tech guide

Immunoassay Analyzers

	Arlington Scientific, Inc. Springville, Utah 801-489-8911 info@arlingtonscientific.com www.arlingtonscientific.com	Awareness Technology, Inc. Palm City, Fla. 772-283-6540 www.awaretech.com	Beckman Coulter Diagnostics Brea, Calif 800-526-3821 onacionales@beckman.com www.beckman.com
1. Brand name of your immunoassay analyzer.	ASI Evolution Automated (RPR) Syphilis Analyzer	ChemWell 2910 ELISA/biochemistry	Access 2 Immunoassay Instrument
2. What year was this version first released to market?	2018	2910	2001
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA CBER 510(k), 2017; FDA CDRH 510(k), 2018; FDA Interpretation Algorithm 510(k) 2020; FDA HCT/P 510(k) 2021	CE mark, 2009; FDA 510(k), 2019 part of Quest system	FDA 510(k)
4. What are the dimensions of the named product?	19 inches x 36 inches x 22 inches	34 inches x 16 inches x 20 inches	19.5 × 39 × 24 in./6.5 sq. ft.
5. What is the intended use or primary function of the product?	Automated RPR syphilis analyzer for diagnostic, blood donor screening, and cadaveric (non-heart beating) tissue screening.	Laboratory IVD and diagnostic use.	Benchtop immunoassay analyzer featuring a space-saving design, user-friendly features and a complete menu of more than 50 tests.
6. What types of specimen/sample does the product employ?	Plasma, serum.	Whole blood, plasma, urine, stool, serum.	Serum, plasma (lithium heparin, EDTA), urine, amniotic fluid, whole blood.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Automated RPR test for syphilis.	Can run virtually any assay and diagnose for the diseases that those assays test for.	Adrenal/pituitary, anemia, bone metabolism, cardiac, diabetes, infectious diseases, sepsis, reproductive, inflammatory, tumor markers, thyroid.
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, test dependent. In biochemistry mode, maximum 200 end point reactions per hour. 170 kinetic reactions per hour.	Stat time until completion of a ß-hCG test: 15 minutes.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Holds 192 samples in rack; processes 190 samples per hour.	Typically 27 or optional 44 reagents and 96 samples,	Maximum specimen capacity: 60 samples. Throughput: maximum 100 tests/hour
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.	Dilutes patient samples onboard. Detects clots/liquid level/short sample. Sample probe obstruction detection. Automatic reflex capability. Onboard software capability to review QC. LIS interface provided/ Bidirectional interface capability. STAT availability. Walkaway capability: 180 minutes or 60 specimens. Not connectable to automation.
11. What is the typical training time for the product?	1 Day	1 to 2 days for complete operation and applications.	Time for basic user training: (2 training slots)/2 days (at vendor site). Advanced training: provided 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 and online support.	Service engineer on-site response time: <24hrs. Modem services provided. Customer support via phone.
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; can be used for diagnostic, blood donor, cadaveric screening.	Can run both ELISA and biochemistry assays, this mixed modality analyzer is an open system with partially closed options when used with FDA 510(k) certified Quest reagent.	Offers the robustness of a reference laboratory immunoassay analyzer in convenient size of a benchtop system • standardization of results and reagents across all volume segments • reliable benchtop system providing the same high-quality results as the core lab.

Beckman Coulter Diagnostics	Binding Site	BioMérieux	DiaSorin Inc.
Brea, Calif 800-526-3821 onacionales@beckman.com www.beckman.com	San Diego, Calif. 800-633-4484 www.us.bindingsite.com	Salt Lake City, Utah 800-682-2666 www.biomerieux-usa.com	Stillwater, Minn. 1-800-328-1482 www.diasorin.com
Unicel DxI 600 Immunoassay Instrument	Optilite	VIDAS 3	LIAISON XL
2006	2015	2015	LIAISON XL, Released in 2010
FDA 510(k)	FDA 510(k), 2015	TUV CE Mark, 2013; FDA 510(k), 2015	CE mark, 2010; FDA 510(k), 2011
67 × 61.5 × 37.5 in./16 sq. ft.	24.4 inches x 37 inches x 27.6 inches	24 inches x 29.5 inches x 25.5 inches	59 inches x 59 inches x 36 inches
Standalone immunoassay analyzer featuring a space-saving design, user-friendly features and a complete menu of more than 50 tests.	Dedicated special protein analyzer to run tests to diagnose, monitor and manage patients with plasma cell disorders and immune status deficiencies.	Diagnosis and patient monitoring.	The Liaison XL is a fully-automated chemiluminescence imunoassay analyzer, performing complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, etc.) as well as measurement and evaluation.
Serum, plasma (lithium heparin, EDTA), urine, amniotic fluid, whole blood.	Serum, urine, and CSF.	Serum, plasma, stool.	Plasma, serum, urine, stool.
Adrenal/pituitary, anemia, bone metabolism, cardiac, diabetes, infectious diseases, sepsis, reproductive, inflammatory, tumor markers, thyroid.	Blood cancers, multiple myeloma, B cell dyscratias and central nervous & immune systems disorders.	Critical care (Procalcitonin, D-DIMER), infectious diseases (SARS-CoV-2, measles, mumps, rubella, varicella, Lyme, C. difficile, H. pylori, toxoplasma, CMV), and pregnancy (HCG).	Infectious diseases, bone and mineral deficiency/sufficiency, endocrinology, hypertension, gastrointestinal.
Stat time until completion of a ß-hCG test: 15 minutes.	Based on the test menu mix, typically, 15 minutes to first test result and 1 minute for each subsequent test result thereafter.	20 minutes (assay dependent); test results automatically sent to LIS (laboratory information system) and available onscreen or printed.	Time to first result is assay dependent, as low as 17 minutes. Random-access or batch depending on laboratory workflow needs.
Maximum specimen capacity: 60 samples. Throughput: maximum 200 tests/hour.	Average 105-120 special protein tests per hour.	Processes up to 36 tests per hour (12 assays onboard simultaneously); stat processing available.	Maximum throughput of 180 tests per hour (assay dependent). Sample racks hold 12 samples, and 10 racks may be loaded at any time.
Dilutes patient samples onboard. Obstruction detection on the sample and reagent probes. Automatic rerun capability. Onboard aliquot capability. Automatic reflex capability. Detects clots/liquid level/short sample.Onboard software capability to review QC. Supports multiple QC lot numbers per analyte. LIS interface provided/Bidirectional interface capability. STAT availability. Walkaway capability: 180 minutes or 60 specimens. Connectable to automation.	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 Laboratory Information Systems (LIS).	Automated pipetting and calibration, onboard dilution, bi-directional connectivity with LIS, sample stability management, integrated quality control, barcode traceability, walkaway processing.	Fully-automated test system allows continuous loading of samples, reagents, and consumables. Customizable for on-board quality control management. Compatible with most LIS and automation lines.
Time for basic user training: (2 training slots)/3 days (at vendor site). Advanced training: provided at vendor site.	1 week user training conducted during CAP accreditation-ready, hands-on validation.	1.5 day training on-site at customer location.	Primary operator training is 3-5 days (on-site) with an advanced operator training option for experienced users (at HQ).
Service engineer on-site response time: <24hrs. Modem services provided. Customer support via phone.	Binding Site's global technical support team including field applications & engineers and in-house specialists.	Remote monitoring; remote support services available 24/7/365 via screen-sharing for immediate solutions; skilled specialists for on-site instrument maintenance.	24/7 phone-based US technical support, with optional remote support (BOMGAR).
Onboard aliquoting quickly frees samples for other analyses; scalable results across all immunoassay systems; liquid, ready-to-use reagents.	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.	Reliable, easy-to-use benchtop immunoassay system with a mean time between failure of more than a year; features routine and emergency (stat) testing in a ready-to-use assay format adaptable to batch or single test runs; offers specialty menu of critical care and infectious disease assays.	RFID traceability of all reagent integrals; consumables and reagents may be loaded on the fly; disposable pipette tips prevent sample carryover; no daily maintenance, instrument monitors maintenance needs; pull-out user workspace; long walk-away time before user intervention is required.

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	Dynex Technologies, Inc. Chantilly, Va. 703-631-7800 www.Dynex.com	Fujirebio US Malvern, Pa. 844-544-3787 www.fujirebio.com	HYCOR Biomedical Garden Grove, Calif 92841 800-382-2527 www.hycorbiomedical.com/ info@hycorbiomedical.com
1. Brand name of your immunoassay analyzer.	Agility	Lumipulse G1200	NOVEOS Immunoassay Analyzer
2. What year was this version first released to market?	Agility; 2013	Lumipulse G1200; US, 2016; OUS, 2008	First release to US market: expected in 2023
3. Specify the authorizing agency and year.	CE mark, 2013	FDA 510(k) - 2016 TUV CE mark - 2011	CE Marked, 2017; FDA 510(k) Clearance K182479, 2018
4. What are the dimensions of the named product?	49 inches x 50 inches x 36 inches	57 inches x 47 inches x 31.5 inches	61.5 inches x 51 inches x, 32.5 inches
5. What is the intended use or primary function of the product?	An open system intended for full automation processing of up to 12, 96-well microplate, ELISA assays (e.g. SARS-CoV-2 assays)	Diagnosis, patient monitoring, drug monitoring	The NOVEOS system requires only 4-µL sample size per test which reduce quantity not sufficient errors, resampling and patient trauma.
6. What types of specimen/ sample does the product employ?	Assay dependent (plasma, serum, stool, urine, whole blood)	Plasma, serum, urine, CSF, other	Serum
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Typical applications include COVID-19, blood pathogens, gastrointestinal, sexually transmitted diseases, respiratory, autoimmune, oncology, and toxicology among many more disease states.	Oncology, infectious disease, metabolic, thyroid, fertility/hormones, immune response, cardiac markers, neurodegenerative, allergy, other	sIgE allergy testing
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to first result is assay dependent; typically, 2 hour for 96-wells. Test results are made available immediately upon plate read and data processing.	30 minutes; test results available on monitor, printer, and via online transmission	Time to first result: 1 hour 55 minutes. Test results are made available via Operator's software or via LIS application in real time.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Agility on-board capacity is 200 samples with continuous load capability. Maximum capacity and throughput are assay dependent; typically 10 96-well plates in 8 hours.	Throughput for all assays is consistent at 120 tests per hour	The instrument offers a true walk-away capability of up to 13 hours when plumbed to an in-house systems.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Agility is a flexible, fully automated open system that increases lab personnel's productivity by maximizing walkaway processing from the beginning of testing by eliminating the front-end setup with up to 16 SmartKit carriers.	The system is capable to connect to lab automation track system. Auto power-on, replenishment of samples, reagents, and consumables on the fly available.	Intuitive , interactive software, bar code readers, LIS capable, on board QC , Levey Jennings charts,
11. What is the typical training time for the product?	1 week onsite at customer location	1 day	Operator training 2 1/2 days
12. What types of technical support are available?	Technical support available by email or telephone. Various levels available including on-site support.	M-F; 8:30 am - 5:30 pm EST and 24/7 365 dys/yr	Technical support call center, teamviewer capabilities for troubleshooting assistance.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Full, walkaway processing from the beginning of testing with up to 16 SmartKit carriers stored on-board for simultaneous runs. Ease-of-use automation assesses testing requirements and develops an efficient work list. The continuous sample loading allows operators to reduce hands-on time by two-thirds of typical open systems.	Unitized immunoreaction cartridge eliminates open bottle stability concerns and reduces reagent waste; 30 minute time to result for all assays; uninterrupted productivity - replenish samples, reagents, and consumables on the fly.	The small sample volume of 4uL also reduces the need for additional blood draws, test prioritization by clinicians and laboratorians. The advanced microparticle technology limits interference from: Biotin, IgG / IgG4, and Solid-phase related cross-reactive carbohydrate determinant (CCD).

Ortho Clinical Diagnostics	Randox Laboratories	Siemens Healthineers	Snibe Diagnostic
Raritan, N.J. 800-828-6316 www.orthoclinicaldiagnostics.com	Kearneysville, W.Va. 304-728-2890 www.randox.com	Tarrytown, N.Y. 800-826-9702 www.siemens-healthineers.us	Shenzhen China 86-755-26501514 sales@snibe.com Website www.snibe.com
Vitros 3600 Immunodiagnostic System	Randox Evidence Series	Atellica Solution	MAGLUMI
2008	2002	US, OUS, 2017	MAGLUMI X3 2021
FDA 510(k), 2008.	CE mark; FDA 510(k); Health Canada license; TGA certificate; KSA SFDA; MFDS; ANVISA.	FDA 510(k), 2017; CE mark, 2017	CE mark, 2021
65 inches x 84 inches x 34 inches	69 inches x 79 inches x 39.3 inches	59.1 inches x 57.2 inches x 45.9 inches	H x W x D=30.71inches x 35.43 inches x29.53 inches
Fully automated immunoassay system with enhanced chemiluminescence technology: laboratory diagnostics for detection, diagnosis, and monitoring	Fully automated biochip array system detects multiple analytes from a single sample.	Diagnostics	In vitro diagnostics
Plasma, serum, urine, whole blood	Multiple matrices, including blood, hair, meconium, oral fluid, postmortem blood, tissue, urine, vitreous humor, whole blood	Amniotic fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine whole blood
Anemia, bone, cardiac, diabetes, endocrine, hepatitis, HIV, metabolic, oncology, thyroid, COVID-19, and sepsis	Adhesion molecules, cardiac markers, cerebral, cytokines, drugs of abuse, endocrine, metabolic, thyroid markers, and tumor markers	Anemia, autoimmune, bone metabolism, cardiac, diabetes, hepatitis, HIV, immunosuppressant drugs, inflammation, liver fibrosis, metabolic, oncology, reproductive endocrinology, sepsis, special identification, therapeutic drug monitoring, thyroid, TORCH, SARS-CoV-2 Antibody*	Performs more than 166 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.
16 minutes minimum; 30-minute average for immunoassay testing. Bidirectional interface provides laboratory information system download/ upload; print is an option	From 55 minutes (array specific)	10 to 54 minutes (assay dependent)	18 minutes
Specimen capacity 90; throughput 189 tests per hour	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	Processes 440 tests per hour (dependent upon test mix).	Up to 72 samples with no-pause continuous loading/unloading function; Throughput: up to 200 tests per hour
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 for result reporting; Automation connectivity ready	Automated system; onboard storage capacity of 500,000 test results; onboard autodetection of specimens; information technology compatability; 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.	Fully automated cuvette loader with single reaction cup; liquid level detection, collision detection, clot detection; auto remeasuring function; sample editing mode; laboratory information system connectivity.
5 days	3 days	3.5 days for level 1 courses; 3 days for level 2 courses.	less than 1 hour
Remote diagnostics, monitoring and troubleshooting, 24/7 phone service, multiple onsite service options	Engineering and technical support specialists deliver onsite installation, training, validation, and 24/7 customer support	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.
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 using reagents or additional samples or time to flag affected results.	Multiplex sample profiling enables users to consider the complete profile,thus facilitating well-informed and accurate conclusions.	Features bi-directional sample transport that's 10x faster than conventional conveyors; automated calibration and quality control; barcode read multi-camera vison system; highest immunoassay testing productivity per square meter; broad and expanding menu; sorting and archiving; integrated decapping; smart remote services focused on reliability.	Reagents/samples continuous loading without waiting or interrupting tests; intuitive indicator light of reagent, sample, and consumables, no need to focus on the monitor; The latest intelligent washing technology and bidirectional temperature control measurement guarantee accurate and reliable results.

Siemens Disclaimer:
*This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.
This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens.