

# tech. guide

## Point-of-Care Assays and Analyzers

### Abbott

Abbott Park, IL  
(877) 441-7440; ClientServices@abbott.com  
www.globalpointofcare.abbott/en/product-details/afinion2-analyzer-us.html

### Abbott Rapid Diagnostics

Lake Forest, IL  
www.globalpointofcare.abbott/en/product-details/id-now-covid-19.html

### Abbott Point of Care

Princeton, NJ  
(609) 454-9000;  
www.pointofcare.abbott/us/en/home

1. What is the brand name of your company's POC assay or analyzer?	Afinion 2 Analyzer	ID NOW	i-STAT 1 analyzer
2. What year was your named product first released to market?	2018 OUS, 2017 US	US and OUS: 2014 (ID NOW was known as Alere i)	2000
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2017; K171650, CE mark: NO981363019/0647-54392	2014: CE Mark, 510(k), CLIA waived	FDA 510(k); CE Mark
4. What are the dimensions of the named product?	7.2" x 7.5" x 13.0"	8.15" W x 5.71" H x 7.64" D	9.25" x 3" x 2.85"
5. What is the intended use or primary function of the product?	Point-of-care applications for diagnosis, screening, and monitoring	Influenza A and B: nasal swab, nasopharyngeal swab; strep A: throat swab; RSV: nasopharyngeal swab; COVID-19 2.0: nasal swab, nasopharyngeal swab	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.
6. What type of specimen/sample does the product employ?	Whole blood, serum, plasma, or urine	Influenza A and B, strep A, RSV, COVID-19 2.0 (available in U.S. under EUA)	Whole blood
7. What types of diseases, conditions, or analytes does the assay detect?	Diabetes, kidney function, upper respiratory infections and lipid and lipoprotein disorders	A single-patient test for use in POC equipment vs. A POC analyzer	15 test cartridges available that include tests for cardiac markers, blood gases, chemistries/electrolytes, endocrinology, coagulation, and hematology
8. This product is:	■ A POC analyzer	■ A single-patient test for use in POC equipment	■ 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?	About 3 mins for HbA1c, 5 mins for ACR, 7-8 mins for lipids, 3-4 mins for CRP with test results displayed on the analyzer screen.	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 2.0: positive results in as little as 6 minutes, negative results in 12 minutes	2-10 min.
11. What are the product's maximum capacity and throughput under ideal conditions?	16 to 17 tests per hour for HbA1c, 9 to 10 tests per hour for ACR, 7 to 8 tests per hour for lipids, and 14 to 15 tests per hour for CRP	Varies by assay and patient results	N/A
12. What is the typical training time for the product?	1 to 2 hours	CLIA-waived	4 hrs. (at customer site)
13. What types of technical support are available?	Live, virtual, phone and online technical support.	Phone, email, in person, virtual (varies based on location)	24/7 technical support
14. What capabilities, features, or accessories distinguish this product from others on the market?	Highly accurate and fast quantitative POC tests. CLIA waived tests for HbA1c monitoring	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.	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.

**Cardinal Health**  
Dublin, OH  
www.cardinalhealth.com/

**EKF Diagnostics**  
Boerne, Texas  
830-249-0772;  
www.ekfusa.com

**EKF Diagnostics**  
Cardiff, UK  
0044 (0)29 20 710570  
www.ekfdiagnostics.com  
info@ekfdiagnostics.com

**Helena Laboratories**  
Beaumont, TX. USA  
(800) 231-5663  
www.helena.com

Cardinal Health Urinalysis Analyzer	STAT-Site WB	DiaSpect	Actalyke Mini II
2020, US	2020	2017 (OUS), 2021 (US)	2003
TUV CE Mark, 2018; FDA 510(k) and CLIA-waiver, 2018	FDA 510(k); CLIA waiver.		FDA 510(k), 2003; CE mark, 2003
3" x 7.5" x 9"	3.7" x 2.2" x 0.6"	7cm x 9cm x 15cm	6" x 6" x 6"
Reads Cardinal Health urine test strips, including microalbumin and creatinine urine strips, and calculates the albumin-to-creatinine ratio	Patient monitoring in a point-of-care setting.	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.	Heparin monitoring
Urine (random, first morning, midstream all acceptable)	Whole blood	Whole blood	Whole Blood
Albuminuria, diabetes monitoring, kidney disease, urinary tract infection, and other renal, urinary, and metabolic disorders.	Detects ketones and glucose.	Anemia	Activated clotting time
■ A POC Analyzer	■ A POC analyzer	■ A POC analyzer	<ul style="list-style-type: none"> <li>■ A single-patient test for use in POC equipment</li> <li>■ A multiplexed test for use in POC equipment</li> <li>■ A POC analyzer</li> </ul>
90 seconds or less (5 seconds on Quick Test Mode); results are displayed on LCD screen and printed on internal thermal printer	About 5 seconds for glucose results, 10 seconds for ketone results. Results are displayed on screen.	The test result appears on the display in less than two seconds.	90-1500 sec Patient Dependent
600 tests/hr under Quick Test Mode 36 tests/hr under Routine Test Mode	More than 60 tests per hour are achievable.	-	20 tests/hour
Can operate without additional training.	1 hour	One hour	1 day
Lifetime customer service and tech support provided by phone/email; Step-by-step quick reference guide; Videos on the website.	Telephone and email technical support.	Our support team is contactable via email, telephone and through our contact form: <a href="https://www.ekfdiagnostics.com/point-of-care-inquiry.html">https://www.ekfdiagnostics.com/point-of-care-inquiry.html</a>	Technical and electronic support 24/7
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)	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.	DiaSpect is palm-sized, making it easily transportable, and ideal for use in any screening setting.	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.

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**Helena Laboratories**  
Beaumont, TX. USA  
(800) 231-5663  
www.helena.com

**HemoSonics**  
Charlottesville, VA  
(800) 280-5589  
www.HemoSonics.com

**iAssay, Inc.**  
San Diego, CA  
Lonnie Adelman,  
(858) 413-POCT (7628)  
info@iAssay.net;www.iAssay.net

1. What is the brand name of your company's POC assay or analyzer?	Abrazo	Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge	CyberReader 2030
2. What year was your named product first released to market?	2016	2019, US (De Novo marketing authorization); 2017, OUS (CE mark)	2021, For Research Only, pending FDA Clearance
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2016	CE mark, 2017; FDA De Novo marketing authorization for Quantra QPlus System, 2019; CE mark for QStat cartridge, 2019.	Pending
4. What are the dimensions of the named product?	9" x 4" x 3"	19.25" x 14" x 12"	8" X 5" X 4"
5. What is the intended use or primary function of the product?	Multianalyte coagulation testing	In vitro diagnostic testing that characterizes hemostasis in a variety of acute care clinical settings.	Point of care diagnostics applications, drugs of abuse monitoring, AWS data management cloud for monitoring test results. Environmental testing
6. What type of specimen/sample does the product employ?	Whole blood, citrated whole blood, citrated plasma	Whole blood	Human: urine, whole blood/plasma, saliva. Environmental: depends on test type
7. What types of diseases, conditions, or analytes does the assay detect?	Prothrombin time, aPTT, activated clotting time	Evaluates blood coagulation in perioperative patients age 18 years+ to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.	Adapts to assays developed by third parties, providing opportunities for a range of diseases and conditions that can be detected.
8. This product is:	<ul style="list-style-type: none"> <li>■ A single-patient test for use in POC equipment</li> <li>■ A multiplexed test for use in POC equipment</li> <li>■ A POC analyzer</li> </ul>	<ul style="list-style-type: none"> <li>■ A single-patient test for use in POC equipment</li> <li>■ A POC analyzer</li> </ul>	<ul style="list-style-type: none"> <li>■ A self-contained POC test (requiring no equipment)</li> <li>■ Other"</li> </ul>
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?	Test dependent; battery life of 8hrs under normal use	Typically 15 minutes or less.	Varies based on type of test being "read" from seconds to minutes (including incubation)
11. What are the product's maximum capacity and throughput under ideal conditions?	PT = 80-100/hour; aPTT = 60/hour; ACT 20-30/hour	Up to 5 single-cartridge tests per instrument per hour.	One assay type at a time, some assay types are multianalyte (for example drug screening cards that hold over 10 drug test strips)
12. What is the typical training time for the product?	1 day	30 minutes to 1 hour.	Less than 20 minutes
13. What types of technical support are available?	Technical and electronic support 24/7	Standard service includes a hotline and technical support weekdays 9 am through 5 pm ET. Emergency telephone and pager support available 24/7. Additional full service options available.	Phone and email support
14. What capabilities, features, or accessories distinguish this product from others on the market?	WiFi and Bluetooth compatible, cartridge based; optional docking station and administrative software; integrated 2D barcode reader, internal quality control performed automatically before every test, optional lockouts for electronic and biological quality control, and operators	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, reducing potential interference. Allows for accurate estimation of the relative contributions of platelets and fibrinogen to clot stiffness.	Open system allowing multiple manufacturer/format/technology test cartridges, connection to iAssay Data Management Cloud enabling interoperability, print selectable results directly from device, walk away mode, AI based test/control line detection.

## Point-of-Care Testing in the Neonatal Population: Importance of Glucose Meter Accuracy

Point-of-care testing is an essential diagnostic tool in neonatal and pediatric patient settings because infants and children experience more rapid changes in clinical status than adults. Fast, accurate, interference-free POCT glucose testing in neonatal settings enables rapid detection or prevention of neonatal hypoglycemia.

In this webinar, Dr. Khosrow Adeli, Professor, Clinical Biochemistry, The Hospital for Sick Kids, Toronto, Ontario, Canada will describe the unique needs and benefits of point of care glucose testing in the neonatal patient population. He will describe the positive impact that accurate, interference-free glucose testing accuracy has had on outcomes and quality of care at Sick Kids Hospital in Toronto, Canada.

By the end of the presentation, the viewer will:

- Become aware of the benefits of point of care testing in the neonatal and pediatric patient population
- Understand the analytical measurement requirements for point-of-care glucose meters used in the neonatal setting
- Learn how point of care testing can affect quality of care, clinical outcome, and laboratory effectiveness



### Primary Presenter

Khosrow Adeli, PhD, FCACB, DABCC, FAACC  
Head and Professor, Clinical Biochemistry  
The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada  
Director, Point of Care Testing Program  
President, International Federation of Clinical Chemistry & Laboratory Medicine (IFCC)

## Ionized Calcium and Ionized Magnesium Testing in Neonatal Populations

Point of care testing for ionized calcium and ionized magnesium are also crucial in caring for neonates. In this presentation, Dr. Naveen Bangia will review up-to-date guidelines for ionized calcium in neonates as well as the benefit of ionized magnesium in neonatal cardiopulmonary bypass surgery. He will also expand on Dr. Adeli's presentation with a review of recent studies addressing limitations of some glucose devices for the neonatal population.



### Presenter

Naveen Bangia, PhD  
North American Director of Medical and Scientific Affairs  
Nova Biomedical

### Webinar Dates:

Thursday, October 20th, 1:00 PM ET  
Thursday, November 3rd, 1:00 PM ET



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[novabiomedical.com/neo-glu-clp](https://novabiomedical.com/neo-glu-clp)

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This program has been approved by the American Association of Critical-Care Nurses (AACN), for 1.00 CERPs, Synergy CERP Category A, File Number 24269. Approval refers to recognition of continuing education only and does not imply AACN approval or endorsement of the content of this educational activity, or the products mentioned.

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**iAssay, Inc.**  
San Diego, CA  
Lonnie Adelman,  
(858) 413-POCT (7628)  
info@iAssay.net;www.iAssay.net

**LumiraDx**  
London, United Kingdom  
(888) 586-4721  
customerservices.us@lumiradx.com  
www.lumiradx.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

SimpleTest 2	LumiraDx Platform	Prime Plus Analyzer	Prime ES Analyzer
2022, For Research Only, pending FDA clearance"	2020, US; 10/10/2020	2018	2017
Pending	CE Mark 11/10/2018 FDA EUA, 8/16/2020;	FDA 510(k) 2018; CE Mark 2017	FDA 510(k) 2018; CE Mark 2017
7" X 9" X 8"	2.87" x 3.82" x 8.27"	18.0" x 14.0" x 15.4"	15.4" x 12.0" x 14.4"
Point of care diagnostics applications, drugs of abuse monitoring, AWS data management cloud for monitoring test results. Environmental testing	In vitro diagnostic analysis in laboratory, near-patient, or point-of-care settings	Point of care blood gas, electrolyte, metabolite and co-oximetry testing	In vitro diagnostic use by health-care professionals in clinical laboratory settings.
Human: urine, whole blood/plasma, saliva. Environmental: depends on test type	Nasal swab; nasopharyngeal swab; capillary whole blood; anticoagulated venous whole blood and plasma; Serum	Whole blood	Whole blood (heparinized), serum, plasma
Adapts to assays developed by third parties, providing opportunities for a range of diseases and conditions that can be detected.	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)	Detects multiple critical care conditions. Test menu: pH, PCO2, PO2, SO2%, Na, K, Cl, TC02, iCa, iMg, glucose, lactate, creatinine, urea, Hb, Hct, MCHC, estimated plasma volume (ePV), CO-ox panel	Na, K, Cl, iCa, iMg, pH, Hct
<ul style="list-style-type: none"> <li>■ A self-contained POC test (requiring no equipment)</li> <li>■ Other"</li> </ul>	<ul style="list-style-type: none"> <li>■ A single-patient test for use in POC equipment</li> <li>■ A multiplexed test for use in POC equipment</li> <li>■ A POC analyzer</li> </ul>	<ul style="list-style-type: none"> <li>■ A POC analyzer</li> </ul>	<ul style="list-style-type: none"> <li>■ A POC analyzer</li> </ul>
Medical and environmental diagnostics testing device that interprets and transmits test results digitally			
Varies based on type of test being "read" from seconds to minutes (including incubation)	< 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	60 seconds; Results are presented by digital display, printed report, and NovaNet POC middleware connectivity already used by over 2/3 of US hospitals.	60 seconds; Results are presented by digital display, printed report, and NovaNet POC middleware connectivity already used by over 2/3 of US hospitals.
Two test drawers, each with one assay type at a time, some assay types are multianalyte (for example drug screening cards that hold over 10 drug test strips)	One test at a time. Some tests are multiplex or have sample pooling capabilities. Time results varies by test.	Up to 45 samples/990 tests per hour	up to 60 samples/420 tests per hour
Less than 20 minutes	CLIA Waived: Self training; Instructor lead training ≈ 30 minutes	30 minutes	30 minutes
Phone and email support	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.	Free 24/7/365 telephone technical support. Onsite applications support on request.	Free 24/7/365 telephone technical support. Onsite applications support on request.
7" touchscreen, open system allowing multiple manufacturer/format/technology test cartridges, connection to iAssay Data Management Cloud enabling interoperability, print selectable results directly from device, walk away mode, AI based test/control line detection.	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 bar-code scanning.	Broad blood gas/critical care test menu. Up to 22 tests, including unique tests for ePV and iMg, are available from one drop of blood. Sensors and reagents are provided in long life, maintenance free cartridges. Onboard automated quality saves time and labor and eliminates the need for IQCP.	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.



efficient

## The Accula SARS-CoV-2 Test

Rapid, accurate PCR testing with visual  
results in ~30 minutes

Features of the Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test:

- **Accuracy and sensitivity**—comparable to standard lab-based PCR [1]
- **Simple workflow**—approximately 1 to 2 minutes of hands-on time
- **Fast turnaround times**—results in about 30 minutes
- **Self-contained testing**—fully integrated single-use cassette and reusable dock
- **Emergency Use Authorization (EUA)**—FDA EUA in CLIA-waived environments

Find out more at [thermofisher.com/accula](https://thermofisher.com/accula)

1. Accula SARS-CoV-2 Test Instructions For Use. Thermo Fisher Scientific. Accessed on 6/10/22. <https://www.thermofisher.com/document-connect/document-connect.html?url=https%3A%2F%2Fassets.thermofisher.com%2Fassets%2FCCG%2FInstructions%2FBL-60061-Accula-SARS-CoV-2-IFU-03FEB2021.pdf>

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**Nova Biomedical**  
Waltham, MA  
(800) 458-5813  
www.novabiomedical.com  
info@novabio.com

**PixCell Medical**  
Yokne'am Illit  
972 4-959-3516  
info@pixcell-medical.com  
www.pixcell-medical.com

**Quidel Corporation**  
San Diego  
(800) 874-1517  
customerservice@quidel.com  
www.quidel.com

1. What is the brand name of your company's POC assay or analyzer?	Allegro Analyzer	HemoScreen	Sofia 2
2. What year was your named product first released to market?	Not yet available in the US or Canada; 2018 (OUS)	2018	2017
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Mark 2018	CE mark 2013; FDA 510(k) 2018; TGA, 2020	FDA 510(k) 2017; TUV CE mark 2017
4. What are the dimensions of the named product?	14.0" x 8.0" x 15.0"	11.8" x 6.9" x 10.2"	4.73" H x 4.73" W x 8.67" D
5. What is the intended use or primary function of the product?	Capillary fingerstick blood analyzer for point of care testing in primary care locations such as private practices, clinics, and pharmacies.	Point of care CBC testing	Point-of-care laboratory diagnostics
6. What type of specimen/sample does the product employ?	Capillary fingerstick blood; urine	One drop of capillary or venous blood	Nasal, nasopharyngeal, nasal wash/aspirate, throat swab samples
7. What types of diseases, conditions, or analytes does the assay detect?	HbA1c, glucose, creatinine, urine albumin, urine creatinine, lipid profile, CRP, triglyceride, Ptt/INR	20 standard blood count parameters, delivering full and accurate CBC results; certain blood cancers, infections, sepsis and other diseases.	Influenza A+B, RSV, group A strep, campylobacter, Lyme disease, SARS antigen (emergency use authorization)
8. This product is:	■ A POC analyzer	■ A POC analyzer	■ A multiplexed test for use in POC equipment ■ 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?	Glucose 6 seconds; creatinine 30 seconds; HbA1c 6.9 minutes	The test takes 5 minutes; results are displayed on the interactive, user-friendly screen.	Between 3-15 minutes. Results are displayed qualitatively onscreen.
11. What are the product's maximum capacity and throughput under ideal conditions?	Varies according to test selection. Dual test bays improve throughput versus single test bay analyzers.	11 x 5-part differential, or 20 x 3-part differential CBC tests per hour.	Depending on workflow mode, one test can be run at a time in walk away mode or several samples can be batched using read now mode for increased throughput.
12. What is the typical training time for the product?	30 minutes	1 hour	30-45 minutes, available online or in person
13. What types of technical support are available?	Free 24/7 telephone technical support. Onsite applications support on request.	Online training, remote diagnostics and remote intervention, remote application support and local technical support.	Telephone and email technical support, with onsite services provided, if needed.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Has the broadest menu of tests available from capillary fingerstick samples. All tests use single-use, pre-calibrated cassettes or test strips. Dual test bays provide improved throughput versus single test bay analyzers.	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.	Sofia 2 is a small bench top analyzer that uses advanced fluorescence detection of antigens. Sofia 2 collects data from test strips inside of a Sofia FIA Test Cassette. Uses proprietary algorithms to analyze the data, interpret and automatically generates an objective result for the target analyte.

**Quidel Corporation**  
San Diego  
(800) 874-1517  
customerservice@quidel.com  
www.quidel.com

**Radiometer America**  
Brea, California  
(800) 736-0600  
www.radiometeramerica.com

**Randox Laboratories**  
United Kingdom  
(0) 28 9442 2413  
www.randox.com

**SEKISUI Diagnostics**  
Burlington, MA  
(800) 332-1042  
info@sekisuidiagnostics.com  
www.sekisuidiagnostics.com

Solana	ABL90 FLEX PLUS	Vivalytic	Acucy
2015	2015	2019	2019
FDA 510(k) 2015; TUV CE mark 2015	FDA 510(k), UL, CE mark, EMC emission, EMC immunity	CE Mark (2019)	US - FDA 510K: K182001, 2018; EU - CE MDSS 118192, 2022
9.4" x 9.4" x 5.9"	17.7" x 9.8" x 11.4"	15.7" x 8.0" x 15.2"	5.7" x 4.7" x 9.3"
Point-of-care laboratory diagnostics	Automated and portable in vitro diagnostic analyzer. Intended for use 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.	Diagnosis at point-of-care
Nasal or nasopharyngeal swabs, nasopharyngeal swabs in transport media, throat swab, unformed stool, vaginal or rectal swabs, urine, cutaneous, or mucocutaneous lesion samples.	Heparinized whole blood	Nasopharyngeal or oropharyngeal swabs, swab (cultures, wounds, axilla, groin and perineum), sputum, & urine.	Nasal and nasopharyngeal swab
Influenza A+B, RSV & hMPV, group A strep, strep C & G strep, group B strep, clostridium difficile, HSV 1+2 & VZV, trichomonas, bordetella pertussis and bordetella parapertussis, SARS-CoV-2 (emergency use authorization)	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).	Influenza A & B
■ A multiplexed test for use in POC equipment ■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A single-patient test for use in POC equipment ■ A POC analyzer
Between 25-50 minutes. Results are displayed qualitatively onscreen.	35 seconds; color display and paper printout; electronic output to hospital or lab information systems and middleware.	Time to result is assay dependent. Results will be displayed on the Vivalytic touchscreen as either quantitative or qualitative.	15 minutes, Results are displayed on screen, and printouts
Depending on sample processing proficiency, 12-24 samples per hour in batch testing.	Up to 1,200 tests per cassette, 44 samples/hour testing for full panel of analytes.	One patient sample/cartridge at one time. In 8 hours can test up to a maximum of 10 patient samples/cartridges; assay dependent.	~24 tests in 8-hour shift (sequentially) or ~72 tests in 8-hour shift (in batches)
1-2 hours, available online or in person.	1 hour (customizable to location's requirements)	Less than 4 hours	~1 hour
Telephone and email technical support, with onsite services provided, if needed.	On-site support, 24/7 telephone support.	Technical support is accessible via telephone, email, and video calling applications.	Phone and email
A simplified molecular testing platform, making molecular diagnostics faster and easier than ever before, without sacrificing performance. Combines Quidel's proprietary helicase-dependent amplification (HDA) with fluorescence detection to deliver results you can trust, in an actionable timeframe.	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.	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 Acucy Influenza A & B test has the best in class performance for flu A with 96.4% sensitivity and 96% specificity.



**Thermo Fisher Scientific**  
Waltham, Mass.  
(800) 556-2323  
www.thermofisher.com

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Bedford, MA  
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werfen.com

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(800) 955-9525  
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Bedford, MA  
(800) 955-9525  
werfen.com

Thermo Fisher Scientific Accula System	GEM Premier ChemSTAT with iQM basic metabolic panel testing system	GEM Premier 5000 with iQM 2 blood gas testing system	GEM Hemochron 100 ACT system
2018, US	US: 2020; OUS: 2019	US: 2017; OUS: 2016	US and OUS: 2021
SARS-CoV-2: FDA, EUA, 2020 Flu A/Flu B: FDA, 510(k), 2018	2019: FDA 510(k) clearance, OUS CE mark	FDA 510(k)-clearance, 2016; OUS CE mark, 2015; NMPA, 2019; Health Canada license, 2020	2021: IDVR, CE mark, FDA 510(k) clearance
Accula Dock: 5.7" x 3.9" x 3.8"	18.5" x 13.1" x 16.3"	18.6" x 13.0" x 16.4"	2" x 7.4" x 4"
Qualitative detection of infectious diseases pathogens	Point-of-care testing in acute care and laboratory settings. Actionable BMP results in 70 seconds enable rapid risk-stratification and prioritization of high-risk acutely ill patients, expedited time to treatment, and improved patient management and quality of care.	Blood gas testing at the point-of-care and laboratory settings. iQM2 provides real-time assurance of results, before, during and after sampling. All-in-one, multi-use GEM PAK cartridges offer ultimate simplicity and GEMweb Plus 500 Custom Connectivity offers complete control.	Whole-blood system for ACT testing, to guide heparin therapy during cardiovascular surgery, cardiology procedures including cardiac ablation, and extracorporeal life support.
Anterior nasal swab, nasal mid-turbinate swab, or throat swab (varies by assay)	Lithium-heparinized whole blood	Heparinized whole blood	Whole blood
SARS-CoV-2, Flu A/Flu B	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. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance.	The instrument provides quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2*) parameters from arterial, venous or capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen-delivery capacity.	The instrument provides quantitative determination for monitoring anticoagulation on patients with heparin in fresh whole blood samples. Two tests available depending on the heparin dose (ACT+: For moderate to high heparin doses; ACT-LR: For low to moderate heparin doses). 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 sub-therapeutic or supratherapeutic.
■ A POC analyzer	■ A POC analyzer	■ A POC analyzer	■ A POC analyzer
About 30 minutes. Test results are visually detected on a lateral flow strip.	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.
1 test per instrument, 1 to 2 tests per hour	Throughput = 16 samples/hour. Each sample provides results for 12 measured parameters and a set of configurable derived parameters.	Throughput = 29 samples/hour	Throughput = 10-15 tests/ hour
1 to 2 hours	Training healthcare professionals to use the system 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) that automatically detects, corrects and documents errors in real-time. The system eliminates the most skill- and labor-intensive aspects of basic metabolic panel testing and quality assurance.	Training healthcare professionals to use the system is simple, with the all-in-one GEM PAK cartridge, no-maintenance analyzer, and a quality management system (iQM2) that automatically detects, corrects and documents errors in real-time. The system eliminates the most skill- and labor-intensive aspects of blood gas testing and quality assurance.	Training healthcare professionals to use the system is simple, with an intuitive user interface, colored touch screen and simplified workflows. The instrument is very configurable and allowed auto-programmed electronic quality control.
Telephone and email technical support	On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.	On-site support, 24/7 telephone support.
The Thermo Fisher Scientific Accula System uses proprietary Oscar PCR technology to shorten thermocycling times and provide a result in about 30 minutes. The system delivers rapid, accurate PCR testing at the point of care with a simple workflow and sensitivity comparable to laboratory-based PCR.	The main differentiators are fast (2 times faster ACT results than other systems), 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).	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.	The main differentiators are fast (2 times faster ACT results than other systems), 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).



# AMP 2022

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