

1. What is the brand name of your company's immunoassay analyzer?
2. What is the latest version of your named immunoassay analyzer; what year was this version first released to market?
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.
4. What are the dimensions of the named product?
5. What is the intended use or primary function of the product?
6. What types of specimen/sample does the product employ?
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?
8. Under ideal conditions, what is the time to first result; how are the test results made available?
9. What are the product's maximum specimen capacity and throughput under ideal conditions?
10. Briefly describe any automation or connectivity features or options.
11. What is the typical training time for the product?
12. What types of technical support are available?
13. What capabilities, features, or accessories distinguish this product from others on the market?

Beckman Coulter Inc	Beckman Coulter Inc	Dynex Technologies Inc
Brea, Calif (800) 526-3821; beckmancoulter.com	Brea, Calif (800) 526-3821; beckmancoulter.com	Chantilly, Va (703) 631-7800; www.dynex.com
UniCel DxI 600 Access immunoassay system	UniCel DxI 800 Access Immunoassay system	Agility
UniCel DxI 600 Access immunoassay system, 2007.	UniCel DxI 800 Access Immunoassay system, 2003.	Agility, 2013.
CE mark, 2007; FDA, 2013.	CE mark, 2007; FDA, 2013.	CE mark, 2013.
67 inches × 61.5 inches × 37.5 inches	67 inches × 67.5 inches × 37.5 inches	49 inches x 50 inches x 36 inches
An in vitro diagnostic device used for the quantitative, semiquantitative, or qualitative determination of various analyte concentrations found in human body fluids.	An in vitro diagnostic device used for the quantitative, semiquantitative, or qualitative determination of various analyte concentrations found in human body fluids.	An open system intended for fully automated processing of up to 12 96-well microplate enzyme immunoassays.
Assay dependent.	Assay dependent.	Plasma, serum, urine, and whole blood.
BR-GI-OV monitors; CK-MB; cortisol; DHEA-S; digoxin; erythropoietin; estradiol; fast hTSH; ferritin; folate; free T3; hFSH; hLH; inhibin A; intact parathyroid hormone ostase; intrinsic factor Ab; myoglobin; prostate-specific antigen and free prostate-specific antigen; progesterone; prolactin; rubella IgG; SHBG; sTf; testosterone; thyroglobulin; total βhCG; total IgE; total T4; toxo IgG; toxo IgM II; TPOAb; troponin I; ultrasensitive insulin, unconjugated estriol; vitamin B12; vitamin D; and many others.	BR-GI-OV monitors; CK-MB; cortisol; DHEA-S; digoxin; erythropoietin; estradiol; fast hTSH; ferritin; folate; free T3; hFSH; hLH; inhibin A; intact parathyroid hormone ostase; intrinsic factor Ab; myoglobin; prostate-specific antigen and free prostate-specific antigen; progesterone; prolactin; rubella IgG; SHBG; sTf; testosterone; thyroglobulin; total βhCG; total IgE; total T4; toxo IgG; toxo IgM II; TPOAb; troponin I; ultrasensitive insulin, unconjugated estriol; vitamin B12; vitamin D; and many others.	Typical applications for autoimmune, cardiology, infectious, microbiology, parasitology, and many more disease states.
13 minutes at minimum; assay dependent.	13 minutes at minimum; assay dependent.	Assay dependent; typical timing is 2 hours; test results are made available immediately upon plate read and data processing.
60-specimen capacity with continuous loading; 200 tests per hour, assay dependent.	120-specimen capacity with continuous loading; 400 tests per hour, assay dependent.	200 samples, with continuous load capability; maximum capacity and throughput are assay dependent; typical is 10 plates in 8 hours.
Laboratory information system connectivity for automatic upload of results and download of test requests; remote system diagnostics; automated reflex testing, derived results calculation, database maintenance, and fluidics exercising; can be integrated with chemistry analyzer.	Laboratory information system connectivity for automatic upload of results and download of test requests; remote system diagnostics; automated reflex testing, derived results calculation, database maintenance, and fluidics exercising; can be integrated with chemistry analyzer.	Simple user navigation and software capability with full interface capability; bar-code technology for all components, ensuring proper sample, error, and result handling.
3 days.	3 days.	1 week onsite at customer location.
On-site applications and field engineering support at customer laboratory; hotline access 24/7.	On-site applications and field engineering support at customer laboratory; hotline access 24/7.	Various levels of technical support and onsite service support available.
Integrates with UniCel DxC chemistry systems; uses chemiluminescent technology; allows operators to load consumables on the fly, without interacting with the system; offers ProService remote diagnostic service capability.	High-throughput immunoassay analyzer; integrates with UniCel DxC chemistry systems; uses chemiluminescent technology; allows operators to load consumables on the fly, without interacting with the system; offers ProService remote diagnostic service capability.	Innovative SmartKit technology; a simple, direct-load solution to front-end preparation that reduces technician time and potential for costly data entry errors, while improving ease-of-use and enhancing the product offerings of reagent kit manufacturers.

Dynex Technologies Inc Chantilly, Va (703) 631-7800; www.dynex.com	Grifols Emeryville, Calif (888) 474-3657; www.grifols.com	Quanterix Lexington, Mass (617) 301-9400; www.quanterix.com	Roche Diagnostics Corp Indianapolis (800) 428-5074; usdiagnostics.roche.com
DS2	Triturus	Simoa HD-1 analyzer	Cobas 4000 analyzer series (Cobas e 411 module)
DS2, 2007.	Version 4.01b, 2008.	Simoa 2.0, 2015.	Cobas e 411 module, 2008.
CE mark, 2007.	CE mark, 1999; FDA Class I, 2003.	n/a	FDA 510(k).
26 inches x 21 inches x 27 inches	34.25 inches x 41.34 inches x 28.35 inches	51.18 inches x 23.62 inches x 62.99 inches	31.4–43 inches x 47.2–67 inches x 28.7–37.4 inches
An open system intended for fully automated processing of up to two 96-well microplate enzyme immunoassays.	An open system capable of performing virtually any kind of enzyme-linked immunosorbent assay (ELISA).	Disease diagnosis through single molecule detection.	Diagnosis or patient monitoring in a low-volume physician office or hospital laboratory setting.
Plasma, serum, urine, and whole blood.	Plasma, serum, or urine, depending on requirements of the ELISA kit.	Cell lysate, cerebrospinal fluid, plasma, serum, and urine samples.	Cerebrospinal fluid, plasma, serum, supernatant, and urine.
Typical applications for autoimmune, cardiology, infectious, microbiology, parasitology, and many more disease states.	Dependent on the ELISA kit used, including tests for autoimmune diseases, biological drug levels, infectious diseases, and more.	Diseases across cardiology, infectious disease, inflammatory, metabolic, neurology, and oncology. Some specific conditions include Alzheimer's disease, cardiac disease, human immunodeficiency virus, prostate cancer, and traumatic brain injuries.	Tests for anemia, bone markers, cardiac markers, diabetes, fertility, general chemistry (CK-MB), growth hormones, hepatitis, infectious disease, rheumatoid arthritis, specific proteins, therapeutic drug monitoring, thyroid function, and tumor markers.
Assay dependent; typical timing is 2 hours; test results are made available immediately upon plate read and data processing.	Depends on the selected configuration; multiple assays can be run on multiple samples, with varying times. Results shown on the screen and on a results sheet.	Less than 20 minutes of hands-on startup time; about 45–60 minutes for a first result and subsequent samples every 45 seconds thereafter. Results are automated and can be viewed and analyzed onboard, or exported to commonly used software packages and laboratory information management systems.	92% of immunoassay reagents take 18 minutes or less.
100 samples, with continuous load capability; maximum capacity and throughput are assay dependent; typical is four plates in 8 hours.	92 samples per batch; four plates per batch; eight tests per batch; four batches simultaneously.	66 samples per hour.	Up to 86 tests per hour.
Built-in user calibration software.	Auto self-test checks all parts of the instrument; quality control program records the evolution of data processed; software-guided worksheet setup; automatic workbench configuration color codes the layout of materials and calculates the required volumes of reagents.	A completely automated experience, from mixing to sample read-out; intuitive touch-screen interface.	n/a
1 week onsite at customer location.	1-day training for basic users; 3 days for advanced users.	Most customers receive an initial training of 1–2 days to run Simoa kits. Customers wishing to develop their own homebrew assays usually require an additional 3–4 day training course.	Varies on site; 4 days at vendor's office.
Various levels of technical support and onsite service support available.	Directly through Grifols.	Support packages depend on the response time required by a customer; most support can be done within minutes remotely.	24/7 phone support; expert installation; onsite support; remote system diagnostics; online classes.
Multifunction robot arm that does everything from pipetting to operating the barcode reader; vertical design and patented multiplate carrier save space, enabling a minimal footprint with maximum consumable storage.	The open system can perform virtually any ELISA on the market, following a self-guided worksheet and workbench setup; choice of fixed needles or disposable tips; dual independent probes speed the process to optimize workflow.	Ability to trap single molecules in femtoliter-sized wells, resulting in 1000x greater sensitivity than conventional immunoassays; designed to provide users with a completely automated experience to ensure consistent results; runs up to a 10-plex on a variety of analyte panels; users can develop and optimize their own assays, leveraging Simoa on markers for which prepackaged assay kits do not exist; priced affordably, and assays are cost-effective.	Standardized reagents, reference ranges, and user interface across entire family of analyzers; analyzer reliability; 9-minute stat assays.

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Roche Diagnostics Corp	Siemens Healthineers	Thermo Fisher Scientific
Indianapolis (800) 428-5074; usdiagnostics.roche.com	Tarrytown, NY (877) 229-3711; www.usa.siemens.com/diagnostics	Waltham, Mass (800) 346-4364; www.thermoscientific.com/diagnostics
Cobas 8000 analyzer series (Cobas e 602 module)	Advia Centaur	Phadia 250 laboratory system
Cobas e 602 module, 2010.	Advia Centaur XPT immunoassay system, 2014 (OUS).	Phadia information data manager (IDM) v5.78 and Phadia 250 ISW v2.33-4, 2015.
FDA 510(k), 2010.	FDA, 2015.	CE mark, 2004; FDA 510(k), 2004.
Up to 52.8 inches x 112.8–289.2 inches x 45.6 inches (37.2 inches including core unit; 44.4 inches including ion-selective electrode module)	66 inches x 77 inches x 41 inches	73 inches × 50 inches × 30 inches plus 26 inch-wide computer stand
Diagnosis or patient monitoring in a high-volume commercial reference lab or hospital laboratory setting.	Laboratory diagnostics.	Separate or combined runs of specific IgE blood tests and autoimmunity tests.
Cerebrospinal fluid, plasma, serum, supernatant, and urine.	Plasma, serum, or urine; assay dependent.	Plasma and serum.
Tests for anemia, bone markers, cardiac markers, diabetes, fertility, general chemistry (CK-MB), growth hormones, hepatitis, infectious disease, rheumatoid arthritis, specific proteins, therapeutic drug monitoring, thyroid function, and tumor markers.	Allergy; anemia and iron metabolism; bone metabolism; cardiac; diabetes; infectious disease (ID); immunosuppressant drugs; metabolic; oncology; reproductive endocrinology; special ID; therapeutic drug monitoring; thyroid; ToRCH.	Allergy and autoimmunity diseases (anti-phospholipid syndrome, autoimmune liver disease, autoimmune thyroid disease, celiac, connective tissue disease, rheumatoid arthritis, and vasculitis/good pasture syndrome).
92% of immunoassay reagents take 18 minutes or less.	18 minutes for most assays. Users can review results, interpretations, and flags; the system can hold test results for review and send results to the laboratory information system.	100 minutes to first result, then every 60 seconds; lab information system connectivity with a bidirectional interface, paper patient reports.
Up to 1,000 samples per hour or 9,800 tests per hour.	180 samples fully loaded; up to 240 tests per hour.	Random access processing of 400–2000 results per week. Each of five sample racks holds up to 10 patient and quality control samples; onboard dilutions.
Modular preanalytics system; Cobas 8100 automated workflow series; Cobas p 312; Cobas p 512; Cobas p 612; postanalytics with Cobas p 501 and Cobas p 701.	Direct connectivity to Siemens automation solutions, the CentralLink data management system, and Siemens remote services; available automatic quality control ordering by test, control, date, and time; automated clot management.	Connect any five Phadia instruments via common software, or more via track connectivity; 28-day calibration stability; onboard refrigerated storage of tests; remote system diagnostics; barcoding for safety and traceability.
Varies on site; 5 days at vendor's office.	4.5 days.	3 to 6 days for allergy or autoimmunity, or both.
24/7 phone support; expert installation; onsite support; remote system diagnostics; online classes.	Siemens remote services.	Field service, technical application specialists, and technical support.
Standardized reagents, reference ranges, user interface across entire family of analyzers; analyzer reliability; 9-minute stat assays; scalable platform using modular design.	Universal 5-position rack holds multiple tube types; no-pause loading and unloading; on-the-fly loading and unloading of samples, reagents, and supplies, stat samples can be front-loaded at any time for immediate sampling; 2D bar-code scanner uploads test definitions with one easy scan; automated daily maintenance and no monthly cleaning procedures; no daily startup procedure; disposable sample tips; automated clot management; software automates repeat and confirmatory testing of reactive samples.	Part of a suite of instruments providing globally marketed technology for serologic testing, specific IgE testing, and autoimmune marker detection.

Thermo Fisher Scientific Waltham, Mass (800) 232-3342; www.thermoscientific.com/ diagnostics	Thermo Fisher Scientific Waltham, Mass (800) 232-3342; www.thermoscientific.com/ diagnostics	Tosoh Bioscience Inc South San Francisco, Calif (800) 248-6764; diagnostics.us.tosohbioscience.com	Tosoh Bioscience Inc South San Francisco, Calif (800) 248-6764; diagnostics.us.tosohbioscience.com
Thermo Scientific Indiko	Thermo Scientific Indiko Plus	AIA-360	AIA-900
Thermo Scientific Indiko, 2011.	Thermo Scientific Indiko Plus, 2011.	AIA-360, 2004.	AIA-900, 2011.
CE mark; FDA 510(k), 2011.	CE mark; FDA 510(k), 2011.	MET Laboratories CE mark, 2004.	MET Laboratories CE mark, 2011.
24.4 inches x 29.5 inches x 27.6 inches (height is 51 inches with cover open)	24.4 inches x 37 inches x 27.6 inches	21 inches x 16 inches x 16 inches	49.09 inches x 50.79 inches x 26.18 inches
A fully automated random access analyzer used to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.	A fully automated random access analyzer used to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.	Diagnosis and monitoring.	Diagnosis and monitoring.
Oral fluid, plasma, serum, urine, and whole blood.	Oral fluid, plasma, serum, urine, and whole blood.	Plasma, serum, and urine; assay dependent.	Plasma, serum, and urine; assay dependent.
A large menu of therapeutic drug monitoring and drugs of abuse screening immunoassays.	A large menu of therapeutic drug monitoring and drugs of abuse screening immunoassays.	Cardiac, diabetes, kidney, metabolic, reproductive, thyroid, and tumor markers.	Anemia, cardiac, diabetes, kidney, metabolic, reproductive, thyroid, tumor markers, and vitamin D.
7–15 minutes; real-time result reporting in the user interface, print, workbook, or through a laboratory information system.	7–15 minutes; real-time result reporting in the user interface, print, workbook, or through a laboratory information system.	Approximately 18 minutes; unidirectional American Society for Testing and Materials interface and thermal printer.	Approximately 18 minutes; bidirectional interface with download and host query.
Random, continuous-feed access with up to 45 calibrator or patient samples; 200 tests per hour; onboard dilutions.	Random, continuous-feed access with up to 54 calibrator, patient, or quality control samples; 350 tests per hour; onboard dilutions.	36 tests per hour; 24 specimens with carousel-based continuous processing.	90 test per hour; 100 specimens with rack-based continuous processing.
System-ready bar-coded reagents.	System-ready bar-coded reagents.	None.	Automated dilutions, automated pretreatment, and auto retest.
1 to 2 days for user and maintenance training.	1 to 2 days for user and maintenance training.	3 days, onsite.	3 days, in house.
24/7 technical support by phone or e-mail; field service; field application specialists.	24/7 technical support by phone or e-mail; field service; field application specialists.	24 hours, 7 days, 365 days a year.	24 hours, 7 days, 365 days a year.
Fully self-contained, with a small footprint; intuitive user interface; full results traceability; easy to use, saving time and costs; expansive menu of liquid, ready-to-use bar-coded reagents.	Fully self-contained, with a small footprint; intuitive user interface; full results traceability; easy to use, saving time and costs; expansive menu of liquid, ready-to-use bar-coded reagents.	Suitable for the physician's office laboratory; small size and low cost; near-patient testing for intact parathyroid hormone; specialty analyzer.	Three configurations from benchtop to more automated larger capacity with the addition of two sizes of test cup sorters.