

- 1) What is the name of your company's point-of-care (POC) product or product line?
- 2) What year did it first appear on the market?
- 3) What analytes does the test detect?
- 4) What diseases or conditions is the test used to manage?
- 5) What is the intended use of the test (check all that apply)?
- 6) This product is:
- 7) If you answered "other," explain briefly.
- 8) Where is this product used (check all that apply)?
- 9) If you answered "elsewhere," explain briefly.
- 10) Intended volume use:
- 11) What is the time to result under ideal conditions?
- 12) What is the typical training time?
- 13) What capabilities, features, or accessories distinguish this product from others on the market?

| Abbott Diabetes Care | Alere | BD Diagnostics |
|--|--|---|
| Alameda, Calif (877) 643-2098; www.abbottdiabetescare.com | Waltham, Mass (877) 262-4669; www.alere.com | San Diego (858) 795-7878; www.bd.com |
| FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring System | epoc Blood Analysis System | BD Veritor System |
| 2014 | 2006 | Flu A+B, 2011; Group A Strep, 2014 |
| Blood glucose and β-ketones | Analytes: pH, pCO ₂ , pO ₂ , Na+, K+, Ca++, Glu, Hct, Lac, Crea, Cl Calculated values: cHCO3-, cTCO ₂ , BE(ecf), BE(b), cSO ₂ , cHgb, eGFR, eGFR-a, AGapK | Group A Strep |
| Diabetes | Blood gas, electrolyte, and metabolite results | Pharyngitis |
| Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | ■ Detection/screening □ Diagnosis □ Measurement/monitoring □ Prediction/monitoring response to therapy |
| □ A self-contained POC test (requiring no equipment) □ A single-patient 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 POC analyzer □ Other | □ A self-contained POC test (requiring no equipment) ■ A single-patient test for use in POC equipment □ A POC analyzer □ Other |
| Requires meters and test strips | | |
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| | | Urgent care and retail clinic |
| ■ High volume ■ Intermediate or variable ■ Low volume | ■ High volume ■ Intermediate or variable ■ Low volume | ☐ High volume ■ Intermediate or variable ☐ Low volume |
| Blood glucose, 5 seconds; β -ketone, 10 seconds | About 30 seconds | Less than 7 minutes total from preparation to result |
| 1 day | 20 to 30 minutes or less of in-service time | Minutes |
| Hospital-grade monitoring system delivers improved Hematocrit performance; individually wrapped test strips that can be used in a no-touch procedure; real-time dual-band wireless; 1D and 2D barcode reader; removable test strip port. | The first cost-effective POC testing solution to leverage Smartcard technology and wireless communication to provide caregivers with real-time, lab-quality blood gas, electrolyte, and metabolite results at the patient bedside. The system is portable, customizable, and easily integrated into clinical workflow. | The first CLIA-waived digital immunoassay (DIA) for Group A Strep. The assay and instrument work together to combine advances in detection particles, optical image recognition, and interpretation algorithms to improve accuracy. This digital, rather than visual, test result provides greater consistency regardless of the user's experience. |

| BD Diagnostics San Diego (858) 795-7878; www.bd.com | Beckman Coulter Brea, Calif (800) 526-3821; www.beckmancoulter.com | Beckman Coulter Brea, Calif (800) 526-3821; www.beckmancoulter.com | Chembio Medford, NY (844) 243-6246; www.chembio.com |
|--|---|---|---|
| BD Veritor System | AU480 | AU680 | DPP HIV 1/2 Assay |
| Flu A+B, 2011; RSV, 2014 | 2009 | 2008 | 2012 |
| RSV | General chemistry, TDM, drugs of abuse, special proteins | General chemistry, TDM, drugs of abuse, special proteins | Antibodies to HIV-1, HIV-2 |
| Respiratory syncytial virus | General wellness, diabetes, malnutrition, therapeutic drug monitoring, thyroid, cardiac, lipidemia, metabolic disorders. | General wellness, diabetes, malnutrition, therapeutic drug monitoring, thyroid, cardiac, lipidemia, metabolic disorders. | HIV-1, HIV-2 infections |
| Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy |
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| Urgent care and retail clinic | | Small hospital, toxicology lab, veterinary lab | CLIA waiver pending; product is available for use in CLIA moderate-complexity settings |
| ☐ High volume ■ Intermediate or variable ☐ Low volume | ☐ High volume ☐ Intermediate or variable ■ Low volume | ■ High volume ■ Intermediate or variable □ Low volume | ■ High volume■ Intermediate or variable■ Low volume |
| Less than 11 minutes total from preparation to result | 4 to 10 minutes | 4 to 10 minutes | Blood, 15 minutes; oral fluid, 30 minutes |
| Minutes | 3 days | 4 days | Minimal |
| The first CLIA-waived RSV test referenced against a higher sensitivity standard than culture. Data suggest that it is often clinically difficult to distinguish between infections from influenza A and RSV and other respiratory viruses. The same sample processed for RSV can also be used for Flu A+B, thus providing three results in less than 11 minutes. | Small footprint, extensive menu (125 assays), STAT interrupt capability, high-performance ISE, low mean time between failure (MTBF). | Extensive menu (125 assays), STAT interrupt capability, high-performance ISE, low MTBF, integration options with automation and immunoassay. | For use with oral fluid, blood, serum, and plasma samples; sharp, distinct test/control lines; no oral fluid "overcollection" problems; soft, foam tip oral fluid collection swab; SampleTainer specimen collection bottle (a safe system for handling potentially infectious samples); open kit controls stability 24 months (50 control runs per vial). |



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| Hemosure Inc | MedMira Inc | Nova Biomedical |
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| Irwindale, Calif (888) 436-6787; www.hemosure.com | Halifax, Nova Scotia (902) 450-1588; www.medmira.com | Waltham, Mass (781) 894-0800; www.novabiomedical.com |
| Hemosure iFOBT (FIT) | Reveal G3 Rapid HIV-1 Antibody Test | Stat Profile Prime CCS |
| 1996 | 2006 | 2014 |
| Hemoglobin | Human serum or plasma | pH, PCO ₂ , PO ₂ , Na, K, Cl, iCa, Glu, Lac, Hct |
| Gastrointestinal bleeding in a number of GI disorders, including diverticulitis, colitis, polyps, and colorectal cancer | HIV-1 | Multiple critical care conditions |
| Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy |
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| | A self-contained, single-use POC test requiring either serum or plasma | |
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| | Used for occupational exposures, urgent labor and delivery screening, and in emergency departments. Well suited for use in hospitals and laboratories, and ideal for batch testing. | |
| ■ High volume■ Intermediate or variable■ Low volume | ■ High volume □ Intermediate or variable □ Low volume | ■ High volume■ Intermediate or variable■ Low volume |
| 5 minutes | 2 minutes | 60 seconds |
| 15 to 30 minutes | Approximately 30 minutes | 15 minutes |
| Known for quality, accuracy, and reliability. Benefits include: the test that is replacing the Guaiac-based test as the recommended test; specific to human hemoglobin; no dietary or medication restrictions; higher compliance; offers the correct level of sensitivity and specificity; reduces false positives; simple, clear, easy-to-read test results in 5 minutes. | Built on patented Rapid Vertical Flow technology; the Reveal G3 is the fastest point-of-care rapid HIV-1 test available. Results are delivered in three steps with 99.9% sensitivity and 99.8% specificity. Delivers results 10x faster than competitors and does not require any specialized equipment or training. | ZERØ maintenance microsensor cartridge technology; fast results; throughput of up to 45 samples per hour; automated; true liquid control quality. |

| Nova Biomedical Waltham, Mass (781) 894-0800; www.novabiomedical.com | Radiometer America Inc Westlake, Ohio (800) 736-0600; www.radiometeramerica.com | Radiometer America Inc Westlake, Ohio (800) 736-0600; www.radiometeramerica.com | Separation Technology Inc Sanford, Fla (800) 777-6668; www.separationtechnology.com |
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| StatStrip Hospital Glucose Monitoring System | ABL90 Flex analyzer | ABL80 Flex series of analyzers (ABL80 Flex; ABL80 Coox; ABL80-OSM) | HemataSTAT II |
| 2006 | 2010 | 2006 | 1993 |
| Glucose | Multi-test sensor cassette tests: pH, pCO ₂ , pO ₂ , K+, Na+, Ca++, Cl-, Glu, Lac, sO ₂ , tHb, O ₂ Hb, COHb, MetHb, HHb, HbF, and currently 48 calculated parameters | Multi-test sensor cassette tests: pH, pCO ₂ , pO ₂ , K+, Na+, Ca++, Cl-, Glu, sO ₂ , tHb, O ₂ Hb, COHb, MetHb, HHb, and currently 30 calculated parameters | Hematocrit |
| Dysglycemia | Respiratory/metabolic acidosis and alkalosis; electrolyte balance; diabetes; sepsis; idiopathis, absorptive, or renal hypercalciuria; hemoglobin and Hgb abnormalities | Respiratory/metabolic acidosis and alkalosis; electrolyte balance; diabetes; sepsis; idiopathis, absorptive, or renal hypercalciuria; hemoglobin and Hgb abnormalities | Anemia, blood loss |
| Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy | Detection/screening Diagnosis Measurement/monitoring Prediction/monitoring response to therapy |
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| Emergency first responder | | | Blood donor screening, veterinary, field use |
| ■ High volume■ Intermediate or variable■ Low volume | ■ High volume ■ Intermediate or variable □ Low volume | ☐ High volume ■ Intermediate or variable ■ Low volume | ☐ High volume ■ Intermediate or variable ☐ Low volume |
| 6 seconds | 35 seconds | 70 seconds | 1 minute, 15 seconds |
| 30 minutes | End user, 1 hour; administrative operator, 3 hours | End user, 1 hour; administrative operator, 3 hours | 20 minutes |
| Rapid screening; single-use glucose biosensors; 1.2 µL whole blood sample; results in 6 seconds; no known interferences; lab-like accuracy validated in over 100 clinical studies worldwide. | Multi-test cassette lasts 30 to 60 days; 35 seconds to results on 65 µL sample; 44 to 55 per hour throughput; easy to use; walk-up ready; one-handed operation; integrated user guides; no user maintenance; automatic quality management supports regulatory compliance; automatically performs continuous checks and corrective actions. | Portable, true battery operation (runs patient samples on battery); fast start-up, warm-up, and analysis time; simple and easy-to-use system; multi-test cassette lasts 30 to 60 days; various models to meet clinical needs (eg, ABL80-OSM version is an oximetry platform to meet the specific needs of the cath lab). | Spins up to six samples in 1 minute. Built-in digital tube reader. Quiet, LCD display of user prompts and results. Optional rechargeable battery for field use. Whole blood controls available requiring no refrigeration and with a 2-year shelf life. Low cost per test. |

| Sekisui Diagnostics | Siemens Healthcare Diagnostics | Stanbio Laboratory, an EKF Diagnostics company | Trinity Biotech |
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| Lexington, Mass (800) 332-1042; www.sekisuidiagnostics.com | Tarrytown, NY (877) 229-3711; www.usa.siemens.com/ diagnostics | Boerne, Tex (800) 531-5535; www.stanbio.com | Jamestown, NY (800) 325-3424; www.trinitybiotech.com |
| OSOM Rapid Tests | RapidPoint 500 System | Uri-Trak 120 Analyzer | UniGold Recombigen HIV-1/2 Rapid test |
| 2000 | 2012 | 2011 | 2004 |
| Strep A, influenza, mono, trichomonas, bacterial vaginosis, hCG, <i>H. pylori</i> | pH: pCO ₂ , pO ₂ ; Electrolytes: Na+: K+, Ca++, Cl-; Metabolites: glucose, lactate; CO-oximetry tHb: sO ₂ , O ₂ Hb, HHb, COHb, MetHb, neonatal total bilirubin; Pleural fluid pH: Na+, K+, Ca++, Cl-, pH, pCO ₂ | Urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, blood, specific gravity, leukocytes | HIV-1/2 |
| Strep A, influenza, mono, trichomonas, bacterial vaginosis, hCG, <i>H. pylori</i> | Critical care testing | General medical health assessment | HIV |
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| | Freestanding emergency departments and surgical centers | | |
| ■ High volume■ Intermediate or variable■ Low volume | ■ High volume ■ Intermediate or variable ■ Low volume | ☐ High volume ■ Intermediate or variable ☐ Low volume | ■ High volume ■ Intermediate or variable ■ Low volume |
| 5 to 10 minutes | Approximately 60 seconds to result | 1 minute | 10 minutes |
| 10 minutes | Varies based on customer experience level and need | < 30 minutes | 1 hour |
| Technical support and online training at www.osomtraining.com. | Equipped with v2.2 software, new and upgraded RapidPoint 500 blood gas systems support ventilator settings, custom demographic fields, and multibyte characters. Connectivity capabilities have been expanded to support dual-port transmission and wireless roaming. The RapidPoint 500 system also now extends pleural fluid pH testing to the US market. | Urine analyzer offering advanced technology providing accurate, consistent, economical, and easy-to-read results. | The only CLIA-waived rapid HIV screening test in a third-generation format that picks up IgM and IgG; provides 100% sensitivity in two steps; results in 10 minutes; affordable price. |