tech guide

Point-of-Care Assays and Analyzers

	BD Sparks, MD (800) 638-8663; www.BD.com	**bioMérieux** Salt Lake City, UT (385) 382-4318 deborah.pitt@biomerieux.com www.biofiredx.com/products/filmarray/spotfire-system	**Cardinal Health** Dublin, OH www.cardinalhealth.com
1. What is the brand name of your company's POC assay or analyzer?	Veritor Plus System	BIOFIRE SPOTFIRE Respiratory Solution: BIOFIRE SPOTFIRE Respiratory Panel (15 pathogens); BIOFIRE SPOTFIRE Respiratory Panel Mini (5 pathogens)	Cardinal Health Urinalysis Analyzer
2. What year was your named product first released to market?	2017	2023 US	2020, US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA, 2017, CE Mark 2017	FDA 510(k) clearance, CLIA waiver	TUV CE Mark, 2018; FDA 510(k) and CLIA-waiver, 2018
4. What are the dimensions of the named product (H x W x D, in inches)?	2" x 3" x 4"	Variable Height depending on number of modules (up to 4 modules), 8.5' width, 12.75' depth	3" x 7.5" x 9"
5. What is the intended use or primary function of the product?	Point-of-care applications	Diagnosing in the point-of-care	Reads Cardinal Health urine test strips, including microalbumin and creatinine urine strips, and calculates the albumin-to-creatinine ratio
6. What type of specimen/sample does the product employ?	Influenza and RSV tests can use nasal swab, nasopharyngeal swab, washes or aspirates; SARS-CoV-2 requires a nasal swab; and Group A Strep requires a throat swab.	Nasophayngeal swab (NPS)	Urine (random, first morning, midstream all acceptable)
7. What types of diseases, conditions, or analytes does the assay detect?	Flu A and B; SARS-CoV-2; RSV; Group A Strep	Upper Respiratory Tract Infection	Albuminuria, diabetes monitoring, kidney disease, urinary tract infection, and other renal, urinary, and metabolic disorders.
8. This product is:	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A multiplexed test for use in POC equipment ■ A POC analyzer	■ A POC Analyzer
10. Under ideal conditions, what is the time to first result; how are the test results made available?	SARS-CoV-2 test requires 15 minutes; Flu and RSV tests require 10 minutes; Group A Strep requires 5 minutes	~15 minutes	90 seconds or less (5 seconds on Quick Test Mode); results are displayed on LCD screen and printed on internal thermal printer
11. What are the product's maximum capacity and throughput under ideal conditions?	Instrument allows for batching; 10 Flu tests in under 20 minutes with Analyze Now mode, 24 SARS-CoV-2 tests per hour	Utilizing 4 modules, the SPOTFIRE system can run 104 tests in an 8 hour shift.	600 tests/hr under Quick Test Mode 36 tests/hr under Routine Test Mode
12. What is the typical training time for the product?	30 min	2-4 hours	Can operate without additional training.
13. What types of technical support are available?	Phone and onsite	Skilled team dedicated to customer success, providing product support, solution training courses, connectivity assistance, and instrument or chemistry related troubleshooting. Customer technical support is available 24 hours a day, 7 days a week.	Lifetime customer service and tech support provided by phone/email; Step-by-step quick reference guide; Videos on the website.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Portable, one-button operation and no-fuss workflow, displays easy-to-read digital results for multiple RTIs. Adapts easily to your workflow with 2 operational modes: Walk Away and Analyze Now and No calibration or maintenance required. Traceability, recording and reportability of results with BD InfoWifi and BD Synapsys connectivity.	Rapid answers (~15 minutes), small footprint, vertically scalable, multiple test on one system, Intutitive System interface, seamless connectivity, state-of-the-art cybersecurity, minimal maintenance.	Ultra-compact size with CLIA-waived certification; Quick Test Mode (5 seconds to result); automatically calculates the microalbumin-to-creatinine ratio (ACR); Cardinal UA10ACR strip provides maximum reimbursement for one single urine strip: 3 CPT codes (81003, 82044, 82570)

Carolina Liquid Chemistries Greensboro, NC (877) 722-8910 contactsales@ carolinachemistries.com www.carolinachemistries.com	**EKF Diagnostics** Cardiff, UK 0044 (0)2920 710570 info@ekfdiagnostics.com www.ekfdiagnostics.com	**EKF Diagnostics** Cardiff, UK 0044 (0)2920 710570 info@ekfdiagnostics.com www.ekfdiagnostics.com	**EKF Diagnostics** Cardiff, UK 0044 (0)2920 710570 info@ekfdiagnostics.com www.ekfdiagnostics.com
RYAN Immunofluorescence Analyzer/ Fentanyl Urine Detection Test	STAT-Site WB	DiaSpect	Hemo Control
2023	2021	2017 (OUS); 2021 (US)	2015 (OUS); 2021 (US)
FDA 510(k); CLIA categorization as moderate complexity; Point-of-Care	FDA 510(k)	TUV CE Mark, 2017; FDA 510(k), 2021	TUV CE Mark 2015; FDA 510(k), 2021
6.25" x 11" x 11"	95.5mm x 57mm x 15mm	70mm x 90mm x 150mm	160mm x 160mm x 68mm
Point-of-care qualitative screen for fentanyl in human urine at a cutoff concentration of 1.0 ng/mL.	Used for the quantitative determination of β-ketones (Beta-Hydroxybutyrate or βHB) and glucose in capillary and venous blood. Intended for whole blood multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.	Intended for the semi-automated measurement of hemoglobin in capillary whole blood and venous whole blood (K2EDTA or lithium heparin) using the DiaSpect hemoglobin cuvettes. For screening, monitoring and as an aid in the diagnosis of anemia.	Intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood. Using the reagent filled microcuvette a small amount of arterial, venous or capillary blood is used for the determination.
Urine	1µl venous and capillary whole blood	Whole blood	Whole blood
Fentanyl	Diabetes Type 1 and Type 2 and the analytes of glucose and β-ketone.	Anemia	Anemia
■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A POC analyzer
< 6 minutes	β-ketone result in 10 seconds Glucose result in 5 seconds	The test result appears on the screen in less than two seconds.	The test result appears on the screen in 25-60 seconds depending on Hb concentration.
It is estimated an operator could perform up to 40T/hr under ideal conditions using "Quick Test Mode."	N/A	N/A	N/A
30 minutes	30 minutes	One hour	One hour
Hotline available 8:00 am–8:00 pm ET.	Support team is contactable via email, telephone and through contact form	Support team is contactable via email, telephone and through contact form	Support team is contactable via email, telephone and through contact form
Point-of-care, rapid test result for fentanyl. Easy-to-use, compact and portable, requiring no additional equipment. Connect with USB, WLAN, and LIS. FDA cleared and categorized.	The STAT-Site WB is used for the quantitative determination of β-ketones (Beta-Hydroxybutyrate or βHB) and glucose in capillary and venous blood. The STAT-Site WB is intended for whole blood multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.	DiaSpect is powered by EKF Link enabling state-of-the-art middleware functionalities including LIS/HIS integration; the analyzer is palm-sized, making it easily transportable and ideal for use in any screening setting.	Hemo Control is powered by EKF Link enabling state-of-the-art middleware functionalities including LIS/HIS integration; a barcode scanner and printer can be attached to enable a streamline workflow.

GenBio San Diego, CA (858) 592-9300 fadler@genbio.com www.genbio.com	**Helena Laboratories** Beaumont, TX. USA (800) 231-5663 www.helena.com	**HemoCue America** Brea, CA; Angelholm, Sweden (Global) (800) 881-1611 hemocue.us; web@hemocue.com	**HemoCue America** Brea, CA; Angelholm, Sweden (Global) (800) 881-1611 hemocue.us; web@hemocue.com
ImmunoFLOW	Actalyke Mini II	HemoCue Hb 801 System	HemoCue Hb 201 DM System
2022	2003	2019	2009
FDA registration, EU CE mark	FDA 510(k), 2003; CE mark, 2003	IVD Medical Device Directive 98/79/EC and carries the CE mark. FDA 510K, 2019	IVD Medical Device Directive 98/79/EC and carry the CE mark. FDA 510K, 2009
0.25" x 1.5" x 1.25"	6" x 6" x 6"	3.4"x5.6"x1.8"	6.70" × 3.66" × 1.97"
Mycoplasma pneumoniae IgM antibody detection for Mycooplasma respiratory disease detection	Heparin monitoring	Intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K2 EDTA and Li-Heparin) in point-of-care settings; for professional in vitro diagnostic use only.	Quantitative determination of hemoglobin in capillary, venous and arterial whole blood, using a specially designed analyzer, and specially designed microcuvettes; for In Vitro Diagnostic use only.
Serum	Whole Blood	Capillary or venous whole blood	Capillary, venous or arterial whole blood
Mycoplasma pneumonia infection	Activated clotting time	Anemia	Anemia
■ 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	■ A POC analyzer	■ A POC analyzer
Simple self contained flow through device cartridge complete in minutes with IgM Mycoplasma pneumoniae test results	90-1500 sec Patient Dependent	Measuring time < 1 second, digital readout	Measuring time 15-60 seconds, digital readout
One device per patient packaged in 25 devices per kit	20 tests/hour	1.0–25.6 g/dL (10–256 g/L, 0.62–15.9 mmol/L)	0-25.6 g/dL (0-256 g/L, 0-15.9 mmol/L)
minutes	1 day	Onsite or online training available, 30 minutes	Onsite or online training available, 2 hours
website (You Tube) and phone technical service	Technical and electronic support 24/7	In-person training, servicing, and maintenance. US-based customer service and technical support available daily offering One-Touch Resolution of inquiries. OnCue Education portal with learning modules, and training certification available 24/7.	In-person training, servicing, and maintenance. US-based customer service and technical support available daily offering One-Touch Resolution of inquiries. OnCue Education portal with learning modules, and training certification available 24/7.
Almost no available POC for Mycoplasma pneumonia to add to your POC respiratory disease tests like COVID or influenza	The gold standard of ACT testing. A variety of activators available including a celite tube, kaolin tube, glass beads tube, and a hybrid tube with all three.	Backed by 40 years of clinically proven performance and complimentary service and support.	Backed by 40 years of clinically proven performance and complimentary service and support. Unidirectional & bi-directional connectivity available through middleware.

FAST. EASY. RELIABLE.

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HemoCue Hb 201+ System	HemoCue WBC System	Quantra Hemostasis System with QPlus & QStat Cartridges	LumiraDx Platform
1986	2008	2017 CE mark. 2019, US (De Novo marketing authorization).	2020, US; 10/10/2020
IVD Medical Device Directive 98/79/EC and carry the CE mark. FDA 510K, 1986	IVD Medical Device Directive 98/79/EC and CE mark. FDA 510K	Quantra QPlus System CE mark, 2017; FDA De Novo marketing authorization for Quantra QPlus System, 2019; CE mark for Quantra QStat cartridge, 2019; FDA 510k approval for Quantra QStat cartridge, 2022.	CE Mark 11/10/2018 FDA EUA, 8/16/2020;
6.0" × 3.35" × 1.69"	7.05" × 5.24" × 4.76"	19.25" x 14" x 12"	2.87" x 3.82" x 8.27"
Quantitative determination of hemoglobin in capillary, venous and arterial whole blood, using a specially designed analyzer, and specially designed microcuvettes.	Indicated for use for quantitative determination of WBC count in capillary or venous whole blood; for in vitro diagnostic use only. Indicated for use in clinical laboratories and for point-of-care settings	In vitro diagnostic testing that characterizes hemostasis in a variety of acute care clinical settings.	In vitro diagnostic analysis in laboratory, near-patient, or point-of-care settings
Capillary, venous or arterial whole blood	Capillary or venous (EDTA) whole blood	Whole blood	Nasal swab; nasopharyngeal swab; capillary whole blood; anticoagulated venous whole blood and plasma; Serum
Anemia	Detect infection	Evaluates blood coagulation in perioperative patients age 18 years+ to assess possible hypocoagulable and hypercoagulable conditions.	SARS-CoV-2 Ag single and pooling test; SARS-CoV-2 Ab; Combo SARS-CoV-2/FLU A/b and SARS-CoV-2/RSV; CRP; D-Dimer; INR; NT-proBNP; HbA1c (not every product available in all regions)
■ A POC analyzer	■ A POC analyzer	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A single-patient test for use in POC equipment ■ A multiplexed test for use in POC equipment ■ A POC analyzer
Measuring time 15-60 seconds, digital readout	Within 3 minutes, digital readout	Typically 15 minutes or less	<90 seconds to 12 minutes depending on test type. Results are displayed on the instrument touchscreen with option to print or report through electronic interface to EMR/LIS
0-25.6 g/dL (0-256 g/L, 0-15.9 mmol/L)	0.3-30.0 × 109/L (300-30000/mm(3), 300-30000/µL)	Up to 5 single-cartridge tests per instrument per hour.	One test at a time. Some tests are multiplex or have sample pooling capabilities. Time results varies by test.
Onsite or online training available, 1 hour	Onsite or online training available, 1 hour	30 minutes to 1 hour.	CLIA Waived: Self training; Instructor lead training ≈ 30 minutes
In-person training, servicing, and maintenance. US-based customer service and technical support available daily, offering one-touch resolution of inquiries. OnCue Education portal with learning modules, and training certification available 24/7.	In-person training, servicing, and maintenance. US-based customer service and technical support available daily, offering one-touch resolution of inquiries. OnCue Education portal with learning modules, and training certification available 24/7.	Standard service includes a hotline and technical support weekdays 9 am to 5 pm ET. Emergency telephone and pager support available 24/7. Additional full service options available.	Extensive technical support available. Dedicated technical support team that can be reached by toll-free phone or email. Onsite support with service engineers and clinical application specialists. An online customer care portal.
Backed by 40 years of clinically proven performance and complimentary service and support.	Backed by 40 years of clinically proven performance and complimentary service and support.	Uses ultrasound to measure the shear modulus of whole blood during coagulation. Blood sample is tested without contact with moving parts or exposure to air, for accurate estimation of the relative contributions of platelets and fibrinogen to clot stiffness.	Results in 35 seconds on 65 ul sample volume for 17 acute-care parameters, automatic QC and peer QC network, full battery operation, uptime >22 hours/day, multiple testing modes such as syringe and capillary, automatic sample mixing, automatic data entry, and barcode scanning.

Nova Biomedical Waltham, MA (800) 458-5813 www.novabiomedical.com info@novabio.com	**Nova Biomedical** Waltham, MA (800) 458-5813 www.novabiomedical.com info@novabio.com	**Nova Biomedical** Waltham, MA (800) 458-5813 www.novabiomedical.com info@novabio.com	**Radiometer America** Brea, CA (800) 736-0600 www.radiometeramerica.com
Prime Plus Analyzer	Prime ES Analyzer	Prime CCS Analyzer	ABL90 FLEX PLUS
2018	2017	2014	2015
FDA 510(k) 2018; CE Mark 2017	FDA 510(k) 2018; CE Mark 2017	FDA 510(k) 2014	FDA 510(k), UL, CE mark, EMC emission, EMC immunity
18.0' X 14 .0" X 1 5.4'	15.4" X 1 2.0' X 14.4"	15.4" X 1 2.0' X 14.4"	17.7″ x 9.8″ x 11.4″
Point of care blood gas, electrolyte, metabolite and co-oximetry testing	In vitro diagnostic analyzer used by healthcare professionals in clincial laboratory settings	Point of care blood gas, electrolyte, metabolite testing	Automated and portable in vitro diagnostic analyzer. Intended for use in laboratory, near-patient, or point-of-care settings.
Whole blood (heparinized)	Whole blood (heparinized), serum, plasma	Whole blood (heparinized)	Heparinized whole blood
Detects multiple critical care conditions. Test menu: pH, pCO_2, pO_2, SO_2%, Na, K, Cl, TCO_2, iCa, iMg, glucose, lactate, creatinine, urea/BUN, tHb, Hct, MCHC, estimated plasma volume(ePV), CO-Ox panel	Provide full assessment of electrolyte balance important in maintaining normal cardiac function. Test menu includes: Na, K, Cl, iCa, iMg, pH, Hct	Detects multiple critical care conditions. Test menu includes: pH, pCO_2, pO_2, SO_2%, Na, K, Cl, TCO_2, iCa, iMg, glucose, lactate, cHb, Hct	Quantitatively measures bilirubin, blood gases, electrolytes, glucose, lactate, oximetry, and pH.
■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A POC analyzer
About 60 seconds to first result. Results are presented by digital display, printed report and NovaNet which is utilized by over 2/3 of US hospitals.	About 60 seconds to first result. Results are presented by digital display, printed report and NovaNet which is utilized by over 2/3 of US hospitals.	About 60 seconds to first result. Results are presented by digital display, printed report and NovaNet which is utilized by over 2/3 of US hospitals.	35 seconds; color display and paper printout; electronic output to hospital or lab information systems and middleware
Up to 45 samples/990 tests per hour	Up to 60 samples/420 tests per hour	Up to 45 samples/450 tests per hour	Up to 1,200 tests per cassette, 44 samples/hour testing for full panel of analytes
30 minutes	30 minutes	30 minutes	1 hour (customizable to location's requirements)
Dedicated technical support team accesible via telephone 24x7x365, onsite comprehensive service.	Dedicated technical support team accesible via telephone 24x7x365, onsite comprehensive service.	Dedicated technical support team accesible via telephone 24x7x365, onsite comprehensive service.	Dedicated technical support team that can be reached by toll-free phone or email. Onsite support. An online Customer Care portal that provides product documentation, technical tools, and educational resources.
Comprehensive and flexible blood gas/critical care test menu. Up to 22 tests, including unique tests for ePV and iMg available from one drop of blood. Maintenance free MicroSensor cards and cartridges. Onboard automated quality control which provides efficiency for staff and eliminates the need for IQCP	Provides full assessment of electrolyte balance important in maintaining normal cardiac function. Test menu includes: Na, K, Cl, iCa, iMg, pH, Hct. Ten-position sample tray accomodates serum and plasma samples in 2.0 and 0.5 ml sample cups.	Essential 10 test critical care menu available from one drop of blood. Maintenance-free MicroSensor cards and cartridges. Onboard automated quality control which provides efficiency for staff and eliminates the need for IQCP.	65 ul sample volume, 17 measured parameters, automatic QC and peer QC network, battery operation capable, uptime >22 hours/day, syringe and capillary testing modes, automatic sample mixing, automatic data entry and barcode scanning, advanced cybersecurity and application control, remote service and support, portable with rolling stand

Randox Laboratories United Kingdom (0) 28 9442 2413 www.randox.com	**Randox Laboratories** United Kingdom (0) 28 9442 2413 www.randox.com	**Roche Diagnostics** Indianapolis, IN (317) 521-2000 indianapolis.poc_caremail@roche.com www.roche.com/solutions/diagnostics/	**Roche Diagnostics** Indianapolis, IN (317) 521-2000 indianapolis.poc_caremail@roche.com www.roche.com/solutions/diagnostics/
VeraSTAT	Vivalytic	CoaguChek XS Plus	CoaguChek XS
2021	2019	2012	2006
CE Mark	CE Mark (2019)	K180684	K060978
6.3" x 7.3" x 9.8"	15.7" x 8.0" x 15.2"	7.28" (L) x 3.82" (W) x 1.70" (H)	5.43" (L) x 3.07" (W) x 1.10" (D)
Point-of-care laboratory diagnostics	Enables sample to answer, cartridge-based molecular diagnostic testing; capable of both hi-plex and lo-plex testing. Nucleic acid extraction, PCR amplification.	Intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek XS Plus system is capable of connecting to a DMS.	Intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy.
Whole blood or serum	Nasopharyngeal or oropharyngeal swabs, swab (cultures, wounds, axilla, groin and perineum), sputum, & urine.	The system uses fresh capillary or non-anticoagulated venous whole blood.	The system uses fresh capillary or non-anticoagulated venous whole blood.
Flexible test menu comprising a range of immunoassay, protein, inflammatory, diabetes & infectious disease markers.	Test menu covering a diverse range of respiratory, genitourinary, and hospital acquired infections, including SARS-CoV-2 (COVID-19).	Measures a patient's International Normalized Ratio (INR).	Measures a patient's International Normalized Ratio (INR).
■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A POC analyzer
Results displayed on screen in as little as 6 minutes. Bluetooth connectivity allows results to be exported.	Time to result is assay dependent. Results will be displayed on the Vivalytic touchscreen as either quantitative or qualitative.	The meter displays the results in about one minute. The meter automatically stores the test result, together with date/time and patient ID to memory.	The meter displays the results in about one minute. The meter automatically stores the test result, together with date/time and patient ID to memory.
One patient sample/cassette at one time.	One patient sample/cartridge at one time. In 8 hours can test up to a maximum of 10 patient samples/cartridges; assay dependent.	Under ideal conditions, is able to store 2,000 patient and 500 QC results with date and time.	Under ideal conditions, is able to store up to 300 test results with date and time.
1 Day	Less than 4 hours	The product is CLIA Waived.	The product is CLIA Waived.
Technical support is accessible via telephone, email and video calling applications.	Technical support is accessible via telephone, email, and video calling applications.	If you or your patients have questions, live technical support is available by phone. 1-800-428-4674	If you or your patients have questions, live technical support is available by phone. 1-800-428-4674
The VeraSTAT is a portable point of care device which delivers rapid results via the use of patented cathodic electrochemiluminescence technology. All necessary reagents are conveniently included in each single use, sealed cassette with no preparation required. Intuitive user interface guides the operator through the entire testing process.	Vivalytic is a lightweight near patient system which consolidates the complex molecular workflow into a fully automated process. It is a closed system to reduce the risk of contamination. The Vivalytic user is only required to complete four easy steps to run a test.	CoaguChek technology reduces heparin interference for more accurate results. The monitoring portfolio offers a single-strip platform for consistency in PT/INR results across the care continuum. It's the only system with a 97% correlation to the lab using a single-strip platform, which means providers can count on consistent and accurate results.	The CoaguChek XS meter is designed for comfort, convenience, and easy reporting. With the CLIA waived CoaguChek XS system, accuracy and convenience are right at hand. This small, handheld, battery-powered meter is ideal for low- to mid-volume office settings. Plus, you can test and treat in one appointment using the fingerstick test that patients prefer.

Roche Diagnostics Indianapolis, IN (317) 521-2000 indianapolis.poc_caremail@roche.com www.roche.com/solutions/diagnostics/	**Roche Diagnostics** Indianapolis, IN (317) 521-2000 indianapolis.poc_caremail@roche.com www.roche.com/solutions/diagnostics/	**Siemens Healthineers** Norwood, MA (781) 688-0350 siemens-healthineers.us/epocnxs	**Siemens Healthineers** Norwood, MA (781) 688-0350 siemens-healthineers.us/rapidpoint500e
Urisys 1100	cobas liat	epoc Blood Analysis System	RAPIDPoint 500e Blood Gas System
2003	2015	US 2007	US 2020
K033548	K111387	FDA 510(k) 2006	FDA 510(k) 2020
5.9" x 11.4" x 3.7"	9.5" x 4.5" x 7.5"	2.83" X 3.35" X 8.46"	21.5" X 11.5" X 16.0"
Is a semi-automated hand held urine testing analyzer for a workload of up to 50 urine samples per day and is designed to improve workflow efficiency in smaller labs, doctor offices and decentralized lab settings like point-of-care.	Is designed to do a PCR analysis on a patient sample; fully automates workflow for the rapid analysis of a single sample, making it ideal for time-sensitive in-office diagnoses.	Point-of-care testing of 13 measured parameters	Point-of-care testing of blood gas, electrolyte, metabolite and co-oximetry parameters
The analyzer collects a urine sample.	Strep A: throat swab; Influenza A/B & RSV: nasopharyngeal swab; SARs-CoV-2: nasopharyngeal swab, nasal swab; SARs-CoV-2 & Influenza A/B: nasopharyngeal swab, nasal swab; C. difficile: fecal swab	Whole blood: arterial, venous, capillary	Whole blood: arterial, venous, mixed venous, capillary and pleural fluid
Used for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood in urine.	Allows you to detect and identify SARS-CoV-2, SARS-CoV-2 & Influenza A/B, Influenza A/B & RSV, Group A Strep, and C. Difficile		
■ A multiplexed test for use in POC equipment ■ POC analyzer	■ A multiplexed test for use in POC equipment ■ POC analyzer	■ A POC analyzer	■ A POC analyzer
Each test pad is read photometrically after about 55–65 seconds.	An accurate positive or negative result is generated in 20 minutes or less.	Less than one minute. Results are displayed on the touchscreen and may be transmitted wirelessly to the LIS/HIS and/or a Bluetooth compatible printer	Approximately one minute. Results are displayed on the touchscreen and may be transmitted to the LIS/HIS
Results can be printed, stored on the meter, or sent to a DMS.	Results can be printed, stored on the meter, or sent to a DMS.	Approximately one sample every 4 minutes	Approximately one sample every 2 minutes
The product is CLIA Waived.	The product is CLIA Waived.	Varies based on role	Varies based on role
If you or your patients have questions, live technical support is available by phone. 1-800-428-4674	If you or your patients have questions, live technical support is available by phone. 1-800-800-5973	Onsite, phone, and online	Onsite, phone and online
The CLIA-waived Urisys 1100 urine analyzer makes testing fast and automatic. With the push of a button, it evaluates the test strip and prints a patient report. Compared to visual testing, this can help make your lab operations more efficient and give busy staff more time for other things.	The high PCR sensitivity and specificity achieved with the cobas liat System enables patients and clinicians to have reassurance in their diagnostic results at all points of care in 20 minutes or less, across a growing menu of assays.	The epoc Blood Analysis System measures 13 parameters on a single room temperature stable test card in less than 1 minute at the patient's bedside. The epoc BGEM (blood gas, electrolytes, metabolites) test card may help reduce the overall costs associated with purchasing and storing multiple cartridges required for other handheld testing systems.	The RAPIDPoint 500e features a maintenance-free design with automated sample integrity checks and three levels of truly independent automatic quality control delivering confidence with every patient result. The unique hands-free sample port and a 24-minute cartridge initialization time enhance ease of use and help maximize analyzer uptime.

Siemens Healthineers Norwood, MA (781) 269-3000 www.siemens-healthineers.com/en-us/diabetes/diabetes/dca-vantage-analyzer	**Visby Medical** San Jose, CA (883) 468-4729 support@visby.com visbymedical.com	**Werfen** Bedford, MA (800) 955-9525 werfen.com	**Werfen** Bedford, MA (800) 955-9525 werfen.com
DCA Vantage Analyzer	Visby Medical Respiratory Health Test	GEM Premier ChemSTAT with iQM basic metabolic panel testing system	GEM Premier 5000 with iQM2 blood gas testing system
US 2007	2022 (US)	US: 2020; OUS: 2019	US: 2017; OUS: 2016
FDA 510(K) 2006	FDA EUA 2022	2019: FDA 510(k) clearance, OUS CE mark	FDA 510(k)-clearance, 2016; OUS CE mark, 2015; NMPA, 2019; Health Canada license, 2020
"7.5"" X 6.7"" X 10.7""	1.5" x 5.5" x 2.5"	18.5" x 13.1" x 16.3"	18.6" x 13.0" x 16.4"
Point-of-care testing for HbA1c monitoring and ACR testing for chronic kidney disease	a single-use (disposable), fully integrated, rapid, automated RT-PCR in vitro diagnostic test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA	Point-of-care testing in acute care and laboratory settings.	Blood gas testing at the point-of-care and laboratory settings.
Whole blood, capillary blood, and urine for ACR	Healthcare provider-collected nasopharyngeal and anterior nasal swab specimens, and healthcare provider-instructed self-collected anterior nasal swab specimens (collected on site)	Lithium-heparinized whole blood	Heparinized whole blood
Diabetes HbA1c (monitoring) CKD (Microalbumin and Creatinine)	Respiratory tract infection consistent with COVID-19 and / or Influenza	The instrument provides quantitative measurements of Na+, K+, Ca++, Cl-, Glu, Lac, Hct, Crea, BUN, tCO2, pH, and pCO2 from arterial and venous heparinized whole blood.	Provides quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and co-oximetry parameters from arterial, venous or capillary heparinized whole blood. Aids in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen-delivery capacity. tBili measurements are used to aid in the assessment of neonatal hyperbilirubinemia only.
■ A POC analyzer	■ A POC analyzer A self-contained POC test (requiring no equipment)	■ A POC analyzer	■ A POC analyzer
About 6 minutes displayed on screen or printed	<30 minutes; visual interpretation on the test device detection window	70 seconds. Results can be viewed on the analyzer screen, printed, or through GEMweb Plus 500 Custom Connectivity or in the LIS, upon data transmission.	45 seconds. Results can be viewed on the analyzer screen, printed, or through GEMweb Plus 500 Custom Connectivity or in the LIS, upon data transmission.
About 10 tests an hour for HbA1c. About 8 tests an hour for ACR.		Throughput = 16 samples/hour.	Throughput = 29 samples/hour
30 minutes	30 minutes	Training is simple, with the all-in-one GEM PAK cartridge, no-maintenance analyzer with an intuitive user interface and simple sampling, and a quality management system (iQM)	Training is simple, with the all-in-one GEM PAK cartridge, no-maintenance analyzer, and a quality management system (iQM2).
Online training and 1-800 support line	Support service line; in-person technical or clinical support as needed	On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.
5 minute sample stability. No manual preparation of sample. Built-in touch screen. Built-in connectivity. NGSP certified.	True PCR results without the need of an instrument	Actionable results in 70 seconds with one venous or arterial lithium-heparinized, whole blood sample, enable rapid clinical decision-making. All-in-one, multi-use GEM PAK cartridge stored at room temperature. iQM provides automated, real-time and continuous quality management, ensuring laboratory quality results at the POC.	Provides automated quality assurance with every sample. With iQM2, featuring IntraSpect technology, potential errors are detected not only before and after, but also during sample analysis, along with real-time correction and documentation. Plus, it's simple—just change the all-in-one GEM PAK once a month.

Werfen Bedford, MA (800) 955-9525 werfen.com	**Werfen** Bedford, MA (800) 955-9525 werfen.com
GEM Hemochron 100 whole blood hemostasis system	ROTEM sigma viscoelastic testing system
US: 2021; Canada: 2023; Europe & UK: 2020;	US: 2022; OUS: 2015
2020: CE mark; FDA 510(k) clearance: 2021; Health Canada: 2023	2015: CE Mark, 2022: IVDR CE mark; 2022: FDA 510(k) clearance
2" x 7.4" x 4"	26" x 15" x 24"
Whole-blood system for ACT testing, to guide heparin therapy during cardiovascular surgery, cardiology procedures including cardiac ablation, and extracorporeal life support.	A fully integrated and automated in vitro diagnostic system designed to monitor and analyze a patient's coagulation status by measuring the viscoelastistic properties of a 3.2% citrated venous or arterial whole blood sample.
Whole blood	Citrated whole blood (venous or arterial)
The instrument provides quantitative determination for monitoring anticoagulation on patients with heparin in fresh whole blood samples. Can be used to determine whether the patient is in therapeutic range when using unfractionated heparin. Can also be used to detect if the patient is subtherapeutic or supratherapeutic.	Point-of-care viscoelastic testing system used in critical bleeding situations. Assays include intrinsic and extrinsic activated clotting, fibrinogen contribution to clot strength and intrinsic clotting in the presence of heparin neutralization. Results are displayed in clot formation time, clot strength, and clot lysis.
■ A POC analyzer	■ A POC analyzer
Dependent on assay, clinical application and hospital-established target times.	Initial results available on screen 8 minutes and actionable results available less than 15 minutes after patient sampling.
Throughput = 11-30 tests/ hour	Throughput = 4-8 tests/hour
Training is simple, with an intuitive user interface, colored touch screen and simplified workflows.	Training can be completed in as little as 10 minutes.
On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.
The main differentiators are fast, simple (enhanced user interface and large touchscreen to enable easy and intuitive operation and improved workflows) and advanced connectivity (encrypted connection, remote Wi-Fi/ethernet and remote configuration).	The A5 parameter provides actionable results in <15 minutes. Closed tube sample introduction eliminates pipetting. Comprehensive view with 4 assays including intrinsic activation (with and without heparinase), extrinsic activation, and fibrinogen contribution. Three of the four assays neutralize heparin.