[tech] guide

Point-of-Care Analyzers

	Alere Inc **Waltham, Mass** **www.alere.com;** **(877) 262-4669**	Magellan Diagnostics Inc **North Billerica, Mass** **(800) 305-0197;** **www.leadcare2.com**	Nova Biomedical **Waltham, Mass** **(781) 894-0800;** **www.novabiomedical.com**
1. What is the brand name of your company's POC analyzer?	Afinion AS100 analyzer	LeadCare II	StatStrip Lactate/StatSensor Creatinine Hospital Meter System
2. What year was your named product first released to market?	2005	2006	2011
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2005; CLIA waiver, 2006; FDA 510(k), 2005.	CE mark, 2006; CLIA waiver, 2006; ETL listed mark, 2006; FDA 510(k), 2006.	FDA 510(k), 2011.
4. What are the dimensions of the named product?	13.4 inches x 6.7 inches x 6.7 inches	3.5 inches x 9.0 inches x 6.5 inches	6.0 inches x 3.25 inches x 1.8 inches
5. What is the intended use or primary function of the product?	Point-of-care applications; monitoring of metabolic control in patients with diabetes.	The LeadCare II blood lead analyzer and test kit are intended for the quantitative measurement of lead in a whole blood sample at the point of care.	Routine screening and serial testing of lactate for rapid detection and monitoring of serious illness such as sepsis or septic shock; point-of-care kidney function testing prior to contrast imaging.
6. What type of specimen/sample does the product employ?	Plasma, urine, or whole blood.	Whole blood.	Whole blood.
7. What types of diseases, conditions, or analytes does the analyzer detect?	Tests for key markers for patients with diabetes, including HbA1c levels and albumin/creatine ratio (ACR).	Lead exposure and lead poisoning.	Lactate, for detection and monitoring of sepsis; creatinine for kidney function testing.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Results in 3 minutes for HbA1c assay, 5 minutes for ACR; test results are made available via a color touch display.	Quantitative results in 3 minutes; produced on analyzer display.	13 seconds for lactate, 30 seconds for creatinine; results are indicated on a color touchscreen and transmitted to the laboratory information system or hospital information system for meters that are interfaced through middleware.
9. What are the product's maximum capacity and throughput under ideal conditions?	20 tests per hour for HbA1c assay.	Intended for immediate sample collection and testing.	240 samples per hour.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Has a fixed factory calibration and performs a self-check upon start-up; integrated error-detection system eliminates erroneous results; patient and control results can be transferred to laboratory information systems and hospital information systems via Ethernet.	Electronically calibrated; prompts users through a three-step process, analyzer detects when the sample has been applied to the sensor and automatically starts the test.	Interfaces with laboratory information systems and hospital information systems via included NovaNet application or through commonly available middleware.
11. What types of technical support are available?	Technical support is available online through the Alere Web site and through a toll-free phone line.	Online training videos and certification; technical support by phone and e-mail.	24/7 phone support.
12. What capabilities, features, or accessories distinguish this product from others on the market?	The compact, multiassay system provides valuable information for diabetes patients at the point of care; can contribute to improving patient compliance and satisfaction with fewer lab and office visits; can help healthcare providers make timely decisions about therapy changes when needed for better patient management.	The FDA-cleared, CLIA-waived blood lead test provides quantitative results in 3 minutes from just two drops (50 µl) of blood.	Rapid lactate screening with 0.6 µl whole blood sample, single-use lactate biosensors, routine screening of lactate allows for rapid detection of serious illness such as sepsis or septic shock; for creatinine, 30-second assessment of renal function by finger stick capillary blood sampling, 1.2 µl whole blood sample, calculated eGFR by either MDRD or Cockcroft-Gault equations right on the meter; lab-equivalent accuracy.

Qualigen Inc **Carlsbad, Calif (877) 709-2169; www.qualigeninc.com**	Roche Diagnostics **Indianapolis (317) 521-2000; www.usdiagnostics.roche.com**	Siemens Healthineers **Norwood, Mass (781) 269-3000; www.siemens.com/poc**
FastPack IP system	Accu-Chek Inform II blood glucose system	Clinitek Advantus analyzer
2001	2012	2006
UL Full Quality Assurance (EC) CE mark, expires 2017; FDA 510(k), 2000.	FDA 510(k), 2012.	CE mark, 2010; EMC, 2006; FDA 510(k), 2006; UL, 2006.
13 inches x 9 inches x 12 inches	1.73 inches x 3.74 inches x 7.60 inches	12.75 inches x 15.75 inches x 13.75 inches
Point-of-care immunoassay applications.	Intended for multiple-patient in vitro diagnostic use in professional healthcare settings; Accu-Chek Inform II meter and Accu-Chek Inform II test strips are for use to quantitatively measure glucose in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertips as an aid in monitoring the effectiveness of glucose control.	Urine chemistry testing.
Plasma or serum.	Whole blood.	Random specimen, should be tested within 2 hours of collection or refrigeration of sample required.
Free T4, hCG, PSA, testosterone, TSH, and vitamin D.	Qualititatively measures glucose as an aid in monitoring the effectiveness of glucose control.	Routine urine tests: albumin, bilirubin, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen; albumin-to-creatinine ratio as kidney disease test.
Results in 12 minutes for all assays except free T4, which is 7 minutes; test results are provided on the display screen at the conclusion of the assay, as well as being printed out directly on the label affixed to the testpack.	Blood glucose results are displayed on the meter's touchscreen within 5 seconds after the addition of a blood sample to the test strip.	About 1 minute; results can be printed or transmitted electronically.
Under normal conditions, the system completes five 12-minute assays in 1 hour, or eight free T4 assays in 1 hour.	Provides results in 5 seconds with a whole blood sample size of 0.6 ml.	Up to 500 strips per hour; 7 seconds per sample.
Allows for the output of test results to a personal computer; internal troubleshooting system; quality control and calibration are run in the identical manner as a patient sample.	Connects to Cobas IT 1000 application to provide users with complete management of POC testing.	Automatically checks each strip for humidity; barcode data entry.
Training performed online via Web cam; technical support available via toll-free phone line.	Service center provides trained technical support specialists 24/7/365; the Roche support network is a field support team composed of trained POC specialists who provide onsite customer support.	Siemens technical support and education available, including online personalized education plan.
The fully automated quantitative immunoassay analyzer is designed for use in any size physician's office laboratory; utilizes sophisticated chemiluminesence technology; versatile and requires minimal bench space; depot service support program, which replaces nonfunctional units overnight.	150 quality checks with each sample; patented AC/DC technology checks range of variables including compensation for hematocrit; meter-level wireless for real-time data transfer without need to dock the meter; extensive studies prove system performance in presence of potential interferences following Clinical and Laboratory Standards Institute guidelines.	Flexible operation to meet workflow needs; automatically recognizes multiple Siemens strip types; self-pacing allows operator to load samples as needed; downloads and prints load list from laboratory information system; accommodates stat testing; network ready; supports up to three different user-defined confirmatory flags; microscopy consolidation; automatically flags and prints sample ID reports for microscopy follow-up.

Upcoming Tech Guides

Each month, *CLP* invites leading IVD manufacturers and clinical laboratory suppliers to complete a standarized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future issues of *CLP:*

SEPTEMBER
Molecular Diagnostic Instruments

OCTOBER
Hematology Analyzers

NOVEMBER
Lab and Patient Safety Products

DECEMBER
Buyer's Guide

To be considered for inclusion, contact associate editor Elaine Sanchez Wilson at ewilson@allied360.com