/yes call for pricing
Distinguishing features (supplied by company)	onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space-saving design	whole blood analyzer for creatinine & TCO2; can analyze whole blood, serum, plasma, urine, CSF, and dialysate
Tabulation does not represent an endorsement by the College of American	*on co-oximeter module	

	y analyzers (for low-volume i	
	Ortho-Clinical Diagnostics	Polymedco, Inc.
	Sales Support 1001 U.S. Highway 202, Raritan, NJ 08869	Marie Longo mlongo@polymedco.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567
Part 7 of 11	800-828-6316 www.orthoclinical.com	800-431-2123 www.polymedco.com
Name of instrument/First year sold in U.S.	Vitros DT 60 II Chemistry System (DT 60 II, DTE, DTSC)/1993	Poly-Chem/2002
List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S.	—/— 15,000 units worldwide	\$58,500/24 150/—
Country where designed/Manufactured/Where reagents mftd.	U.Ś./U.S./U.S.	Japan/Japan/U.S.
Operational type/Reagent type	batch, random access, discrete/self-contained single-use cartridges-packag- es-slides	batch, random access/open reagent system
Sample handling system/Model type	—/benchtop	rack/benchtop
Dimensions in inches (H $ imes$ W $ imes$ D)/Instrument footprint	6.75 × 18.75 × 13.75/1.8 sq ft (DT 60 II)	30×24×22/—
Tests available on instrument in U.S.	ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN-urea, glucose, Mg, total	APOa1, APOb, LPa, DHDL, DLDL, NEFA, NA, K, CL, C3, C4, PREALB, IGA, IGM, IGG, RF, CRP, ASO, FRCRP, MALB, FRUC, HGA1C, ALB, AMY, ALP, ALT, AST, TBIL,
	bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium,	DBII, BUN, CAL, CHOL, CK, CO2, CREAT, GGT, GLUC, IRON, LDH, LIP, MG, PHOS, TP,
	ALT, cholinesterase, LDH, theophylline, CO2, sodium, potassium, chloride, urine creatinine, CK-MB	TRIG, UA, FERR, TRANS, DTIBC
Tests cleared but not clinically released	none	_
Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	none none	_
		AD0444 AD0F AD0044 AD00444/
Research-use-only assays/Tests in development	none/none	APOA11, APOE, APOC11, APOC111/—
User-defined methods implemented for what analytes	none	glutamine, glutamate, lactate, ammonia
Methods supported/Immunoassay methods	potentiometry, colorimetric, enzymatic/—	photometry, RISE
No. of direct ion selective electrode channels • Must load separate reag, pack for each specimen/No. of diff.	4 yes/1	3 no/—
assays in pack		
Separate reag. pack for each test run No. of different measured assays onboard simultaneously	yes one per module (DT 60 II, DTE II, DTSC II)	no 43
No. of different assays programmed, calibrated at once	1	43
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag.	none /	60/60 40/200
containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard	—/—/no	4 hrs/28 days/yes (8°C)
Multiple reag. configurations supported	no	yes
Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	<u>no</u>	yes no
Reag. only cost per reportable result for standard chemistries/	-/-/-	—I—I—
Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays	_/_/_	18 min to first result/40 specimens/1,000 tests
System is liquid, dry, or reconstituted onboard	dry	liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/— no/—	no/— yes/50,000 tests
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	10 μL no/no	— yes/yes
Requires dedicated water system/Water consumption in L per hour	no/none	yes/7
Noise generated in decibels Dedicated pediatric sample cup/Dead volume		60 yes/—
Primary tube sampling/Pierces caps on primary tubes	no/no	yes/no
Sample bar-code reading capability/Autodiscrimination	no/—	on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/no
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	Ξ	yes yes
Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	_/_/_ _	yes/yes/no yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high	no/no no/no	yes/yes yes/yes
results/Increased to rerun out-of-linear-range low results		
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	no no/yes	no no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	reagent lot changes no/no	daily/7–14 days/—/— no/yes
Automatic shutdown/startup programmable	110/110	III/ yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	15 tests	2 min, 450 specimens
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	75 tests	10 min, 180 specimens
Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	20 tests none	11 min, 180 specimens —
How often QC required/Onboard SW capability to review QC	every 24 hr/no	per shift-daily/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	no/no yes	yes/no yes
Data mgmt. capability/Instrument vendor supplies LIS interface	—/no	onboard/no
Lab information systems with which interfaces up and running in	—/III0 —	LabDAQ, Data Innovations, Soft Computer, Misys
active user sites Bidirectional interface capability	no	broadcast download, host query
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes —	yes no
How labs get LOINC codes for reagent kits	_	-
Lab can control analyzer remotely	no	no
Interface avail. (or will be) to automated specimen handling system	00	no
Modem servicing available/Can diagnose own malfunctions/	no/yes/yes	no/no/no
Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	—/yes	24 hrs/yes
Mean time between failures/To repair failures	_i_	—/— ·
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: 5 min; weekly: 5 min; monthly: none no/no	daily: 5 min; weekly: 10 min; monthly: 2.5 hrs no/no
Training provided with purchase/Advanced oper. training avail.	yes/—	3 days on site, 3 days at vendor office/yes
Annual service contract cost (24 h/7 d)		\$8,500 (M-F, 8 am-9 pm EST)
Distinguishing features (supplied by company)	disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reag, prep.; indiv, packaged test slides	small benchtop analyzer ideal for POL, as primary system in small lab, or a back-up system in a large lab; onboard reusable cuvettes provide cost savings
	elim. waste and facilitate rapid analysis; dry-slide technology minimizes the	on disposables; large reagent menu
	effects of interferences to provide accurate results	

Part 8 of 11	Polymedco, Inc. Marie Longo mlongo@polymedco.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567 800-431-2123 www.polymedco.com	Randox Laboratories marketing@randox.com 4065 Oceanside Blvd., Ste. Q, Oceanside, CA 92056 760-639-1500 www.randox.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	SPOTCHEM EZ/2006 \$9,400/45 90/— Japan/Japan/U.S. discrete/self-contained single-use cartridges/packages/slides tray/benchtop 13.5 × 8 × 6.5/—	Rx Daytona/2005 —/— >800 units worldwide Japan/Japan/U.K. random access, discrete/self-contained multi-use cartridges-packages-slides removable ring/benchtop 30.2 × 24.8 × 20.2 sq ft/—
Tests available on instrument in U.S. Tests cleared but not clinically released	CHOL, TRIG, HDL, GLU, FRUC, ALT, AST, ALB, ALP, AMY, BUN, CAL, CK, CREAT, GGT, PHOS, LDH, MG, TBIL, TP, UA, PANEL 1(ALB, BUN, GLU, CRE, CAL), PANEL 2(ALP, TBIL, ALT, AST, TP), LIPID PANEL (CHOL, TRIG, HDL, CLDL)	*acid phos., alb., aldolase, ALT, ammonia, alk. phos., AST (GOT), amylase, panc. amylase, bilirubin (direct/total), calcium, total CO2, cholesterol, HDL-C, LDL-C, CK-NAC, CK-MB, complement C3/C4, copper, CRP, HS CRP, FR CRP, creatinine, ferritin, fructosamine, glucose, GGT, HbA1c, IgA, IgE, IgG, IgM, LDH, lipase, lithium, ASO, lipoprotein(a), ApoA1, ApoB, microalb., magnes., myoglobin, sodium, prealbumin, phosphorus, potas., RF, iron, phenobarbital, phenytoin, digoxin, digitoxin, theophylline, gentamicin, valp. acid, carbamazapine, transferrin, TIBC, total protein, triglycerides, uric acid, BUN/urea, urinary protein, zinc, ISE Na, others
Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development	 /LDL	— — — **acetic acid, Apo E, Apo CII, Apo CII, ApoAII, alpha-1-antitryp, α -1-acid glycoprotein, bile acids, butyryl choline., others/—
User-defined methods implemented for what analytes	_	acetaminophen, drugs of abuse, salicylate cyclosporine, alcohol, glycerol-3- phosphate, oxidase, phospholipids, maltose, T4, T-uptake
Methods supported/Immunoassay methods No. of direct ion selective electrode channels Must load separate reag, pack for each specimen/No. of diff.	optical measurement of reflection intensity of reagent color reaction — yes/single strips and panel strips available	photometry, potentiometry (ISE), immunoturbidimetry, latex-enhanced immunoturbidimetry/— 3 Na+, K+, CL- no/50 to 2,205
assays in pack • Separate reag. pack for each test run	yes	no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag.	9 card calibration —/— —/—	30 60 —/60 27/71 to 1,053
containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	—/—/no no yes no	8 hr/30 days/yes (8° to 15°C) yes yes yes
Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes		
Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored	up to 15/1/up to 9 dry no/—	—/40/— liquid no/45
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	no/— 5 μL no/no no/—	yes/5 years 2 μL no/no yes/7.5 daily 60
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	no/— no/no by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes	yes/40 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container)	yes no no	yes — yes
Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	no/yes/no no no/no	yes/yes/no yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert	no no/no no	yes/yes yes/yes
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	no/no —/per box/—/— no/no	no/yes daily/28 days/7 days/— no/yes
Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine Album., direct & total bili., AST, ALT, ALP	— 9 min, 48 samples per hr 9 min, 48 samples per hr	—, 270 specimens —, 315 specimens —, 180 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	daily/no no/no no	60 sec shortest: daily; longest: at customer discretion/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites	onboard/no —	onboard/no —
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes yes no	yes (host query) yes yes no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures	depot service/yes	within 24 hr/yes —/—
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	daily: 1 min; monthly: 5 min no/no 1 day on site/no —	daily: 5 min; weekly: 15 min no/no 3 days on site/yes —
Distinguishing features (supplied by company)	small analyzer ideal for stat labs, small POLs, ERs, and imaging centers; analyzer and reagent test strips are CLIA waived; dry chemistry strips, excellent stability, and shelf life; single test strips and panel strips available, customizable testing	comprehensive clinical and research test menu, benchtop, low water consumption, automatic start, multi-speed mixing, Windows software *Contact company for complete list

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Part 9 of 11	Response Biomedical Corporation Marcia Zucker mzucker@responsebio.com 1781 75th Avenue W., Vancouver, BC, V6p 6P2, Canada 732-603-1194 www.responsebio.com	Roche Diagnostics Corp. Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-4804 www.roche.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Ramp/2005 available upon request/— 25/700+ Canada/Canada/Canada discrete/self-contained single-use cartridges-packages-slides	Cobas Integra 400 Plus/1999 \$175,000/— 550/>2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multi-use cassettes
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	—/handheld 6×10.5×10/—	rack/benchtop $30 \times 53 \times 26/9.6$ sq ft
Tests available on instrument in U.S.	troponin I, CK-MB, myoglobin, NT-proBNP, influenza A/B, anthrax, botulinum, ricin, pox	* α -1-acid glycoprot., α -1-antitryp., apo A1 & B, antistrepto0, comp. C3c & C4, cerul., CRP latex, CRP(hs), hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACPP, ALP, ALT, α -amy. pancreatic, AP, AST, cholinest., CK-MB, γ -glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., C02, creat. jaffe, creat. enzy., fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, Cl, Li, acet., amik., carb., dig., gent., lido., NAPA, pheno., pheny., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T4, T-up, D-dimer, MPA, others
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	— — BNP	none none lipoprotein A
Research-use-only assays/Tests in development User-defined methods implemented for what analytes	_/_ _	none/none —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff.	immunoassay/quantitative lateral flow immunochromatographic assay none no/—	photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced 4 no/1
assays in pack • Separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	no 1 50 0/— 1/—	no 36 tests plus applications for urine & CSF up to 999 0/0 36/50–800 tests, cassettes
Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes	//no no no//	2 weeks/8 to 12 weeks/yes (12°C) yes yes no —/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	test performed immediately dry no no/—	176/90/1,808 liquid yes/1,500 no/— 1 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	yes/no no/ no/ no/ no/no	no/no no/2 maximum — —/— yes/no
Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes yes — —	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes — yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	/yes/ / no/no /	yes/yes — no/no yes/yes yes/yes
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes —/— —/once per reagent lot–automatic/—/— yes/no	yes yes/yes 5 hr/once per lot/each lot & 12 weeks/each lot & 12 weeks yes/yes
Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	——————————————————————————————————————	369 tests 369 tests 250 tests none 24 hr/yes yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites	no/no Telcor, Aegis POC	onboard/yes (addt'l cost) all major LIS vendors
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	no yes yes — —	yes (broadcast download & host query) yes yes — —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	yes —
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/—/— —/yes —/overnight replacement — no/— 1 day on site/no —	yes/yes/yes /yes/
Distinguishing features (supplied by company)	two levels of control performed with every test; Ramp ratio corrects for variability inherent in other lateral flow systems	unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium
		*Contact company for complete list

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	Roche Diagnostics Corp.	SDI Biomed Inc.
	Ken Dean kendean@roche.com	Robert Silverberg rs@sdibiomed.com
Part 10 of 11	9115 Hague Rd., Indianapolis, IN 46256 317-521-7538 www.poc.roche.com	23679 Calabasas Road, #241, Calabasas, CA, 91302 818-349-4464 www.sdibiomed.com
1 411 10 01 11	517-521-7556 www.poc.roche.com	WWW.suibionicu.com
Name of instrument/First year sold in U.S.	cobas c111/2007	SDI CA 480 Clinical Chemistry System/2004
List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S.	\$49,000/10 60/1,700	\$85,000/— >50/>600
Country where designed/Manufactured/Where reagents mftd.	Switzerland/Switzerland/Germany	Europe/Europe/United States
Operational type/Reagent type	random access/self-contained multi-use cartridges-packages-slides	random access/self-contained single-use cartridges-packages-slides
Canada handing ayatan /Madal tuna	usel./henselsten	udeal with 4 independent comments/handston
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	rack/benchtop $18.9 \times 28.4 \times 21.7/4.3$ sq ft	wheel, with 4 independent segments/benchtop $40.5 \times 25.4 \times 17.7/7.2$ sq. ft.
Tests available on instrument in U.S.	albumin, ALT, ALP, ammonia, amylase (pancreatic), AST, bicarbonate, D-bilirubin,	albumin, alkaline phosphatase, ALT, amylase, AST, CO2, direct bilirubin, total
	T-bilirubin, bun, calcium chloride, cholesterol, CK, CK-MB, creatinine Jaffe, creatinine plus, CRP, GGT, glucose HbA1c, HDL cholesterol, lucitate, LDH, LDL	bilirubin, calcium, cholesterol, CK, creatinine, Gamma-GT, glucose-HK, D-HDL, iron, phosphorus, LDH-L, magnesium, total protein, triglycerides, urea nitrogen,
	cholesterol, lipase, magnesium, microalbumin, phosphate, potassium, sodium,	uric acid, D-LDL, UCRP WR, fructosamine, ferritin, HbA1c
	total protein, triglycerides, uric acid	
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance	— CRP HHs, ethanol, homocysteine	none none
Tests not available in U.S. but available in other countries	—	na
Research-use-only assays/Tests in development	—/cystatin-C, D-dimer	none/drugs of abuse
User-defined methods implemented for what analytes	_	none
Methods supported/Immunoassay methods	photometry, potentiometry	photometry, poteniometry/selected methodologies
No. of direct ion selective electrode channels	3	gnotonieu y, potenionieu y/selecteu meulodologies 3
Must load separate reag. pack for each specimen/No. of diff.	no	no/ —
assays in pack • Separate reag. pack for each test run	70	no
No. of different measured assays onboard simultaneously	no 17	no 33
No. of different assays programmed, calibrated at once	112	33
No. of user-definable (open) channels/No. active simultaneously	0/—	0/available on request
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	17/50–200	30/150 per container
Shortest/Median onboard reag. stability/Refrigerated onboard	120 hrs/28 days/yes	14 days/30 days/yes (14°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	no —/—/—	yes —/—/—
Therapeutic drugs/Special analytes	' '	' '
Walkaway capacity in minutes/No. of specimens/No. of tests-assays		165/40/33
System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored	liquid	liquid
Uses washable cuvettes/Replacement frequency	yes/60 no/—	no yes/analyzer uses permanent quartz cuvettes
Minimum sample volume aspirated precisely at one time	2–15 µL	3 μL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	no/.3 standby: 44.4, running: 51.2	no/1
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, by handheld scanner as tubes are loaded onto instrument	yes/yes
Reagent bar-code reading capability	(2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes	yes
Bar-code placement per CLSI standard Auto2A	-	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes/no (ISE only) yes	yes/yes/no yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/yes
Sample volume can be reduced to rerun out-of-linear-range high	yes/yes	yes/no
results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	·	30 minutes/once per week/once per week
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TCO2	7 min, 100 specimens	1.5 min., 60
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album, disset 8 tetal bill, AST ALT ALB	11 min, 100 specimens	6 min. 48 sec, 60
Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	13 min, 100 specimens immediately upon completion of currently running test	7 min. 12 sec, 50 3 min.
How often QC required/Onboard SW capability to review QC	daily/yes	8 hrs/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/—
Lab information systems with which interfaces up and running in	_	Schylab, LabDaq, Fletcher Flora, Medcom
active user sites	you (broadcost download, book supers)	1100
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download, host query) yes	yes yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	_	_
Lab can control analyzer remotely	no	no
Interface avail. (or will be) to automated specimen handling system	no	no
Modem servicing available/Can diagnose own malfunctions/	no/yes/no	yes/yes/yes
Determine malfunctioning component	1107 300/110	jour jour jou
On-site time of svc. engineer/Onboard error codes for troubleshooting	—/yes	yes, guaranteed within 24 hours/yes
Mean time between failures/To repair failures	216 days/1.5 hrs	10,000 hours/2 hours
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: 15 min; weekly: 1 min; monthly: 10 min no/no	daily: 5 min.; weekly: 15 min.; monthly: 15 min. yes/no
Training provided with purchase/Advanced oper. training avail.	yes (5 days on site)/no	4 days on site or 4 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	\$4,500	\$7,500
Distinguishing features (supplied by company)	compact size, truly automated, consistent results with larger cobas analyzers	nermanent cuvettee enhoard iet wach/dru evetem eiv minutee te firet reerit
produktioning readures (supplied by company)	compact 5126, may automateu, consistent results with larger codas analyzers	permanent cuvettes, onboard jet wash/dry system, six minutes to first result, notebook-like operator interface, small footprint

	y analyzers (for low-volume is	,
Part 11 of 11	Siemens Healthcare Diagnostics 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com	Vital Diagnostics USsales@vitaldiagnostics.com 27 Wellington Road, Lincoln, RI 02865 800-345-2822 www.vitaldiagnostics.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2007 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	Dimension Xpand Plus Integrated Chemistry System/2004 —/— —/— U.S./U.S./U.S. continuous random access/self-contained single-use & multi-use cartridges racks/floor-standing $45\times51\times31$ (without monitor)/10.6 sq ft	Envoy 500 Chemistry Analyzer/2005 \$75,000/60 120/— Italy/Italy/U.S. random access/self-contained multi-use cartridges-packages-slides rotor/benchtop 27 × 40 × 23/10 sq ft
Tests available on instrument in U.S.	ser. acetamino., acid phos., alb., alk. phos., ALT, ammonia, amylase, AST, automated HDL & LDL, , C3 compl., C4, calc., carbemaz., C02, chlor., cholesterol, CRP, creat. kin., creatinine, CK-MB isoenzyme, digitoxin, digoxin, ethyl alcohol, gentamicin, GGT, glucose, HbA1c, IgA/G/M, iron, lactic acid, LDH, lidoc., lipase, lith., magnes., microalb., n-acetylprocain., NT-pro BNP, phenobart., pheny., phosphorus, potas., prealbum., procainam., pseudocholinest., ser. salicyl., sod., ser. TCA, theophyl., thyronine uptake, TIBC, tobramycin, tot. protein, tPSA, tot. T4/thyroxine, transferrin, triglycerides, urea nitrog., uric acid, urine amphet. Screen, urine barbitura. screen, benzodiazep., cannabinoids, cocaine metabolite, methadone, opiates, phencyclidine, TBIL, DBIL, cyclosporine, ferritin, fPSA, free T4/thyroxine, hCG, myqlobin, TSH, triiodothyronine, trop. l, others	general chemistry, albumin, bilirubin, direct, bilirubin, total, calcium, creatinine, glucose, iron, total, magnesium, phosphorus, protein, total, urea nitrogen (BUN), uric acid, enzyme, alanine aminoTransferase (ALT), alkaline phosphatase, amylase, aspartate transaminase (AST), creatine phosphokinase (CPK), gamma glutamyl transferase (GGT), lactate dehydrogenase (LDH), lipid, direct LDL, triglycerides, direct HDL, cholesterol, electrolyte, carbon dioxide, chloride, potassium, sodium, special chemistries, hemoglobin A1c
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development	— — — — — — — — — — — — — — — — — — —	— — — — — — — — — — — — — — — — — — —
User-defined methods implemented for what analytes	_	UIBC, glyoMark, cystatin C
No. of direct ion selective electrode channels Must load separate reag. pack for each specimen/No. of diff. assays in pack Separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	photometry, potentiometry, turbidimetric assays/Integrated Multisensor Technology, heterogenous EIA using HM, Emit, latex turbidimetric 3 no/— no 47 190	photometry, potentiometry 4 no/— no 40 40
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use	10/10 47/15–360 72 hr/30 days/yes (2° to 8°C) yes yes	500/40 40/150 7 hrs/21 days/yes (12° to 15°C) yes yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes —/—/— can be hrs/60/>1,000 liquid, no reagent prep required by operator yes/12,000 no/—	no —/—/— 240 min/52 specimens/150 tests liquid no yes/never
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	2 μL yes/no yes/up to 4 to 4.5 μL <70 no/20 μL yes/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	1 μL yes/no no/2 >60 no/— yes/no sample loaded on the analyzer by internal barcode scanner (2 of 5 interleaved,
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes yes yes yes yes/yes/no yes	UPC, Codabar, codes 39 & 128)/no yes no yes yes/yes/no yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes/yes yes/yes yes/yes yes yes yes(Na, K, CI)/yes	no/no yes/yes yes/yes yes no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	every 2 hrs, autocalibrate/—/60–90 days/30 days not required/—	4 min/21 days/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	2 min, 62 specimens 4 min, 62 specimens 8 min, 62 specimens 60 sec steady state, 2 min from standby daily/yes yes/yes yes	3:45 min, 37 specimens 6:10 min, 45 specimens 9:26 min, 26 specimens >1 min 4-24 hrs yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability	optional add-on/yes (additional cost) interfaces available for all major LIS vendors yes (broadcast download & host query)	optional add-on (Vital Diagnostics) Antek, Fletcher-Flora, Orchard, Skyler Lab, Data Innovations, Sunquest broadcast download
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes yes no	yes yes no —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 2–8 hr/yes —/— daily: 5 min; weekly: 10 min; monthly: 15 min no/no 5 days on site, 4 days at vendor offices/no multiple types	yes/yes/yes within 24 hrs/yes —/— daily: 5 min; weekly: 15 min; monthly: 5 min yes/no 5 days on site/yes \$8,995 (M-F, 8 am-8 pm)
Distinguishing features (supplied by company)	consolidated low-volume workstation integrates immunoassays onboard with other chemistries; allows single platform to meet more than 95 percent of testing needs; eliminates sample splitting, aliquotting	CO2 performed as an electrolye; four-parameter onboard dry ISE; 570 tests per hour