tech guide

Immunoassay Analyzers

	Arlington Scientific, Inc. Springville, Utah 801-489-8911 info@arlingtonscientific.com www.arlingtonscientific.com	Beckman Coulter Diagnostics Brea, Calif. 800-526-3821 onacionales@beckman.com www.beckmancoulter.com	Binding Site San Diego, Calif. 800-633-4484 www.us.bindingsite.com
1. What is the brand name of your company's immunoassay analyzer?	ASI Evolution Automated (RPR) Syphilis Analyzer	Access 2 Immunoassay Instrument	Optilite
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2018	Access 2: 2001.	2015
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	FDA 510(K)	FDA 510(k), 2015
4. What are the dimensions of the named product?	19" x 36" x 22"	19.5" x 39" x 24" / 6.5 sq. ft.	24.4" x 37" x 27.6"
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.	Benchtop 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.
6. What types of specimen/sample does the product employ?	Plasma, serum.	Serum, plasma (lithium heparin, EDTA), urine, amniotic fluid, whole blood.	Serum, urine, and CSF.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Automated RPR test for syphilis.	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.
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.	Time to first result varies by assay, as low as 8.5 minutes. STAT Troponin I is 13 minutes.	Based on the test menu mix, typically, 15 minutes to first test result and 1 minute for each subsequent test result thereafter.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Holds 192 samples in rack; processes 190 samples per hour.	Maximum specimen capacity: 60 samples. Throughput: maximum 100 tests/hour.	Average 105-120 special protein tests per 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.	Dilutes patient samples onboard. Detects clots/liquid level/short sample. Sample probe obstruction detection. Automation reflex/repeat capability. Onboard software capability to review QC. Bidirectional interface capability. STAT capability.	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).
11. What is the typical training time for the product?	1 Day	Time for basic user training: 2.5 days.	1 week user training conducted during CAP accreditation-ready, hands-on validation.
12. What types of technical support are available?	24-hour phone support available with top-tier service plan.	24-hour customer support via phone, remote monitoring capability and on-site service available. Additional on-site service and applications support packages are available.	Binding Site's global technical support team including field applications & engineers and in-house specialists.
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.	Offers the robustness of a reference laboratory immunoassay analyzer in the 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.	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.

BioMérieux	**DiaSorin Inc.**	**Gold Standard Diagnostics**	**HYCOR Biomedical**
Salt Lake City, Utah 800-682-2666 www.biomerieux-usa.com	Stillwater, Minn. 1-800-328-1482 www.diasorin.com	Davis, Calif. (530) 759-8000 info@us.goldstandarddiagnostics.com; www.gsdx.us/	Garden Grove, Calif 92841 800-382-2527 www.hycorbiomedical.com info@hycorbiomedical.com
VIDAS 3	LIAISON XL	ThunderBolt ELISA & CLIA Analyzer	NOVEOS Immunoassay Analyzer
2015	LIAISON XL, Released in 2010	2012	First release to US market: expected in 2023
TUV CE Mark, 2013; FDA 510(k), 2015	CE mark, 2010; FDA 510(k), 2011	FDA 510(k) exempt, CE marked	CE Marked, 2017; FDA 510(k) Clearance K182479, 2018
24" x 29.5" x 25.5"	59" x 59" x 36"	W: 25.2", D: 22.5", H: 17.7"	61.5" x 51" x, 32.5"
Diagnosis and patient monitoring.	Automated high-volume chemiluminescence immunoassay floor model analyzer for *in vitro* diagnostic analysis. Performs complete sample processing, measurement, and evaluation.	Fully automated, 2-plate open platform immunoanalyzer that can run ELISA and Chemiluminescence (CLIA) assays.	The NOVEOS system requires only 4-µL sample size per test which reduce quantity not sufficient errors, resampling and patient trauma.
Serum, plasma, stool.	Plasma, serum, urine, stool (assay dependent)	Serum and plasma; fecal if assay produces a supernatant, whole blood, urine, CSF, synovial fluid, bronchial lavage	Serum
Critical care (Procalcitonin, D-DIMER), infectious diseases (measles, mumps, rubella, varicella, Lyme, *C. difficile*, *H. pylori*, toxoplasma, CMV), and pregnancy (HCG).	Broad specialty testing menu of >60 assays spanning infectious disease, infection management, gastrointestinal, hepatitis & HIV, bone & mineral metabolism, and endocrinology	Can run virtually any EIA or CLIA assay with walk-away and fully automated processing.	sIgE allergy testing
20 minutes (assay dependent); test results automatically sent to LIS (laboratory information system) and available onscreen or printed.	16 minutes (assay dependent). Results available on user software with filter and validation customization prior to printing or transmission via LIS.	Avg 1 hr.; full-plate run is 2 hrs.	Time to first result: 1 hour 55 minutes. Test results are made available via operator's software or via LIS application in real time.
Processes up to 36 tests per hour (12 assays onboard simultaneously); stat processing available.	Capacity for 120 samples loaded simultaneously. Continuous sample loading supports up to 171 tests per hour (assay dependent). STAT capability.	192 samples total	The instrument offers a true walk-away capability of up to 13 hours when plumbed to an in-house systems.
Automated pipetting and calibration, onboard dilution, bi-directional connectivity with LIS, sample stability management, integrated quality control, barcode traceability, walkaway processing.	Compatible with most automation tracks and laboratory information systems (LIS), QC software with L-J charts, RFID technology for complete reagent traceability, real-time monitoring of all system functions, remote support software available.	Barcode scanned slide-in racks allow for autodetection of specimens; system malfunctions addressed via remote monitoring; SMS/e-mail notification for run completion or error	Intuitive, interactive software, bar code readers, LIS capable, on board QC, Levey Jennings charts,
1.5 day training on-site at customer location.	3-5 days at customer site, optional advanced operator training at HQ.	3-4 days	Operator training 2 1/2 days
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 U.S. technical support with optional remote support (Beyond Trust).	24-hour phone support available	Technical support call center, teamviewer capabilities for troubleshooting assistance.
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.	Simplified specialty testing consolidation that leverages automation to drastically reduce staff hands-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.	Space saving: high capacity in a 2 x 2 ft. fooprint; open architecture: program any EIA or CLIA protocol; fully customizable with flexible and intuitive software; cost saving: low instrument price point with no routine consumables required	The small sample volume of 4uL also reduces the need for additional blood draws, test prioritization by clinicians and laboratorians. The advanced micro-particle technology limits interference from: Biotin, IgG/IgG4, and Solid-phase related cross-reactive carbohydrate determinant (CCD).

Meridian Bioscience	QuidelOrtho	Randox Laboratories	Roche Diagnostics
Cincinnnati, Ohio 513-271-3700 mbi@meridianbioscience.com www.meridianbioscience.com	Raritan, N.J. 800-828-6316 www.quidelortho.com	Kearneysville, W.Va. 304-728-2890 www.randox.com	Indianapolis, Ind. John Kleinschmidt john.kleinschmidt@roche.com diagnostics.roche.com/US
Curian	Vitros 3600 Immunodiagnostic System	Randox Evidence Series	cobas pro e 801 Immunoassay Module
US, OUS, 2020	2008	2002	OUS - 2019 US - 2020
FDA 510(k), CE mark	FDA 510(k), 2008	CE mark; FDA 510(k); Health Canada license; TGA certificate; KSA SFDA; MFDS; ANVISA.	FDA 2019
4.9" x 4.5" x 4.6"	65" x 84" x 34"	69" x 79" x 39.3"	53" x 113" x 46"
Diagnosis	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.	Diagnosis, patient monitoring, therapeutic drug monitoring, drugs of abuse testing
Stool	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, stool
Helicobacter pylori, Campylobacter-specific antigen including C. jejuni, C. coli, C. upsaliensis, and C. lari	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	Cardiac, thyroid, fertility, bone, tumor markers, infectious diseases, anemia, hepatitis, sepsis, growth, specific proteins, rheumatoid arthritis, ISD
20 minutes	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)	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.
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	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.
Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS.	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	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.
30 minutes	5 days	3 days	4.5 days in Indianapolis, additional time on site
Phone support	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	24 hour phone support, large field support team
Gastrointestinal-focused immunofluorescent analyzer; eliminates subjectivity commonly associated with colorimetric assays; each assay has a simple stool sample prep device with a 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 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.	ECL technology offers low end sensitivity, broad measuring range, fast assay times. Hitachi quality and reliability. Reduced calibrations and extended on-board stabilities.

Roche Diagnostics	Siemens Healthineers	Siemens Healthineers	Snibe Diagnostic
Indianapolis, Ind. John Kleinschmidt john.kleinschmidt@roche.com diagnostics.roche.com/US	Tarrytown, N.Y. 800-826-9702 www.siemens-healthineers.us	Tarrytown, N.Y. 800-826-9702 www.siemens-healthineers.us	Shenzhen China 86-755-26501514 sales@snibe.com www.snibe.com
cobas pure e 402 Immunoassay module	Atellica Solution	BN II Nephelometer	MAGLUMI
OUS - 2021 US - 2022	US, OUS, 2017	US, OUS - 1994	MAGLUMI X3 2021
FDA 2022	FDA 510(k), 2017; CE mark, 2017	CE Mark - 1994; IVD Mark - 2004; IVDR Mark - 2015; RoHS - 2015	CE mark, 2021
69" x 58" x 48"	59.1″ x 57.2″ x 45.9″	36" (H) X 49" (W) X 25" (D)	H x W x D=30.71inches x 35.43 inches x29.53 inches
Diagnosis, patient monitoring, therapeutic drug monitoring, drugs of abuse testing	Diagnostics	Diagnosis, patient monitoring	In vitro diagnostics
Plasma, serum, urine, CSF, whole blood, stool	Amniotic fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine, cerebrospinal fluid	Plasma, serum, urine, whole blood
Cardiac, thyroid, fertility, bone, tumor markers, infectious diseases, anemia, hepatitis, sepsis, growth, specific proteins, rheumatoid arthritis, ISD	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*	Gammopathies, renal disease, inflammation, rheumatoid disease, chronic kidney disease, cardiovascular disease, allergic disease, anemia & iron metabolism, coagulation disorders, nutritional assessment, chronic alcohol abuse, complement activity, blood-CSF barrier function	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.
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)	8 minutes to first result, depending on assay; available via instrument display & LIS	18 minutes
Up to 120 patient results/hr.	Processes 440 tests per hour (dependent upon test mix).	Average throughput of about 130 tests/hour with 2+ hours walk-away time, depending on test mix; onboard capacity of up to 100 samples & 35 reagents	Up to 72 samples with no-pause continuous loading/unloading function; throughput: up to 200 tests per hour
Can be configured with a chemistry module to for an integrated solution.	Minimizes operator intervention with an option to automate quality control, daily maintenance, bubble detection, clot detection, level sensing, dilutions, and reflex/retesting.	Automated sample processing & analysis via connectivity to Aptio Automation solution & sample bar code reader; Software comports to FDA CFR 21part11 (data security & integrity) and can bidirectionally connect to LIS, LIMS or similar	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.
4.5 days in Indianapolis, additional time on site	3.5 days for level 1 courses; 3 days for level 2 courses.	Variable, and depending on end-user proficiency needs: Basic user needs = 1-2 hours for online course + 3-4 hours hands-on training; For in-depth training = 1-2 hour online course + full day hands-on training	less than 1 hour
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.	Technical application consultants; scientific consultants; field service	24/7/365 service hotline; after-sales technical support specialist assistance with method validation; machine maintenance.
ECL technology offers low end sensitivity, broad measuring range, fast assay times. Hitachi quality and reliability. Reduced calibrations and extended on-board stabilities.	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.	Over 65 assay protocols; wide measurement range; continuous sample & reagent loading does not interrupt current workload; random-access processing eliminates sample batching; low-volume sample handling; optimized reaction conditions & assay-specific, operator-independent antigen-excess security; 2+ hours of walk-away time	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.