tech guide

Immunoassay Analyzers

	Binding Site Part of Thermo Fisher Scientific San Diego, CA 800-633-4484 thermofisher.com/bindingsite	**Diasorin** Stillwater, MN 800-328-1482 www.diasorin.com	**Diasorin** Stillwater, MN 800-328-1482 www.diasorin.com
1. What is the brand name of your company's immunoassay analyzer?	Optilite	LIAISON XS	LIAISON XL
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?	2015	LIAISON XS, Released in 2019	LIAISON XL, Released in 2010
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2015	CE Mark, 2019; FDA 510(k), 2022	CE Mark, 2010; FDA 510(k), 2011
4. What are the dimensions of the named product?	24.4" x 37" x 27.6"	28" x 50" x 29.5"	59" x 59" x 35.5"
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.	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.
6. What types of specimen/sample does the product employ?	Serum, urine, and CSF.	Plasma, serum, urine, stool (assay dependent)	Plasma, serum, urine, stool (assay dependent)
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	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.
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.	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.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	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).
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 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.
11. What is the typical training time for the product?	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.
12. What types of technical support are available?	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).
13. What capabilities, features, or accessories distinguish this product from others on the market?	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 hands-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 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.

DYNEX Technologies, Inc. Chantilly, VA 800-288-2354 customerservice@dynex.com www.dynex.com	**HYCOR Biomedical LLC** Garden Grove, CA www.hycorbiomedical.com	**HYCOR Biomedical LLC** Garden Grove, CA www.hycorbiomedical.com	**Meridian Bioscience** Cincinnnati, OH 513-271-3700 mbi@meridianbioscience.com www.meridianbioscience.com
Agility Automated ELISA System	NOVEOS	NOVEOS flex	Curian
2013	US NOVEOS 2018; OUS NOVEOS 2017;	OUS NOVEOS flex 2024	US, OUS, 2020
FDA registered; CE mark; Health Canada license	CE Mark 2017 NOVEOS; FDA 510(k) NOVEOS 2018;	IVDR NOVEOS flex 2023	FDA 510(k), CE mark
49" x 50" x 36"	51" x 61.5" x 32.5"	45.7" x 54" x 32.5"	4.9" x 4.5" x 4.6"
Open, fully automated system with up to 12 plates that processes a high-volume of ELISA assays	FDA 510(k): The NOVEOS Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum. CE Mark: The NOVEOS Total IgE assay is an in vitro quantitative assay for the measurement of total IgE in human serum or plasma. CE Mark: The NOVEOS Specific IgE assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma.	CE Mark:The NOVEOS Total IgE assay is an in vitro quantitative assay for the measurement of total IgE in human serum or plasma. CE Mark: The NOVEOS Specific IgE assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma.	Diagnosis
Serum and plasma; some urine and stool supernatant with testing and validation	Serum (US) & serum and plasma (EU)	Serum and plasma (only EU)	Stool
Runs ELISA assays with walk-away processing	Specific IgE detection for allergy (US) Specific IgE and Total IgE detection for allergy (EU)	Specific IgE and Total IgE detection for allergy (EU)	Helicobacter pylori, Campylobacter specific antigen including C. jejuni, C. coli, C. upsaliensis, and C. lari, Shiga toxin-producing E. coli (STEC) including Shiga Toxin 1&2.
Time to first result dependent on assay protocol; results sent directly to laboratory information system (LIS) and can be printed or saved as PDF or CSV file.	100 minutes	48 minutes	20 minutes
200 sample capacity; continuous sample loading	10,500	4,500	Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop.
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.	Highly automated throughput system; barcode reading, bidirectional LIS connected, walkaway, LLD, runs multiple assay simultaneously, real-time quality control, remote access, touchscreen interface.	Highly automated throughput system; barcode reading, bidirectional LIS connected, walkaway, LLD, runs multiple assay simultaneously, real-time quality control, remote access, touchscreen interface.	Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS.
3-4 days of onsite training at customer site	1 day onsite	1 day onsite	30 minutes
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 troubleshooting assistance.	24 hour technical support, service plans (onsite PM) and remote access	24 hour technical support, service plans (onsite PM) and remote access	Phone support
Fully automated system with up to 12 plates and capacity for up to 16 DYNEX SmartKits (for reagents) that eliminate nearly all manual liquid transfers; three robotic arms for continuous loading of up to 200 samples.	Full walk-away capability.liquid, ready-to-use reagents allowing much larger lot sizes. Cutting-edge immunochemistry for high sensitivity and an excellent low-end precision, reliable results for better clinical decisions. Intuitive user interface allows ease of training and routine operation. Using only 4µL sample per test.	Liquid, ready-to-use reagents allowing much larger lot sizes. Cutting-edge immunochemistry for high sensitivity and an excellent low-end precision, reliable results for better clinical decisions. Intuitive user interface allows ease of training and routine operation. Using only 4µL sample per test.	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.

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	QuidelOrtho San Diego, CA 800-828-6316 NAMarketing@quidelortho.com www.quidelortho.com	**Randox Laboratories** Kearneysville, W.Va. 304-728-2890 www.randox.com	**Siemens Healthineers** Tarrytown, NY 800-888-7436 https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems
1. What is the brand name of your company's immunoassay analyzer?	VITROS 3600 Immunodiagnostic System	Randox Evidence Series	Atellica CI Analyzer
2. What is the latest version of your named immunoassay analyzer; what year was this version released?	2008 (US)	2002	US 2023, OUS, 2022
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	510(k) 2008 (US)	CE mark; FDA 510(k); Health Canada license; TGA certificate; KSA SFDA; MFDS; ANVISA.	FDA 510(k) 2023; CE Mark 2022
4. What are the dimensions of the named product?	65" × 84" × 35"/19.4 sq. ft.	69" x 79" x 39.3"	63.0" x 80.1" x 36.8"
5. What is the intended use or primary function of the product?	Fully automated immunoassay test system for diagnostic testing of infectious diseases, therapeutic drug monitoring, and a broad menu for patient monitoring.	Fully automated biochip array system detects multiple analytes from a single sample.	In-vitro diagnostics
6. What types of specimen/sample does the product employ?	Serum, plasma, urine, whole blood	Multiple matrices, including blood, hair, meconium, oral fluid, postmortem blood, tissue, urine, vitreous humor, whole blood	Amniotic fluid, cerebrospinal fluid, plasma, serum, urine, whole blood.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	More than 100 immunoassay tests on a single platform covering a broad range of conditions and categories, including: Anemia, bone disease, cardiology, diabetes, inflammation, infectious disease, metabolic function, etc.	Adhesion molecules, cardiac markers, cerebral, cytokines, drugs of abuse, endocrine, metabolic, thyroid markers, and tumor markers	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.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	First result of immunoassay testing is 16-73 minutes. Real-time results data stream to LIS available.	From 55 minutes (array specific)	10 to 54 minutes (assay dependent); greater than 50% of the immunoassay menu has a TTFR of under 14-mins or less. Additionally, STATS are aspirated in 60 seconds.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Continuous load and unload of 31 reagent pack positions and 90 sample positions (10 are dedicated to STAT testing). On-board test capacity of up to 3,100 assays and maximum throughput of up to 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 up to 120 Immunoassay tests per hour (dependent on test mix).
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Connectable to VITROS Automation Solutions and E-Connectivity Technology interactive system management for remote support.	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 by automating most maintenance activities, bubble detection, clot detection, level sensing, dilutions, and temperature and humidity environmental controls.
11. What is the typical training time for the product?	General operator training 5 hours; go live training 12 hours; remote training programs available.	3 days	Options available include: Choice of any 3 training events: key operator-3 days, general operator-1 day, or advanced operator Training-3 days); Atellica Solution Lab Manager virtual training (2 hrs); PEPConnect on-demand online courses.
12. What types of technical support are available?	Phone hotline support 24/7/365; on-site technical and service support; remote support and troubleshooting.	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 analyzers standardized Atellica User Interface and software package.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Combines three high-quality intelligent technologies into a single system that is self-monitoring, highly efficient, and easy to use; all on a waterless system. These include MicroWell and enhanced chemiluminescence testing, MicroSensor for detecting endogenous interferences and Intellicheck Technology for monitoring.	Multiplex sample profiling enables users to consider the complete profile,thus facilitating well-informed and accurate conclusions.	Independent integration of chemistry and immunoassay modules to maximize throughput; barcode read multi-camera vison system; broad and expanding menu; standardized menu across portfolio; up to 90 days on-board stability of reagents; dynamic User Interface featuring patent-pending Lab Evaluation integrated analytics for assay verification.; smart remote services focused on reliability.

Siemens Healthineers Tarrytown, NY 800-888-7436 https://www.siemens-healthineers.com/en-us/integrated-chemistry/systems	**Snibe Diagnostic** Shenzhen, China 86-755-26501514 sales@snibe.com www.snibe.com	**Snibe Diagnostic** Shenzhen, China 86-755-26501514 sales@snibe.com www.snibe.com
Atellica Solution (Atellica IM 1300, Atellica IM 1600)	MAGLUMI	MAGLUMI
US, OUS, 2017	MAGLUMI 800; 2014	MAGLUMI 2000; 2009
FDA 510(k) 2023; CE Mark 2022	CE mark, 2014	CE mark, 2009; FDA 510(k),2017
59.1” x 57.2” x 45.9”	H x W x D=22.05" x 40.16" x28.35"	H x W x D=34.25" x 53.15" x25.20"
In-vitro diagnostics	In vitro diagnostics	In vitro diagnostics
Amniotic fluid, cerebrospinal fluid, plasma, serum, urine, whole blood.	Plasma, serum, urine, whole blood	Plasma, serum, urine, whole blood
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 256 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.	Performs more than 256 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.
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	17 minutes
Processes up to 440 tests per hour (dependent upon test mix).	Up to 40 samples with no-pause continuous loading/unloading function; throughput: up to 180 tests per hour	Up to 144 samples with no-pause continuous loading/unloading function; throughput: up to 180 tests per hour
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.	Barcode reader recognition or analyzer automatic numbered; liquid level detection, clot detection; auto remeasuring function; sample editing mode; LIS connection, automatic read sample information; ready-to-use, no pretreatment required; radiofrequency identification tags.	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; ready-to-use, no pretreatment required; radiofrequency identification tags.
Options available include: key operator-3.5 days; general operator-3 days; advanced operator training-3 days; Atellica Solution Essentials virtual training-0.5 day); Atellica Solution Lab Manager virtual training (2 hrs); PEPConnect on-demand online courses.	less than 1 hour	less than 1 hour
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; aftersales technical support specialist assistance with method validation; machine maintenance.	24/7/365 service hotline; aftersales technical support specialist assistance with method validation; machine maintenance.
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.	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.	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.