

tech. guide

Clinical Chemistry and Integrated Analyzers

1. What is the brand name of your company's clinical chemistry or integrated analyzer?
2. What is the latest version of your named clinical chemistry or integrated analyzer?
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.
4. What are its dimensions?
5. What is the intended use or primary function of the product?
6. What types of specimen/sample does the product employ?
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?
8. Under ideal conditions, what is the time to first result; how are the test results made available?
9. What are the product's maximum capacity and throughput under ideal conditions?
10. Briefly describe any automation or connectivity features or options.
11. What is the typical training time for the product?
12. What types of technical support are available?
13. What capabilities, features, or accessories distinguish this product from others on the market?

Abbott

Chicago, IL
globalpointofcare.abbott

Abbott Point of Care

Princeton, NJ
609-454-9000
www.globalpointofcare.abbott

Advanced Instrument

Norwood, MA
781-320-9000
aicompanies.com

ID NOW	i-STAT TBI Plasma (operates on i-STAT Alinity instrument)	Osmo1 Single-Sample Micro-Osmometer
2014: CE Mark, 510(k), CLIA waived	2021	2017
2014: CE Mark, 510(k), CLIA waived	FDA 510(k), 2021.	Exempt, 2017
8.15" W x 5.71" H x 7.64" D	10.10" x 5.60" x 3.20"	15" x 14" x 15"
A rapid, instrument-based, isothermal system for the qualitative detection of infectious diseases at the point of care.	In vitro diagnostic to aid in the evaluation of patients with mild traumatic brain injury (GCS 13-15) in conjunction with other information.	Measures the osmolality of body fluids using the freezing point depression method.
Influenza A and B: nasal swab, nasopharyngeal swab, Strep A: throat swab, RSV: nasopharyngeal swab, COVID-19: nasal swab, nasopharyngeal swab, throat swab	Plasma	Plasma, serum, stool, urine, whole blood, and more.
Detects influenza A and B, strep A, RSV, COVID-19 (COVID-19 assay is available in the US under FDA EUA).	Provides quantitative measurements and semi-quantitative interpretation of two biomarkers of brain injury, glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1)	Osmolality testing can help evaluate the body's water balance, investigate hyponatremia, detect toxins, and monitor the effectiveness of treatments for conditions adversely affecting a person's osmolality.
Results vary by assay. Positive results returned in 2 minutes for Strep A 2 assay and in 5 minutes for Influenza A & B 2 assay. Negative results for all assays returned in 13 minutes or less.	15 minutes after sample preparation. Results available on instrument display, electronic records, or printed	Test time is 90 seconds. Results can be saved, printed, or exported via USB/ethernet connection.
Varies by assay and patient results	The instrument is always ready to use. A new test can be performed every 15 minutes.	Performs 40 tests per hour.
Out-of-the-box connectivity to industry leading open platform connectivity solutions	Automated quality controls and requires minimal operator interaction. An internal electronic quality control is performed with every patient test. Allows efficient management of patient data through wireless or wired transmission of data. Auto QC Pass/Fail with QC & CAL/VER Scheduler.	Includes programmable QC alerts, LIS connectivity, onboard Levey-Jennings charts, and touch-screen operation.
CLIA-waived	60 minutes	2 hours.
Phone, email, in person, virtual (varies based on location)	Remote & on-site support is available. Technical bulletins and product updates are located on the website.	24/7 hotline phone and email support available. Service agreements and installation, training, and validation support available for purchase.
Delivers lab-accurate results faster than any other molecular method. As a result, you can make confident, effective and meaningful decisions for your patients at the point of care.	An onboard quality system within the i-STAT Alinity instrument automatically monitor nearly 150 sensor characteristics that may impact the accuracy of results. Notifies operator of critical information, indicating when results is normal, abnormal, or critical. Permits documentation of important patient information. .	Reliable results with low 20 µL sample requirement. Delivers the security, connectivity, quality control, and ease of use to maximize productivity and keep the busiest clinical chemistry labs in compliance.

Beckman Coulter

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800-526-3824
www.beckmancoulter.com

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Carolina Liquid Chemistries

Greensboro, NC
877-722-8910
contactsales@carolinachemistries.com
www.carolinachemistries.com

AU 480 chemistry analyzer	DxC 700 AU chemistry analyzer	AU 5800 chemistry analyzer	CLC 6410 instrument family (CLC 800, CLC 1600, CLC 6410).
2007	2017	2012 (US), 2010 (OUS)	CLC 800; 2016.
FDA 510(k), 2010; CE mark, 2009.	FDA 510(k), 2016; CE mark, 2017.	FDA 510(k), 2011; CE mark, 2010.	FDA 510(k); CLIA categorization as instrument family.
47" x 57" x 30"	51" x 49" x 35"	50" x 168" x 62" (model dependent)	CLC 800, 42" x 31" x 45"; CLC 1600, 50" x 35" x 44"; CLC 6410 (varies).
General diagnosis and management of disease state conditions, including diabetes, substance abuse testing, and therapeutic drug monitoring.	General diagnosis and management of disease state conditions, including diabetes, substance abuse testing, and therapeutic drug monitoring.	General diagnosis and management of disease state conditions, including diabetes, substance abuse testing, and therapeutic drug monitoring.	Clinical chemistry analyzer.
Cerebrospinal fluid, plasma, serum, urine.	Cerebrospinal fluid, plasma, serum, urine, whole blood.	Cerebrospinal fluid, plasma, serum, urine.	Plasma, serum.
Tests for allergy, bone metabolism, diabetes, immunosuppressant therapy, malnutrition, oncology, specialty proteins, therapeutic drug monitoring, and more.	Tests for allergy, bone metabolism, diabetes, immunosuppressant therapy, malnutrition, oncology, specialty proteins, therapeutic drug monitoring, and more.	Tests for allergy, bone metabolism, diabetes, immunosuppressant therapy, malnutrition, oncology, specialty proteins, therapeutic drug monitoring, and more.	A variety of analytes, conditions, and diseases.
First results in 8 minutes and 38 seconds, 9 seconds between tests. Results can be displayed, printed, and transmitted to a laboratory information system.	First results in 8.5 minutes, 4.5 seconds between tests. Results can be displayed, printed, and transmitted to a laboratory information system.	First results in 8.5 minutes, 3.6 seconds between tests. Results can be displayed, printed and transmitted to a laboratory information system.	Estimated time to first result is 10 minutes; each subsequent test result follows at 15-second intervals.
Performs 400 photometric tests/hour; up to 800 tests per hour with ion selective electrode.	Performs 800 photometric tests per hour; up to 1,200 tests per hour with ion selective electrode.	Performs up to 2,000-8,000 photometric tests per hour; up to 9,800 tests per hour with dual ion selective electrode (model dependent).	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).
Integrates with REMISOL Advance clinical informatics. Built-in analyzer functions include autorepeat with autodilution, advanced QC, advanced calibration.	Automation connectivity options include Power Express preanalytical automation, Dx A 5000 preanalytical automation, Power Link connection to DxI 600/800. Integrations with clinical informatics include REMISOL Advance, DxONE Product Suite.	Automation connectivity options include Power Express preanalytical automation, Dx A 5000 preanalytical automation, Integrations with clinical informatics include REMISOL Advance, DxONE Product Suite. .	Discrete, random access, batch, and stat priority; halogen lamp; independent sample and reagent probes; 340–800 nm wavelength barcode scanning of samples.
Basic virtual operator training is 4 days.	Basic virtual operator training is 4 days.	Basic virtual operator training is 4 days.	Customized 4-day training at corporate training facility or in customer lab.
Field service and hotline; applications support available globally; various service agreement options available.	Field service and hotline; applications support available globally; various service agreement options available. PROService remote service tool available to help maximize instrument uptime.	Field service and hotline; applications support available globally; various service agreement options available. PROService remote service tool available to help maximize instrument uptime.	Hotline available 8:00 am–8:00 pm ET; validation assistance; affordable after-sales service and support contracts.
Ideal for small- to mid-sized hospitals and laboratories or dedicated specialty chemistry or STAT analyzer for larger institutions. Compact, reliable, and cost-effective with robust testing capabilities, efficient reagent and consumable use, and convenient operational features.	Suitable for mid- to high-volume laboratories, broad menu, intuitive software, STAT capability, compatible with preanalytical automation, more uptime with low maintenance, autorepeat with autodilution capability, built-in quality control program, open channel reagent capability.	Powerful throughput, suitable for high- and ultra high-volume core laboratories, continuous operation with minimal downtime and easy maintenance, scalable capacity up to four models, intelligent sample management system, STAT capability, autorepeat, compatible with preanalytical automation, immunoassay, and clinical IT.	Suited for laboratories that have multiple locations requiring analyzers in a variety of sizes; all instruments in the family use the same reagents.

Diatron

Budapest, Hungary
36 1-436-9800
www.diatron.com

EKF Diagnostics

Boerne, Texas
830-249-0772
www.ekfusa.com

ELITechGroup

Paris, France.
US Headquarters: Logan, UT

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US Headquarters: Logan, UT

P500	Excel chemistry analyzer	Envoy 500+ Chemistry System	Selectra ProM Chemistry Systems
OUS, 2015; US, 2016.	2008	Envoy 500+ launched in 2014 Envoy 500 launched in 2005	Selectra ProM chemistry system with TouchPro Software launched in the US in 2012
TUV CE mark, 2015; FDA, 2016.	FDA 510(k).	FDA 510(k) clearance, 2005	FDA 510(k) clearance, 2011
34.6" x 27.6" x 26"	15.75" x 14.5" x 5.5"	27" x 40" x 23"	30" x 48" x 24"
Diagnosis.	Measurement of a range of clinical chemistry parameters.	Diagnosis, patient monitoring	Diagnosis, patient monitoring, therapeutic drug monitoring
Plasma, serum, urine, whole blood.	Cerebrospinal fluid, plasma, serum, urine (test dependent); multiple samples can be run.	Plasma, serum, urine, whole blood	Plasma, serum, urine, whole blood
General chemistry, BMP, CMP, lipids, and special proteins.	Albumin, alkaline phosphatase, ALT/SGPT, amylase, AST/SGOT, calcium, chloride, cholesterol, CK (NAC), CK-MB, creatinine, gamma-GT, glucose (hex), glucose (trinder), glycohemoglobin, iron (total), magnesium, potassium, phosphorus, more.	Certain kidney, liver, heart and bone diseases, along with diabetes	Certain kidney, liver, heart and bone diseases, along with diabetes
First results in approximately 7 minutes. Results available via Windows-based software and editable complete A4 patient report.	Time to first result depends on the test procedure and the skill of the end-user.	Depends upon test mix but 3 minutes minimum. Results available on-screen, transmitted to LIS (optional) and printed.	Depends upon test mix but 5 minutes minimum. Results available on-screen, transmitted to LIS (optional) and printed.
Performs 420 tests per hour.	Throughput is dependent on the test procedure and the skill of the end-user.	52 samples, 490 tests/hr	35 samples, 180 tests/hr
Intelligent software, high-quality components, multi-functional pipetting arm, user-friendly interface, uninterrupted workflow, inventory management, remote access and diagnostics, and cost-effective operation.	Controlled by microprocessor; samples read using flowcell module so reagent consumption optimized; 18-position incubator and PC-style keyboard. Equipped to handle end-point, kinetic, and enzyme immunoassays. Open system accommodates 120 programs; all routine Stanbio chemistry tests are preprogrammed.	Onboard real-time quality control, remote diagnostics, onboard data management, onboard auto inventory (volume determination), automatic rerun, autocalibration, auto shutdown, programmable startup	Onboard real time quality control, remote diagnostics, onboard data management, configurable result checks provide autoverification, onboard auto inventory (volume determination), automatic rerun, autocalibration, auto shutdown, programmable startup
1 week.	Use of the analyzer can begin after a review of the operator's manual.	5 days	3 days
Technical support team.	Available via e-mail or a toll-free phone support line, Monday through Friday, 8:00 am–5:00 pm CT.	Mon - Fri, 8:00 a.m. - 7:00 p.m. EST	Mon - Fri, 8:00 a.m. - 7:00 p.m. EST
Benchtop, fully automated clinical chemistry system comprised of advanced Windows-based software, state-of-the-art components, and a user-friendly interface. Includes a full range of reagents, controls, and calibrators.	Preprogrammed to run the range of Stanbio chemistry reagents, but can also be configured to meet the needs of individual laboratories.	One of the fastest benchtop chemistry analyzers with 4-parameter onboard dry ISE; reusable glass cuvettes; small footprint; remote diagnostics; liquid stable, ready-to-use reagents.	TouchPro software with smart icons guides the operator through daily workflow, including configurable daily checklists; ELITech ProServe remote-assist diagnostics and Internet-based training; combination of onboard PSID, host-query LIS, and configurable result checks provide autoverification, improved walkaway, and error reduction; liquid-stable, ready-to-use reagents.

ELITechGroup

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Selectra ProS Chemistry Systems	EUROLabWorkstation	Pentra C400 chemistry system	Yumizen C1200 chemistry system
Selectra ProS chemistry system with TouchPro Software launched in the US in 2012	2015	Pentra C400, 2014	Yumizen C1200, 2020
FDA 510(k) clearance, 2011	UL certification 61010-1: 2012, CU 72180312; UL 61010-2-101: 2015	FDA 510(k); Health Canada licensed; CE Mark	FDA 510(k); Health Canada licensed
36" x 30" x 24"	115.0" x 31.9" x 33.8"	48" x 12" x 17"	43 inches x 48 inches x 33 inches
Diagnosis, patient monitoring	To provide efficient sample loading and fast turnaround times, helping to combat the challenges laboratories are currently facing.	Benchtop, used to screen and monitor patients for a variety of disease states in the physician office, small clinic, pain management clinics, reference labs, and rural hospitals.	Used to screen and monitor patients for a variety of disease states in the large clinic, pain management clinics, reference labs, and rural and community hospital laboratories.
Plasma, serum, urine, whole blood	Serum, plasma, and cerebrospinal fluid.	Plasma, serum, urine.	Plasma, serum, urine.
Certain kidney, liver, heart and bone diseases, along with diabetes	Detection of antibodies or antigens linked to neurodegenerative disease, kidney markers, inflammatory bowel diseases, bone turnover markers, infectious agents, and others conditions.	Complete chemistry menu including tests for CMP; BMP; lipid, hepatic, renal, and anemia panels; diabetes; TDMs; DAUs and adulterants; vitamin D, immunoglobulins and rheumatoid factor; C3/C4; insulin; hsCRP.	Complete chemistry menu including tests for CMP; BMP; lipid, hepatic, renal, and anemia panels; diabetes; TDMs; DAUs and adulterants; vitamin D, immunoglobulins and rheumatoid factor; C3/C4; insulin; hsCRP.
Depends upon test mix but 5 minutes minimum. Results available on-screen, transmitted to LIS (optional) and printed.	Approx 90-120 mins including incubation.	CMP 11 minutes, BMP 8 minutes, lipid 11 minutes, CMP/lipid panels 12 minutes, BMP/lipid panels 11 minutes. Results: Bidirectional LIS, print report.	CMP 12 minutes, BMP 12 minutes, lipid 12 minutes, CMP/lipid panels 12 minutes, BMP/lipid panels 12 minutes. Results: Bidirectional LIS, print report
25 samples, 140 tests/hr	Up to 200 assays per hour and more than 800 samples on board.	420 tests/hour including ISEs; 60 samples random continuous access; 52 onboard reagents; R1/R2 in same cartridge takes up less space; 40 open channels.	1200 tests/hour including ISEs; 84 samples random continuous access; 41 onboard reagents; program 100 applications; autoloader capacity 65 samples.
Onboard real-time quality control, remote diagnostics, onboard data management, configurable result checks provide autoverification, onboard auto inventory (volume determination), automatic rerun, autocalibration, auto shutdown, programmable startup.	Fully automated processing of indirect immunofluorescence assays: up to 750 reaction fields per run. Automatic identification of patient samples, reagents, slides and dilution plates - 100% traceability.	Completely automated system with lot and calibration monitoring, test countdown, onboard real-time QC. Barcoded host query walkaway capabilities. Onboard IFUs and user's manual. Auto-validation.	Optional autoloader. Auto-startup/shutdown with maintenance workflow. Clot and cap/crash detection. Liquid level sensing probes. Reagent and calibration expiry date monitoring, test countdown, onboard real-time QC monitoring. Autovalidation.
3 days	1-2 days for the main operator. There is also additional workflow training available if needed and that would add another day.	Three days in Irvine, Calif, and two days on site."	Four days in Irvine, Calif, and four days on site.
Mon - Fri, 8:00 a.m. - 7:00 p.m. EST	On-demand and onsite technical support as needed.	24/7/365 phone support; onsite Monday-Friday 8:00 am - 5:00 pm; weekends and evenings by contract.	24/7/365 phone support; onsite Monday-Friday 8:00 am - 5:00 pm; weekends and evenings by contract.
TouchPro software with smart icons guides the operator through daily workflow, including configurable daily checklists; ELITech ProServe remote-assist diagnostics and Internet-based training; combination of onboard PSID, host-query LIS, and configurable result checks provide autoverification, improved walkaway, and error reduction; liquid-stable, ready-to-use reagents.	Complete walk-away processing; high capacities; minimized hands-on times and high result integrity; convenient ready-to-use reagents; flexible workflow adaptation; high throughput; flexible loading; individual configuration; more than 200 EUROIMMUN ELISA; flexible open system.	Broad menu of moderately complex DAU, routine and specialty chemistry assays. No water, drain, or special electrical required. Open system. Disposable cuvettes reduce exposure to BBP and carryover potential. Connects to Horiba Lite Data Management System for consolidated patient reports. LIS connectivity.	Compact design with high throughput capacity. Optional autoloader for workflow efficiencies. Micro-volume technology for sample and reagent; important for pediatric and geriatric patients. Auto-startup/shutdown & maintenance workflow. Reaction carousel design eliminates bacterial growth, potential for flooding. Better than industry standard MTBF.

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Nova Biomedical

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www.novabiomedical.com

IDS-iSYS Multi-Discipline Automated System	IDS-i10 Next Generation Immunoanalyzer	EasyRA	Stat Profile Prime Plus
US: 2010, CE: 2008 CFDA: 2014	US: 2018 CE: 2015	Medica EasyRA; 2009	2018
CE mark: 2009 FDA 510k: 2010	CE mark: 2018 FDA 510k: 2010	FDA 510(k), 2007; CE mark.	CE mark, 2017; FDA 510(k), 2018; FDA 510(k) for point-of-care use, 2020.
27.6" x 41.3" x 29.5"	26.8" x 40.9" x 23.8"	15" H x 40" W x 26" D	18" x 14" x 16"
Used for automated processing of chemiluminescence immunoassays (ChLIA) for autoimmune, allergy and infection diagnostics as well as antigen detection.	Used for automated processing of chemiluminescence immunoassays (ChLIA) for autoimmune, allergy and infection diagnostics as well as antigen detection.	Diagnosis, patient monitoring, toxicology/drugs of abuse.	Performs more than a dozen blood chemistry assays on capillary, heparinized arterial, and venous whole blood.
Serum, plasma, urine or saliva.	Serum, plasma, urine or saliva.	Serum, plasma, urine	Arterial, mixed venous, venous, or heparinized whole blood.
SARS-CoV-2 antibodies, disorders of the adrenal gland, and more.	SARS-CoV-2 antibodies, disorders of the adrenal gland, and more.	Provides quantitative results on analytes indicative of hepatic, renal, metabolic, electrolyte, and other physiological disturbances.	Quantitative determination of more than 22 blood chemistry parameters.
Less than 25 minutes.	Less than 25 minutes.	~8 minutes for basic metabolic panel; ~12 minutes for comprehensive metabolic panel; results available by printout, onscreen, and via a laboratory information system.	Results available onscreen and printed.
Up to 15 assay reagents. Up to 120 samples. Up to 120 tests/hour.	Up to 10 assay reagents. Up to 60 samples. Up to 170 tests/hour.	300 tests/hr ; 480 tests/hr with ISE.	Tests 40 to 60 samples per hour.
Single pipetting arm; liquid level detection by capacitance; clot detection by pressure transducer; internal and external rinsing between each pipetting; possibility of specific rinses; preheating of sampling; sample volumes from 4 µL to 300 µL.	Single pipetting arm; liquid level detection by capacitance; clot detection by pressure transducer; internal and external rinsing between each pipetting; possibility of specific rinses; preheating of sampling; sample volumes from 4 µL to 300 µL.	Imports and exports data via LIS system; sample barcode reader; automatic tracking and entry of reagent information; automated sample sensing and pipetting; ; Levey-Jennings charts for QC results; Instrument diagnostics; on-board diagnostics and individual component monitoring.	Automated, true liquid quality control; continuously monitors status and performance of all analytical components; auto calibration.
Aligned to the needs of our customers, from basic operator level training to IDS-iSYS Multi-Discipline Automated System expert.	Aligned to the needs of our customers, from basic operator level training to IDS-iSYS Multi-Discipline Automated System expert.		About 1 hour for primary operator training on operation, maintenance, troubleshooting, and set-up, performed at installation.
On-demand service and support facility provided by regional customer care centers.	On-demand service and support facility provided by regional customer care centers.	Phone technical assistance from 8:00AM – 8:00PM ET Monday-Friday.	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.
A long heritage of instrument production; excellent correlation with gold-standard assays; independent test cuvette processing; clot system to prevent measurement interruption; decontamination concept, preventing sample carry-over; samples, reagents and consumables traceability.	Random access instruments; minimal calibration effort; connection to a laboratory track system; autoimmune, allergy and infection parameters as well as antigen detection on one instrument; short reaction times; high throughput; convenient and reliable operation.	Direct ISE. Small footprint. 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. Carryover avoidance programmed on RFID chip. self-contained analyzer, requiring no external water source or waste drainage.	Zero-maintenance microsensor cartridge technology in a miniaturized sensor card format. Clot block flow path; individual cartridges for sensors, calibrators, and liquid quality control. Broad menu including iMg, BUN, creatinine, CO-oximetry, estimated plasma volume (ePV), Oxygen Index.

Tests Available:

- pH
- PCO₂
- PO₂
- SO₂%
- Hct
- Hb
- MCHC
- Na
- K
- Cl
- TCO₂
- iCa
- iMg
- GLU
- Lac
- Urea
- Creat
- CO-Ox
- ePV
Estimated Plasma Volume



Standardize Blood Gas and Critical Care Testing with Nova Prime Analyzers



The Nova Prime critical care platform offers 4 models with flexible test menus and as many as 22 critical care tests, including unique tests for iMg, Urea, Creatinine, Estimated Plasma Volume (ePV), and Mean Corpuscular Hemoglobin Concentration (MCHC). This is by far the largest number of model and test menu choices offered by any blood gas company and they are linked together by common reagents, operating procedures, user interfaces and the NovaNet™ point-of-care connectivity platform which is already used by 2/3 of U.S. hospitals.

The benefits of this unmatched flexibility are reduced costs, standardized operating procedures and the largest overall menu of tests to satisfy the NICU, ICU, ED, Lab, and Pulmonary department.

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OPTI Medical Systems

Roswell GA
www.optimedical.com/en/
 770-510-4444, 800-727 43399

Ortho Clinical Diagnostics

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 800-828-6316
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 800-828-6316
www.orthoclinicaldiagnostics.com

PerkinElmer

Waltham, MA
 800-762-4000 or 203-925-4602
www.perkinelmer.com

OPTI CCA- TS2 blood gas and electrolyte analyzer	Vitros XT 7600 integrated system	Vitros XT 3400 chemistry system	QSight Triple Quadrupole LC-MS/MS Series 200 and 400
2013	OUS, 2018; US, 2018.	OUS, 2020; US, 2020.	2018
CE mark, 2017; FDA 510(k), 2018; Emergo 98/79/EC, ISO 13485:2003, MDSAP ISO:2016 certification	FDA 510(k), 2018; CE mark, 2018.	FDA 510(k) instrument family, 2019; CE mark, 2019.	Research use only (RUO)
Height 4.7", Width 14.2", Depth 9.1"	68" x 110" x 34.9"	52.6" x 58" x 34.2"	20" x 20" x 48" (Series 200) 20" x 20" x 54" (Series 400)
Assess blood pH, partial pressure of carbon dioxide (pCO ₂), and partial pressure of oxygen (pO ₂) in heparinized whole blood (arterial, venous, or capillary) samples near or within patient care areas.	Fully automated and integrated clinical chemistry and immunoassay test system that utilizes XT MicroSlides. For diagnostic testing, patient monitoring, and therapeutic drug monitoring.	Fully automated clinical chemistry test system that utilizes XT MicroSlides. For diagnostic testing, patient monitoring, and therapeutic drug monitoring.	For determination of compounds in food, cannabis, environmental, and biological samples.
Whole blood, serum and plasma.	Cerebrospinal fluid, plasma, serum, urine, whole blood, *amniotic fluid. (*Not commercially available in U.S.)	Cerebrospinal fluid, plasma, serum, urine.	plasma, serum, urine, whole blood, DBS.
Conduct quick, accurate and efficient basic testing of pH, PCO ₂ , PO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, BUN, Lac, tHb and SO ₂ , depending on the cassette configuration.	More than 100 immunoassay and clinical chemistry tests on a single platform.	More than 50 clinical chemistry tests on a single platform.	Therapeutic drug monitoring, clinical and forensic toxicology analysis, steroid hormones, vitamin D, biotherapeutic peptides and other clinical application.
Typical cycle time is <210 seconds. Results can be saved, printed, or exported via USB/ ethernet connection.	First result for potentiometric: 2.5 minutes; colorimetric: 6 minutes; immuno-rate: 8 minutes; microtip: 8-16 minutes; microwell: 16-73 minutes.	First result for potentiometric: ~2.5 minutes; colorimetric: ~6 minutes; immuno-rate: ~9 minutes. Real-time results data stream to LIS available.	Time to first results varies depending on the test, a single test with a short sample preparation may be completed in less than 15 minutes.
25 samples per hour	Continuous load and unload of 150 reagent and 90 sample positions. XT MicroSlides onboard test capacity of up to 16,780 tests and maximum theoretical throughput up to 1,320 tests per hour.	Continuous load and unload of 97 reagent and 80 sample positions. XT MicroSlides onboard test capacity of up to 10,680 tests and maximum theoretical throughput up to 1,130 tests per hour.	Sample capacity up to 1,152 positions. Depending on the running time of the test and configuration the system can run up to 600 samples/day.
The disposable, single-use cassette contains all elements needed for calibration, measurement and waste containment.	Connectable to Vitros Automation Solutions and e-Connectivity interactive system management for remote support.	Connectable to Vitros automation solutions and e-Connectivity interactive system management for remote support.	Sample preparation can be automated connecting the system with JANUS G3 liquid handler (optional). Connectivity with interactive system management for remote service and support.
1 hour	General operator training 8 hours; go live training 12 hours; remote training programs available.	General operator training 5 hours; go live training 12 hours; remote training programs available.	Operator training 5 days; remote training programs available.
The OPTI Medical Service Hotline (U.S. market only) 24/7. Troubleshooting assistance or application information regarding OPTI Medical analyzer just contact the OPTI Medical Service Hotline.	Phone hotline support 24/7/365; onsite technical and service support; remote support and troubleshooting.	Phone hotline support 24/7/365; onsite technical and service support; remote support and troubleshooting.	Specialized on-site and remote technical, service support and troubleshooting. Services are provided by PerkinElmer Applied.
Reduces the risk of pre-analytical errors with Automatic Sample Aspiration, bubble-clot detection, and step wise prompts. Heated Measuring Chamber ensures accurate results even in a cold operating room. It directly measures tHb and sO ₂ by optical reflectance. Measured tHb does not have interference from plasma expanders commonly used during bypass.	Ortho Care #1 ranking by Service Trak for superior service and support. First pass yield of 96.5% ensures right result the first time. Detects and mitigates the impact of sample quality on results. No water or drain required; self-contained onboard waste management eliminates special requirements for off-board plumbing.	Ortho Care #1 ranking by Service Trak for superior service and support. Detects and mitigates impact of sample quality on results. No water or drain required; self-contained onboard waste management eliminates special requirements for off-board plumbing.	Small footprint, open system, highest sensitivity; easy-to-use with ready to implement methods; patented flow-based technology; laminar Flow Ion Guide; dual Source technology for multiplexing; StayClean with Hot Surface Induced Desolvation-HSID-provide robustness of analysis of complex matrices and less maintenance for complex matrices.



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Clinical Chemistry and Integrated Analyzers

1. What is the brand name of your company's clinical chemistry or integrated analyzer?

2. What is the latest version of your named clinical chemistry or integrated analyzer?

3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.

4. What are its dimensions?

5. What is the intended use or primary function of the product?

6. What types of specimen/sample does the product employ?

7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?

8. Under ideal conditions, what is the time to first result; how are the test results made available?

9. What are the product's maximum capacity and throughput under ideal conditions?

10. Briefly describe any automation or connectivity features or options.

11. What is the typical training time for the product?

12. What types of technical support are available?

13. What capabilities, features, or accessories distinguish this product from others on the market?

PerkinElmer

Waltham, MA
800-762-4000 or 203-925-4602
www.perkinelmer.com

Qsight 210 MD Screening System

2017

FDA 510 (k), 2017

20" X 20" X 48"

A semi-automated triple quadrupole detector intended to identify compounds in human samples by ionizing the compounds and separating the resulting ions according to their mass.

DBS

Screening for in-born errors of metabolism

Time to first results varies depending on the test, a single test with a short sample preparation may be completed in less than 15 minutes.

Over 1,000 injections in a single unattended run.

DBS sample preparation can be automated. Automated import of QC targets and IS concentrations by a barcode reader. Connectivity with interactive system management for remote service and support.

Operator training 5 days; remote training programs available.

Specialized on-site and remote technical, service support and troubleshooting services.

Enable throughput and productivity for DBS in-born error screening; delivers a combination of self-cleaning MSMS instrumentation that provides system uptime through a three-step method-setup process; incorporates Modular Simplicity 3Q MD software to acquire, quantify, and report with data viewing options and remote diagnostic.

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QSight 225 MD

2019

CE-IVD, 2019

20" X 20" 48"

Designed for routine high throughput quantitation; offers expanded screening for a variety of inborn errors of metabolism with a wide analyte panel, and access to Tier 2 chromatography.

plasma, serum, urine, whole blood, DBS

In-born errors of metabolism, tier 2 confirmatory testing. Kit-based analysis for vitamin D, Therapeutic drug monitoring, steroid hormones and drug of abuse testing.

Time to first results varies depending on the test, a single test with a short sample preparation may be completed in less than 15 minutes.

With the automated configuration is possible to run up to: 600 specimens/day/4,200 tests/day.

Sample preparation can be automated connecting the system with JANUS G3 liquid handler (optional). Depending on the test, automated import of QC targets and IS concentrations by a barcode reader. Connectivity with interactive system management for remote service and support.

Operator training 5 days; remote training programs available.

Specialized on-site and remote technical, service support and troubleshooting service.

Enables throughput and productivity. Delivers a combination of self-cleaning MSMS instrumentation that provides system uptime, a simple three-step method-setup process and a unique dual source design. Designed with class-leading sample capacity. Optimized UHPLC workflows. Modular Simplicity 3Q MD software to acquire, quantify and report.

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SuperFlex Chemiluminescent Immunoassay System

2022

CE-Mark - 2018; IVDR - Class A - 2022

24.21" x 31.18" x 26.38"

Diagnosis and patient monitoring applications

Human serum, plasma, and whole blood (in primary tubes)

Myo, CKMB, cTnl, NT-proBNP, PCT, CRP, Anti-SARS-CoV-2 IgG, Anti-SARS-CoV-2 Ab

1-12 assays in 5-15 minutes; Bi-directional communication and LIS support

Up to 48-60 samples (primary tubes) can be processed per hour with 5-15-minute assays. Automatic sampling and one-click operation.

Fully automatic chemiluminescence platform assays the contents of specific substance in a certain specimen by collecting the signal with a photomultiplier tube according to the relationship between the signal and concentration of test substance.

3-6 hours maximum. Installation and training can be done in 1 day.

Specialized on-demand services are provided by PerkinElmer Applied Genomics.

Fast: analyze 1-12 assays in 5-15 minutes; hands-free processing of up to 24 samples per run; automatic sampling and one-click operation. Reduces the risk of laboratory acquired infections. Assay cartridges are ready to use. The 12 independent channels facilitate economy of reagents while delivering flexibility.

Radiometer America

Brea, CA
800-736-0600
www.radiometeramerica.com

Randox Laboratories

Kearneysville, WV
304-728-2890
www.randox.com

Roche Diagnostics

Indianapolis
800-428-5076
www.diagnostics.roche.com

Thermo Fisher Scientific

Waltham, MA
781-467-9749
cascadion.info@thermofisher.com
www.thermofisher.com/cascadion

ABL800 Flex series	Randox RX series	Cobas Pro integrated solutions	Thermo Scientific Cascadion SM Clinical Analyzer
Enhanced with AQUIRE connectivity, 2015.	Randox RX imola, 2006.	2020	OUS, 2018; US, 2020
FDA 510(k), CE mark.	CE mark; FDA 510(k); Health Canada Licensed; TGA certificate; CFDA; KSA SFDA; MFDS; ANVISA.	CE mark, 2018; FDA 510(k) 2019.	Cascadion Analyzer: Class I listed with FDA; Cascadion 25-Hydroxy Vitamin D assay: FDA-listed as Class II exempt with special controls; Cascadion Analyzer and Vitamin D Assay: Health Canada Licensed
22" x 28" x 21"	27" x 38" x 23"	56" x 188" x 48"	55.2" H X 88.6" W X 37.8" D
Automated benchtop analyzer intended for <i>in vitro</i> testing in acute care and laboratory settings. Measures pH, blood gas, electrolyte, metabolite, and oximetry parameters.	Clinical chemistry suitable for mid- to high-volume laboratories. Primary functions include diagnosis and monitoring of patient samples.	Fully automated, integrated clinical chemistry and immunoassay platform for diagnostic testing, patient monitoring, therapeutic drug monitoring, and viral load monitoring.	Measurement of small molecule analytes by fully automated liquid chromatography - tandem mass spectrometry (LC-MS/MS).
Whole blood.	Plasma, serum, urine.	Cerebrospinal fluid, plasma, serum, urine, whole blood.	Serum, plasma
Quantifies patient blood acid/base balance, hemoglobin status, and partial pressure of carbon dioxide and oxygen. Analyzes electrolyte balance. Measures metabolite concentrations.	More than 100 unique, high-performing assays. Testing capabilities and analyzer detection profile can be broken down by autoimmune disease, metabolic, bone profile, cardiac, diabetes, and more.	More than 185 clinical chemistry and immunoassay tests, including anemia, cardiac function, diabetes, infectious disease, oncology, sepsis, and toxicology.	25-Hydroxy Vitamin D3, D2 and Total-Available; Immunosuppressive drugs- FDA 510(k) and Health Canada Pending. Not currently for sale in the US or CA).
Time to result between 80 and 135 seconds depending on parameters tested. Results available onscreen, printed, or logged on AQUIRE data manager and transmitted to laboratory information system.	First result in 9 minutes. Results retrievable via various search options, can be downloaded and printed or transmitted to LIMS.	First result in 11 to 12 minutes for basic and comprehensive metabolic panels; 10 to 11 minutes for stat cardiac and critical-care assays; 18 to 27 minutes for routine immunoassays.	First result in approximately 30 minutes; subsequent results approximately every 2 minutes thereafter.
18 to 24 samples per hour to measure up to a full panel of 18 stat parameters along with reporting additional derived parameters.	Performs 400 photometric tests and up to 560 tests per hour including ISE.	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.	Holds 60 uncapped primary sample tubes or sample cups; throughput of up to 25 samples per hour.
FLEXQ module enables automated scanning/mixing of blood samples. AQM system automatically performs pre-scheduled and real-time quality checks, initiates corrective actions without manual intervention, and documents activities for compliance.	On-board reagent inventory management system; integrated barcode reader for samples and reagents with LIMS connectivity, stat capabilities and advanced QC software automatically generating Levy-Jennings charts, calibration curves and more.	Connectable to Roche (Cobas 8100 and CCM) and selected third-party automation systems. Automatic dilutions, reflex testing, onboard troubleshooting.	Bi-directional host-query LIS interface allows for automated order processing and results reporting. Priority sample, and automatic start-up features. Interface in development to the Inpeco FlexLab Total Laboratory Automation.
2 hours (customizable to location's requirements).	Average time for basic user training is 3 days.	Key operator training typically 4.5 days in Indianapolis; training for additional operators conducted at customer site.	3 day key operator training
Dedicated technical support team by phone or email; onsite support with service engineer and clinical application specialists; online customer care portal.	1-year warranty on all new analyzers. Global customer and technical support 24/7 with onsite response time within 24 hours.	24/7/365 telephone support; onsite technical and service support; remote support and troubleshooting; onboard user assistance.	Phone hotline support; dedicated regional onsite service and support; active remote access support enabling predictive support
Reliable results from low volume blood samples (as low as 35 ul with micro-mode); automated quality control; automatically scan and link operator, patient, and sample ID; interference-protected glucose, lactate, and creatinine results; advanced optical system ensures high-quality co-oximetry results.	Cost-effective, random access, small footprint, benchtop clinical chemistry analyzer delivering consistent high-quality results. Capable of performing 560 tests per hour boosting intuitive software, stat capabilities, and extensive testing menu with direct HbA1c testing capabilities.	Automatic calibration for selected chemistries, reduced maintenance, modular concept, stat assays for cardiac and critical care tests.	Fully automated, random access LC-MS/MS system, measuring analytes directly for enhanced accuracy. Designed for quick and easy implementation and walkaway operation, with no specialized LC-MS/MS knowledge needed.