

Part 1 of 5	Abbott Point of Care Laetitia Crouch laetitia.crouch@abbott.com Princeton, NJ 609-454-9000 www.pointofcare.abbott/us/en/home	Abbott Point of Care Laetitia Crouch laetitia.crouch@abbott.com Princeton, NJ 609-454-9000 www.pointofcare.abbott/us/en/home	Alfa Wassermann Diagnostic Technologies Tanya De Boer tdeboer@alfawassermannus.com West Caldwell, NJ 800-220-4488 www.alfawassermannus.com
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES			
Name of instrument	i-STAT 1 analyzer	Piccolo Xpress	ACE Axlcel
Type of instrument	combination chemistry/immunoassay	chemistry	chemistry
Operational type/Model type	—/handheld	—/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	—/2000	\$16,500/2006	—/2012
Targeted hospital bed size/Targeted daily test volume	all/—	—	—/15–50 comprehensive metabolic panel/lipids
Company manufactures instrument	yes	no (manufactured by Abaxis)	yes (also sold by McKesson, Henry Schein, Medline)
Other models in this family of analyzers	—	—	ACE Alera
No. of units in clinical use in U.S./Outside U.S. (countries)	≥ 30,000/—	2,500/4,000	—
Dimensions (H × W × D)/Instrument footprint (square feet)	9.25 × 3 × 2.85 in./< 1 sq. ft.	12.75 × 6 × 8 in./< 1 sq. ft.	33 × 28 × 26 in./10 sq. ft.
Weight empty/Weight fully loaded	—	—	150 lbs./150 lbs.
Tests available on analyzer in U.S.	troponin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium, potassium, chloride, hematocrit, pH, PCO ₂ , PO ₂ , TCO ₂ , ACTc, ACTk, more	ALP, ALT, AST, GGT, amylase, albumin, total protein, total bilirubin, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, more	ALT, ALB, ALP, AMY, AST, DBILI, TBILI, BUN, calcium, CO ₂ , chloride, CHOL, CK, CREAT, ferritin, GGT, GLU, HbA1c, HDL, PHOS, iron, LDH, lipase, LDL, magnesium, potassium, more
Tests not available in U.S. but available in other countries	—	—	—
Tests in development for analyzer	—	—	—
No. of different measured assays onboard simultaneously	—	14—complete metabolic panel	40 (200 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	—	15 (15 can be active simultaneously)
Test throughput per hour/Assay run time	—	—	165/—
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	potentiometry, amperometry, conductometry	photometry, enzymatic	photometry, potentiometry, turbidimetric homogeneous EIA
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2 min./—	12 min./—	4 min./35 specimens per hr.
• Basic metabolic panel	2 min./—	12 min./—	—
• Complete metabolic panel	—	12 min./—	—
Typical time delay from ordering stat test until aspiration of sample	none	none	10 sec.
Immunoassay:			
Fully automated microplate immunoassay system	—	—	—
Methodologies supported	—	—	—
Separation methodologies	—	—	—
Stat time until completion of a β-hCG test	10 min.	—	—
• Typical time delay from test order to aspiration of sample	none	—	—
Stat time until completion of a cTn test	10 min.	—	—
• Typical time delay from test order to aspiration of sample	none	—	—
Approx. No. of tests per reagent set or pack/Reagent type	—/self-contained single use	—/self-contained single use	30–900/closed reagent system with open reagent channels
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (0°–8°C)/yes	yes (10°–14°C)/yes
Reagent lot tracking/Reagent inventory	—	—	yes/yes
Reagent form/Reagents barcoded	— (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	yes/no	yes/no	no/no
Walkaway capability/Walkaway duration	yes/—	yes/12 min.	yes/75 min. or 75 specimens or 248 tests/assays
Design of sample handling system	—	—	ring
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/yes (can store up to 248 cuvettes)
Min.—max. sample volume that can be aspirated at one time	16 μL minimum	80–100 μL of whole blood, serum, or plasma	3–200 μL
Min. reaction volume/Min. specimen volume/Min. dead volume	—	—	150 μL/53 μL/50 μL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling/Pierces caps on primary tubes	no/no	no/no	yes (tubes [in mm]:13 × 75, 13 × 100, 16 × 75, 16 × 100)/yes
Protects against probe collision	no	no	no
Detects clots/liquid level/short sample	yes/no/yes	yes/no/yes	no/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/—/—/yes	no/—/—/yes	no/no/no/no
Dilutes patient samples onboard/Susceptibility to carryover	no/—	no/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	no/no	no/no	yes/no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: each test)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: each test)	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	each test/—/—/each test/each test	each test/—/—/each test/—	3 hrs./—/—/30 days/—
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes/yes	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management			
Sample barcode-reading capability/Autodiscrimination	manually by user	manually by user	automated collection onboard instrument
Lab can control analyzer from remote computer	yes/yes	yes/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Instrument can diagnose its own malfunctions	yes	yes	no
System malfunctions can be diagnosed via remote monitoring	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
UPS backup power supply/Data-management capability	yes	yes	no
LIS or EHR systems interfaced	no/optional add-on	yes/onboard	no/onboard
LIS interface provided/Bidirectional interface capability	—	—	CGM LabDaq, Orchard Harvest, Schuyler House SchuyLab, J&S LabTrak, Merge LIS, Apex Healthcare
Modem servicing provided/Service engineer on-site response time	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)	no/yes (host query)
	yes/— (product replacement within 24 hrs.)	yes/— (24-hr. return merchandise authorization turnaround of loaner)	yes/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	—	—	daily: 15 min.; weekly: 20–30 min.; monthly: 30–40 min.
Maintenance records kept onboard for user/vendor	—	—	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	—	—	no
Training included with purchase/Avg. time for basic user training	—	yes/1–2 hrs. (supplemented by free webcast)	yes (1 training slot)/4.5 days (location based on sales contract)
Advanced operator training/Where advanced training is held	yes/customer site	yes/customer site	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes/—	yes (1 year)/—	yes (1 year)/various options available
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests CLIA-waived menu of tests, including basic metabolic panel uses 2 drops of whole blood or plasma 	<ul style="list-style-type: none"> comprehensive CLIA-waived menu of tests; 16 disks (11 CLIA waived) represent commonly ordered chemistry panels CLIA-waived comprehensive metabolic panel works with 3 simple steps 	<ul style="list-style-type: none"> self-contained analyzer; closed-tube sampling; stat interrupt capability; onboard sample and reagent refrigeration onboard reagent inventory management; ready-to-use reagents; integrated ISE module; no external water source or waste drainage Internet connectivity allows for external technical support, remote access, and laboratory integration
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 2 of 5

FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES

Awareness Technology
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Name of instrument	ChemWell 2910	Access 2	Pictus 500 (P500)
Type of instrument	combination chemistry/immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access/benchtop	continuous random access/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	\$32,000/1999	—/2001	\$42,860/2016
Targeted hospital bed size/Targeted daily test volume	200–500/200–400	—	20–100/500–2,500
Company manufactures instrument	yes	yes (also sold by McKesson, Henry Schein)	yes
Other models in this family of analyzers	ChemWell Fusion, ChemWell 2, ChemWell 2902	Unicel Dxl 600, Unicel Dxl 800	Pictus 700 (P700)
No. of units in clinical use in U.S./Outside U.S. (countries)	10/2,393	—	> 40/≤ 200 (Europe, Latin America, Africa, Middle East, Asia)
Dimensions (H × W × D)/Instrument footprint (square feet)	18.63 × 36.25 × 21.50 in./6 sq. ft.	18.5 × 39 × 24 in./6.5 sq. ft.	24.4 × 35.4 × 26 in./6.4 sq. ft.
Weight empty/Weight fully loaded	78 lbs./78 lbs.	200 lbs./—	253 lbs./271 lbs.
Tests available on analyzer in U.S.	infectious disease, autoimmune, EBV TORCH, bacterial infections, childhood diseases, fertility, tumor marker	ferritin, folate, vitamin B12, testosterone, CEA, EPO, 25(OH) vitamin D total, ostease, troponin I, CK-MB, rubella IgG, toxo IgG, AFP (ONTD), DHEA-S, AMH, TPO Ab, AFP, PSA, more	full drugs-of-abuse menu and general chemistry
Tests not available in U.S. but available in other countries	—	—	63 barcoded clinical chemistry parameters, including substrates, electrolytes, enzymes, specific proteins
Tests in development for analyzer	—	—	vitamin D
No. of different measured assays onboard simultaneously	15 (12 can be run and calibrated at one time)	24 (24 can be run and calibrated at one time)	up to 72
No. of user-definable (open chemistry) channels	—	0	variable
Test throughput per hour/Assay run time	chemistry: 200 (27 tests in throughput); ELISA: depends on assay/6–120 min. (avg. 90 min. for ELISA)	100/13–55 min.	420/30–1,200 sec. (avg. 300 sec.)
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	photometry	—	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	60 sec./60 specimens per hr.
• Basic metabolic panel	—	—	450 sec./40 specimens per hr.
• Complete metabolic panel	—	—	540 sec./20 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	—	24 sec.
Immunoassay:			
Fully automated microplate immunoassay system	yes (open system: 27–44 tests per unit; 96 wells per microplate)	—	—
Methodologies supported	chemiluminescence, EIA, biochemistry, chemistry	—	—
Separation methodologies	coated microwell	—	—
Stat time until completion of a β-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	96/open reagent system	50 per pack or 100 per kit/self-contained single use	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (delta 12°C from ambient)/yes	yes/yes	yes (8°±2°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/—	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/no	— (closed reagent system)/yes	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	no/no	—	no/no
Walkaway capability/Walkaway duration	yes/90 min. or 96 specimens or 12 tests/assays	yes/180 min. or 60 specimens	yes/180 min. or 95 specimens or 1,000 tests/assays
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/yes (can store up to 294 cuvettes)	yes/yes (can store up to 80 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–200 µL	5 µL minimum	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/100 µL/40 µL	—/dependent on specimen container/100 µL	180 µL/22 µL/100 µL
Dedicated pediatric sample cup	—	yes (dead volume: 100 µL)	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 13 × 75, 12 × 75, others)/no	yes (tubes [in mm]: 12 × 75, 13 × 75, 16 × 75, 16 × 85, 13 × 100, 16 × 100)/no	yes (tubes [in mm]: 13 × 75 up to 16 × 100)/no
Protects against probe collision	yes	—	yes
Detects clots/liquid level/short sample	no/yes/yes	yes/yes/yes	yes/yes/no
Detection for hemolysis/icterus/lipemia/clots	no/no/no/no	no/—/—/—	no/no/no/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	—	yes (can be programmed to perform dilutions prior to analysis)/30 parts per million
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/yes	no/no	yes/yes
Analyzer requires dedicated water supply	no (less than 1 L/8 hr. consumption during operation)	no	no (2 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 7 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/7 days/7 days	—	8 hrs./—/7 days/14 days/14 days
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/no	—	yes/yes
Supports multiple QC lot numbers per analyte	yes	—	yes
Waste management			
Sample barcode-reading capability/Autodiscrimination	automated collection onboard instrument, direct to drain yes (UPC, Code 39)/no	— yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	manually by user (direct to drain option in some settings) yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	—	yes
Instrument can diagnose its own malfunctions	yes (can order parts without operator intervention)	no	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply/Data-management capability	no/onboard	no/—	yes/onboard
LIS or EHR systems interfaced	Meditech, Sunquest	—	AP Visions, Schuyler House, CGM LabDaq, others
LIS interface provided/Bidirectional interface capability	no/no	—	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/48 hrs.	—	no/48 hrs.
Mean time between failures	180–270 days (displays error codes for troubleshooting)	—	1 per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 25 min.; monthly: 25 min.	—	daily: 30 min.; weekly: 1 hr.; monthly: 2 hrs.
Maintenance records kept onboard for user/vendor	no/no	—	no/no
Maintenance training demonstration module onboard	no	—	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer site)	yes/—	yes (2 training slots)/3 days (at customer site)
Advanced operator training/Where advanced training is held	yes/vendor site	—	yes (extra charge)/vendor site (preferred) or customer site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/various options available	—	yes (1 year)/ \$5,500
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> complete plate washing system; efficient wash time; 8-probe wash head for aspiration and dispense flexible reagent expansion: sample positions may be used for additional reagents, enhancing customized workflow assay editor system (AES) allows programming of analyzer to menu that best meets labs' needs 		<ul style="list-style-type: none"> uninterrupted workflow Windows-based, intuitive, user-friendly software high-quality components for long stability and result reliability
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 3 of 5	ELITechGroup Dianna Poissant d.poissant@elitechgroup.com Smithfield, RI 401-642-8400 www.elitechgroup.com	ELITechGroup Dianna Poissant d.poissant@elitechgroup.com Smithfield, RI 401-642-8400 www.elitechgroup.com	Gold Standard Diagnostics Christina Brusca cbrusca@gsdx.us Davis, CA 530-759-8000 www.gsdx.us
Name of instrument	Envoy 500+	Selectra ProM	Bolt
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/benchtop	batch, random access, continuous random access, discrete/benchtop	batch/benchtop
List price/First year sold in U.S.	\$85,000/2014	\$64,375/2012	—/2017
Targeted hospital bed size/Targeted daily test volume	—/20–80 patients	—/10–40 patients	50–500/1–300
Company manufactures instrument	—	yes	yes
Other models in this family of analyzers	Envoy 500	Selectra ProS	—
No. of units in clinical use in U.S./Outside U.S. (countries)	260/—	25/6,000	20/40
Dimensions (H × W × D)/Instrument footprint (square feet)	27 × 40 × 23 in./10 sq. ft.	30 × 48 × 24.4 in./8.1 sq. ft.	19 × 21 × 22 in./3.5 sq. ft.
Weight empty/Weight fully loaded	209 lbs./219 lbs.	210 lbs./—	59.5 lbs./60 lbs.
Tests available on analyzer in U.S.	glucose, total iron, magnesium, phosphorus, total protein, urea nitrogen, uric acid, ALT, ALP, AST, amylase, CK, GGT, LDH, lipase, HbA1c, direct LDL, triglycerides, direct HDL, cholesterol, more	albumin, direct bilirubin, total bilirubin, calcium, creatinine, uric acid, ALT, ALP, AST, amylase, CK, GGT, LDH, lipase, HbA1c, direct LDL, triglycerides, direct HDL, cholesterol, more	—
Tests not available in U.S. but available in other countries	—	APO A1, APO B, CRP, haptoglobin, IgA, IgG, IgM, microalbumin, microprotein, orosomucoid, prealbumin, transferrin	—
Tests in development for analyzer	—	—	—
No. of different measured assays onboard simultaneously	40 (40 can be run and calibrated at one time)	36 (96 can be run and calibrated at one time)	> 8 (> 8 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	500 (40 can be active simultaneously)	10 (10 can be active simultaneously)	—
Test throughput per hour/Assay run time	490/—	180/—	—/avg. 90 min.
Chemistry:			
No. of direct ion-selective electrode channels	4	4	—
Detection methods	potentiometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	3 min., 45 sec./37 specimens per hr.	5 min./66 specimens per hr.	—
• Basic metabolic panel	10 min./588 specimens per hr.	—/27 specimens per hr.	—
• Complete metabolic panel	15 min./266 specimens per hr.	13 min., 35 sec./12 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	3 min.	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	yes (96 tests per unit; 96 wells per microplate)
Methodologies supported	—	—	chemiluminescence, EIA
Separation methodologies	—	—	coated microwell
Stat time until completion of a β-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	varies/open reagent system	varies/self-contained multiuse	—/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (10°–15°C)/yes	yes (10°C)/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	no/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/yes
Walkaway capability/Walkaway duration	yes/240 min. or 52 specimens or > 1,000 tests/assays	yes/240 min. or 62 specimens or 720 tests/assays	yes/—
Design of sample handling system	ring	ring	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/no	yes/—	no/no
Min.–max. sample volume that can be aspirated at one time	1–100 µL	1–30 µL	1–400 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	300 µL/1 µL/100 µL	220 µL/1 µL/250 µL	300 µL/1 µL/200 µL
Dedicated pediatric sample cup	no	yes (dead volume: 100 µL)	no
Primary tube sampling/Pierces caps on primary tubes	yes (all tube sizes)/no	yes (tubes [in mm]:12 × 75)/no	yes (tubes [in mm]: 12 × 75, 13 × 75, 16 × 75, 12 × 100, 13 × 100, 16 × 100)/no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/yes	no/no/no/no	no/no/no/no
Dilutes patient samples onboard/Susceptibility to carryover	yes/—	yes/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	yes/no	no/no
Analyzer requires dedicated water supply	no (1 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	4 hrs./—/—/7–31 days/—	4–8 hrs./2 weeks min./when indicated (if QC fails)/28 days/—	—
Automatic programmable start/Automatic programmable shutdown	yes (7 min. avg. start-up time)/no	yes (15 min. avg. start-up time)/yes	no/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	no
Waste management	automated collection onboard instrument, direct to drain yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	automated collection onboard instrument, direct to drain yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	manually by user yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	yes	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply/Data-management capability	yes/onboard	yes/onboard	—/onboard
LIS or EHR systems interfaced	CGM LabDaq, Schuyler House SchuyLab, McKesson Horizon Lab	CGM LabDaq, Schuyler House SchuyLab, McKesson Horizon Lab	Sunquest, Orchard Harvest, CGM LabDaq, Meditech 5.65
LIS interface provided/Bidirectional interface capability	no/yes (host query)	no/yes (broadcast download and host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/24 hrs.	yes/24 business hrs.	no/48 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	420 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	weekly: 15 min.; monthly: 15 min.	daily: 5 min.; weekly: 5 min.; monthly: 15 min.	daily: 5 min.; weekly: 30 min.
Maintenance records kept onboard for user/vendor	yes/no	yes/no	some records/no
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer site)	yes (2 training slots)/3 days (at customer site)	yes/2–3 hrs. (at customer or vendor site)
Advanced operator training/Where advanced training is held	yes/customer site	yes/customer site	yes (extra charge)/customer or vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$8,995 (M–F, 8 AM–8 PM)	yes (1 year)/\$4,500 (M–F, 8 AM–8 PM)	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> fast benchtop chemistry system reusable glass cuvettes eliminate cost of disposable cuvettes 4-parameter (Na+, K+, Cl-, CO2) dry electrodes reduce costs and maintenance time, increase reliability of results 	<ul style="list-style-type: none"> benchtop chemistry with moderately complex drugs-of-abuse and therapeutic drug monitoring testing TouchPro software with smart icons guides operator through daily workflow, including configurable daily checklists 4-parameter (Na+, K+, Cl-, CO2) dry electrodes reduce costs and maintenance time, increase reliability of results 	<ul style="list-style-type: none"> small footprint for small laboratory spaces no consumable tips and bottles; greatly reduced consumable use for lowering laboratory expenses simple 1-plate affordable design
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 4 of 5

FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES

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800-445-9853 www.medtest.com

Name of instrument	Penra C400 chemistry	HYTEC 288 PLUS immunoassay	SPOTCHEM EZ chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/benchtop	batch, random access, discrete/benchtop	discrete/benchtop
List price/First year sold in U.S.	\$100,000/2006	\$55,000/1999	\$12,500/2006
Targeted hospital bed size/Targeted daily test volume	≤ 250/1,200	200/variable	—
Company manufactures instrument	yes (also sold by Henry Schein, McKesson, Thermo Fisher, Medline, LSI)	yes (also sold by distribution partners)	no (manufactured by Arkray)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	600/1,800	> 100/> 200 (Canada, Europe, Middle East, South America)	≥ 100/≥ 100
Dimensions (H × W × D)/Instrument footprint (square feet)	25 × 40 × 28 in./7.7 sq. ft.	29.5 × 42.5 × 27.5 in./8 sq. ft.	6.5 × 13.5 × 8 in./—
Weight empty/Weight fully loaded	264 lbs./266 lbs.	198 lbs./198 lbs.	12 lbs./—
Tests available on analyzer in U.S.	total protein, chloride, glucose, magnesium, triglycerides, amylase, cholesterol, BUN, iron, ferritin, TIBC, transferrin, uric acid, total bilirubin, creatinine, lactic acid, potassium, more	total/specific IgE	ALT, AST, BUN, cholesterol, glucose, HDL, total protein, panel 1 (ALB, BUN, GLU, CRE, CAL), panel 2 (ALP, T-BIL, ALT, AST, TP), lipid panel (HDL-C, TC, triglyceride, LDL-C), more
Tests not available in U.S. but available in other countries	apolipoprotein A1, apolipoprotein B, beta 2 microglobulin, fructosamine, CK-MB, anti-strep O, haptoglobin, more	specific IgG	—
Tests in development for analyzer	—	—	—
No. of different measured assays onboard simultaneously	55 (55 can be run and calibrated at one time)	up to 288 (up to 288 can be run and calibrated at one time)	8 (up to 21 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	40 (40 can be active simultaneously)	3	—
Test throughput per hour/Assay run time	420 (4 tests in throughput)/1–10 min. (avg. 5 min.)	48 (288 tests in throughput)/up to 6 hrs.	—
Chemistry:			
No. of direct ion-selective electrode channels	3	—	0
Detection methods	photometry, potentiometry, enzyme immunoassay	—	optical measurement of reflection intensity of reagent color reaction
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	< 5 min./37 specimens per hr.	—	—
• Basic metabolic panel	< 7.5 min./35 specimens per hr.	—	9 min./48 specimens per hr.
• Complete metabolic panel	< 11 min./23 specimens per hr.	—	9 min./48 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	—	—
Immunoassay:			
Fully automated microplate immunoassay system	—	no	—
Methodologies supported	—	enzyme immunoassay	—
Separation methodologies	—	none (all assays homogeneous)	—
Stat time until completion of a β-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	100–400/self-contained multiuse, open reagent system	20 or 10/self-contained multiuse	—/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	no/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	no/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no	dry chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes	no/yes	yes/yes
Walkaway capability/Walkaway duration	yes/180 min. or 60 specimens or > 800 tests/assays	yes/288 tests/assays	yes/up to 15 min. or 1 specimen or up to 8 tests/assays
Design of sample handling system	rack	rack	tray
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 432 cuvettes)	no/— (can store up to 288 cuvettes)	no/no
Min.–max. sample volume that can be aspirated at one time	2–60 µL	50 µL maximum	5 µL minimum
Min. reaction volume/Min. specimen volume/Min. dead volume	180 µL/300 µL/100 µL	10 µL/50 µL/100 µL	—
Dedicated pediatric sample cup	yes (dead volume: 100 µL)	no	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 13 × 75, 13 × 100, 16 × 100)/no	yes/no	no/no
Protects against probe collision	yes	no	no
Detects clots/liquid level/short sample	yes/yes/yes	no/—/yes	no/no/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/yes	no/no/no/no	no/no/no/no
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/< 1 part per 10,000	no/—
Automatic rerun capability	yes	no	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	no/no	no/no
Analyzer requires dedicated water supply	no (average of .5 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: monthly)	no (calibrants are not stored onboard)/no
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	2 hrs. automatic/—/—/14 days avg./—	—/—/—/—/monthly	—/—/—/—/per box/—
Automatic programmable start/Automatic programmable shutdown	yes (5 min. avg. start-up time)/—	no/yes	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/no	no/no
Supports multiple QC lot numbers per analyte	no	yes	no
Waste management	direct to drain or container if no drain available	manually by user or automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	no
System malfunctions can be diagnosed via remote monitoring	yes	no	no
UPS backup power supply/Data-management capability	no/onboard	yes/onboard	no/onboard
LIS or EHR systems interfaced	CGM LabDaq, Orchard, Cerner, Sunquest, Meditech, Schuyler House	—	—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	yes (additional cost)/yes (host query)	no/no
Modern servicing provided/Service engineer on-site response time	no/< 24 hrs.	yes/within 48 hrs.	no/— (depot service)
Mean time between failures	2 per year avg. (displays error codes for troubleshooting)	210 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: < 15 min.; monthly: < 30 min.	daily: 10–15 min.; weekly: 20–25 min.; monthly: 20–25 min.	—
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	yes/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (3 training slots)/2 days (location is user preference)	yes (2 training slots)/2 days (at customer site)	no/—
Advanced operator training/Where advanced training is held	yes (extra charge)/vendor site	no/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • can run up to 55 assays onboard with 420 quality results/hr. • no requirement for an external water system; remote diagnostics available for real-time troubleshooting • flexible, open-channel system with capability of having 40 third-party reagents onboard 	<ul style="list-style-type: none"> • menu • ease of use • quality of results 	

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Part 5 of 5	Nova Biomedical info@novabio.com Waltham, MA 800-458-5813 www.novabiomedical.com	Roche Diagnostics Brittany Greiner brittany.greiner@roche.com Indianapolis, IN usdiagnostics.roche.com/en/core_laboratory/analyzers.html	Roche Diagnostics Brittany Greiner brittany.greiner@roche.com Indianapolis, IN usdiagnostics.roche.com/en/core_laboratory/analyzers.html
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES			
Name of instrument	Stat Profile Prime CCS Comp	cobas c 311	cobas e 411
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	batch, random access, discrete/benchtop	random access/floor standing	continuous random access/benchtop
List price/First year sold in U.S.	—/2014	\$125,000/2009	disk: \$150,000; rack: \$165,000/2008
Targeted hospital bed size/Targeted daily test volume	—	< 100/< 200	< 100/< 200
Company manufactures instrument	yes	no (manufactured by Hitachi High-Technologies)	no (manufactured by Hitachi High-Technologies)
Other models in this family of analyzers	Prime Plus (not yet FDA cleared)	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	> 250/> 2,500 (> 50 countries)	> 800/> 10,000 (> 50 countries)
Dimensions (H × W × D)/Instrument footprint (square feet)	15.4 × 12.0 × 14.4 in./1 sq. ft.	50 × 52 × 34 in./8.5 sq. ft.	disk: 31.4 × 47.2 × 28.7 in.; rack: 31.4 × 67 × 37.4 in./ disk: 9.4 sq. ft.; rack: 17.4 sq. ft
Weight empty/Weight fully loaded	17.9 lbs./—	551 lbs./625 lbs.	disk: 397 lbs.; rack: 551 lbs./disk: 397 lbs.; rack: 551 lbs.
Tests available on analyzer in U.S.	measured: pH, PCO2, PO2, Na+, K+, Cl-, Ca++, Glu, Lac, Hct; calculated: SO2%, HCO3-, TCO2, Be-efc, Be-b, SBC, O2Ct, O2Cap, A, AaDO2, a/A, RI, PO2/FiO2, anion gap, P50, Hb, more	> 100 tests for anemia, diabetes, cardiac, TDM, DAT, general chemistries, specific proteins, ISE, D-dimer, homocysteine	> 75 assays for anemia, bone, tumor, diabetes, fertility, hormone, thyroid, cardiac, hepatitis, infectious disease, growth hormones, torch, sepsis, rheumatoid arthritis, more
Tests not available in U.S. but available in other countries	Mg++, TCO2, BUN, creatinine, tHb, O2Hb, COHb, MetHb, HHb, tBil, HbF, SO2%	acid phosphatase total serum, acid phosphatase non-prostatic serum, alpha-1 microglobulin, GLDH, HBDH, more	anti-HTLV-1/II, CA 27-24, CMV IgG avidity, digitoxin, free B-hCG, GDF-15, HBsAg II quant, IL-6, NSE, P1NP, PAPP-A, more
Tests in development for analyzer	—	IgG subclass 1–4	17-OH progesterone, active B12, aldosterone/renin, more
No. of different measured assays onboard simultaneously	10 (10 can be run and calibrated at one time)	42 photometrics, 3 ISEs (up to 90 can be run and calibrated at one time)	18 (18 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	10 (10 can be active simultaneously)	0
Test throughput per hour/Assay run time	45 (10 tests in throughput)/1 min.	300 (300 tests in throughput)/3–10 min. (avg. 7 min.)	86 (86 tests in throughput)/9–27 min. (avg. 18 min.)
Chemistry:			
No. of direct ion-selective electrode channels	4	3	—
Detection methods	photometry, potentiometry	photometry, potentiometry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	60 sec./45 specimens per hr.	5 min./150 specimens per hr.	—
• Basic metabolic panel	—	8 min./60 specimens per hr.	—
• Complete metabolic panel	—	11 min./27 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	< 10 sec.	< 1 min.	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	no (32 wells per microplate)
Methodologies supported	—	—	electrochemiluminescence
Separation methodologies	—	—	magnetic particle
Stat time until completion of a β-hCG test	—	—	9 min.
• Typical time delay from test order to aspiration of sample	—	—	< 1 min.
Stat time until completion of a cTn test	—	—	9 min.
• Typical time delay from test order to aspiration of sample	—	—	< 1 min.
Approx. No. of tests per reagent set or pack/Reagent type	up to 500/self-contained multiuse, MicroSensor Card	50–800/self-contained multiuse	100–200/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no (room temperature)/yes	yes (5°–15°C)/yes	no (20°±3°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	—	yes/60–180 min. or 108 specimens or 45 tests/assays	yes/30–60 min. or 30 specimens (disk), 75 specimens (rack) or 2,000–3,000 tests/assays
Design of sample handling system	manual	ring	disk: ring; rack: rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	yes/yes (can store up to 66 cuvettes)	no/yes (can store up to 360 assay tips, 180 assay cups)
Min.–max. sample volume that can be aspirated at one time	50–100 µL	1–35 µL	10–50 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/50 µL/—	6 µL/51 µL/50 µL	100 µL/10 µL/100 µL
Dedicated pediatric sample cup	no	yes (dead volume: 50 µL)	yes (Hitachi cup: 100 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (all tube sizes)/no	yes (tubes [in mm]: 16 × 75, 16 × 100, 13 × 75, 13 × 100)/no	yes (tubes: 13–16 mm diameter)/no
Protects against probe collision	no	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/yes	yes/yes/yes/yes	no/no/no/yes
Dilutes patient samples onboard/Susceptibility to carryover	no/—	yes (can be programmed to perform sample dilutions prior to analysis)/23 parts per million	yes/0 (uses disposable tips)
Automatic rerun capability	no	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/yes	yes/yes	yes/yes
Analyzer requires dedicated water supply	no	yes (12 L/hr. consumption during operation)	no (3 L consumption for 250 tests)
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (automated calibration every 2 hrs.)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: every new lot of reagent)	yes/yes
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	2 hrs./—/—/—/—	24 hrs./per lot/per lot/per lot/—	—/—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	yes (10 min. warm-up time)/yes	no/yes	yes (4 min. avg. start-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	automated collection onboard instrument	direct to drain	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, PDF417)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply/Data-management capability	no/onboard	yes/onboard	yes/onboard
LIS or EHR systems interfaced	—	—	—
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/no	yes (included in instrument price)/yes (broadcast download and host query)	yes (included in instrument price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/— (depot service)	yes/< 24 hrs.	yes/< 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	213 days (displays error codes for troubleshooting)	325 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	monthly: 5 min.	daily: 5 min.; weekly: 18 min.; monthly: 38 min.	daily: 5 min.; weekly: 6 min.; monthly: 11 min.
Maintenance records kept onboard for user/vendor	yes/yes	yes/yes	some records/some records
Maintenance training demonstration module onboard	no	yes	yes
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/15 min. (at customer site)	yes (1 training slot)/1 week (at both vendor and customer sites)	yes (1 training slot)/1 week (key operator training at vendor site, follow-up training at customer site)
Advanced operator training/Where advanced training is held	yes/customer site	yes/vendor site	yes (extra charge)/vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (5 years)/—	yes (1 year)/—	yes (1 year)/various options available
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • zero-maintenance microsensor cartridge technology uses Nova measurement technology in miniaturized sensor card • individual cartridges for sensors, calibrators, and liquid QC • unique Clot Block flow path to eliminate downtime associated with introduction of a clotted sample 	<ul style="list-style-type: none"> • drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage • minimizes downtime with industry-leading engineering and service; 213-day mean time between repair visits (average) • speeds up turnaround time for high-volume and stat assays 	<ul style="list-style-type: none"> • drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage • minimizes downtime with industry-leading engineering and service; 325-day mean time between repair visits (average) • speeds up turnaround time for high-volume and stat assays
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			