tech guide

Immunoassay Analyzers

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1. What is the brand name of your company's immunoassay analyzer?	AF-100C Single-Channel Benchtop FIA Analyzer	ASI Evolution Automated (RPR) Syphilis Analyzer	DxI 9000 Access Immunoassay Analyzer
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2023	2020	2023 for USA, 2022 for OUS
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE 2023; IVDR 2023	FDA CBER 510(k), 2020; FDA CDRH 510(k), 2020; FDA Interpretation Algorithm 510(k) 2020; FDA HCT/P 510(k) 2021	FDA 510(k), 2022; CE mark, 2022
4. What are the dimensions of the named product?	3.31" x 4.57"x 9.84"	19" x 36" x 22"	63" x 41" x 79"
5. What is the intended use or primary function of the product?	Handheld point-of-care AF-100C is a single-channel, portable, and rechargeable compact FIA analyzer.	Fully automated RPR syphilis (nontreponemal) analyzer for diagnostic, blood donor screening, and cadaveric (non-heart beating) tissue screening.	Automated in vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.
6. What types of specimen/sample does the product employ?	Serum, plasma,whole blood, urine	Plasma, serum.	Serum, plasma, urine, amniotic fluid, whole blood (assay dependent, partial list)
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	70+ assays enable the detection of various analytes, including hormones, cancer markers, cardiac markers, drugs of abuse, inflammation, and infectious diseases.	*Bacterium Treponema Pallidum* (Syphilis)	Adrenal/pituitary, anemia, bone metabolism, cardiac, diabetes, sepsis, reproductive, inflammatory, tumor markers, thyroid, and infectious disease
8. Under ideal conditions, what is the time to first result; how are the test results made available?	In 3-15 minutes, available to view on 7" IPS capacitive touch screen.	12 minutes; available to view results and images of wells.	Varies by assay, as low as 8 minutes. Access high sensitivity Troponin I is less than 12 minutes."
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Single channel handheld FIA analyzer	Holds 192 samples in rack; processes 190 samples per hour.	450 tests/hr max (one-step assays). 140 sample tubes, unique continuous loading feature. Primary tube released after aliquot is made (approx 1 minute)
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Real-time auto-printing on internal thermal printer; automatically reading of batch number and calibration information in the RFID card.	Automates the processing, analysis, reporting, and archiving of results for RPR screens and titers. Ability to work with LIMs	Automation connection capable. SimpleSolve onboard guide empowers the user to resolve instrument issues quickly through instrument-guided troubleshooting steps, minimizing downtime. Calibration curve stability up to 64 days (assay dependent).
11. What is the typical training time for the product?	In hours; easy-to-use	1-2 days	3 days in-person for key operators in California
12. What types of technical support are available?	Global technical support team support with top-tier service plan.	24-hour phone support, service plans (for onsight service) and remote access.	The DxI 9000 offers remote service through DxS IntelliServe utilizing advanced analytical tools for predictive and preventive analytics. Call center 24/7, with supportive onsite service.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Single-channel, compact, portable, and rechargeable system, allowing users to operate it in various settings, especially in areas where laboratories aren't available. Its high sensitivity and specificity ensure accurate results with a wide range of assays. The fully charged system supports continuous test 1,920 tests without power supply.	Performs 190 RPR syphilis tests per hour; can provide titers up to 1:2,048; can be used for diagnostic, blood donor, cadaveric screening. Available automated smart rack for pre-loading racks, pos ID, auto populates samples into analyzer."	We deliver meaningful process and product innovation to optimize your workflow featuring ZeroDaily maintenance on an analyzer that has up to 4 hours of walkaway time, offering a second line of defense in process monitoring with PrecisionVision technology, and substrate technology providing measurement capability at lower concentration levels.

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Optilite	LIAISON XS	LIAISON XL	Agility Automated ELISA System
2015	LIAISON XS, Released in 2019	LIAISON XL, Released in 2010	2013
FDA 510(k), 2015	CE Mark, 2019; FDA 510(k), 2022	CE Mark, 2010; FDA 510(k), 2011	FDA registered; CE mark; Health Canada license
24.4″ x 37″ x 27.6″	28" x 50" x 29.5"	59" x 59" x 35.5"	49" x 50" x 36"
Dedicated special protein analyzer to run tests to diagnose, monitor and manage patients with plasma cell disorders and immune status deficiencies.	Automated small to medium-volume chemiluminescence immunoassay benchtop model analyzer for in vitro diagnostic analysis. Performs complete sample processing, measurement, and evaluation.	Automated high-volume chemiluminescence immunoassay floor model analyzer for in vitro diagnostic analysis. Performs complete sample processing, measurement, and evaluation.	Open, fully automated 12-plate system that processes a high-volume of ELISA assays
Serum, urine, and CSF.	Plasma, serum, urine, stool (assay dependent)	Plasma, serum, urine, stool (assay dependent)	Serum and plasma; some urine and stool supernatant with testing and validation
Blood cancers, multiple myeloma, B cell dyscrasias and central nervous & immune systems disorders.	Broad specialty testing menu of >28 assays spanning infectious disease, infection management, gastrointestinal, hepatitis and & HIV, bone & mineral metabolism, and endocrinology.	Broad specialty testing menu of >60 assays spanning infectious disease, infection management, gastrointestinal, hepatitis and & HIV, bone & mineral metabolism, and endocrinology.	Runs ELISA assays with walk-away processing
Based on the test menu mix, typically, 15 minutes to first test result and 1 minute for each subsequent test result thereafter.	17 minutes (assay dependent). Results available on user software with filter and validation customization prior to printing or transmission via LIS.	16 minutes (assay dependent). Results available on user software with filter and validation customization prior to printing or transmission via LIS.	Time to first result dependent on assay protocol; results sent directly to LIS and can be printed or saved as PDF or CSV file
Average 105-120 special protein tests per hour.	Capacity for 48 samples loaded simultaneously. Continuous sample loading supports up to 85 tests per hour (assay dependent).	Capacity for 120 samples loaded simultaneously. Continuous sample loading supports up to 171 tests per hour (assay dependent).	200 sample capacity; continuous sample loading
Optilite re-dilutes all assays to end result which means even the highly elevated myeloma samples are resulted without manual intervention. Optilite is bi-directionally interfaced with LIS.	Compatible with most LIS, QC software with L-J charts, RFID technology for complete reagent traceability, real-time monitoring of all system functions, remote support software available.	Easily pairs with the majority of laboratory automation tracks, compatible with most LIS, QC software with L-J charts, RFID technology for complete reagent traceability, real-time monitoring of all system functions, remote support software available.	High-throughput, fully automated system with walk-away processing; 2D barcode scanning with barcode reading plate gripper; standalone middleware called LIS-LINK for LIS connectivity, liquid level sensing; clot detection. Runs multiple complex assays simultaneously.
1 week user training conducted during CAP accreditation-ready, hands-on validation.	3-5 days at customer site.	3-5 days at customer site, optional advanced operator training at HQ.	4 days of onsite training at DYNEX office
Binding Site's global technical support team including field applications & engineers and in-house specialists.	24/7 phone-based U.S. technical support with optional remote support (Beyond Trust).	24/7 phone-based U.S. technical support with optional remote support (Beyond Trust).	U.S. technical support includes onsite installation, training and support by field service engineers and field application specialists; phone support available 8 am-5 pm EST; remote support services available via screen-sharing for trouble-shooting assistance
Designed to bring simplicity to complex processes in the lab 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.	Compact benchtop system; all-in-one computer and touchscreen monitor, eliminating the need for keyboard and mouse. Simplified specialty testing consolidation that leverages automation to drastically reduce staff hand-on time versus traditional methods. No daily maintenance required and most assays are ready-to-use with liquid onboard calibrators.	Simplified specialty testing consolidation that leverages automation to drastically reduce staff hand-on time versus traditional methods. Most assays are ready-to-use with liquid onboard calibrators. No daily maintenance and continuous loading of samples, reagents, and consumables. Workflow and support teams to consult on operational efficiency.	12-plate fully automated system with capacity for 16 DYNEX SmartKits (for reagents) that eliminate nearly all manual liquid transfers; three robotic arms for continuous loading of up to 200 samples.

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UNIQO 160	SPIFE	Randox Evidence Series	cobas pro e 801 Immunoassay Module
US/OUS 2023	Nexus; 2023	2002	OUS - 2019 US - 2020
CE Marked, 2023 FDA 510(k) exempt, Class I device for in-vitro diagnostics	FDA 510(k)	CE mark; FDA 510(k); Health Canada license; TGA certificate; KSA SFDA; MFDS; ANVISA.	FDA 2019
47.24" x 35.43" x 27.56"	41" x 31" x 29"	69" x 79" x 39.3"	53" x 113" x 46"
The UNIQO 160 automates sample preparation, processing, and microscopy for immunofluorescence testing.	Identify immunoglobulins and determine clonality augmenting serum protein electrophoresis affording diagnosis and management of patients.	Fully automated biochip array system detects multiple analytes from a single sample.	Diagnosis, patient monitoring, therapeutic drug monitoring, drugs of abuse testing
Serum, plasma	Serum, urine, CSF	Multiple matrices, including blood, hair, meconium, oral fluid, postmortem blood, tissue, urine, vitreous humor, whole blood	Plasma, serum, urine, CSF, whole blood, stool
Automimmune and infectious diseases	Myeloproliferative blood disorders such as multiple myeloma and amyloidosis as well as central nervous system disorders.	Adhesion molecules, cardiac markers, cerebral, cytokines, drugs of abuse, endocrine, metabolic, thyroid markers, and tumor markers	Cardiac, thyroid, fertility, bone, tumor markers, infectious diseases, anemia, hepatitis, sepsis, growth, specific proteins, rheumatoid arthritis, ISD
Varies per assay with average time of 18 mins.	Batched on gels 3, 6, 9, or 15 each run. Read manually immediately after development or scanned after in less than one minute and viewed/managed in QST+.	From 55 minutes (array specific)	All Immunoassays are 9, 18 or 27 minutes. Additional ~1 min for pipetting. STAT requests can be transmitted as completed, typically results are transmitted once all are complete.
160 samples	Up to 15 samples every 75 minutes.	Up to 90 patient samples per hour; two sample rings can each hold 90 sample tubes or cups, reporting more than 2,070 results per hour	Up to 300 patient results/hr.
The UNIQO 160 automates immunofluoresence testing, including sample preparation, processing, slide mounting, coverslipping, microscopy, and image acquisition. It includes middleware that enables secure communications with the laboratory LIS.	Full automation from primary tube. QuickScan Touch Plus is bidirectionally connected to LIS and incorporates a unique modular structure for long term disease management.	Automated system; onboard storage capacity of 500,000 test results; onboard autodetection of specimens; information technology compatability; quality control package; refrigerated reagent storage	Up to 4 modules can be configured on one core, and can be integrated with chemistry & ISE modules. Cobas pro can be connected to automation tracks.
3-5 days	2 days	3 days	4.5 days in Indianapolis, additional time on site
All-inclusive 1-year factory warranty, extended warranty options, onsite training, and on-demand technical support	24 hour phone support, field technical support	Engineering and technical support specialists deliver onsite installation, training, validation, and 24/7 customer support	24 hour phone support, large field support team
The UNIQO 160 offers fully walk-away automation that performs the steps of IFA testing within a single instrument. It offers a truly hands-free experience that is ideal for labs that need to simplify workflows for significant improvements in efficiency. It can hold 160 samples while processing up to 18 different workflows in a single run.	While semi-automated solutions are available from Helena, SPIFE Nexus is the only fully automated system on the market, and it is coupled to an enabling technology for interpretation, data storage, and disease management.	Multiplex sample profiling enables users to consider the complete profile,thus facilitating well-informed and accurate conclusions.	ECL technology offers low-end sensitivity, broad measuring range, fast assay times. Hitachi quality and reliability. Reduced calibrations and extended on-board stabilities.

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cobas pure e 402 Immunoassay module	Atellica Solution (Atellica IM 1300, Atellica IM 1600)	MAGLUMI	GEMINI Compact Microplate ELISA Processor
OUS - 2021 US - 2022	US, OUS, 2017	MAGLUMI 2000, 2009	Released 2009 (US,OUS)
FDA 2022	FDA 510(k) 2023; CE Mark 2022	CE mark, 2009; FDA 510(k),2017	CE IVD (IVDR Complient), FDA 510(k) exempt
69" x 58" x 48"	59.1" x 57.2" x 45.9"	34.25" x 53.15" x25.20"	29.5" x 49.2" x 35.4"
Diagnosis, patient monitoring, therapeutic drug monitoring, drugs of abuse testing	In-vitro diagnostics	In vitro diagnostics	Flexible, open, and full automated ELISA Processing
Plasma, serum, urine, CSF, whole blood, stool	Amniotic fluid, cerebrospinal fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine, whole blood	Plasma, serum, whole blood, stool, liquor.
Cardiac, thyroid, fertility, bone, tumor markers, infectious diseases, anemia, hepatitis, sepsis, growth, specific proteins, rheumatoid arthritis, ISD	Anemia, autoimmune, bone metabolism, cardiovascular, coagulation disorders, diabetes, drugs of abuse/toxicology, hepatitis, immunosuppressant drugs, infectious disease, inflammation, kidney disease, liver fibrosis, metabolic, oncology, reproductive endocrinology, sepsis, therapeutic drug monitoring, thyroid.	Performs more than 236 assays for diagnosis of anemia, autoimmune, bone metabolism, cancer, cardiac disease, drug monitoring, Epstein-Barr virus, fertility, glycometabolism, hepatic fibrosis, immunoglobulin, infectious disease, inflammation monitoring, kidney function, prenatal. screening, thyroid disease, etc.	Infectious disease, autoimmune disease, allergy testing
All Immunoassays are 9, 18, or 27 minutes. Additional ~1 min for pipetting. STAT requests can be transmitted as completed, typically results are transmitted once all are complete	10 to 54 minutes (assay dependent); greater than 50% of the immunoassay menu has a TTFR of 14-mins or less. Additionally, STATS are aspirated in 6-60 seconds.	17 minutes	Depending on test design
Up to 120 patient results/hr.	Processes up to 440 tests per hour (dependent upon test mix).	Up to 144 samples with no-pause continuous loading/unloading function; throughput: up to 180 tests per hour	Initial Loading of Samples: 144 + Continuous Loading on 2-3 ELISA Plates per Run.
Can be configured with a chemistry module to for an integrated solution.	Most maintenance activities are automated, bubble detection, clot detection, level sensing, dilutions, and reflex/retesting, environmental controls. Automated quality control, materials stored onboard. Option for built-in auto sample sorting, decapping, sealing, archiving.	Inpeco Automation Track Connectable; barcode reader recognition or analyzer automatic numbered; liquid level detection, clot detection; auto remeasuring function; sample editing mode; LIS connection, automatic read sample information.	Fully automated system with complete process control. LIS connectivity. Patient and QA reports. Capacitive liquid level detection with optional barometric process control for total pipetting safety.
4.5 days in Indianapolis, additional time on site	Options available include: 1 day Virtual Training; up to 3 days General Operator Training; up to 4 days Key Operator Training, up to 3 days Advanced Training, PEPConnect on-demand online courses.	less than 1 hour	1-2 Days
24 hour phone support, large field support team	Various support and service models available. Remote user assistance via the Service button. Optional Guardian Program can help predict impending failures with help predict impending failures with proactive, real-time, remote monitoring.	24/7/365 service hotline; after sales technical support specialist assistance with method validation; machine maintenance.	Various options available
ECL technology offers low-end sensitivity, broad measuring range, fast assay times. Hitachi quality and reliability. Reduced calibrations and extended on-board stabilities.	Bi-directional sample transport 10x faster than conventional conveyors; auto calibration and QC processing material stored onboard with auto deployment; high testing productivity per square meter; broad and expanding menu; built-in sorting, archiving, decapping, sealing; dynamic user interface featuring patent-pending Lab Evaluation integrated analytics for assay verification.	FDA 510(K) cleared; Inpeco Automation Track Connectable; no-pause sample and reagent continuous loading/unloading function; RFID tags store all reagent information; target for small and mid-size labs; the sampling needle is coated with Teflon to eliminate cross-contamination and ensure the specificity and accuracy of the result	Lot data management via barcode scanning, processing of multi-preparation test designs, archiving of samples and plates, disposable pipetting tips to eliminate cross contamination risks.