tech	Advanced Instruments	Alcor Scientific	Alfa Wassermann Diagnostic Technologies
Clinical Chemistry and Integrated Analyzers	Norwood, Mass (781) 320-9000 www.aicompanies.com	Smithfield, RI (401) 737-3774 www.alcorscientific.com	West Caldwell, NJ (800) 220-4488 www.alfawassermannus.com
 What is the brand name of your company's clinical chemistry or integrated analyzer? 	A ₂ 0 advanced automated osmometer	miniiSED	Ace Axcel clinical chemistry system
2. What is the latest version of your named clinical chemistry or inte- grated analyzer; what year was this version first released to market (US, OUS)?	2012	2020	2012
 Specify the authorizing agency, type, and year of the product's regulatory authorizations. 	FDA 510(k) exempt, 2012.	FDA 510(k) exempt.	FDA 510(k), 2012.
4. What are the dimensions of the named product?	22.8 inches x 23.6 inches x 20.5 inches	9.5 inches x 7.1 inches x 10.4 inches	33 inches x 28 inches x 26 inches
5. What is the intended use or primary function of the product?	Measures the osmolality of body flu- ids for use in the diagnosis and treat- ment of body fluid disorders.	Diagnosis and patient monitoring.	In vitro diagnostic use to quantify constituents of blood and other flu- ids.
6. What types of specimen/sample does the product employ?	Body fluids, including plasma, serum, stool, urine, and whole blood.	Whole blood.	Plasma, serum.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Osmolality testing can help evaluate the body's water balance and its abil- ity to produce and concentrate urine; investigate low sodium levels; detect the presence of toxins in the body; and monitor the electrolyte balance of patients receiving osmotically active drug therapies.	Measures inflammation in the body.	Electrolytes, enzymes, general chem- istries, and homogeneous immuno- assays.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	First results in 180 seconds. Results can be saved, printed, or exported via USB or ethernet connection.	First results in 15 seconds. Results can be viewed onscreen, printed, or transmitted to a laboratory informa- tion system.	Approximately 9 minutes for basic metabolic panel; approximately 14 minutes for comprehensive metabolic panel; results available by printout, onscreen, and via a laboratory infor- mation system.
9. What are the product's maximum capacity and throughput under ideal conditions?	Tests 20 samples in less than 1 hour.	Performs 180 tests per hour.	Performs 165 tests per hour; 285 tests per hour with ion-selective electrode.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	System draws samples directly from primary tubes, self-cleans between tests, and scans sample identification barcodes. System offers programma- ble quality control alerts, laboratory information system connectivity, and onboard Levey-Jennings charts.	Fully automated system for measur- ing erythrocyte sedimentation rate. Internal barcode reader ensures positive patient identification. Easily connects with any laboratory informa- tion system.	Closed tube sampling; remote access via Internet connectivity.
11. What is the typical training time for the product?	2 hours.	Less than 1 hour.	4.5 day in-house training course.
12. What types of technical support are available?	24/7 hotline phone and email sup- port; installation, training, validation services, and service contracts are available for purchase.	Technical assistance by phone; prompt service and repair at factory; loaner instruments available if neces- sary.	Customer solution center provides 24-hour coverage, 365 days a year.
13. What capabilities, features, or accessories distinguish this prod-uct from others on the market?	Delivers results with security, con- nectivity, quality control, and ease of use to maximize productivity and keep the busiest clinical chemistry labs in compliance.	Fully automated single-position erythrocyte sedimentation rate analyzer that uses only 100 μ L of sample, tested directly from an ethylenediaminetetraacetic acid tube.	Internet connectivity; closed-tube sampling; stat interrupt capability; onboard sample and reagent refrig- eration; onboard reagent inventory management; ready-to-use reagents; self-contained analyzer, requiring no external water source or waste drain- age; award-winning support.

Awareness Technology

Beckman Coulter

www.beckmancoulter.com

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(800) 526-3821

Palm City, Fla (772) 283-6540 www.awaretech.com

ChemWell-T DxC 700 AU chemistry analyzer Model 4620, 2014. 2017 CE mark; NRTL ISO 13485:2016 cer-FDA 510(k), 2016; CE mark. tification. Analyzer, 49 inches x 51 inches x 15.75 inches x 20.5 inches x 19.7 35 inches; sampler, 29 inches x 37 inches inches x 41 inches. General diagnosis and management Clinical diagnosis and monitoring of of disease state conditions, including patient samples via processing of diabetes, immunosuppressant monigeneral chemistries and turbidimetric toring, substance abuse testing, and assavs. therapeutic drug monitoring. Plasma, serum, stool, urine, and Cerebrospinal fluid, plasma, serum, whole blood urine, whole blood. Broad disease state application, with tests for allergy, bone metabolism, diabetes, drugs of abuse, general Many available tests for diseases of chemistry, general wellness, immuthe blood, cholesterol, diabetes, gout, nosuppressant therapy, malnutriand more. tion, oncology, specialty proteins, therapeutic drug monitoring, and toxicology. Time to first result varies. A single test with a short incubation may be First results in 8 minutes, 38 seccompleted in less than 5 minutes. onds. Results can be displayed, Results are displayed immediately printed, and transmitted to a laboraon acceptance and can be printed or tory information system. exported to file. Performs 800 photometric tests per Performs 100 tests per hour. hour; up to 1,200 tests per hour with ion selective electrode. Automation connectivity options include Power Express preanalytical automation, DxA 5000 preanalytical Imports and exports data via file share with a laboratory information system; sample barcode reader; autoautomation, and Power Link conmated reagent and sample sensing and pipetting; real-time assay quality nection to DxI 600/800 immunoassay systems. IT-connected options control based on user programming. include Remisol Advance clinical IT and DxOne clinical IT. Built-in analyzer Instrument diagnostics include error messaging and user-initiated self functions include autorepeat with testing. autodilution, advanced quality control, and advanced calibration. 2 to 3 days. 5 days. Phone, email, video conferencing, Field service and hotline; applications support available globally; various onsite technical support (with contract). service agreement options available. Suitable for mid- to high-volume laboratories, broad menu, intuitive Small footprint, easy to maintain, open system, preprogrammed examsoftware, stat capability, compatible ple tests, runs chemistry and turbidity with preanalytical automation, low tests, continuous loading, customizmaintenance, autorepeat with autodiable racks, ion-selective electrode lution capability, built-in quality control program, open-channel reagent optional.

capability.

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Optilite special protein analyzer	CLC 6410 instrument family (CLC 800, CLC 1600, CLC 1600, CLC 6410).	Excel chemistry analyzer	Envoy 500+ chemistry system
2015	CLC 800; 2016.	2008	Envoy 500+, 2014.
FDA 510(k), 2015.	FDA 510(k); CLIA categorization as instrument family.	FDA 510(k).	FDA 510(k), 2005.
24.4 inches x 37 inches x 27.6 inches	CLC 800, 42 inches x 31 inches x 45 inches; CLC 1600, 50 inches x 35 inches x 44 inches; CLC 6410 (modular; size varies).	15.75 inches x 14.5 inches x 5.5 inches	27 inches x 40 inches x 23 inches
Dedicated special protein ana- lyzer performs tests to diagnose, monitor, and manage patients with plasma cell disorders and immune deficiencies.	Clinical chemistry analyzer.	Measurement of a range of clinical chemistry parameters.	Diagnosis, patient monitoring.
Cerebrospinal fluid, serum, urine.	Plasma, serum.	Cerebrospinal fluid, plasma, serum, urine (test dependent); multiple samples can be run.	Plasma, serum, urine, whole blood.
B cell dyscrasias, blood cancers, central nervous system disorders, immune system disorders, mul- tiple myeloma.	A variety of analytes, conditions, and diseases.	Albumin, alkaline phosphatase, ALT/SGPT, amylase, AST/SGOT, bilirubin (total), bilirubin (direct), calcium, chloride, cholesterol, CK (NAC), CK-MB, creatinine, gamma- GT, glucose (hex), glucose (trinder), glycohemoglobin, iron (total), HDL, LDL, LDH, magnesium, potassium, protein (total), phosphorus, sodium, triglycerides, urea nitrogen, uric acid.	Diabetes and certain bone, heart, kidney, and liver diseases.
Typically, 15 minutes to first result and 1 minute for each sub- sequent result.	Estimated time to first result is 10 minutes; each subsequent test result follows at 15-second intervals.	Time to first result depends on the test procedure and the skill of the end-user.	First results in a minimum of 3 min- utes. Results are available onscreen, printed, or transmitted to a laboratory information system.
Performs 105 to 120 special pro- tein tests per hour.	CLC 800, up to 400 tests per hour; CLC 1600, up to 1200 tests per hour with ion-selective electrode; CLC 6410, up to 6400 tests per hour (four modules).	Throughput is dependent on the test procedure and the skill of the end-user.	Holds 52 samples; performs 490 tests per hour.
Optilite redilutes to end result, which means that even highly elevated myeloma samples are resulted without manual interven- tion. Optilite is bidirectionally interfaced with laboratory infor- mation systems.	Discrete, random access, batch, and stat priority; halogen lamp; indepen- dent sample and reagent probes; 340–800 nm wavelength barcode scanning of samples.	The instrument is controlled by a microprocessor; samples are read using a flowcell module to ensure that reagent consumption is optimized; features an 18-position incubator and a PC-style keyboard. Equipped to handle endpoint, kinet- ic, and enzyme immunoassays. The open system accommodates 120 programs; all routine Stanbio chem- istry tests are preprogrammed.	Onboard real-time quality control, remote diagnostics, onboard data management, onboard auto inven- tory (volume determination), auto- matic rerun, autocalibration, auto shutdown, programmable startup.
1 week user training.	Customized 4-day training at corporate training facility or in customer lab.	Use of the analyzer can begin after a review of the operator's manual.	5 days.
Global technical support team includes field applications specialists and engineers, and in- house specialists.	Hotline available 8:00 am-8:00 pm ET; validation assistance; afford- able after-sales service and support contracts.	Technical support is available via e-mail or a toll-free phone support line, Monday through Friday, 8:00 am–5:00 pm CT.	Monday through Friday, 8:00 am-8:00 pm ET.
Designed to simplify complex processes with enhanced efficiency (minimized reagent usage), optimized workflow (elimination of manual sample dilutions), and trusted results (using one of three methods of antigen excess detection).	Suited for laboratories that have multiple locations requiring analyz- ers in a variety of sizes; all instru- ments in the family use the same reagents.	Preprogrammed to run the range of Stanbio chemistry reagents, but can also be configured to meet the needs of individual laboratories.	A fast benchtop chemistry analyzer with four-parameter onboard dry ion- selective electrode; reusable glass cuvettes; small footprint; remote system diagnostics; liquid stable, ready-to-use reagents.

Fujirebio

Malvern, Pa (844) 544-3787 www.fujirebio.com	Beaumont, Texas (409) 842-3714 www.helena.com
Lumipulse G1200	V8 capillary electrophoresis system
OUS, 2008; US, 2016.	V8 Nexus; OUS, 2017; US, 2018.
TUV CE mark, 2011; FDA 510(k), 2016.	FDA 510(k); CE mark.
57 inches x 47 inches x 31.5 inches	35.24 inches x 26.77 inches x 26.77 inches x 26.77 inches
Diagnosis, patient monitoring, drug monitoring.	Serum protein analysis and characterization; hemoglobin (variants); carbohydrate-deficien transferrin (CDT; international only); glycomics CDT (interna- tional only).
Cerebrospinal fluid, plasma, serum, urine, other.	Plasma, serum, urine.
Tests for allergy, cardiac mark- ers, fertility/hormones, immune response, infectious diseases, meta- bolic disorders, neurodegenerative diseases, oncology, thyroid disor- ders, and more.	Hemoglobinopathy, kidney disease, liver disease, multiple myeloma.
First results in 30 minutes. Results available onscreen, printed, and via online transmission.	First results in 30 minutes.
Time to result is 30 minutes for all assays; performs 120 tests per hour.	Performs 100 tests per hour.
Able to connect to lab automation track systems; auto power-on; avail- able replenishment of samples, reagents, and consumables on the fly.	Fully automated; can connect to most laboratory information systems; quality control for indi- vidual capillaries; sophisticated troubleshooting software; intui- tive 'smart' data interpretation.
1 day.	2 days.
Monday through Friday, 8:30 am-5:30 pm ET.	24/7.
Unitized immunoreaction cartridge eliminates open-bottle stabil- ity concerns and reduces reagent waste; uninterrupted productivity by replenishing samples, reagents, and consumables on the fly.	Track capability; unique assays; gel integration; can connect to gel patient data management software.

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Armored RNA Quant is a technology developed jointly by Ambion, Inc. and Cenetron Diagnostics, LLC (US patents #5,677,124, #5,919,625, #5,939,262, #6,214,982, and #6,399,307), Armored RNA Quant is a registered trademark of Ambion and Cenetron Diagnostics. For Research Use Only. Not For Use in Diagnostic/ Procedures.

	Horiba Medical	Instrumentation Laboratory	Medica
Clinical Chemistry and Integrated Analyzers	Irvine, Calif (888) 903-5001 www.horiba.com	Bedford, Mass (800) 955-9525 www.instrumentationlaboratory. com	Bedford, Mass (800) 777-5983 www.medicacorp.com
 What is the brand name of your company's clinical chemistry or integrated analyzer? 	Pentra C400	Gem Premier ChemStat with iQM test- ing system	EasyRA clinical chemistry analyzer
2. What is the latest version of your named clinical chemistry or integrated analyzer; what year was this version first released to market (US, OUS)?	Version 2.0, 2006.	OUS, 2019; US, 2020.	EasyRA clinical chemistry analyzer with software enhancements, 2016.
 Specify the authorizing agency, type, and year of the product's regulatory authorizations. 	FDA 510(k); CE mark; Health Canada cleared.	FDA 510(k), 2019; CE mark, 2019.	FDA 510(k), 2008; CE mark, 2008.
4. What are the dimensions of the named product?	25 inches x 40 inches x 28 inches	18.5 inches x 13.1 inches x 16.3 inches	15 inches x 40 inches x 26 inches
5. What is the intended use or pri- mary function of the product?	Fully automated benchtop chemistry analyzer using colorimetry, turbidim- etry, and potentiometry technologies for the diagnosis and monitoring of patients with metabolic disease states.	Point-of-care testing in acute care and laboratory settings; actionable basic metabolic panel results in rapid risk stratification and prioritization of high- risk acutely ill patients, expedited time to treatment, and improved patient man- agement and quality of care.	Automated benchtop chemistry analyzer for in vitro diagnostic use in testing routine and special chemistries.
6. What types of specimen/sam- ple does the product employ?	Plasma, serum, urine, whole blood.	Arterial or venous lithium-heparinized whole blood.	Plasma, serum, urine. Refer to test reagent package insert for speci- men requirements.
7. What types of diseases, condi- tions, or analytes do tests per- formed on the analyzer detect?	Tests include an anemia panel; basic metabolic panel; comprehensive meta- bolic panel; hepatic panel; lipid panel; renal panel; diabetes/HbA1c; drugs of abuse and adulterants; immunoglobu- lins IgA, IgE, IgG, IgM; therapeutic drug monitoring; and vitamin D.	Provides quantitative measurements of blood urea nitrogen, chloride, creati- nine, glucose, hematocrit, ionized cal- cium, lactate, partial pressure of carbon dioxide, pH, potassium, sodium, and total carbon dioxide to aid in the diag- nosis of a patient's acid/base status, electrolytes, and metabolite balance.	Routine and special chemistries, including tests for anemia, cardiac markers, diabetes, electrolytes, enzymes, hepatic disease markers, renal disease markers, specific proteins, urine drug screening, and wellness testing.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	First results in 11 minutes for a com- prehensive medical panel, at a rate of 15 per hour; 12 seconds for every subsequent test result. Results reported onscreen, printed, or via a laboratory information system interface.	First results in 70 seconds. Results can be viewed on the analyzer's screen, printed, through GEMweb Plus custom connectivity, or via data transmission to a laboratory information system.	Time to first result is test- dependent. Basic metabolic panel provides first result in less than 8 minutes. Results are displayed onscreen and can be printed or sent to a laboratory information system.
 What are the product's maxi- mum capacity and throughput under ideal conditions? 	Holds 60 samples and 55 reagents, with 44 refrigerated positions. Throughoutput of 420 tests per hour with ion-selective electrode tests.	Tests 16 samples per hour; each sam- ple provides results for 12 measured parameters and a set of configurable derived parameters.	Up to 240 tests per hour (combina- tion of photometric assays and ion- selective electrode tests).
10. Briefly describe any automa- tion or connectivity features or options that pertain to the product.	Provides random continuous access to samples and reagents. Liquid level sensing; crash and clot detection; automatic pre- and postdilutions and reruns; reagent management; cuvette changer and reagent/results trace- ability; integrated reagent and sample barcode reader; bidirectional and host query interface.	Features intelligent quality manage- ment (IQM), an active quality man- agement program that continuously monitors the analytical process with real-time, automatic error detection, correction, and documentation of all corrective actions, replacing external quality control.	Reagents labeled via radio- frequency identification automate reagent management; primary tube sampling; positive sample identifi- cation with laboratory information system connectivity; liquid level sensing; easy troubleshooting and diagnostic tools along with remote system diagnostics option.
11. What is the typical training time for the product?	3.5 days at Horiba Medical training facility.	Approximately 15 minutes.	3 to 4 days at customer site.
12. What types of technical support are available?	Technical support hotline 24/7/365; onsite field service support; systems integration specialist support for instal- lations.	Onsite support; 24/7 telephone support.	Hotline support Monday through Friday, 8:00 am-8:00 pm ET; remote instrument diagnostics for trouble- shooting; onsite service available.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Benchtop chemistry analyzer does not require a water system, drain, or spe- cial electrical requirements. Provides 40 open channels for expanded menu needs. Suitable for physician office laboratories, clinics, or small hospital laboratories.	Enables rapid clinical decisionmaking. All-in-one, multiuse Gem Pak cartridge can be stored at room temperature. IQM ensures laboratory-quality results at the point of care.	Fully automated; touchscreen user interface employs color-coded icons. Reagents are liquid stable, ready-to-use. Modular design for easy maintenance, troubleshoot- ing, and repair. Remote instrument diagnostics.

Medical Electronic Systems	Mindray North America
Los Angeles (866) 557-9064 www.mes-global.com	Mahwah, NJ (425) 881-0361 www.mindraynorthamerica.com
SQA Vision automated sperm quality analyzer	BA 800M
Updated, 2020.	OUS, 2010; US, 2016.
FDA 510(k); TUV CE mark; ISO 13485; Canadian Medical Devices Conformity Assessment System certifica- tion.	FDA 510(k); CE mark.
40 Inches x 20.5 inches x 20.5 inches	47 inches × 91 inches × 40 inches
Intended for rapid assessment of sperm characteristics for male fertility testing and treat- ment.	Clinical diagnostic testing, including drugs of abuse, electrolytes, general chemistry, HbA1c, special analytes, urine chemistry analysis, and vitamin D.
Semen.	Serum, urine, whole blood (HbA1c assay).
Male infertility.	Cholestrol evaluation, dehydration, dia- betic evaluation, drugs of abuse and pain management, kidney function, liver func- tion, malnutrition, pancreatitis, vitamin D level.
System requires 180 seconds for calibration and quality con- trol; 75 seconds for the semen analysis.	Time to first result is assay-dependent, and varies from 1 minute to 13.08 min- utes. Results are available onscreen and printed.
Performs 35 to 40 tests per hour.	Total capacity is 440 tubes (capacity of sample delivery module is 300, capacity of onboard carousel sample tray is 140).
Fully automated calibration, stabilization, and self test when powered on and before each test; fully automated testing cycle.	Auto startup; auto rerun; autodilution; sample probe clot detection; probe vertical/horizontal collision protection; reagent probe bubble detection; empty reagent detection.
Less than 2 hours.	3 days at customer site.
Live daytime call support; 24/7 e-mail support; after hours call-back service.	Remote assistance, hotline, and onsite service.
Fully automated to eliminate subjectivity associated with manual methods; more precise and accurate than other auto- mated solutions; easy to use, self-calibrating.	Autoloader can handle up to 300 sample tubes; large capacity return buffer area; equipped with three sample lanes for rou- tine, stat, and return samples. Separate stat key available to facilitate emergency samples; capable of performing assays with up to four reagent components. Easy access to ion-selective electrode module

located in the front of the analyzer.

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	Nova Biomedical	Roche Diagnostics	Sebia
Clinical Chemistry and Integrated Analyzers	Waltham, Mass (781) 894-0800 www.novabiomedical.com	Indianapolis (800) 428-5076 www.diagnostics.roche.com	Norcross, Ga (800) 835-6497 www.sebia-usa.com
 What is the brand name of your company's clinical chemistry or integrated analyzer? 	Stat Profile Prime Plus	Cobas Pro integrated solutions	Capillarys 3
2. What is the latest version of your named clinical chemistry or inte- grated analyzer; what year was this version first released to market (US, OUS)?	2018	2020	Capillarys 3 Tera Row; OUS, 2016; US, 2017.
 Specify the authorizing agency, type, and year of the product's regulatory authorizations. 	CE mark, 2017; FDA 510(k), 2018; FDA 510(k) for point of care use, 2020.	CE mark, 2018; FDA 510(k), 2019.	FDA 510(k), 2019; CE mark.
4. What are the dimensions of the named product?	18 inches x 14 inches x 16 inches	56 inches x 188 inches x 48 inches	21.3 inches x 35.4 inches x 26.4 inches
5. What is the intended use or pri- mary function of the product?	Performs more than a dozen blood chemistry assays on capillary, heparin- ized arterial, and venous whole blood.	Fully automated and integrated clinical chemistry and immunoas- say platform for diagnostic test- ing, patient monitoring, therapeu- tic drug monitoring, and viral load monitoring.	Diagnosis and monitoring of diabe- tes; hemoglobin variant detection; and protein electrophoresis for mul- tiple myeloma.
6. What types of specimen/sample does the product employ?	Arterial, mixed venous, venous, or hepa- rinized whole blood.	Cerebrospinal fluid, plasma, serum, urine, whole blood.	Serum, urine, whole blood.
7. What types of diseases, condi- tions, or analytes do tests per- formed on the analyzer detect?	Quantitative determination of more than a dozen blood chemistry param- eters, including blood urea nitrogen, creatinine, glucose, hematocrit, ionized calcium, lactate, oxygen saturation, pH, potassium, sodium, and total hemo- globin.	More than 175 clinical chemistry and immunoassay tests, includ- ing anemia, cardiac function, diabetes, infectious disease, oncology, sepsis, and toxicology.	Multiassay analyzer for automated immunofixation (Immunotyping), carbohydrate-deficient transferrin testing, diabetes/HbA1c, hemo- globin variant testing, and multiple myeloma.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	First result in 1 minute. Results avail- able onscreen and printed.	First result in 11 to 12 minutes for basic and comprehensive metabolic panels; 10 to 11 min- utes for stat cardiac and critical- care assays; 18 to 27 minutes for routine immunoassays.	Analyzer produces 12 results in 18 minutes, for an average 1.5 minutes per result.
9. What are the product's maximum capacity and throughput under ideal conditions?	Tests 40 to 60 samples per hour.	Holds 300 samples at one time; maximum throughput of 900 tests per hour for ion selective electrode tests; 1,000 tests per hour for chemistries; 300 tests per hour for immunoassays.	Performs 115 serum protein elec- trophoresis tests per hour; systems can be linked for a maximum throughput of 345 tests per hour.
10. Briefly describe any automa- tion or connectivity features or options that pertain to the product.	Automated, true liquid quality control; continuously monitors status and per- formance of all analytical components (including sensors, reagents, calibrators, sample integrity, software, and electron- ics); auto calibration.	Connectable to Roche (Cobas 8100 and CCM) and selected third-party automation systems. Automatic dilutions, reflex test- ing, onboard troubleshooting.	Integrated LCD touchscreen, auto- mated startup and shutdown, pro- grammable maintenance, one-touch reagent and waste management, radio-frequency identification tags for full traceability of all reagents.
11. What is the typical training time for the product?	About 1 hour for primary operator training on operation, maintenance, troubleshooting, and set-up, performed at installation.	Key operator training typically 4.5 days, in Indianapolis; training for additional operators con- ducted at customer site.	Customized training plan for each lab; typically 2 to 3 days of onsite training.
12. What types of technical support are available?	24/7/365 technical hotline support; analyzer installation; onsite corrective maintenance within 8 business hours of call; multilevel technical support plans available for an annual fee.	24/7/365 telephone support; onsite technical and service support; remote support and troubleshooting; onboard user assistance.	24-hour hotline; requests can also be submitted via website.
13. What capabilities, features, or accessories distinguish this prod- uct from others on the market?	Zero-maintenance microsensor car- tridge technology in a miniaturized sensor card format. Clot block flow path; individual cartridges for sensors, calibrators, and liquid quality control; non-lysing cooximeter.	Automatic calibration for selected chemistries, reduced maintenance, modular concept, stat assays for cardiac and criti- cal care tests.	Fully automated capillary elec- trophoresis analyzer suitable for special and core chemistry labs, providing high-resolution separation for added medical value with opera- tional efficiencies.

Sebia	Siemens Healthcare Diagnostics	Thermo Fisher Scientific	Tosoh Bioscience
Norcross, Ga (800) 835-6497 www.sebia-usa.com	Tarrytown, NY (914) 631-8000 www.siemens-healthineers.com	Waltham, Mass (781) 467-9749 www.thermofisher.com	South San Francisco, Calif (800) 248-6764 www.tosohbioscience.us
Capillarys 3	Dimension EXL 200 integrated chemistry system	Cascadion SM clinical analyzer	AIA 900 benchtop
Capillarys 3 Octa Row; OUS, 2018; US, 2019.	Updated, 2020.	OUS, 2018; US, 2020.	OUS, 2010; US, 2011.
FDA 510(k), 2017; CE mark.	FDA 510(k), 2008, 2013; CE mark, 2010.	CE mark, 2018; FDA Class II exempt with special controls, 2020.	TUV CE mark, 2009; FDA 510(k), 2011.
21.3 inches x 35.4 inches x 26.4 inches	56 inches x 49 inches x 41 inches	55.1 inches x 88.6 inches x 37.8 inches	30 inches x 40 inches x 26 inches
Diagnosis and monitoring of diabe- tes; hemoglobin variant detection; and protein electrophoresis for mul- tiple myeloma.	Diagnosis, patient monitoring, thera- peutic drug monitoring.	Measurement of small molecule analytes, including assays for drugs of abuse testing, therapeutic drug monitoring, and 25-OH vitamin D testing.	Diagnosis and patient monitoring
Serum, urine, whole blood.	Cerebrospinal fluid, plasma, serum, urine, whole blood.	Plasma, serum, whole blood.	Plasma, serum, urine (analyte depen- dent).
Multiassay analyzer for automated immunofixation (Immunotyping), carbohydrate-deficient transferrin testing, diabetes/HbA1c, hemo- globin variant testing, and multiple myeloma.	More than 100 general chemistry tests and immunoassays, including tests for anemia, bone metabolism, cardiac function, diabetes, fertility, oncology, therapeutic drug monitor- ing, thyroid disease, and toxicology.	Measures 25-OH Vitamin D2, vita- min D3, and total vitamin D for the assessment of vitamin D deficiency, insufficiency, sufficiency, and toxic- ity.	Tests for anemia, cardiac markers, diabetes, kidney markers, metabolic function, reproductive function, thy- roid disorders, tumor markers, and more.
Analyzer produces 8 results in 18 minutes, for an average 2.25 min- utes per result.	Time to first result is assay-depen- dent, and varies from less than 1 minute to 32 minutes.	First result in approximately 30 min- utes; subsequent results approxi- mately every 2 minutes thereafter.	First result in 18 minutes. Results are printed on thermal paper and can be exported to a laboratory information system.
Performs 80 serum protein electro- phoresis tests per hour.	Performs 440 photometric chemis- try tests, 187 integrated multisensor technology tests, or 167 heteroge- neous immunoassay tests per hour.	Holds 60 uncapped primary sample tubes or sample cups; throughput of up to 25 samples per hour.	Analyzer can process 50 samples with one test each, or up to 16 samples with 5 tests each (80 tests); maximum throughput is 90 tests per hour.
Integrated LCD touchscreen, auto- mated startup and shutdown, pro- grammable maintenance, one-touch reagent and waste management, radio-frequency identification tags for full traceability of all reagents.	Connectivity available to VersaCell X3, Aptio automation, and Atellica IT systems; performs tests in random order; automated reagent preparation, reflex testing, reruns, and dilutions; automated hemolysis, icterus, and lipemia measurements.	Bidirectional host-query laboratory information system interface allows for automated order processing; other features include priority sample capability, foam and clot detection, probe alignment check, and liquid level sensor.	Random access, direct tube sampling, liquid level sensing, autodilution, abnormal values flag, clot detection, dedicated disposable tip, automatic counting of tips, tips can be replaced without interrupting workflow.
Customized training plan for each lab; typically 2 to 3 days of onsite training.	3 days at customer site.	3-day key operator training.	3 days.
24-hour hotline; requests can also be submitted via website.	Phone hotline support 24/7; onsite technical and service support; remote troubleshooting.	Dedicated regional field service and support teams; global specialized technical support; next business day onsite response; regional hot- line support; active remote access support enabling predictive support.	24/7 telephone support.
Fully automated capillary elec- trophoresis analyzer suitable for special and core chemistry labs, providing high-resolution separation for added medical value with opera- tional efficiencies.	Integrates general chemistry tests with immunoassays; automated onboard immunosuppressant drug assays; ready-to-use reagents and automated calibration, control, and system check procedures.	Fully automated, random access LC-MS/MS system, measuring ana- lytes directly for enhanced accuracy, precision, and specificity compared to immunoassays.	Primary-tube sampling; unitized test cups; dry reagent technology; no reagent preparation; automated sample pretreatment; accepts load of up to 100 samples.