

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 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?

Alfa Wassermann Diagnostic Technologies
West Caldwell, NJ
800-220-4488
www.AlfaWassermannUS.com

Beckman Coulter
Brea, CA
800-526-3821
dylee@beckman.com
www.beckmancoulter.com

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ACE Excel clinical chemistry system

ACE Excel clinical chemistry system; 2012

FDA 510(k), 2012

33" x 28" x 26" benchtop analyzer

Diagnostic testing and monitoring in physician offices, clinics, small hospitals, and reference labs.

Plasma, serum, urine

General chemistry testing for various disease states including anemia, cardiac function, diabetes, electrolytes, kidney function, liver function. Open channels available.

Time to first results depends on test mix. First CMP available in 12 minutes. Results can be displayed, printed, and transmitted to LIS.

285 tests per hour with ISE

On-board reagent inventory management, closed tube sampling, dilution and auto-rerun, calibration monitoring, stat interrupt, and on-board sample and reagent refrigeration.

On-site training for 3 days

Phone support available 24 hours per day, 365 days per year. Field service available with contract.

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.

DxC 500i Clinical Analyzer

DxC 500i Clinical Analyzer: US - 2025 OUS - 2024

CE Mark 2023, FDA 510(k) 2025

48.8" H x 100" W x 30.3" D

Chemistry and immunoassay diagnostic testing

Serum, plasma, urine, CSF, whole blood, amniotic fluid, and fecal

Chemistry includes: Anemia, cardiovascular, diabetes, drugs of abuse, general chemistry, proteins, Immunoassay includes: Adrenal/pituitary, anaemia, bone metabolism, cardiovascular, diabetes, infectious disease

Chemistry: Time to first result is 8.5 minutes Immunoassay: The time to first result is 18 minutes. Test results are automatically sent to LIS.

Immunoassay: Up to 100 tests per hour. Clinical chemistry: Up to 400 photometric tests per hour, and 800 tests/hour with ISE.

DxS IntelliServe, auto rerun/reflex, automated maintenance, In evaluation and real time QC, auto order QC, autodetection of various specimen containers, auto sample preparation for whole blood HbA1c testing, auto dilution/condense, auto reagent check

4.5 working days at Beckman Coulter 2-3 days at customer site

24/7 technical support. Troubleshooting hotline, field service engineer availability, and remote connectivity through DxS IntelliServe

The streamlined workflow of the new sample handler with dynamic prioritization allows for prioritizing immunoassay and chemistry testing based on sample urgency, without operator intervention. Easy reagent management includes ready-to-use reagents. FlexMode operations enhance lab flexibility and maintenance independence.

DxC 500 AU Chemistry Analyzer

DxC 500 AU Chemistry Analyzer: US - 2024; OUS - 2024

CE Mark 2022, FDA 510(k) 2023

48" H x 61" W x 31" D

Chemistry diagnostic testing

Serum, plasma, urine, CSF, whole blood, and fecal

Chemistry: Anemia, cardiovascular, diabetes, drugs of abuse, general chemistry, proteins, therapeutic drug monitoring, thyroid, immunosuppressive drugs

Patient testing is equivalent to 8.5 minutes from sample dispense for photometric assays. Test results are automatically sent to LIS.

Up to 400 photometric tests per hour, up to 800 tests/hour with ISE.

DxS IntelliServe, auto rerun/reflex, automated maintenance, In evaluation and real time QC, auto order QC, autodetection of various specimen containers, auto sample preparation for whole blood HbA1c testing, auto dilution/condense, auto reagent check

4 working days at Beckman Coulter 2-3 days at customer site"

24/7 technical support is available. Troubleshooting Hotline, field service engineer availability, and remote connectivity through DxS IntelliServe

The intuitive user interface features user-friendly software that guides workflow and anticipates laboratory needs. Commonly replaced parts can be changed in 3 steps, in 60 seconds, and without tools. Standardization across the AU family. Offers a broad and expanding menu of six sigma quality assays.

Carolina Liquid Chemistries Greensboro, NC 877-722-8910 contactsales@carolinachemistries.com www.carolinachemistries.com	Carolina Liquid Chemistries Greensboro, NC 877-722-8910 contactsales@carolinachemistries.com www.carolinachemistries.com	Diazyme Laboratories, Inc. Poway, CA 858-455-4768 support@Diazyme.com www.diazyme.com	Gold Standard Diagnostics Davis, CA 888-977-GSDX (4739) or (530) 759-8000: gsd.info@us.goldstandarddiagnostics.com www.goldstandarddiagnostics.com
EasyRA	CLC 6410 instrument family (CLC 800, CLC 1600, CLC 6410).	Diazyme DZ-Lite c270	AIX1000 Fully automated RPR Syphilis testing
Medica EasyRA; 2009	CLC 800; 2016.	DZ-Lite c270, launched 2018.	1st Release March 2016 and 2.0 Hardware Sliding Rack April 2022
FDA 510(k), 2007; CE mark.	FDA 510(k); CLIA categorization as instrument family.	FDA 510(k), 2018, CE Marked	AIX1000 FDA/CE Mark March 2016
15" x 40" x 26"	CLC 800, 42" x 31" x 45"; CLC 1600, 50" x 35" x 44"; CLC 6410, modular; size varies.	22" x 32" x 26"	W: 25.2", D: 22.4", H: 17.7", H (open): 36".
For general chemistries and toxicology/drugs of abuse screening. A moderately complex fentanyl assay is available for this analyzer.	Clinical chemistry analyzer.	For general chemistries and special chemistries; ready-to-use reagents for diagnostic testing and monitoring	For nontreponemal RPR Syphilis testing.
Plasma, serum, urine.	Plasma, serum, urine.	Plasma, serum, urine, CSF, whole blood, dialysate	Whole blood
Provides quantitative results on analytes indicative of hepatic, renal, metabolic, electrolyte, and other physiological disturbances.	A variety of analytes, conditions, and diseases.	A variety of analytes, conditions, and diseases including cardiac function, cancer, diabetes, liver and kidney function, vitamin and electrolytes.	Automated RPR syphilis testing agglutination based
~8 minutes for basic metabolic panel; ~12 minutes for comprehensive metabolic panel; results available by printout, onscreen, and via a laboratory information system.	Estimated time to first result is 10 minutes; each subsequent test result follows at 15-second intervals.	12 minutes time to first result; results are displayed, or can be printed and transmitted to LIS.	20 minutes to first result, screen 192 samples in 90 minutes
Up to 300 photometric tests/hr; 480 tests/hr with ISE.	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).	Up to 270 tests/hr (assay dependent)	192 samples every 90 minutes (4 x 48 well plates)
Imports and exports data via LIS system; sample barcode reader; automatic tracking and entry of reagent information; automated sample sensing and pipetting.	Discrete, random access, batch, and stat priority; halogen lamp; independent sample and reagent probes; 340–800 nm wavelength barcode scanning of samples.	Discrete, random access, batch, and stat priority; on-board reagent refrigeration; barcoded sample tubes, Bi-directional interface with host query, photometric electrolytes requiring less maintenance. Auto washing with heated water.	Fully automated solution for RPR screens and titers, sample to result automated reactive/non-reactive determination using pattern recognition software, archival of results, robust software, moderately complex system and cleared as a closed system
Customized 2-4-day training at customer lab.	Customized 4-day training at corporate training facility or in customer lab.	Customized 2-4-day training at customer lab.	Approx. 5 days in house with field applications team
Hotline available 8:00 am–8:00 pm ET; validation assistance; affordable after-sales service and support contracts.	Hotline available 8:00 am–8:00 pm ET; validation assistance; affordable after-sales service and support contracts.	Service line available from 8am–5pm PST; installation, training, and validation assistance included; affordable after-sales service and support contracts.	Full field applications, technical services, field service engineers for on-site support
Direct ISE. Small footprint. RFID-tagged reagents allow reading and writing capability. All reagent parameters programmed on the wedge, no data entry. Easy-to-replace components. Carryover avoidance programmed on RFID chip. self-contained analyzer, requiring no external water source or waste drainage.	Suited for laboratories that have multiple locations requiring analyzers in a variety of sizes; all instruments in the family use the same reagents.	Suited for laboratories needing high throughput and a large test menu (including several special chemistries) in a compact, bench-top analyzer. No external water, waste, or cooling unit required.	Fully automated solution for RPR screens and titers, high capacity, reduced labor cost vs. manual, full sample traceability, proprietary image recognition algorithm gives objective results.

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Clinical Chemistry and Integrated Analyzers

Jant Pharmacal Corp
Encino, CA
818-986-8530
info@jantdx.com
https://www.jantdx.com/

Mindray
Shenzen, China
416-826-1663
A.Chen@mindray.com
www.mindray.com/na/products/
laboratory-diagnostics/

Nova Biomedical
Waltham, MA
781-894-0800
www.novabiomedical.com

1. What is the brand name of your company's clinical chemistry or integrated analyzer?	RAMP 200 Response Bio Cardiac Diagnostic System	BS480	Stat Profile Prime Plus
2. What is the latest version of your named clinical chemistry or integrated analyzer?	RAMP 200	2014	2018
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations	FDA (510k), CE	CE 2010, FDA 510(k) 2014	CE mark, 2017; FDA 510(k), 2018; FDA 510(k) for point-of-care use, 2020
4. What are the dimensions of the named product?	105mm x 195mm x 177mm - Control Module (CM); 96mm x 195mm x 185mm - Test Module. (TM)	46" x 28" x 45" (W x D x H)	18" x 14" x 16"
5. What is the intended use or primary function of the product?	Used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.	General chemistries and drugs of abuse, standalone instrument	For 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.
6. What types of specimen/sample does the product employ?	Whole blood - EDTA	Plasma, serum, urine, whole blood (HA1C)	Arterial, mixed venous, venous, or heparinized whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Heart failure, acute MI,	Liver, hepatic and renal diseases. Open system for esoteric tests	Quantitative determination of more than 22 blood chemistry parameters.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	An average of 15 minutes	Depends on test mix, e.g. CMP 14 minutes, In 8 hours 232 CMP's, external printout, displayed on screen, sent to LIS	Results in about 1 minute, available onscreen and printed.
9. What are the product's maximum capacity and throughput under ideal conditions?	6 tests with 3 test modules (TMs)	400 tests/hr 560tests/hr with ISE	Tests 40 to 60 samples per hour.
10. Briefly describe any automation or connectivity features or options	No calibration needed. Every cartridge has its reference values recorded on the lot card. Internal quality control runs automatically every time the instrument is powered on. It can also be initiated manually.	Autocalibration, auto QC, auto bubble, clot and crash detection, auto recovery, operators manual built in to software, touch screen, onboard reagent inventory, reagent refrigeration, dilution, auto rerun, HIL indecies, stat interrupt.	Automated, true liquid quality control; continuously monitors status and performance of all analytical components; auto calibration.
11. What is the typical training time for the product?	Specific to customer's needs	Application training 2-3 days, depends on class size	About 30 minutes for primary operator training on operation, maintenance, troubleshooting, and set-up, performed at installation.
12. What types of technical support are available?	24/7 customer support	Technical hotline, service, and application	24/7/365 technical hotline support; onsite comprehensive service. Annual preventive maintenance in years 2-5.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Compact, modular system with up to 6 independent ports. No calibration or maintenance required. Throughput of 18-36 tests/hour with 3TMs. Rapid test results for Troponin I, CK-MB, Myoglobin and NT-proBNP. Unique POC test for NT-proBNP with diagnostic accuracy comparable to Roche.	Open System, MTBF 2500 hours, reliable, efficient, cost effective, fully automated, discrete, random access, dry heat incubation, temperature stable.	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.

QuidelOrtho
San Diego, CA
800-828-6316
www.quidelortho.com

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

Siemens Healthineers
Tarrytown, NY
800-888-7436
<https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems/atellica-solution-analyzers>

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Tarrytown, NY
800-888-7436
<https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems>

Vitros XT 3400 Chemistry System	RX imola	Atellica Solution (Atellica CH 930 Analyzer)	Atellica CI Analyzer (Integrated Chemistry and Immunoassay Analyzer)
OUS, 2020; US, 2020	2006	US, OUS, 2017	US 2023, OUS, 2022
FDA 510(k) instrument family, 2019; CE mark, 2019	CE mark; FDA 510(k); Health Canada Licensed; TGA Certificate; CFDA; KSA SFDA; MFDS; ANVISA.	Atellica CH 930 CE marked date: 9/14/2017, 510k clearance date: 2/11/2015	FDA 510(k) 2023; CE Mark 2022
52.6" x 58" x 34.2"	27" x 38" x 23"	53.7" (h) x 58.7" (w) x 45.5" (d)	63.0" (H) 80.1" (W) x 36.8" (D)
Fully automated clinical chemistry test system that utilizes XT MicroSlides. For diagnostic testing, patient monitoring, and therapeutic drug monitoring.	Clinical chemistry testing suitable for mid-to-high-volume laboratories. Primary functions include diagnosis and monitoring of patient samples.	In-vitro diagnostics	In-vitro diagnostics
Cerebrospinal fluid, plasma, serum, urine.	Serum, plasma, urine & whole blood	Serum, plasma, CSF, urine, whole blood (assay specific)	Serum, plasma, CSF, urine, whole blood (assay specific)
More than 50 clinical chemistry tests on a single platform.	More than 100 unique, high-performing assays. Capabilities and detection profile can be broken down by autoimmune disease, metabolic, bone profile, cardiac, diabetes, and more.	Diabetes, drugs of abuse/toxicology, general chemistry, specific proteins, therapeutic drug monitoring	Diabetes, drugs of abuse / Toxicology, general chemistry, specific proteins, therapeutic drug monitoring
First result for potentiometric: ~2.5 minutes; colorimetric: ~6 minutes; immuno-rate: ~9 minutes. Real-time results data stream to LIS available.	First result in 9 minutes. Results retrievable via various search options, can be downloaded and printed or transmitted to LIMS.	TTFR from 18 sec to 10 min. Results available through user interface as each test completes. Additionally, STATS are aspirated in 6-60 seconds.	TTFR from 18 sec to 10 min. Results available through User Interface as each test completes. Additionally, STATS are aspirated in 6-60 seconds.
XT MicroSlides onboard test capacity of up to 10,680 tests and maximum theoretical throughput up to 1,130 tests per hour.	Performs 400 photometric tests and up to 560 tests per hour including ISE.	Up to 1800 tests/hour: 1200 tests/hour photometric + 600 tests/hour IMT	Up to 1000 tests/hour: 600 tests/hour photometric + 400 tests/hour IMT
Connectable to Vitros Automation Solutions and e-Connectivity interactive system management for remote support.	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.	Automated maintenance, quality control, calibrations, stored onboard. Auto sorting, decapping, sealing, archiving, connecting to TLA. Lab evaluation analytics for traceability & inspection readiness, guided workflows, custom navigation and alerting.	Auto detection of sample integrity (HIL), auto repeat testing, liquid level sensing, lab evaluation analytics for traceability & inspection readiness, guided workflows, custom navigation and alerting.
General operator training 5 hours; go live training 12 hours; remote training programs available.	Average time for basic user training is 3 days.	Key Operator-3.5 days; General Opr-3 days; Advanced Opr Training-3 days; Essentials virtual training-0.5 day; Lab Mgr virtual training-2 hrs; PEPConnect on-demand.	Lab Mgr virtual training (2 hrs); Key Opr-3 days and/or General Opr-3 days; Advanced Operator Training-3 days; PEPConnect online on-demand and self-guided education.
Phone hotline support 24/7/365; onsite technical and service support; remote support and troubleshooting.	1-year warranty on all new analyzers. Global customer and technical support 24/7 with onsite response time within 24 hours.	Various support and service models available. Remote user assistance, Optional Guardian Program can help predict impending failures in real time.	Various support and service models available. Remote user assistance via the Service button on analyzer.
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.	Cost-effective, random access, small footprint, benchtop clinical chemistry analyzer delivering consistent high-quality results. Capable of performing 560 tests per hour boasting intuitive software, stat capabilities and extensive testing menu with direct HbA1c testing capabilities.	Bi-directional sample transport 10x faster than conventional conveyors; auto deploy Cal & QC processing mat'l stored onboard; high testing productivity per square meter; broad and expanding menu; built-in sorting, archiving, decapping, sealing; dynamic User Interface with patent-pending Lab Evaluation integrated analytics for assay verification.	Optional configuration with Atellica Sample Handler featuring built-in decapper & sealer, allowing bi-directional sample transport 10x faster; auto deploy Cal & QC processing material stored onboard; high testing productivity per square meter; built-in sorting, archiving, decapping, sealing; dynamic user interface with patent-pending Lab Evaluation software.