tech guide

Point-of-Care Assays and Analyzers

	Abbott Abbott Park, Ill (224) 667-6100 www.alere.com	BioFire Diagnostics Salt Lake City (801) 736-6354 www.biofiredx.com	Brava Diagnostics/MBio Boulder, Colo (303) 952-2905 www.BravaDx.com
1. What is the brand name of your company's POC assay or analyzer?	Afinion 2 Analyzer	FilmArray Respiratory Panel EZ (RPEZ)	Brava Covid-19 Antibody Panel, LightDeck Analyzer
2. What year was your named product first released to market (US, OUS)?	2019, US	2016	2020, US
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); CLIA waived complexity status.	FDA EUA, 2020.
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	20 inches x 36 inches x 20 inches	6.5 inches x 8.6 inches x 9.0 inches
5. What is the intended use or primary function of the product (eg, diagnosis, patient monitoring, point-of-care applications, therapeutic drug monitoring, viral load monitoring)?	Diagnosis and monitoring.	Identification of infectious disease pathogens.	Qualitative detection of infectious disease pathogens.
6. What type of specimen/sample does the product employ (eg, plasma, serum, urine, whole blood)?	Whole blood or urine.	Nasopharyngeal swab.	Serum and plasma (whole blood planned).
7. What types of diseases, conditions, or analytes does the assay detect?	Diabetes.	Identifies pathogens related to upper respiratory infections.	Detects SARS-CoV-2 antibodies (covid-19).
8. This product is:	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ❑ A multiplexed test for use in POC equipment ■ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ■ A multiplexed test for use in POC equipment ❑ A POC analyzer ❑ Other	❑ A self-contained POC test (requiring no equipment) ❑ A single-patient test for use in POC equipment ■ A multiplexed test for use in POC equipment ❑ A POC analyzer ❑ Other
9. 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 minutes for HbA1c and 5 minutes for albumin/creatinine ratio.	About 60 minutes. Test results are available in printout format.	5 minutes on screen. Test results are available in print as a PDF or exported to Excel.
11. What are the product's maximum capacity and throughput under ideal conditions?	16 to 17 tests per hour for A1C and 9 to 10 tests per hour for ACR	8 tests per work day.	10 to 12 tests per hour.
12. What is the typical training time for the product?	1 to 2 hours.	Training includes instrument setup, user training, and running positive and negative controls, and can be completed within 3 hours.	Minimal training is needed for non-laboratory professionals.
13. What types of technical support are available?	Live, virtual, phone, and online technical support.	24-hour tech support and field application specialists to assist with installation and onsite troubleshooting.	Product instructions and customer support via phone and email.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Fastest A1C test in US market and top choice for POC A1C testing among HCPs.	Syndromic polymerase chain reaction-based testing that requires only one nasopharyngeal swab; more comprehensive and accurate than rapid antigen tests.	Lab-quality results in 5 minutes. The LightDeck platform reports quantitative results for multiple tests from one sample, including integral controls.

Quantra®
QPlus® System

Completely Enclosed Cartridge System
No Blood Manipulation After Sample Collection

Safe, Rapid, Reliable

Coagulation Testing near the Patient

The Quantra QPlus System is a novel **Point-of-Care viscoelastic testing** (VET) hemostasis analyzer that provides actionable information on coagulation characteristics of perioperative patients* at the point of care.

Rapidly evaluate:

- Clot time (CT, CTH)
- Likely influence of **Heparin** (CTR)
- Clot stiffness (CS)
- **Fibrinogen** contribution to clot stiffness (FCS)
- **Platelet** contribution to clot stiffness (PCS)

With hands-on time of less than 60 seconds and **NO PIPETTING**, the Quantra system leverages innovative ultrasound technology to provide reliable results **in 15 minutes or less.**

*Indicated for Cardiovascular Surgery and Major Orthopedic surgery.
Results obtained with the Quantra QPlus System should not be the sole basis for patient diagnosis. **RX Only.**
Consult the HemoSonics product instructions for use for complete information.

"The Quantra is the only device on which we can operate safely without needing specialized rooms and a biohazard cabinet..."

– Ekaterina Baryshnikova PhD,
IRCCS Policlinico San Donato, Milan, Italy

"In some cases, POCT diagnostics requires the pipetting of potentially contaminated/infectious patient samples. This is not necessary for devices with cassette structure like the Quantra. Furthermore, the advantage of the Quantra is that no moving parts come into contact with blood. This is a unique benefit that reduces the risk of infections among our medical staff."

– Dr. Florian Raimann, Anesthesiologist, University Hospital Frankfurt, Germany

www.HemoSonics.com

HEMOSONICS
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EKF Diagnostics	HemoSonics	Instrumentation Laboratory	Nova Biomedical
Boerne, Texas (830) 249-0772 www.ekfusa.com	Charlottesville, Va (800) 280-5589 www.HemoSonics.com	Bedford, Mass (800) 955-9525 www.instrumentationlaboratory.com	Waltham, Mass (781) 894-0800 novabiomedical.com
STAT-Site WB	Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge	GEM Premier ChemStat with iQM testing system	Stat Profile Prime Plus
2020	2019, US (De Novo marketing authorization); 2017, OUS (CE mark)	2020, US; 2019, OUS	2014
FDA 510(k); CLIA waiver.	CE mark, 2017; FDA De Novo marketing authorization for Quantra QPlus System, 2019; CE mark for QStat cartridge, 2019.	FDA 510(k), 2019; OUS CE mark, 2019.	FDA 510(k), 2018.
3.7 inches x 2.2 inches x 0.6 inches	19.25 inches x 14 inches x 12 inches	18.5 inches x 13.1 inches x 16.3 inches	18.2 inches x 14.2 inches x 15.5 inches
Patient monitoring in a point-of-care setting.	In vitro diagnostic testing that characterizes hemostasis in a variety of acute care clinical settings.	Point-of-care testing in acute care and laboratory settings.	In vitro diagnostic use by healthcare professionals in clinical laboratory settings.
Whole blood.	Whole blood.	Lithium-heparinized whole blood.	Whole blood.
Detects ketones and glucose.	Evaluates blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.	Quantitatively measures 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.	Detects multiple critical care conditions.
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About 5 seconds for glucose results, 10 seconds for ketone results. Results are displayed on screen.	Typically 15 minutes or less.	About 70 seconds. Results can be viewed on the analyzer screen, printed, or through GemWeb Plus 500 custom connectivity or in the laboratory information system.	60 seconds.
More than 60 tests per hour are achievable.	Up to 5 single-cartridge tests per instrument per hour.	16 samples per hour. Each sample provides results for 12 measured parameters and a set of configurable derived parameters.	45 samples per hour.
1 hour.	30 minutes to 1 hour.	15 minutes.	15 minutes.
Telephone and email technical support.	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.	Technical support on-site and via telephone.	24/7 phone support.
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.	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. Dial display simplifies interpretation.	Actionable results in 70 seconds with one venous or arterial lithium-heparinized, whole blood sample enable rapid clinical decision-making. All-in-one, multiuse Gem Pak cartridge stored at room temperature. iQM provides automated, real-time, and continuous quality management, ensuring laboratory quality results.	Maintenance-free MicroSensor cartridge technology; fast results, with throughput up to 45 samples per hour; automated, true liquid QC; disposable, non-lysing CO-oximeter technology; onboard bidirectional connectivity; remote review and control.

New Drugs of Abuse Calibration Verification

CalVer FLQ Drugs of Abuse for Roche Systems

Order Number: K931M-4

Package Size: 4 x 3 mL

Open Vial: 3 days when stored at 2-8°C

Analytes: 6-AM, AMPH, BARB, BENZ, BUP, COCA, METH, OPIA, OXY, PCP, and THC

CalVer FLQ Drugs of Abuse for Beckman AU

Order Number: K821M-4

Package Size: 4 x 3 mL

Open Vial: 7 days when stored at 2-8°C

Analytes: 6-AM, AMPH, BARB, BENZ, Benzoylecgonine, BUP, METH, OPIA, OXY, PCP, and THC

Providing value to our customers through:

- A broad line of superior quality universal & analyzer specific products.
- Personalized technical support from our experienced laboratory professionals.
- AUDITOR QC, a free and easy to use online data reduction service providing “instant reports”.

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ABL90 Flex Plus	FastPack IP system, produced by Qualigen for Sekisui Diagnostics	CliniTek Status+ Analyzer	CliniTek Status Connect System
2015	FastPack IP system; 2011	2010, US; 2009, OUS	2010, US; 2009, OUS
FDA 510(k); UL; CE mark; EMC emission; EMC immunity	CE mark; FDA 510(k), 2011.	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.
17.7 inches x 9.8 inches x 11.4 inches	9 inches x 13 inches x 12 inches	6.2 inches x 6.7 inches x 10.7 inches	7.5 inches x 6.7 inches x 10.7 inches
In vitro diagnostic analysis in laboratory, near-patient, or point-of-care settings.	Delivers test results for diagnosing and monitoring disease states as well as replacement therapy.	Point-of-care in vitro urinalysis.	Point-of-care in vitro urinalysis.
Heparinized whole blood.	Serum only for free thyroxine (FT4); serum or plasma for all other tests.	Random/spot urine.	Random/spot urine.
Quantitatively measures bilirubin, blood gases, electrolytes, glucose, lactate, oximetry, and pH.	Free thyroxine, human chorionic gonadotropin, prostate-specific antigen, sex hormone binding globulin, testosterone, thyroid-stimulating hormone, and vitamin D.	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.
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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.	FT4 results are available in 7 minutes; all other test results are available in approximately 12 minutes.	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.
1,200 tests per cartridge, 44 samples per hour testing all analytes.	5 to 8 tests per hour, depending on the assay mix. Connects to laboratory information system software.	One patient sample is tested at a time.	One patient sample is tested at a time.
Generally 1 hour (customizable to the location's requirements).	A Web-based training class takes 3 hours and includes product and CLIA requirements.	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.
Toll-free phone or email. On-site support is also available. An online customer care portal provides tools and educational resources.	Technical support is available on weekdays from 6 am through 5 pm PT, and on weekends from 8 am through 5 pm PT.	Phone support 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.
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.	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.	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, barcoding of test information, operator and patient IDs.

We Know How
to Deliver
Consistently Fast,
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Reliable Results.

You Know Why
That Matters.

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is a
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