tech guide

Point-of-Care Assays and Analyzers

	Abbott Lake Forest, Ill (855) 731-2288 www.abbott.com	Abbott Lake Forest, Ill (855) 731-2288 www.abbott.com	Abbott Lake Forest, Ill (855) 731-2288 www.abbott.com
1. What is the brand name of your company's POC assay or analyzer?	Cholestech LDX system	ID Now (formerly Alere i)	Afinion 2 test system
2. What year was your named product first released to market (US, OUS)?	1992	US, 2015; OUS, 2014.	US, 2018; OUS, 2017.
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	TUV CE mark, 1992; FDA 510(k), 1992; CLIA waived complexity status, 1996.	TUV electrical safety, 2014; CE mark, 2014; FDA 510(k), 2014.	Afinion ACR CE mark, 2017; FDA 510(k), 2017; CLIA moderate complexity status, 2017. Afinion HbA1c FDA 510(k), 2017; CLIA waived complexity status, 2017. Afinion HbA1c Dx FDA 510(k), 2018; CLIA moderate complexity status, 2018.
4. What are the dimensions of the named product (H x W x D, in inches)?	8.25 inches x 4.75 inches x 5 inches	8.15 inches x 5.71 inches x 7.64 inches	7.17 inches x 7.48 inches x 13 inches
5. What is the intended use or primary function of the product (eg, diagnosis, patient monitoring, point-of-care applications, therapeutic drug monitoring, viral load monitoring)?	Provides quantitative determination of glucose and lipid test results.	Rapid diagnosis at the point of care.	Provides point-of-care test results for albumin:creatinine ratio (ACR), C-reactive protein (CRP), HbA1c, and lipids, for diagnosis and monitoring.
6. What type of specimen/sample does the product employ (eg, plasma, serum, urine, whole blood)?	Whole blood (fingerstick and plasma).	Nasal, nasopharygeal, or throat swab samples, depending on the tests being performed.	ACR requires urine sample. CRP and lipid panel can use fingerstick whole blood, plasma, serum, or venous whole blood. HbA1c can use fingerstick or venous whole blood sample.
7. What types of diseases, conditions, or analytes does the assay detect?	Assessment and monitoring of cardiovascular risk.	Influenza A and B, respiratory syncytial virus (RSV), Streptococcus A.	Diabetes, risk of diabetes, kidney disease, cardiovascular risk, and infections (for appropriate use of antibiotics).
8. This product is:	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other
9. Under ideal conditions, what is the time to first result; how are the test results made available?	The test time is 5 minutes; results are displayed on the analyzer and its printer.	The influenza A&B test provides positive results in 5 minutes, and complete results in 13 minutes. The RSV test provides complete results in 13 minutes. The Strep A test provides positive results in 2 minutes, complete results in 6 minutes.	Instrument self-test takes less than 2 minutes; ACR takes 5 minutes; CRP takes 3 minutes; HbA1c takes 3 minutes; lipid panel takes 7 minutes.
10. What are the product's maximum capacity and throughput under ideal conditions?	Maximum throughput is approximately 11 tests per hour.	ID Now runs single-assay tests with no limits to throughput.	Maximum throughput is 20 tests per hour.
11. What is the typical training time for the product?	Approximate training time is 30 minutes to 1 hour.	CLIA waived status requires no training. Nevertheless, sales team and commercial leaders can provide 30–45 minute training upon implementation.	Approximate training time is 30 minutes to 1 hour.
12. What types of technical support are available?	Technical support by telephone; in-person support available in some locations.	Technical support by telephone; in-person support available in some locations.	Technical support by telephone; in-person support available in some locations.
13. What capabilities, features, or accessories distinguish this product from others on the market?	The only POC analyzer to provide high-performance glucose and lipid test results from a single fingerstick sample.	Instrument-based, isothermal system for the qualitative detection of infectious diseases; quality control lock-out; bidirectional connectivity eliminates interpretation and transcription errors.	Menu includes first POC HbA1c test cleared as an aid in the diagnosis of diabetes. Exceptional accuracy while being extremely simple and easy to use. Broad menu of tests expands utility for primary care providers.

	BD Sparks, Md (800) 638-8663 www.BD.com	BioFire Diagnostics Salt Lake City (801) 736-6354 www.biofiredx.com	EKF Diagnostics Boerne, Texas (800) 531-5535 www.ekfusa.com
1. What is the brand name of your company's POC assay or analyzer?	Veritor System; Veritor Plus System	FilmArray Respiratory Panel EZ (RPEZ)	HemoPoint H2
2. What year was your named product first released to market (US, OUS)?	2011; 2017	2016	US, 2008.
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	FDA	FDA 510(k); CLIA waived complexity status.	FDA CLIA waived complexity status, 2008.
4. What are the dimensions of the named product (H x W x D, in inches)?	2 inches x 3 inches x 4 inches	20 inches x 36 inches x 20 inches	6.25 inches x 6.25 inches x 2.5 inches
5. What is the intended use or primary function of the product (eg, diagnosis, patient monitoring, point-of-care applications, therapeutic drug monitoring, viral load monitoring)?	Influenza A and B; respiratory syncytial virus (RSV); Group A Streptococcus.	Identification of infectious disease pathogens.	Point of care monitoring of anemia.
6. What type of specimen/sample does the product employ (eg, plasma, serum, urine, whole blood)?	Influenza and RSV tests can use nasal swab, nasopharyngeal swab, washes, or aspirates; Group A Strep requires a throat swab.	Nasopharyngeal swab.	Whole blood.
7. What types of diseases, conditions, or analytes does the assay detect?	Flu A and B; RSV; Group A Strep.	Identifies pathogens related to upper respiratory infections.	Hemoglobin and hematocrit.
8. This product is:	❑ A self-contained POC test (requiring no equipment) ■ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ■ A multiplexed test for use in POC equipment ❑ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other
9. Under ideal conditions, what is the time to first result; how are the test results made available?	Flu and RSV tests require 11 minutes; Group A Strep test requires 6 minutes.	About 60 minutes. Test results are available in printout format.	Test results are available in 25–60 seconds and can be viewed onscreen.
10. What are the product's maximum capacity and throughput under ideal conditions?	Instrument allows for batching; 10 tests can be performed in 1 hour and 52 minutes.	The system can run 8 tests per work day.	Around 30 tests per hour.
11. What is the typical training time for the product?	30 minutes.	Training includes instrument setup, user training, and running positive and negative controls, and can be completed within 3 hours.	One hour.
12. What types of technical support are available?	Phone and onsite.	24-hour tech support; field application specialists assist with installation and onsite troubleshooting.	Telephone technical support is available during normal working hours.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Print enabled; automated traceability with scanning module to eliminate manual logs; automated synchronization with patient records through cellular connectivity.	Syndromic polymerase chain reaction-based testing that requires only one nasopharyngeal swab; more comprehensive and accurate than rapid antigen tests.	Provides hemoglobin result and a hematocrit calculation within 60 seconds. Photometric azide methemoglobin method ensures high precision (CV <2%). The system's memory can store 4,000 patient results.

Instrumentation Laboratory Bedford, Mass (800) 955-9525 www.instrumentationlaboratory.com	**Instrumentation Laboratory** Bedford, Mass (800) 955-9525 www.instrumentationlaboratory.com	**Instrumentation Laboratory** Bedford, Mass (800) 955-9525 www.instrumentationlaboratory.com	**Nova Biomedical** Waltham, Mass (781) 894-0800 www.novabiomedical.com
VerifyNow system	GEM Premier 5000 with iQM 2 blood gas testing system	Hemochron Signature Elite	StatStrip Lactate / StatSensor Creatinine Hospital Meter system
2004	US, 2017; OUS, 2016.	2006	2011
CE mark, 2004; FDA 510(k), 2004; TUV, 2004.	CE mark, 2015; FDA 510(k), 2016.	CE mark, 2005; FDA 510(k), 2005; TUV, 2005.	FDA 510(k), 2011.
6.5 inches x 9.5 inches x 9.3 inches	18.6 inches x 13 inches x 16.4 inches	2.0 inches x 7.5 inches x 3.7 inches	6.0 inches x 3.25 inches x 1.8 inches
A whole blood test used in the laboratory or point-of-care (POC) setting to measure platelet function.	Performs clinical chemistry tests in laboratory and point-of-care (POC) settings (eg, cardiovascular operating room, intensive care unit, neonatal intensive care unit).	Monitoring unfractionated heparin and warfarin.	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.
Citrated whole blood.	Heparinized whole blood.	Fresh whole blood and citrated whole blood.	Whole blood.
Assess platelet function in the presence of antiplatelet therapy agents.	Provides quantitative measurements of chloride, ionized calcium, glucose, hematocrit, lactate, pH, pCO2, pO2, potassium, sodium, total bilirubin and CO-oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2) parameters from arterial, capillary, or venous heparinized whole blood.	Detects that the patient is in therapeutic range when using unfractionated heparin or warfarin.	Lactate for the detection and monitoring of sepsis; creatinine for kidney function testing.
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Dependent on assay, time to result is 3 to 5 minutes, post sample incubation. Results are displayed onscreen or via the manufacturer's optional printer.	Time to result is 45 seconds from sample aspiration, including time for sample-specific quality checks through iQM2 IntraSpect technology.	Dependent on assay, clinical application, and hospital-established target times.	Lactate results are available in 13 seconds; creatinine results are available in 30 seconds.
Throughput is between 10 and 15 tests per hour, depending on the assay.	Throughput is 29 tests per hour.	The system can perform 324 tests in 24 hours.	240 samples per hour.
1–2 hours.	All of the most skill- and labor-intensive aspects of blood gas testing and quality assurance are eliminated.	1–2 hours.	15 minutes.
24 hours a day technical support	24 hours a day technical support	24 hours a day technical support.	24/7 phone support.
Provides simple, rapid assessment of antiplatelet-therapy response; system is easy to use, fully contained, single-use, whole-blood testing device; no pipetting or sample handling required; results in less than 15 minutes	Features iQM2 IntraSpect technology; potential errors are detected before, during, and after sample analysis; real-time error correction and documentation.	Broadest menu for POC coagulation testing; fastest time to result; supports blood conservation protocols by requiring only 1–2 drops of whole blood.	For lactate screening, single-use lactate biosensors; 0.6 µL whole blood sample. For creatinine, assessment of renal function by fingerstick capillary blood sampling; 1.2 µL whole blood sample.

Nova Biomedical Waltham, Mass (781) 894-0800 www.novabiomedical.com	**Nova Biomedical** Waltham, Mass (781) 894-0800 www.novabiomedical.com	**Radiometer America** Brea, Calif (800) 736-0600 www.radiometeramerica.com	**Radiometer America** Brea, Calif (800) 736-0600 www.radiometeramerica.com
StatStrip Hospital Glucose Monitoring system	Stat Profile Prime Plus	ABL 80 Flex Series	ABL 90 Flex Plus
2006	2014	2011	2015
FDA 510(k), 2006.	FDA 510(k), 2018.	FDA 510(k); UL; CE mark.	FDA 510(k); UL; CE mark.
5.8 x 3 x 1.2 inches	18.2 x 14.2 x 15.5 inches	16 inches x 9 inches x 11 inches	17.7 inches x 9.8 inches x 11.4 inches
Intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary fingerstick blood, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heelstick specimens.	Intended for in vitro diagnostic use by healthcare professionals in clinical laboratory settings for the quantitative determination of BUN, Cl-, COHb, Creat, Glu, Hct, Hb, HHb, iCa, iMg, K+, Lac, MetHb, Na+, O2HB, PCO2, pH, PO2, SO2%, and TCO2 in heparinized whole blood.	Automated and portable in vitro diagnostic analyzer that measures blood gases, electrolytes, glucose, oximetry, and pH. Intended for use in laboratory, near-patient, or point-of-care settings.	Automated and portable in vitro diagnostic that measures bilirubin, blood gases, electrolytes, glucose, lactate, oximetry, and pH. Intended for use in laboratory, near-patient, or point-of-care settings.
Whole blood.	Whole blood.	Heparinized whole blood.	Heparinized whole blood.
Quantitative determination of glucose.	Multiple critical-care conditions.	Quantitatively measures blood gases, electrolytes, glucose, oximetry, and pH.	Quantitatively measures bilirubin, blood gases, electrolytes, glucose, lactate, oximetry, and pH.
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6 seconds.	60 seconds.	Results are available in 60–140 seconds, depending on the version; onboard color display and printer; electronic output to hospital information systems, laboratory information systems, and middleware.	Results are available in 35 seconds; onboard color display and printer; electronic output to hospital information systems, laboratory information systems, and middleware.
600 samples per hour.	Up to 45 samples per hour.	Flex and CO-oximetry offer 300 tests per cartridge, and can handle 26 samples per hour; oximetry-only (OSM) version offers 600 tests per cartridge, and can handle 60 samples per hour.	System offers 1200 tests per cartridge, and can handle 44 samples per hour.
15 minutes.	15 minutes.	Customized to the location's requirements.	Customized to the location's requirements.
24/7 phone support.	24/7 phone support.	Phone and onsite support with service engineer and clinical application specialists.	Phone and onsite support with service engineer and clinical application specialists.
First glucose meter system cleared by FDA for use with critically ill patients; single-use glucose biosensors; 1.2 µL whole blood sample; no known interferences; lab-like accuracy.	Maintenance-free MicroSensor cartridge technology; automated, true liquid quality control; disposable, non-lysing CO-oximeter technology; onboard bidirectional connectivity; remote review and control.	OSM features full battery operation; sensor cartridges range from 25 to 600 tests for up to 30 days; automatic quality management; built-in printer; color touchscreen.	Automatic quality control; full battery operation; up to 30 day in-use; high uptime of more than 22 hours per day; 65 µL sample volume for 17 acute-care parameters; automatic sample mixing.

Sekisui Diagnostics Burlington, Mass (781) 652-7800 www.sekisuidiagnostics.com	**Siemens Healthineers** Norwood, Mass www.usa.siemens.com/poc	**Trinity Biotech** Jamestown, NY (800) 325-3424 www.trinitybiotech.com	**Trinity Biotech** Jamestown, NY (800) 325-3424 www.trinitybiotech.com
FastPack IP system, produced by Qualigen for Sekisui Diagnostics	Epoc blood gas analyzer	UniGold Recombigen HIV-1/2 rapid kit	Syphilis Health Check
FastPack IP system; 2011	2007	2004	2011
CE mark; FDA 510(k), 2011.	FDA 510(k)	FDA PMA, 2004.	FDA 510(k), 2011.
9 inches x 13 inches x 12 inches	Host, 1.06 inches x 3.03 inches x 5.78 inches; reader, 2 inches x 3.35 inches x 8.46 inches	N/A	N/A
Delivers test results for diagnosing and monitoring disease states as well as replacement therapy.	A handheld, wireless solution that provides blood gas, electrolyte, and metabolite results at the patient's side in less than 1 minute.	Single-use rapid immunoassay for the qualitative detection of antibodies to HIV-1 or HIV-2.	Qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum, or plasma.
Serum only for free thyroxine (FT4); serum or plasma for all other tests.	Whole blood.	Test has CLIA waived complexity status for whole blood fingerstick and venipuncture samples, and moderate complexity status for serum and plasma samples.	Test has CLIA waived complexity status for whole blood fingerstick samples, and moderate complexity status for serum, plasma, and venipuncture whole blood samples.
Free thyroxine, human chorionic gonadotropin, prostate-specific antigen, sex hormone binding globulin (SHBG), testosterone, thyroid-stimulating hormone, and vitamin D.	Blood gases (pH, pCO2, pO2, TCO2), electrolytes (Ca++, Cl-, Hct, K+, NA+) and metabolites (BUN, creatinine, glucose, lactate).	Human immunodeficiency virus (HIV).	*Treponema pallidum* (syphilis).
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The system produces 5 to 8 tests per hour, depending on the assay mix.	Less than 1 minute.	Results in 10 minutes.	Results in 10 minutes.
Onboard internal quality control is run automatically each day; connects to laboratory information system software through RS232 port; set up through RelayMed software.	Approximately 3–4 minutes.	N/A	N/A
A Web-based training class takes 3 hours, and includes product and CLIA requirements.	N/A	Training is available.	Training is available.
Technical support is available on weekdays from 6 am through 5 pm PT, and on weekends from 8 am through 5 pm PT.	Phone support; warranty swap-out.	Technical support is available by phone 24/7.	Technical support is available by phone 24/7.
The first point-of-care analyzer performing quantitative immunoassay tests in the physician's office; physicians can obtain laboratory-quality immunoassay results for their patients in minutes.	Calibration is performed before the sample is introduced, eliminating wasted samples. Each room-temperature test card includes 13 critical tests; complete results can be transmitted wirelessly in less than 1 minute.	Each kit includes 20 tests. Picks up IgM and IgG antibodies for earlier detection at an affordable price; 100% sensitivity.	Each kit includes 20 tests. Can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. CLIA waived complexity status encourages wider availability and easier access.