

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; what year was this version first released to market?
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations
4. What are the dimensions of the named product?
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?

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www.AlfaWassermannUS.com

Beckman Coulter
Brea, CA
800-526-3824
www.beckmancoulter.com

Carolina Liquid Chemistries
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ACE Excel clinical chemistry system	AU 480 chemistry analyzer	CLC 6410 instrument family (CLC 800, CLC 1600, CLC 6410).
ACE Excel clinical chemistry system; 2012	2007	CLC 800; 2016
FDA 510(k), 2012	FDA 510(k), 2010; CE mark, 2009	FDA 510(k); CLIA categorization as instrument family
33" x 28" x 26" benchtop analyzer	47" x 57" x 30"	CLC 800, 42" x 31" x 45"; CLC 1600, 50" x 35" x 44"; CLC 6410 (modular; size varies).
Automated benchtop chemistry analyzer using liquid, ready-to-use reagents for diagnostic testing and monitoring in physician offices, clinics, small hospitals, and reference labs.	General diagnosis and management of disease state conditions, including diabetes, substance abuse testing, and therapeutic drug monitoring.	Clinical chemistry analyzer.
Plasma, serum, urine	Cerebrospinal fluid, plasma, serum, urine	Plasma, serum, urine
General chemistry testing for various disease states including anemia, cardiac function, diabetes, electrolytes, kidney function, liver function. Open channels available.	Tests for allergy, bone metabolism, diabetes, immunosuppressant therapy, malnutrition, oncology, specialty proteins, therapeutic drug monitoring, and more.	A variety of analytes, conditions, and diseases.
Time to first results depends on test mix. First CMP available in 12 minutes. Results can be displayed, printed, and transmitted to LIS.	First results in 8 minutes and 38 seconds, 9 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.
285 tests per hour with ISE	Performs 400 photometric tests/hour; up to 800 tests per hour with ion selective electrode.	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).
On-board reagent inventory management, closed tube sampling, dilution and auto-rerun, calibration monitoring, stat interrupt, and on-board sample and reagent refrigeration.	Integrates with REMISOL Advance clinical informatics. Built-in analyzer functions include autorepeat with autodilution, advanced QC, advanced calibration.	Discrete, random access, batch, and stat priority; halogen lamp; independent sample and reagent probes; 340–800 nm wavelength barcode scanning of samples.
On-site training for 3 days	Basic virtual operator training is 4 days.	Customized 4-day training at corporate training facility or in customer lab.
Phone support available 24 hours per day, 365 days per year. Field service available with contract.	Field service and hotline; applications support available globally; various service agreement options.	Hotline available 8:00 am–8:00 pm ET; validation assistance; affordable after-sales service and support contracts.
Reliable technology in self-contained benchtop analyzer. No external water, waste, or cooling unit required. Closed-tube sampling with liquid, ready-to-use reagents. Award-winning service & support. ACE Excel manufactured in United States.	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.	Suited for laboratories that have multiple locations requiring analyzers in a variety of sizes; all instruments in the family use the same reagents.

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Diazyme DZ-Lite c270	EasyRA
DZ-Lite c270; 2018	Medica EasyRA; 2009
FDA 510(k)	FDA 510(k), 2007; CE mark
22" x 32" x 26"	15" x 40" x 26"
Clinical chemistry analyzer for general chemistries and special chemistries.	Clinical chemistry analyzer for general chemistries and toxicology/drugs of abuse screening. A moderately complex fentanyl assay is available for this analyzer.
Plasma, serum, urine, whole blood	Plasma, serum, urine
A variety of analytes, conditions, and diseases.	Provides quantitative results on analytes indicative of hepatic, renal, metabolic, electrolyte, and other physiological disturbances.
12 minutes time to first result.	~8 minutes for basic metabolic panel; ~12 minutes for comprehensive metabolic panel; results available by printout, onscreen, and via a laboratory information system.
Up to 270 tests/hr (assay dependent)	up to 300 photometric tests/hr; 480 tests/hr with ISE.
Discrete, random access, batch, and stat priority; no disposable cuvettes; barcoded sample tubes; bi-directional interface with host query; photometric electrolytes requiring less maintenance. Supports 1, 2, 3 & 4-reagent assays. Auto washing with heated water. Current, daily, & cumulative QC. Westgard algorithms.	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 & individual component monitoring.
Customized 2- to 4-day training at customer lab.	Customized 2- to 4-day training at customer lab.
Hotline available 8:00 am–8:00 pm ET; installation, training, and validation assistance included; after-sales service and support contracts.	Hotline available 8:00 am–8:00 pm ET; validation assistance; after-sales service and support contracts.
Suited for laboratories needing high throughput and a large test menu (including several special chemistries) in a compact, benchtop analyzer.	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.

ANALYZERS for CLINICAL LABORATORIES of ALL SIZES

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Diazyme DZ-Lite™ c270

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CLC800

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(800t/hr w/ISE)



CLC1600

up to 900t/h*
(1200t/hr w/ISE)



CLC6410

up to 1600t/hr* per module
up to 960t/hr on ISE module



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LIQUID CHEMISTRIES CORP.

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* photometric tests per hour

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Envoy 500+ Chemistry System	FreezePoint Freezing Point Osmometer	VAPRO Vapor Pressure Osmometer Model 5600	EUROLabWorkstation
Envoy 500+ launched in 2014 Envoy 500 launched in 2005	released in US and CE marked as a self declare product in June 2020.	The VAPRO Vapor Pressure Osmometer Model 5600; CE marked in 2010 under the IVDD as a self declared product; US release 2010	2015
FDA 510(k) clearance, 2005	Does not require specific release	Does not require specific release	UL certification 61010-1: 2012, CU 72180312; UL 61010-2-101: 2015
27" x 40" x 23"	8.1" x 14.2" x 8.7"	8" x 11" x 14"	115.0" x 31.9" x 33.8"
Diagnosis, patient monitoring	For routine measurements in the medical field and also suitable for measurements in research and industry to determine the total osmolality of aqueous solutions.	Brings simplicity, convenience, and accuracy to the routine determination of osmolality to help meet the demands of today's clinical and research laboratory.	To provide efficient sample loading and fast turnaround times, helping to combat the challenges laboratories are currently facing.
Plasma, serum, urine, whole blood	The FreezePoint will determine the osmolality of any homogenous aqueous sample.	Any biological solution, including whole blood, serum, plasma, urine, and sweat, as well as complex specimens such as tissue samples. Ability to use 10µL (standard), 2µL, 20µL and 60µL sample holders.	Serum, plasma, and cerebrospinal fluid
Certain kidney, liver, heart, and bone diseases, along with diabetes	Non-specific testing to determine the osmolality of a sample.	Non-specific testing to determine the osmolality of a sample.	Detection of antibodies or antigens linked to neurodegenerative disease, kidney markers, inflammatory bowel diseases, bone turnover markers, infectious agents, and others conditions.
Depends upon test mix but 3 minutes minimum. Results available onscreen, transmitted to LIS (optional), and printed.	With this instrument and a sample size as small as 15µl, can receive rapid results in 60 seconds.	Once equilibrated, results within 60 seconds.	Approx 90-120 mins including incubation
52 samples, 490 tests/hr	50 results per hour	30-40 results per hour	Up to 200 assays per hour and more than 800 samples on board.
Onboard real-time quality control, remote diagnostics, onboard data management, onboard auto inventory (volume determination), automatic rerun, autocalibration, auto shutdown, programmable startup	Automatic, two- or three-point calibration to ensure users are always confident of the accuracy of results. Easily controlled via a touch screen display and step-by-step user guidance.	Auto-calibration, self-cleaning thermocouple, self-diagnostics, statistical analysis, and computer interface with printout.	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.
5 days	3-4 hours	3-4 hours	1-2 days for the main operator. Additional workflow training available if needed, which would add another day.
Mon - Fri, 8:00 am-7:00 pm ET	Phone, email, onsite	Phone, email, onsite	On-demand and onsite technical support as needed.
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.	Easily controlled via a touch screen display and step-by-step user guidance. Can receive rapid results in 60 seconds. Built-in printer, PC connectivity, and data saving in stand-by mode. Optional barcode reader input and CSV or XML output.	Superb accuracy with error rate less than 1% in the clinical range. Thermocouple cleans itself, reducing maintenance and improving performance. Easy calibration parameters with the push of a button. Optional printer and USB output.	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.

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SPIFE Nexus	Stat Profile Prime Plus	Vitros XT 7600 Integrated System	Vitros XT 3400 Chemistry System
2022	2018	OUS, 2018; US, 2018	OUS, 2020; US, 2020
TGA ARTG, 2022; FDA 510(k) exempt, 2022	CE mark, 2017; FDA 510(k), 2018; FDA 510(k) for point-of-care use, 2020	FDA 510(k), 2018; CE mark, 2018	FDA 510(k) instrument family, 2019; CE mark, 2019
41" X 31" X 29"	18" x 14" x 16"	68" x 110" x 34.9"	52.6" x 58" x 34.2"
Fully automated quantitative and/or qualitative identification of abnormal proteins, including monoclonal gammopathies in serum and urine using protein electrophoresis and immunofixation. Alkaline and Acid Hemoglobin methods intended for qualitative and semi-quantitative determinations of hemoglobins.	For use by healthcare professionals in clinical laboratory and point-of-care settings. Provides acid base, electrolyte, metabolite, CO-Oximetry, and renal panel results on heparinized arterial and venous whole blood.	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.
Serum, urine, whole blood hemolysates	Arterial, mixed venous, venous, or heparinized whole blood	Cerebrospinal fluid, plasma, serum, urine, whole blood, *amniotic fluid. (*Not commercially available in U.S.)	Cerebrospinal fluid, plasma, serum, urine.
Primarily used to detect monoclonal gammopathies. Can detect malignancy such as multiple myeloma or Waldenstrom's macroglobulinemia. Hemoglobin variants clinically important when lead to sickling disorders, thalassemia syndromes, lifelong cyanosis, hemolytic anemias, or erythrocytosis.	Quantitative determination of more than 22 blood chemistry parameters.	More than 100 immunoassay and clinical chemistry tests on a single platform.	More than 50 clinical chemistry tests on a single platform.
Fully automated gel electrophoresis. Results completed and scanned for densitometric review in 100 minutes without any operator interaction.	Results in about 1 minute, available onscreen and printed.	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.
500 SPE or UPE samples per 8-hour shift, 75 IFE profiles per 8-hour shift, 100 Hb samples per 8-hour shift	Tests 40 to 60 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.
Full LIS and networking capabilities. Helena's QuickScan Touch Plus software with networked SQL database allows remote editing and interpretation, linking to other Helena gel and CE data and integrated reporting with historic results.	Automated, true liquid quality control; continuously monitors status and performance of all analytical components; auto calibration.	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.
2 hours	About 30 minutes for primary operator training on operation, maintenance, troubleshooting, and set-up, performed at installation.	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.
24/7/365 phone support; onsite Monday-Friday 8:00 am-5:00 pm	24/7/365 technical hotline support; onsite comprehensive service. Annual preventive maintenance in years 2-5. All onsite service performed by a Nova field support specialist.	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.
Gel electrophoresis is gold standard methodology with highest sensitivity for detection of abnormal proteins. Fully automated gel electrophoresis system offers hands-free operation, ease of interpretation, excellent resolution, reagent conservation, and rapid turnaround.	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.	Ortho Care #1 ranking by ServiceTrak for superior service and support. 96.5% of tests run are released the first time with no manual interventions. 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.	Ortho Care #1 ranking by ServiceTrak 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.

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cobas pro integrated solutions	cobas pure integrated solutions
2020	2022
FDA 510(k), 2019; CE mark, 2018	FDA 510(k), 2022; CE mark, 2021
56" H x 188" W x 48" D	68.9" H x 96.5" W x 31.5" D
Fully automated, integrated clinical chemistry and immunoassay platform for diagnostic testing, patient monitoring, therapeutic drug monitoring, and viral load monitoring.	Diagnostics: clinical chemistry (CC), immunochemistry (IA), and ion selective electrode (ISE) analyzer
Plasma, serum, urine, whole blood, cerebrospinal fluid	Plasma, serum, urine, whole blood, cerebrospinal fluid
A broad menu of more than 186 tests for clinical chemistry, immunoassay, and ISE - including many unique high medical value assays in areas such as cardiac, infectious disease, oncology, women's health, diabetes, and neurology.	A broad menu of more than 186 tests for clinical chemistry, immunoassay, and ISE - including many unique high medical value assays in areas such as cardiac, infectious disease, oncology, women's health, and neurology.
Immunoassay reaction times in 9 minutes/18 minutes/27 minutes; all clinical chemistry assay reaction times in 10 minutes or less	Immunoassay reaction times in 9 minutes/18 minutes/27 minutes; all clinical chemistry assay reaction times in 10 minutes or less
Holds up to 800 samples at one time; Maximum throughput of 1,800 tests per hour for ISE tests; 2,000 tests per hour for CC; 600 tests per hour for IA.	Throughput of up to 870 tests/hour* *The throughput/hour is theoretical maximum that can be achieved on specific instrument configuration and test mix.
Integrates CC, IA, and ISE testing. To simplify daily operation, provides features that minimize hands-on work (e.g. automated maintenance, long reagent OBS, cobas AutoCal, etc.). Connects to Roche and select third-party automation systems.	Integrates CC, IA and ISE testing. To simplify daily operation, provides features that minimize hands-on work (e.g. automated maintenance, predictive reagent loading, long on-board reagent stability and decreased calibration time with cobas AutoCal).
Key operator training typically 4.5 days in Indianapolis; training for additional operators conducted at customer site. User assistance videos onboard the analyzer.	~5 days plus user assistance videos onboard the analyzer
24/7/365 telephone support; onsite technical and service support; remote support and troubleshooting; onboard user assistance.	24 hours a day, 7 days per week
Integrates CC, IA, and ISE testing, giving access to a menu of >186 assays including 9-min STAT assays. Features minimize hands-on work for operators. Provides standardized results and operation to cobas pure integrated solutions.	Integrates CC, IA, and ISE testing on a footprint of ~21 square feet, giving access to a menu of >186 assays. Features minimize hands-on work for operators. Provides fully standardized results and operation to cobas pro integrated solutions.

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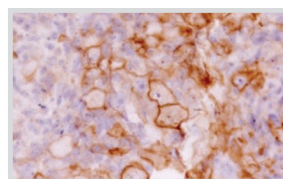
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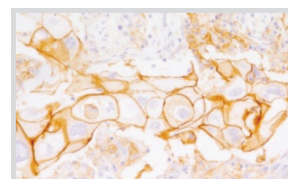
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