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 Brea, Calif. 800-526-3821 www.beckmancoulter.com
1. What is the brand name of your company's immunoassay analyzer?	ASI Evolution Automated (RPR) Syphilis Analyzer	ChemWell 2910 ELISA/biochemistry	Unicel DxI 600
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2018	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; FDA Interpretation Algorithm 510(k) 2020; FDA HCT/P 510(k) 2021	CE mark, 2009; FDA 510(k), 2019 part of Quest system	CE mark 2006, FDA 510(k) 2007
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	67 inches x 61.5 inches x 37.5 inches
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	Immunoassay diagnostics
6. What types of specimen/sample does the product employ?	Plasma, serum.	Whole Blood, plasma, urine, stool, serum	Plasma, serum, urine, amniotic fluid, whole blood, and saliva (assay dependent)
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Automated RPR test for syphilis.	As an open system analyzer the ChemWell 2910 can run virtually any assay and diagnose for the diseases that those assays test for.	Adrenal/pituitary, anemia, bone metabolism, cardiac, diabetes, infectious disease, prostate health, reproductive health, sepsis, thyroid, tumor markers
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.	Assay dependent, Access hsTnI <17min. Available by print or automated LIS reporting
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,	60 samples with continuous loading/unloading: throughput of 200 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.	CLSI standardized connectivity to automation lines with on-board aliquot storage and tube release, sample detection for clots
11. What is the typical training time for the product?	1 Day	1 to 2 days for complete operation and applications	3 days
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.	PROService - remote service tools along with 24/7 phone and field support
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.	The ChemWell 2910 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.	Onboard aliquoting quickly frees samples for other analyses; scalable results across all immunoassay systems; liquid, ready-to-use reagents; load-on-the-fly capabilities for all reagents and consumables

	Binding Site	bioMérieux	DiaSorin Inc.
	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
1. What is the brand name of your company's immunoassay analyzer?	Optilite	VIDAS 3	Liaison XL
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2015	2015	Liaison XL, Released in 2010
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2015	TUV CE mark, 2013; FDA 510(k), 2015	CE mark, 2010; FDA 510(k), 2011
4. What are the dimensions of the named product?	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
5. What is the intended use or primary function of the product?	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.
6. What types of specimen/sample does the product employ?	Serum, urine, and CSF	Serum, plasma, stool	Plasma, serum, urine, stool
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Blood cancers, multiple myeloma, B cell dyscratias and central nervous & immune systems disorders	Sepsis (PCT), thrombosis (D-DIMER), infectious diseases (measles, mumps, rubella, varicella, Lyme, C. difficile, H. pylori, toxo, COVID-19) and pregnancy (HCG)	Infectious diseases, bone and mineral deficiency/sufficiency, endocrinology, hypertension, gastrointestinal.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	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
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	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.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	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.
11. What is the typical training time for the product?	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).
12. What types of technical support are available?	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)
13. What capabilities, features, or accessories distinguish this product from others on the market?	Optilite is a special protein assay analyzer 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.

	Diazyme Laboratories, Inc. Poway, Calif. 858-455-4768 www.diazyme.com	Dynex Technologies, Inc. Chantilly, Va. 703-631-7800; www.Dynex.com	Dynex Technologies, Inc. Chantilly, Va. 703-631-7800 www.Dynex.com
1. What is the brand name of your company's immunoassay analyzer?	DZ-Lite	Agility	DS2
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	DZ-Lite 3000 Plus Chemiluminence	Agility; 2013	DS2; 2007
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2017	CE mark, 2013	CE mark, 2007
4. What are the dimensions of the named product?	59.8 inches x 56.7 inches x 30 inches	49 inches x 50 inches x 36 inches	26 inches x 21 inches x 27 inches
5. What is the intended use or primary function of the product?	Aid in diagnosis, patient monitoring, and treatment	The Dynex Agility is an open system intended for full automation processing of up to 12, 96-well microplate, ELISA assays (e.g. SARS-CoV-2 assays)	The Dynex DS2 is an open system intended for full automation processing of up to 2, 96 well microplate, ELISA assays (e.g. SARS-CoV-2 assays)
6. What types of specimen/sample does the product employ?	Serum and plasma	Assay dependent (plasma, serum, stool, urine, whole blood)	Assay dependent (plasma, serum, stool, urine, whole blood)
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Infectious diseases, cardiovascular diseases, autoimmune diseases, bone metabolism, hormones	Typical applications include COVID-19, blood pathogens, gastrointestinal, sexually transmitted diseases, respiratory, autoimmune, oncology, and toxicology among many more disease states.	Typical applications include COVID-19, blood pathogens, gastrointestinal, sexually transmitted diseases, respiratory, autoimmune, oncology, and toxicology among many more disease states.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to first result: 17 minutes, but varies upon assay. Results available as printout, .txt or .xls file, or sent directly to LIMS.	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.	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.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	144 samples loaded at a time. Throughput: up to 120 tests/hour, but varies upon assay.	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.	DS2 on-board capacity is 100 samples with continuous load capability. Maximum capacity and throughput are assay dependent; typically 4 96-well plates in 8 hours.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Continuous random or batch access, STAT available, refrigerated sample and reagent area, clot detection, liquid level detection, short sample detection, autodilution, onboard control chart, and bidirectional LIMS communication.	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.	DYNEX DS2 ELISA System is the 2-microplate compact, fully automated open system that delivers automated sample processing, incubation, reagent addition, washing, and detection with more processing capacity in less than 4 square feet bench space so you can run any assay from any vendor.
11. What is the typical training time for the product?	1 to 2 days for both operation and maintenance	1 week onsite at customer location	1 week onsite at customer location
12. What types of technical support are available?	Phone, email, and on-site support.	Technical support available by email or telephone. Various levels available including on-site support.	Technical support available by email or telephone. Various levels available including on-site support.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Magnetic Microbeads as a separation technology, Shortened reaction time by enlarging the reaction area of antigens and antibodies (assay dependent), enhancing the sensitivity by better fast capturing of antigens and antibodies, reducing inter- or intra-assay discrepancies significantly by mixing the reagents thoroughly in a liquid separation platform.	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.	The DS2 system footprint is less than four square feet of linear counter space to process up to two 96-well microplates and 100 specimens making it ideal for lab's expanding workload, run any assay from any vendor, and the ability to bring in tests that are currently being sent out; it utilizes the same linear space as manual incubator and reader.

	Fujirebio US Malvern, Pa. 844-544-3787 www.fujirebio.com	Grifols Emeryville, Calif. micah.majarian@grifols.com www.diagnostic.grifols.com	Meridian Bioscience Cincinnati, Ohio 513-271-3700 mbi@meridianbioscience.com www.meridianbioscience.com
1. What is the brand name of your company's immunoassay analyzer?	Lumipulse G1200	SQII	Curian
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	Lumipulse G1200; US, 2016; OUS, 2008	SQII; 2018	US, OUS, 2020
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k) - 2016 TUV CE mark - 2011	CE mark	FDA 510(k), CE mark
4. What are the dimensions of the named product?	57 inches x 47 inches x 31.5 inches	26 inches x 21.3 inches x 26.8 inches	4.9 inches x 4.5 inches x 4.6 inches
5. What is the intended use or primary function of the product?	Diagnosis, patient monitoring, drug monitoring	Patient screening	Diagnosis
6. What types of specimen/sample does the product employ?	Plasma, serum, urine, CSF, other	Assay dependent, serum or plasma	Stool
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Oncology, infectious disease, metabolic, thyroid, fertility/ hormones, immune response, cardiac markers, neurodegenerative, allergy, other	Autoimmune and infectious disease	Helicobacter pylori
8. Under ideal conditions, what is the time to first result; how are the test results made available?	30 minutes; test results available on monitor, printer, and via online transmission	Assay dependent	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.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Throughput for all assays is consistent at 120 tests per hour	N/A	Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	The system is capable to connect to lab automation track system. Auto power-on, replenishment of samples, reagents, and consumables on the fly available.	N/A	Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS
11. What is the typical training time for the product?	1 day	3 days	30 minutes
12. What types of technical support are available?	M-F; 8:30 am - 5:30 pm EST and 24/7 365 dys/yr	Onsite and phone	Technical support is available. The analyzer is packaged with a quick-start user guide and a USB drive that includes the operator's manual.
13. What capabilities, features, or accessories distinguish this product from others on the market?	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 SQII is a compact, automated ELISA analyzer for processing ELISA assays. It is a flexible, open system designed for most ELISA applications in clinical diagnostics, such as autoimmune and infectious diseases, or therapeutic drug monitoring.	Gastrointestinal focused immunofluorescent analyzer provides objective, rapid results, helping to eliminate subjectivity related to interpreting and reporting visually-based test results. Curian's Aioprep (all-in-one) sample prep provides a simple, standardized 3-step workflow and clean sample handling, allowing for easy training and implementation. Intuitive user interface with dual mode capability to batch samples or as single-patient runs.

	Ortho Clinical Diagnostics Raritan, N.J. 800-828-6316	Randox Laboratories Kearneysville, W.Va. 304-728-2890 www.randox.com	Roche Diagnostics Indianapolis, Ind. 800-428-5076 https://diagnostics.roche.com/
1. What is the brand name of your company's immunoassay analyzer?	Vitros 3600 Immunodiagnostic System	Randox Evidence Series	Cobas e 801 {Cobas 8000 and Cobas Pro platforms}
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2008	2002	2016 OUS; 2017 US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2008.	CE mark; FDA 510(k); Health Canada license; TGA certificate; KSA SFDA; MFDS; ANVISA.	CE mark 2016; FDA 510(k) 2017
4. What are the dimensions of the named product?	65 inches x 84 inches x 34 inches	69 inches x 79 inches x 39.3 inches	Varies depending on configuration.
5. What is the intended use or primary function of the product?	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. Suited for laboratories with throughput of more than 2070 tests per hour	Diagnosis, patient monitoring, therapeutic drug monitoring
6. What types of specimen/sample does the product employ?	Plasma, serum, urine, whole blood	Multiple matrices, including blood, hair, meconium, oral fluid, postmortem blood, tissue, urine, vitreous humor, whole blood	Plasma, serum, urine, CSF, whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	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 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.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	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)	For STAT 9-minute assays TFR is ~10-11 minutes. Routine 18- & 27-minute assays TFR is ~19-28 minutes from initial pipettting. Test results available as completed on control unit screen; STAT results sent directly as completed to the LIS.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	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 2070 results per hour	Up to 300 results per hour
10. Briefly describe any automation or connectivity features or options that pertain to the product.	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	All Cobas analyzers can be connected to Roche's automation solutions (cobas 8100 & CCM), as well as selected 3rd party automation. The e 801 features extended calibration (28 days for pack cal, 84 days for lot cal), as well as long on-board stabilities (ave. 110 days). All dilutions, reruns and reflex testing is performed automatically.
11. What is the typical training time for the product?	5 days	3 days	5 days
12. What types of technical support are available?	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	Remote, hotline, and local support team
13. What capabilities, features, or accessories distinguish this product from others on the market?	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 bidirectional sample transport with industry leading assay incubation times. Best in class reagent on-board stability and calibration frequency.

	Siemens Healthineers Tarrytown, N.Y 800-826-9702 www.siemens-healthineers.us	Snibe Diagnostic Shenzhen, China sales@snibe.com www.snibe.com	Stratec SE Birkenfeld, Germany www.stratec.com
1. What is the brand name of your company's immunoassay analyzer?	Atellica solution	Maglumi	KleeYa
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	US, OUS, 2017	Maglumi 2000, 2009	OUS 2021
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2017; CE mark, 2017	CE mark, 2009; FDA 510(k),2017	CE mark 2020
4. What are the dimensions of the named product?	59.1 inches x 57.2 inches x 45.9 inches	34.25 inches x 53.15 inches x 25.20 inches	58 inches x 52 inches x 27 inches (monitor excluded)
5. What is the intended use or primary function of the product?	Diagnostics	In vitro diagnostics	In vitro diagnostics
6. What types of specimen/sample does the product employ?	Amniotic fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine, whole blood	Plasma, serum, urine, whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	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 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.	Open system for bead-based immunoassays
8. Under ideal conditions, what is the time to first result; how are the test results made available?	10 to 54 minutes (assay dependent)	17 minutes	Assay dependent; results are stored and available onscreen, printed, and via interface with a laboratory information system (LIS)
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Processes 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	Processes 120 tests per hour, with continuous loading
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Minimizes operator intervention with an option to automate quality control, daily maintenance, bubble detection, clot detection, level sensing, dilutions, and reflex/retesting.	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 infomation; ready-to-use, no pretreatment required; radiofrequency identification tags store all reagent information; two-point recalibration; automatic and optional ratio for high concentration sample dilution; Bidirectional LIS connection by TCP/IP and COM	Add-ons like onboard real-time quality control and troubleshooting tool for remote service activities
11. What is the typical training time for the product?	3.5 days for level 1 courses; 3 days for level 2 courses.	less than 1 hour	3-5 days
12. What types of technical support are available?	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; aftersales technical support specialist assistance with method validation; machine maintenance.	Various support and service models available
13. What capabilities, features, or accessories distinguish this product from others on the market?	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.	FDA 510(K) cleared; Inpeco automation track connectable; no-pause sample and reagent continuous loading/unloading function; radiofrequency identification 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	Full random-access open system for bead-based immunoassays. Highly flexible software with dedicated feature setup for assay development purposes (individually programmable assay steps with different dilution profiles and rerun/reflex settings).