tech. guide

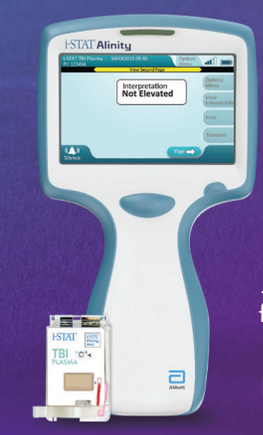
Point-of-Care Assays and Analyzers

	Abbott	Abbott	Abbott
	Abbott Park, IL 877-441-7440; ClientServices@abbott.com; https://www.globalpointofcare.abbott/en/product-details/afinion2-analyzer-us.html	Chicago, IL www.abbott.com www.globalpointofcare.abbott	Chicago, IL abbott.com/poct
1. What is the brand name of your company's POC assay or analyzer?	Afinion 2 Analyzer	DIGIVAL	ID NOW
2. What year was your named product first released to market (US, OUS)?	2019, US	2017, US; 2016, OUS	US and OUS: 2014 (ID NOW was known as Alere i)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	FDA 510(k), 2018; K171650.	FDA 510(k), 2017; CE mark, 2016	2014: CE Mark, 510(k), CLIA waived
4. What are the dimensions of the named product (H x W x D, in inches)?	7.2 inches x 7.5 inches x 13.0 inches	7.7 inches x 4.9 inches x 6.3 inches	8.15" W x 5.71" H x 7.64" D
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)?	Diagnosis and monitoring.	Point-of-care and laboratory diagnostics	Qualitative detection of infectious diseases at the point of care.
6. What type of specimen/sample does the product employ (eg, plasma, serum, urine, whole blood)?	Whole blood or urine	Urine sample, nasal swab sample, nasalpharyngeal sample	Influenza A and B: nasal swab, nasopharyngeal swab; strep A: throat swab; RSV: nasopharyngeal swab; COVID-19: nasal swab, nasopharyngeal swab, throat swab
7. What types of diseases, conditions, or analytes does the assay detect?	Diabetes	Influenza A&B, legionella, streptococcus pneumoniae (assay availabillity may vary by country)	Influenza A and B, strep A, RSV, COVID-19 (available in U.S. under EUA).
8. This product is:	■ A POC analyzer	■ A POC analyzer	■ A single-patient test for use in POC equipment **vs.** A POC analyzer
9. If you answered "other," explain briefly.			
10. Under ideal conditions, what is the time to first result; how are the test results made available (limit 150 characters, with spaces)?	About 3 minutes for HbA1c and 5 minutes for albumin/creatinine ratio with test results displayed on the analyzer screen.	15 minutes: Results are displayed on a display screen and stored in memory, and can be printed or uploaded to a compatible data management system.	Influenza A and B: positive results in as little as 5 minutes, negative results in 13 minutes; strep A: positive results in as little as 2 minutes, negative results in 6 minutes; RSV: results in 13 minutes or less; COVID-19: results in 13 minutes or less
11. What are the product's maximum capacity and throughput under ideal conditions (limit 150 characters, with spaces)?	16 to 17 tests per hour for A1C and 9 to 10 tests per hour for ACR	One patient sample is tested at a time.	Varies by assay and patient results
12. What is the typical training time for the product?	1 to 2 hours.	30 minutes	CLIA-waived
13. What types of technical support are available?	Live, virtual, phone, and online technical support.	Telephone and email technical support.	Phone, email, in person, virtual (varies based on location)
14. What capabilities, features, or accessories distinguish this product from others on the market (limit 350 characters, with spaces)?	Fastest, highly accurate A1C test in U.S. market and top choice for POC A1C testing among HCPs.	DIGIVAL eliminates operator subjectivity and provides consistency in the reading of rapid lateral flow test assays. DIGIVAL is designed to quickly interpret, capture, and transmit test results. Choose between Read Now Mode and Walk Away Mode to best suit your workflow.	ID NOW delivers lab-accurate results faster than any other molecular method. As a result, you can make confident, effective, and meaningful decisions for your patients at the point of care.

ACCIDENTS HAPPEN.
HEAD CT DOESN'T HAVE TO.

INTRODUCING THE i-STAT TBI PLASMA TEST, A BIOMARKER-BASED ASSAY DESIGNED TO ASSESS THE NEED FOR CT IN MILD TRAUMATIC BRAIN INJURY (mTBI)*

>90% of CT for suspected TBI shows no evidence of traumatic abnormality.[1] What if you didn't have to order so many scans? Now you don't, thanks to this game-changing biomarker assay that can help assess the need for CT. With a negative predictive value of 99.3%, that's leading-edge technology.[2]



i-STAT TBI Plasma
for use with the i-STAT Alinity System

Learn more at abbottmtbitest.com

*The *i-STAT TBI Plasma* test should be used in conjunction with other clinical information. It is not intended to be used as a point-of-care device. For use with plasma prepared from EDTA-anticoagulated specimens. For *in vitro* diagnostic use only. For intended use and complete product information, visit pointofcare.abbott.

REFERENCES: 1. Korley FK et al. *J Head Trauma Rehabil*. 2016. **2.** i-STAT TBI Plasma Cartridge. Instructions for use. Abbott Point of Care Inc. Abbott Park, IL; 2021.

Abbott

Point-of-Care Assays and Analyzers	**Abbott Point of Care** Princeton, NJ 609-454-9000; www.pointofcare.abbott/us/en/home	**BD** Sparks, MD 800-638-8663 www.BD.com	**Cardinal Health** Dublin, OH https://www.cardinalhealth.com/
1. What is the brand name of your company's POC assay or analyzer?	i-STAT 1 analyzer	Veritor Plus System	Cardinal Health Urinalysis Analyzer
2. What year was your named product first released to market?	2000	2017	2020, US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k); CE Mark	FDA, 2017, CE Mark 2017	TUV CE Mark, 2018; FDA 510(k) and CLIA-waiver, 2018
4. What are the dimensions of the named product?	9.25 × 3 × 2.85 in.	2 inches x 3 inches x 4 inches	3 in x 7.5 in x 9 in
5. What is the intended use or primary function of the product?	The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for the in vitro quantification of various analytes in whole blood. The i-STAT System is for in vitro diagnostics use.	Point-of-care applications	Reads Cardinal Health urine test strips, including microalbuminlbumin and creatinine urine strips, and calculates the albumin-to-creatinine ratio
6. What type of specimen/sample does the product employ?	Whole Blood	Influenza and RSV tests: nasal swab, nasopharyngeal swab, washes or aspirates; SARS-CoV-2: nasal swab; group A strep requires a throat swab	Urine (random, first morning, midstream all acceptable)
7. What types of diseases, conditions, or analytes does the assay detect?	15 test cartridges available that include tests for cardiac markers, blood gases, chemistries/electrolytes, endrocrinology, coagulation, and hematology	Flu A and B; SARS-CoV-2; RSV; group A strep	Albuminuria, diabetes monitoring, kidney disease, urinary tract infection, and other renal, urinary, and metabolic disorders.
8. This product is:	■ A POC analyzer	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A POC Analyzer
9. If you answered "other," explain briefly.			
10. Under ideal conditions, what is the time to first result; how are the test results made available?	2-10 min.	SARS-CoV-2 test requires 15 minutes; flu and RSV tests require 11 minutes; group A strep requires 6 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?	N/A	Instrument allows for batching; 10 Flu tests in under 20 minutes with Analyze Now mode, 24 SARS-CoV-2 tests per hour	600 tests/hr under Quick Test Mode 36 tests/hr under Routine Test Mode
12. What is the typical training time for the product?	4 hrs. (at customer site)	30 min	Can operate without additional training.
13. What types of technical support are available?	24/7 technical support	Phone and onsite	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?	Fast, lab-quality results: test with the patient in minutes, no waiting on results from the lab. Simple to use: clear and comprehensive instruction. Broad test menu: single-use i-STAT test cartridges cover a broad menu in a single platform. Connect to multiple POC data management systems. Comprehensive 24/7 technical support.	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.	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)

MyPOCtest.com	**MyPOCtest.com**	**EKF Diagnostics**	**Hemex**
Greensboro, NC (877) 722-8910; contactsales@carolinachemistries.com; MyPOCtest.com	Greensboro, NC (877) 722-8910; contactsales@carolinachemistries.com; MyPOCtest.com	Boerne, Texas 830-249-0772; www.ekfusa.com	Portland, OR 971-801-2573, info@HemexHealth.com www.HemexHealth.com
Status COVID-19/Flu A&B Antigen Test	Fastep COVID-19 IgG/IgM Antibody Rapid Test Device	STAT-Site WB	Gazelle
2021 (US)	2020 (US)	2020	Q4, 2020 OUS
FDA Emergency Use Authorization, CLIA categorized as Waived, 2021, EUA Number: EUA210015 dated February 4, 2021.	FDA Emergency Use Authorization, Fingerstick is CLIA categorized as Waived. 2020, EUA Number: EUA200487 dated September 23, 2020	FDA 510(k); CLIA waiver.	CE Mark 2019, Registered in India, Ghana, Nigeria, Kenya, and Tanzania
Lateral flow device	Lateral flow device	3.7 inches x 2.2 inches x 0.6 inches	6.0 inches x 7.7 inches x 10.3 inches
In vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from SARS-CoV-2, influenza A, and influenza B.	Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood.	Patient monitoring in a point-of-care setting.	Point-of-care diagnosis (including newborns) and monitoring
Nasopharyngeal swab specimens	Venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood.	Whole blood	Whole blood
Nucleocapsid antigen from SARS-CoV2, influenza A and influenza B	IgM and IgG antibodies to SARS-CoV-2	Detects ketones and glucose.	Hb Variant (Sickle Cell Disease, Thalassemia)
■ A self-contained POC test (requiring no equipment)	■ A self-contained POC test (requiring no equipment)	■ A POC analyzer	■ A single-patient test for use in POC equipment
15 minutes	15 minutes	About 5 seconds for glucose results, 10 seconds for ketone results. Results are displayed on screen.	8 minutes for onscreen, digital results. Test results also available in printout format.
Single-use test device; 25 tests per box.	Single-use test device; 20 tests per box.	More than 60 tests per hour are achievable.	5-6 tests per hour
< 15 minutes	< 15 minutes	1 hour	30 minutes
Video training, Zoom conference support	Video training, Zoom conference support	Telephone and email technical support.	Onscreen video instructions, technical support through distributors.
Differentiation of nucleocapsid antigen from SARS-CoV-2, influenza A and influenza B in a single test device.	Targets both Spike and Nucleocapsid Measure | Estimate | Confidence Interval: IgM+ sensitivity (PPA) | (30/30) 100% | (88.7%; 100%); IgM- specificity (NPA) | (79/80) 98.8% | (93.3%; 98.8%); IgG+ sensitivity (PPA) | (27/30) 90.0% | (74.4%; 96.5%); IgG- specificity (NPA) | (80/80) 100% | (95.4%; 100%); combined sensitivity | (30/30) 100% | (88.7%; 100%); combined specificity | (79/80) 98.8% | (93.3%; 98.8%)	Handheld point-of-care analyzer that uses whole blood to test for either ketones or glucose within 10 seconds. Calibrated using EKF's Beta-Hydroxybutyrate LiquiColor reagent. Battery operated, touch button strip ejection, auto-switch-off after 3 minutes of no use. Stores 400 results.	Identifies and quantifies types of hemoglobin to identify 16 conditions and monitor treatment. Fast, affordable, easy-to-use tests with high correlation to HPLC. No cold chain.

Point-of-Care Assays and Analyzers	**HemoSonics** Charlottesville, VA 800-280-5589 www.HemoSonics.com	**iAssay, Inc.** San Diego, CA Lonnie Adelman, 619-884-9220; info@iassay.net; www.iassay.net	**Nova Biomedical** Waltham, Mass (781) 894-0800 novabiomedical.com
1. What is the brand name of your company's POC assay or analyzer?	Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge	CyberReader 2030	Stat Profile Prime ES
2. What year was your named product first released to market?	2019, US (De Novo marketing authorization); 2017, OUS (CE mark)	2021, For Research Only, pending FDA Clearance	2017
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2017; FDA De Novo marketing authorization for Quantra QPlus System, 2019; CE mark for QStat cartridge, 2019.	Pending	FDA 510(k), 2018.
4. What are the dimensions of the named product?	19.25 inches x 14 inches x 12 inches	8 X 5 X 4	15.4 inches x 12 inches x 14.4 inches
5. What is the intended use or primary function of the product?	In vitro diagnostic testing that characterizes hemostasis in a variety of acute care clinical settings.	Point of care diagnostics applications, drugs of abuse monitoring, cloud-based test results monitoring. Environmental testing.	In vitro diagnostic use by healthcare professionals in clinical laboratory settings.
6. What type of specimen/sample does the product employ?	Whole blood	Human: urine, whole blood/plasma, saliva. Environmental: depends on test type	Whole blood
7. What types of diseases, conditions, or analytes does the assay detect?	Evaluates blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.	iAssay's product adapts to assays developed by third parties, providing opportunities for a range of diseases and conditions that can be detected.	Electrolytes
8. This product is:	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A self-contained POC test (requiring no equipment) ■ Other	■ A POC analyzer
9. If you answered "other," explain briefly.		Medical and environmental diagnostics testing device that interprets and transmits test results digitally	
10. Under ideal conditions, what is the time to first result; how are the test results made available?	Typically 15 minutes or less.	Varies based on type of test being "read" from seconds to minutes	60 seconds
11. What are the product's maximum capacity and throughput under ideal conditions?	Up to 5 single-cartridge tests per instrument per hour.	One assay type at a time, some assay types are multianalyte	45 samples per hour.
12. What is the typical training time for the product?	30 minutes to 1 hour.	Less than 20 minutes	15 minutes.
13. What types of technical support are available?	Standard service includes a hotline and technical support weekdays 9 am through 5 pm ET. Emergency telephone and pager support is available at all times. Additional full service options are also available.	Phone and email support	24/7 phone support.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Quantra System 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, thereby reducing potential interference. Direct measurement of shear modulus allows for accurate estimation of the relative contributions of platelets and fibrinogen to clot stiffness.	Agnostic to company type, i.e. reads tests from multiple suppliers without requiring "their reader." Connection to cloud enabling database for interoperability	Ten-position sample tray accommodates serum, plasma, and urine samples in 2 mL and 5 mL sample cups; maintenance-free cartridge system; advanced MicroSensor technology; no warm-up time for calibrator cartridge; compact size.

PixCell Medical	Radiometer America	Randox Laboratories	Sekisui Diagnostics
Yokne'am, Illit +972-4-959-3516, info@pixcell-medical.com, https://www.pixcell-medical.com	Brea, Calif. 800-736-0600 www.radiometeramerica.com	United Kingdom (0) 28 9442 2413 www.randox.com	Burlington, Mass 781-652-7800 www.sekisuidiagnostics.com
HemoScreen	ABL90 Flex Plus	Vivalytic	FastPack IP system, produced by Qualigen for Sekisui Diagnostics
2018	2015	2019	FastPack IP system; 2011
CE-mark, 2013; FDA 510(k), 2018; TGA, 2020.	FDA 510(k); UL; CE mark; EMC emission; EMC immunity	CE Mark (2019)	CE mark; FDA 510(k), 2011.
10.2 x 6.9 x 11.8	17.7 inches x 9.8 inches x 11.4 inches	15.7 x 8.0 x 15.2	9 inches x 13 inches x 12 inches
Point-of-care CBC testing	In vitro diagnostic analysis in laboratory, near-patient, or point-of-care settings.	Enables sample to answer, cartridge-based molecular diagnostic testing; capable of both hi-plex and lo-plex testing. Nucleic acid extraction, PCR amplification.	Delivers test results for diagnosing and monitoring disease states as well as replacement therapy.
One drop of capillary or venous blood	Heparinized whole blood.	Nasopharyngeal or oropharyngeal swabs, swab (cultures, wounds, axilla, groin and perineum), sputum, & urine.	Serum only for free thyroxine (FT4); serum or plasma for all other tests.
20 standard blood count parameters, delivering full and accurate CBC results; certain blood cancers, infections, sepsis and other diseases.	Quantitatively measures bilirubin, blood gases, electrolytes, glucose, lactate, oximetry, and pH.	Test menu covering a diverse range of respiratory, genitourinary and hospital acquired infections, including SARS-CoV-2 (COVID-19)	Free thyroxine, human chorionic gonadotropin, prostate-specific antigen, sex hormone binding globulin, testosterone, thyroid-stimulating hormone, and vitamin D.
■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A POC analyzer
The test takes 5 minutes; results are displayed on the interactive, user-friendly screen.	About 35 seconds. Test results are available on a color display and as a paper printout, or as electronic output to hospital or lab information systems and middleware.	Time to result is assay dependant. Results will be displayed on the Vivalytic touchscreen as either quantitative or qualitative.	FT4 results are available in 7 minutes; all other test results are available in approximately 12 minutes.
11 x 5-part differential CBC per hour or 20 x 3-part diff	1,200 tests per cartridge, 44 samples per hour testing all analytes.	One patient sample/cartridge at one time. In 8 hours can test up to a maximum of 10 patient samples/cartridges; assay dependant.	5 to 8 tests per hour, depending on the assay mix. Connects to laboratory information system software.
1 hour	Generally 1 hour (customizable to the location's requirements).	Less than 4 hours	A Web-based training class takes 3 hours and includes product and CLIA requirements.
Online training, remote diagnostics and remote intervention, remote application support and local technical support	Toll-free phone or email. On-site support is also available. An online customer care portal provides tools and educational resources.	Technical support is accessible via telephone, email and video calling applications.	Technical support is available on weekdays from 6 am through 5 pm PT, and on weekends from 8 am through 5 pm PT.
Imaging flow cytometry combines ul sample volumes, high-speed microscopic imaging, and morphological classification by AI. Single use cartridges contain all reagents and the sample. The analyzer is maintenance free, and portable without need for calibration. It is the fastest, dry, full CBC analyzer.	Results in 35 seconds on 65 µL sample volume for 17 acute-care parameters: automatic quality control and peer QC network; full battery operation; uptime more than 22 hours per day; can run syringe, capillary, and test tube samples; automatic sample mixing; automatic data entry; advanced cybersecurity features; remote service and support.	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.	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.

Point-of-Care Assays and Analyzers	**Siemens Healthineers** Tarrytown, NY 888-826-9702; www.siemens-healthineers.com	**Siemens Healthineers** Tarrytown, NY 888-826-9702; www.siemens-healthineers.com	**Mesa Biotech,** *part of Thermo Fisher Scientific* San Diego, CA 858-800-4929 info@mesabiotech.com www.thermofisher.com/mesa
1. What is the brand name of your company's POC assay or analyzer?	CLINITEK Status+ Analyzer	CLINITEK Status Connect System	Thermo Fisher Scientific Accula System
2. What year was your named product first released to market?	2010, US; 2009, OUS	2010, US; 2009, OUS	2018, US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark; FDA 501(k); CLIA-waived urine dip and hCG rapid test.	CE mark; FDA 501(k); CLIA-waived urine dip and hCG rapid test.	SARS-CoV-2: FDA, EUA, 2020 Flu A/Flu B: FDA, 510(k), 2018 Strep A: FDA, 510(k), 2020 RSV: FDA, 510(k), 2018
4. What are the dimensions of the named product?	6.2 inches x 6.7 inches x 10.7 inches	7.5 inches x 6.7 inches x 10.7 inches	Accula Dock: 5.7 inches x 3.9 inches x 3.8 inches
5. What is the intended use or primary function of the product?	Point-of-care in vitro urinalysis.	Point-of-care in vitro urinalysis.	Qualitative detection of infectious disease pathogens
6. What type of specimen/sample does the product employ?	Random/spot urine.	Random/spot urine	Nasal swab, nasal mid-turbinate swab, or throat swab (varies by assay)
7. What types of diseases, conditions, or analytes does the assay detect?	Assists in diagnosis related to kidney function, urinary tract infections, metabolic disorders (such as diabetes mellitus), liver function, pregnancy.	Assists in diagnosis related to kidney function, urinary tract infections, metabolic disorders (such as diabetes mellitus), liver function, pregnancy.	SARS-CoV-2, flu A/flu B, RSV, strep A
8. This product is:	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A single-patient test for use in POC equipment ■ A POC analyzer	■ A POC analyzer
9. If you answered "other," explain briefly.			
10. Under ideal conditions, what is the time to first result; how are the test results made available?	Typically 60 seconds for urine dipstick tests, including ACR and PCR. Up to 5 minutes for hCG pregnancy cassette test. Results are displayed on screen, printed, or uni-directionally transmitted to a laboratory information system and/or middleware.	About 60 seconds for urine dipstick tests, including ACR and PCR. Up to 5 minutes for hCG pregnancy cassette test. Results are displayed on screen, printed, or bi-directionally transmitted to a laboratory information system, middleware, or electronic medical record.	30 minutes. Test results are visually detected on a lateral flow strip.
11. What are the product's maximum capacity and throughput under ideal conditions?	One patient sample is tested at a time.	One patient sample is tested at a time.	1 test per instrument, 1 to 2 tests per hour
12. What is the typical training time for the product?	Online training through PEP connect or a remote training program takes approximately 1 hour.	Online training through PEP connect or a remote training program takes approximately 1 hour.	1 to 2 hours
13. What types of technical support are available?	Phone support is available, as is an analyzer swap out if the product is under warranty or covered by an extended service agreement.	Phone support is available, as is an analyzer swap out if the product is under warranty or covered by an extended service agreement.	Telephone and email technical support.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Auto-check technology allows for automatic detection of humidity overexposure and test strip configuration; uniquely offers urine test strips and hCG rapid testing on one system; offers standardization of urine testing end-to-end solution from lab to physician office; system offers features for operator lockout.	Auto-check technology allows for automatic detection of humidity overexposure and test strip configuration; uniquely offers urine test strips and hCG rapid testing on one system; offers standardization of urine testing end-to-end solution from lab to physician office; system offers control features for operator and QC management/lockout, 2D barcoding of test information, operator and patient IDs.	The Thermo Fisher Scientific Accula System combines the accuracy of PCR with unparalleled speed and simplicity, delivering visual results in 30 minutes. The system delivers highly accurate PCR testing at the point of care with a simple workflow and sensitivity comparable to laboratory-based PCR.

Visby Medical	**Werfen**	**Werfen**	**Werfen**
San Jose, CA 1-833-GoVisby(1-833-468-4729) www.visbymedical.com Support@visby.com	Bedford, MA 800-955-9525 werfen.com	Bedford, MA 800-955-9525 werfen.com	Bedford, MA 800-955-9525 werfen.com
Visy Medical Sexual Health Click Test	GEM Premier ChemSTAT with iQM basic metabolic panel testing system	GEM Premier 5000 with iQM2 blood gas testing system	Hemochron Signature Elite analyzer
2021, US	US: 2020; OUS: 2019	US: 2017; OUS: 2016	2006
FDA 510(k), CLIA-waived	FDA 510(k)-cleared in February 2019; OUS CE mark received in June 2019	FDA 510(k)-cleared in December 2016; OUS CE mark received in 2015; NMPA approved in 2019; Health Canada license received in April 2020	CE mark, 2005; FDA 510(k), 2005; TUV, 2005
4″ x 3.3″ x 1.5″	18.5 inches x 13.1 inches x 16.3 inches	18.6 inches x 13.0 inches x 16.4 inches	2 inches x 7.5 inches x 3.7 inches
Qualitative dectection of infectious disease pathogens in women	Point-of-care testing in acute care (e.g., ED, ICU) and laboratory settings.	Blood gas testing at the point-of-critical care (e.g., ICU, NICU, CVOR) and laboratory settings.	Whole-blood microcoagulation analyzer used for the monitoring of unfractionated heparin and warfarin.
Self-collected vaginal swab	Lithium-heparinized whole blood	Heparinized whole blood	Fresh whole blood and citrated whole blood. Dependent on test type.
Chlamydia, gonorrhoeae, trichomonoas	The instrument provides quantitative measurements of sodium (Na+), potassium (K+), ionized calcium (Ca++), chloride (Cl-), glucose (Glu), lactate (Lac), hematocrit (Hct), creatinine (Crea), blood urea nitrogen (BUN), total carbon dioxide (tCO2), pH, and partial pressure of carbon dioxide (pCO2) from arterial and venous heparinized whole blood.	Provides quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2*) parameters from arterial, venous or capillary heparinized whole blood.	Reports the anticoagulation effects of patient or QC sample when mixed with different reagents. Can be used to determine whether the patient is in therapeutic range when using unfractionated heparin or warfarin. Can also be used to detect if the patient is subtherapeutic or supratherapeutic.
■ A Self Contained POC test (requiring no equipment)	■ A POC analyzer	■ A POC analyzer	■ A single-patient test for use in POC equipment
15 seconds of hands-on time, 28 minutes time to visual-read result	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.	Dependent on assay, clinical application and hospital-established target times.
Unlimited; not limited by instruments. Single use, disposable.	Throughput = 16 samples/hour. Each sample provides results for 12 measured parameters and a set of configurable derived parameters.	Throughput = 29 samples/hour	The system can perform 10-15 tests per hour.
Training is available but not required. Please follow the instructions for use and quick reference guide.	Training healthcare professionals to use the system is simple, with the all-in-one GEM PAK cartridge, no-maintenance analyzer.	Training healthcare professionals to use the system is simple, with the all-in-one GEM PAK cartridge, no-maintenance analyzer.	1-2 hours.
Product instructions via PDF and video; customer support via phone and email.	On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.
The only all-in-one, instrument-free PCR CLIA-waived point-of-care device for chlamydia, gonorrhea, and trichomonoas. Fits in the palm of your hand. Portable, scalable, and flexible. Not limited by an instrument or permanent bench space.	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.	Broadest menu for POC coagulation testing; fastest time to result; supports blood conservation protocols by requiring only 1-2 drops of whole blood.