tech guide

Immunoassay Analyzers

	Arlington Scientific Springville, Utah (801) 489-8911 www.arlingtonscientific.com	Awareness Technology Palm City, Fla (772) 283-6540 www.awaretech.com	Bio-Rad Laboratories Hercules, Calif (800) 224-6723 www.bio-rad.com
1. What is the brand name of your company's immunoassay kit or analyzer?	ASI Evolution RPR syphilis analyzer	ChemWell 2910 ELISA/biochemistry	BioPlex 2200 system
2. What is the latest version of your named immunoassay kit or analyzer; what year was this version first released to market (US, OUS)?	2018	ChemWell 2910.	2006
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA CBER 510(k), 2017; FDA CDRH 510(k), 2018.	CE mark, 2009; FDA 510(k), 2019.	FDA 510(k), 2015.
4. What are the dimensions of the named product (H x W x D)?	19 inches x 36 inches x 22 inches	16 inches x 34 inches x 20 inches.	53 inches x 72 inches x 34 inches
5. What is the intended use or primary function of the product?	Automated RPR syphilis analyzer for testing and blood donor screening.	Laboratory in vitro diagnostic use.	Diagnosis.
6. What types of specimen/sample does the product employ?	Plasma, serum.	Plasma, serum, stool, urine, whole blood.	Plasma, serum
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Automated RPR test for syphilis.	An open-system analyzer capable of running virtually any assay, and providing diagnoses for the pertinent diseases.	51 total analytes, including autoimmune, infectious disease, and vitamin D testing.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	12 minutes; available to view results and images of wells.	In ELISA mode, timing is assay dependent. In biochemistry mode, maximum of 200 endpoint reactions per hour.	45 minutes (assay dependent).
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Holds 192 samples in rack; processes 190 samples per hour.	Holds 96 samples; typically holds 27 reagents, with option up to 44 reagents; can perform 170 kinetic reactions per hour.	Processes approximately 800 samples per day; up to 2,200 results per hour (up to 22 tests).
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Automates the processing, analysis, reporting, and archiving of results for RPR screens and titers.	Automation for endpoint and kinetic assays. Quality control software prevents timing conflicts. Optional barcode scanning.	Detects clots, liquid level, and short sample; detects hemolysis and icterus; dilutes patient samples onboard; sample volume can be diluted to rerun out-of-linear range high results; performs autocalibration and supports multipoint calibration; autoprogrammable start; onboard real-time quality control; onboard software capability to review QC.
11. What is the typical training time for the product?	Half a day.	1 to 2 days for complete operation and applications.	5 days at vendor site.
12. What types of technical support are available?	24-hour phone support available with top-tier service plan.	Phone support with a trained technician; online support.	Diagnosis of system malfunctions via remote monitoring; modem servicing provided; response time for onsite service engineer is less than 24 hours.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Performs 190 RPR syphilis tests per hour; can provide titers up to 1:2048.	An open, mixed-modality system that can perform both ELISA and biochemistry assays; partly closed options when used with FDA 510(k)-certified Quest reagents.	Full random-access automation with innovative multiplex chemistry; compatible track line connectivity; internal quality control beads run simultaneously with each patient specimen; simultaneously detects multiple analytes in a single tube; small sample volume (5 µL).

Diazyme Laboratories Poway, Calif (858) 455-4768 www.diazyme.com	Dynex Technologies Chantilly, Va (703) 631-7800 www.dynex.com
DZ-Lite 3000 Plus chemiluminescence analyzer	Agility
2017	Agility, 2013.
FDA 510(k), 2017.	CE mark, 2013.
59.8 inches x 56.7 inches x 30 inches	49 inches x 50 inches x 36 inches.
Diagnosis and treatment.	Laboratory in vitro diagnostic use.
Plasma, serum.	Assay dependent; plasma, serum, stool, urine, whole blood.
Bone metabolism, cardiovascular diseases, hormones, infectious diseases, inflammation.	An open-system analyzer for performing diagnostic assays for autoimmune diseases, blood pathogens, gastrointestinal diseases, infectious diseases (eg, covid-19), oncology, respiratory diseases, sexually transmitted diseases, toxicology, and many more disease states.
17 minutes (assay dependent).	Time to first result is assay dependent; processing a 96-well plate typically requires 2 hours. Test results are made available immediately upon plate read and data processing.
Holds 144 samples at a time, with continuous loading.	Assay dependent; typical onboard capacity is 200 samples, with continuous load capability; typical throughput is 10 96-well plates in 8 hours.
Flash chemiluminescence label (ABEI); random access; stat available; refrigerated sample area with independent power supply; clot and liquid level detection; autodilution available; bidirectional interface with laboratory information system (LIS).	Flexible, fully automated system that maximizes walkaway processing by eliminating front-end setup, with up to 16 SmartKit carriers.
2 days.	1 week onsite at customer location.
Phone, email, onsite support.	Technical support available by email or telephone. Various levels available, including onsite support.
Uses magnetic microbeads as a separation technology; enhanced sensitivity and shortened reaction time by enlarging the reaction area for antigens and antibodies (assay dependent); thoroughly mixes reagents in a liquid separation platform to significantly reduce interassay and intraassay discrepancies.	Full walkaway processing from the beginning of testing; ease-of-use automation assesses testing requirements and develops an efficient work list; continuous sample loading allows operators to reduce hands-on time by two-thirds over typical open systems.

Fujirebio US	Medtox Diagnostics	Meridian Bioscience	Ortho Clinical Diagnostics
Malvern, Pa (844) 544-3787 www.fujirebio.com	Burlington, NC (800) 334-1116 www.medtoxdiagnostics.com	Cincinnati, Ohio (513) 271-3700 www.meridianbioscience.com	Raritan, NJ (800) 828-6316
Lumipulse G1200	MedtoxScan reader test system	Curian	Vitros 3600 immunodiagnostic system
US, 2016; OUS, 2008.	Rev H2; 3.0.1	US, OUS, 2020.	2008
FDA 510(k), 2016; TUV CE mark, 2011.	FDA 510(k), 2009.	FDA 510(k), CE mark.	FDA 510(k), 2008.
57 inches x 47 inches x 31.5 inches	4 inches x 7 inches x 9 inches	4.9 inches x 4.5 inches x 4.6 inches	65 inches x 84 inches x 34 inches.
Diagnosis, patient monitoring, drug monitoring.	Test for the presence of drugs of abuse.	Diagnosis.	Laboratory diagnostic system for detection, diagnosis, and monitoring.
Cerebrospinal fluid, plasma, serum, urine, other.	Urine.	Stool.	Plasma, serum, urine, whole blood.
Allergy, cardiac markers, fertility/ hormones, immune response, infectious disease, metabolic disorders, neurodegenerative disease, oncology, thyroid disorders, other.	Drugs of abuse.	*Helicobacter pylori.*	Anemia, bone, cardiac, covid-19, diabetes, endocrine, hepatitis, HIV, metabolic, oncology, thyroid, and sepsis.
30 minutes; test results available onscreen, printed, and via online transmission.	10 minutes; results are stored and available onscreen, printed, and via interface with a laboratory information system (LIS).	20-minute room temperature incubation followed by 18 seconds to analyze; results are stored and available onscreen, printed, via interface with a laboratory information system (LIS), or exported via USB.	16 minutes minimum; 30-minute average for immunoassay testing. Results can be printed or are available via bidirectional interface to a laboratory information system.
Processes 120 tests per hour.	Processes one specimen every 10 minutes.	Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop.	Specimen capacity 90; throughput 189 tests per hour.
Connects to lab automation track system; auto power-on; available replenishment of samples, reagents, and consumables on the fly.	Results can be interfaced so that results flow from the reader to an LIS.	Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS.	Fully automated immunoassay system with enhanced chemiluminescence technology; connected to company server for troubleshooting and data downloads; includes Vitros Intellicheck technology, which monitors, verifies, and documents diagnostic checks throughout sample and assay processing; automation connectivity ready.
1 day.	15 to 30 minutes.	30 minutes.	5 days.
24/7/365.	Technical support is available from 8:00 am to 5:00 pm ET.	Phone support is available. The analyzer is packaged with a quick-start user guide and a USB drive that includes the operators manual.	Remote system diagnostics, monitoring, and troubleshooting; 24/7 phone service; multiple onsite service options.
Unitized immunoreaction cartridge eliminates open-bottle stability concerns and reduces reagent waste.	Comprehensive test solution with 13-analyte panel test and reader for the hospital lab market; walkaway processing frees up technician time for other tasks; automated reading of results eliminates technician subjectivity and errors.	Gastrointestinal-focused immunofluorescence analyzer; simple stool sample prep device removes subjectivity in reading the colorimetric result; every assay has a simple, three-step workflow, allowing for easy training and implementation; intuitive user interface has dual-mode capability to run samples in either batch or single-patient runs.	Intellicheck technology provides process control and monitoring to reduce misreported results and provide real-time quality status and traceability. Waterless system with single-use disposable tips. MicroSensor detects hemolysis, icterus, lipemia, and turbidity without requiring additional samples, reagents, or time.

Randox Laboratories	Siemens Healthineers	Snibe Diagnostic	Stratec
Kearneysville, WVa (304) 728-2890 www.randox.com	Tarrytown, NY (800) 826-9702 www.siemens-healthineers.us	Shenzhen, China www.snibe.com	Birkenfeld, Germany www.stratec.com
Randox Evidence series	Atellica solution	Maglumi X8	Gemini combo
2002	US, OUS, 2017.	Maglumi X8, 2019.	US, OUS, 2012.
CE mark; FDA 510(k); Health Canada license; TGA certificate (Australia); KSA SFDA (Saudi Arabia); MFDS (Korea); ANVISA (Brazil).	FDA 510(k), 2017; CE mark, 2017.	CE mark, 2019.	FDA exempt (21 CFR 862.2160), 2012; CE mark, 2012.
69 inches x 79 inches x 39.3 inches	59.1 inches x 57.2 inches x 45.9 inches	75.6 inches x 46.5 inches x 59 inches.	30 inches x 49 inches x 26 inches
Detects multiple analytes from a single sample.	Diagnostics.	For large labs and hospitals with high volume.	In vitro diagnostics.
Multiple matrices, including blood, hair, meconium, oral fluid, post-mortem blood, tissue, urine, vitreous humor, whole blood.	Amniotic fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine.	Food samples, liquor, plasma, serum, urine, whole blood.
Adhesion molecules, cardiac markers, cerebral disorders, cytokines, drugs of abuse, endocrine, metabolic disorders, thyroid markers, tumor markers.	Anemia, autoimmune disorders, bone metabolism, cardiac markers, diabetes, hepatitis, HIV, immunosuppressant drugs, metabolic disorders, oncology, reproductive endocrinology, sepsis, special identification, therapeutic drug monitoring, thyroid markers, Torch markers.	Performs more than 160 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, and more.	Allergy testing, autoimmune diagnostics, donor screening, food analyses, infectious diseases.
From 55 minutes (assay dependent).	10 to 54 minutes (assay dependent).	15 minutes.	30 to 60 minutes (depending on incubation requirements).
Processes 90 patient samples per hour; sample rings can each hold 90 sample tubes or cups, reporting more than 2,070 results per hour.	Processes 440 tests per hour (dependent upon test mix).	Holds up to 300 samples, with continuous loading and stat processing available; throughput up to 600 tests per hour (single module).	Holds 144 samples, plus continuous loading opportunity; up to 3 plates, 16 slides.
Automated system; onboard storage capacity of 500,000 test results; onboard autodetection of specimens; information technology compatibility; quality control package; refrigerated reagent storage.	Minimizes operator intervention with an option to automate quality control, daily maintenance, bubble detection, clot detection, level sensing, dilutions, and reflex/retesting.	Auto remeasuring function; sample editing mode; laboratory information system connectivity; barcode recognition; ready-to-use, no pretreatment required calibrators and internal controls included; radio-frequency identification tags store all reagent information; two-point recalibration.	Walkaway processing of immunofluorescence assays; full onboard process control; laboratory information system connectivity.
3 days.	3.5 days for level 1 courses; 3 days for level 2 courses.	N/A	Less than 1 day.
24/7 customer support from engineering and technical support specialists.	Optional Guardian program can help predict impending failures with proactive, real-time, remote monitoring. Remote user assistance via the service button.	24/7/365 service hotline; after-sales technical support specialist assistance with method validation; machine maintenance.	Various support and service models available.
Multiplex sample profiling facilitates complete and accurate conclusions; fully automated biochip array system suited for laboratories with throughput of more than 2,070 tests per hour.	Features bidirectional sample transport that's 10x faster than conventional conveyors; automated calibration and quality control; highest immunoassay testing productivity per square meter; broad and expanding menu; smart remote services focused on reliability.	Modular expanding flexibility; capable of integrating several modules, including Snibe immunoassay, biochemistry, and ion-selective electrode modules; capable of linking to laboratory automation system.	Touchscreen-controlled system; highly flexible open software; archiving of samples; retest management; total flexibility of multipreparation assays (eg, quantiferon).