tech guide

Microbiology Systems

	Affinity Biosensors Santa Barbara, Calif 805-960-5100 www.lifescaleinstruments.com	Beckman Coulter Diagnostics Brea, Calif www.beckmancoulter.com	Becton Dickinson Integrated Diagnostics Franklin Lakes, NJ 201-847-6800 www.bd.com
1. What is the brand name of your company's microbiology system?	LifeScale-AST	DxM 1096 MicroScan WalkAway system	BacTec FX Blood Culture System
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	N/A	FDA 510(k), 1991; CE mark, 2018	FDA(k), 2008; CE Mark, 2008
3. What are the dimensions of the named product?	18.1 inches x 28.4 inches x 28.5 inches	29 inches x 38.5 inches x 34 inches.	Top: 37 inches x 24.5 inches x 34.25 inches; bottom: 78.25 inches x 24.5 inches x 34.25 inches
4. What is the intended use or primary function of the product?	Rapid antimicrobial susceptibility testing	In vitro identification (ID) and antimicrobial susceptibility testing (AST) patterns of microorganisms isolated from clinical specimens.	Rapid detection of bacteria, fungi, yeast, and mycobacteria in clinical blood cultures, sterile body fluids, and platelet specimens.
5. What types of specimen/sample does the product employ?	Positive blood cultures	Diverse specimen types (blood, sputum, stool, tissue, urine).	Blood, platelet unit, sterile body fluid
6. What types of diseases, conditions, or analytes does the system detect?	Bacteria resistant to antimicrobial(s) leading to, for example, sepsis	Aerobic, anaerobic, and fastidious bacteria	Blood stream infections caused by bacteria, fungi, yeast, or mycobacteria and platelet unit contamination caused by bacteria, fungi, or yeast.
7. Which methodology or clinical standard of care does the product use?	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for acid-fast bacteria (AFB) ❑ Parasitemia (%) ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types) ■ Other	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for acid-fast bacteria (AFB) ❑ Parasitemia (%) ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types) ■ Other	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ■ Blood cultures ❑ Fluorochrome staining for acid-fast bacteria (AFB) ❑ Parasitemia (%) ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types) ■ Other
8. If you answered "other," explain briefly.	Minimum inhibitory concentration (MIC) for gram-negative bacteria from positive blood cultures	Minimal inhibitory concentration (MIC) testing following CLSI guidelines	QC testing of platelet units; mycobacterial infection of sterile body fluids
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Up to 5 x 96-well microtiter plates in an 8-hour shift	96 MicroScan panel (test) capacity with 96 wells per panel	Up to 200 bottles (top instrument) or 400 bottles (bottom)
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Diagnostic capabilities to alert for sensor change or addition of fresh reagents. Automatically generates MIC results and clinical breakpoints.	Automated incubation, test interpretation, and reagent control. Automates ID/AST testing; able to process conventional and rapid ID/AST simultaneously. Automates detection of atypical results, epidemiology reports, quality control.	Automated and ergonomically designed, with vial-activated workflow, onboard barcode scanner, integrated computer touchscreen, and bottle-anywhere technology.
11. What is the typical training time for the product?	2 days on-site training	On-demand training available 24 hours a day, 7 days a week	1.5 days on-site training for laboratory; in-service training for specimen collection for nurses and phlebotomists
12. What types of technical support are available?	Telephone, email, online	24/7 call center support	24/7 on-site field service support, remote system support, and remote support via mobile reality applications
13. What capabilities, features, or accessories distinguish this product from others on the market?	Rapid generation of clinically actionable MIC results from positive blood cultures for up to five samples in a single 8-hour work period by each LifeScaleAST instrument	Simultaneous processing of conventional, rapid, and specialty panels on a single automated platform. Accurate resistance detection for the toughest pathogens. Data management of lab test results from order to LIS transmission increases efficiency in busy laboratories.	An integrated solution that includes a scalable and modular BacTec FX instrument, uniquely formulated media, and the Synapsys Microbiology Informatics Solution, a secure data management system with on-demand insights supporting quality improvement initiatives.

Basic Metabolic Panel. *STAT.*

INTRODUCING **the GEM Premier ChemSTAT, a rapid Basic Metabolic Panel analyzer from Instrumentation Laboratory. Offering a customized menu for the emergency department, lab-quality Creatinine (Crea) results and advanced connectivity, this new solution ensures simplicity at the point of care or in the lab. Features Intelligent Quality Management (iQM) for quality-assured testing to support rapid triage and patient care—STAT.**

In a single, venous or arterial lithium-heparinized whole-blood sample

Na^+	K^+	Ca^{++}	Cl^-	Glu	Crea
BUN	tCO_2	Hct	Lac	pH	pCO_2

Calculated parameters

eGFR (MDRD)
eGFR (CKD-EPI)

Acute Care Diagnostics

For more information, please contact your local Werfen representative/distributor or visit InstrumentationLaboratory.com.

Instrumentation Laboratory
A Werfen Company

GEM Premier ChemSTAT is not available in all countries. Not Health Canada-licensed. Not available in Canada.

Becton Dickinson Integrated Diagnostics Franklin Lakes, NJ 201-847-6800 www.bd.com	BioFire Diagnostics Salt Lake City 801-736-6354 www.biofiredx.com	Biomérieux Durham, NC 919-620-2000 www.biomerieux-usa.com	Biomérieux Durham, NC 919-620-2000 www.biomerieux-usa.com
Phoenix identification and susceptibility testing system.	FilmArray Torch	Vitek MS	Bact/Alert Virtuo
FDA 510(k), 2013; CE mark, 2016	FDA 510 K, 2016, CE mark, 2016	FDA 510(k), 2013; CE mark 2011	FDA 510(k), 2017; CE mark 2014
21 inches x 32 inches x 30 inches	base 19 inches x 30 inches; height up to 34 inches depending on the number of modules installed	75.5 inches x 27.5 inches x 33.5 inches	77.2 inches x 28.7 inches x 35.8 inches
Identification and antimicrobial susceptibility testing of clinically significant bacteria. Provides rapid results for most aerobic and facultative anaerobic gram-positive bacteria as well as yeast and yeast-like organisms.	Automated in vitro diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. For use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens.	Mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry to identify microorganisms cultured from human specimens.	Automated microbial test system capable of incubating, agitating, and continuously monitoring for the detection of aerobic, facultative, and anaerobic microorganism growth from blood and other normally sterile body fluids.
Not for direct use with clinical specimens; analyzes pure isolates of clinically significant bacteria from all sample types.	Blood, bronchoalveolar lavage, cerebrospinal fluid, stool, sputum.	Not for direct use with clinical specimens. Isolates are taken from cultures on agar plates or cultured from solid media.	Blood; sterile body fluids.
Identification and susceptibility information to help support patient management decisions.	Common pathogens causing respiratory, gastrointestinal, meningitis/encephalitis, pneumonia, and sepsis syndromes.	Organism identification for bacteria (including mycobacterium), molds, and yeasts.	System is intended to provide organism recovery and detection of microorganisms from blood and other normally sterile body fluids.
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Bacteria or yeast that have been obtained from clinical specimens.	Nested multiplex PCR (nmPCR)	MALDI-TOF technology	N/A
50 panels per instrument; two instruments can be stacked for capacity of 100 panels per day.	Maximum throughput with 12 modules is 351 for RP2.1 panel (approximately 45 minutes run time), and 264 for all other panels (approximately 1 hour run time).	192 isolates tested per equipment run	428 blood cultures per instrument
System has self-calibration and self-diagnostic capabilities and alerts may be generated to recommend spare part replacement. Panels are auto-detected by the system when loaded. The system is compatible with BD remote support services.	Automated sample-to-answer system with LIS interface capability. Software automatically evaluates the built-in controls and determines the results.	Automated identification system with Vitek 2 compatability. Automated reports and connectivity to LIS and middleware. Results interpreted and reported electronically.	Fully automated blood culture system (autoloading, auto-unloading, autoscanning). Automated bottle and instrument reports, including automated calibration tracking. Automated reports and connectivity to LIS and middleware.
3 days on-site training	1 hour	2 days of on-site training. Off-site training is also available.	2 days of on-site training. Off-site training is also available.
24/7 tech support by phone, email, and chat.	Global 24/7 telephone support	24/7 support by phone, email, chat. Remote and on-site support available.	24/7 support by phone, email, chat. Remote and on-site support available.
Uses dual growth technology and a delayed growth algorithm to ensure accurate data. Panels have doubling dilutions to support detection of emerging resistance. Panels provide regular screening of resistance markers, including carbapenemase-producing organisms. Data management supports clinical reporting and surveillance.	Interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. Sample to answer in approximately 1 hour. Reagents are stable at room temperature. Scalable with two to 12 modules per base.	The first MALDI-TOF-based system FDA cleared for clinical use. Database includes over 1,300 clinically relevant organisms and is FDA cleared for the identification of over 400 organisms including mycobacteria, *Nocardia* spp., and molds.	The first fully-automated blood culture system. It enables automated loading and unloading of blood culture bottles, automatically detects the fill level volume on bottles, and provides real-time notifications and active monitoring.

Biomérieux Durham, NC 919-620-2000 www.biomerieux-usa.com	**Biomérieux** Durham, NC 919-620-2000 www.biomerieux-usa.com	**Clever Culture Systems** Bäch, Switzerland www.cleverculturesystems.com	**Great Basin Scientific** West Valley City, Utah 888-320-7636 www.gbscience.com
Vitek 2 Compact	Vitek 2 60	Apas Independence	Great Basin Scientific
FDA 510(k), 2005	FDA 510(k), 1999	FDA 510(k), 2016; CE mark, 2019	FDA 510(k), 2012
23.6 inches x 28.3 inches x 26.8 inches	26 inches x 39 inches x 28 inches	62.99 inches x 78.74 inches x 31.5 inches.	6.3 inches x 17.2inches x 21.4 inches
Automated identification and antimicrobial susceptibility testing of most clinically and/or industry significant organisms (bacteria and yeast) routinely isolated in a microbiology laboratory.	Automated identification and antimicrobial susceptibility testing of most clinically and/or industry significant organisms (bacteria and yeast) routinely isolated in a microbiology laboratory.	Standalone automated microbiology culture plate reader that also sorts into significant and nonsignificant growth.	Infectious disease diagnosis
All specimen types.	All specimen types.	Urine, infection control screening.	Stool, nasopharyngeal swab, vaginal/rectal swab, positive blood culture.
Bacterial and yeast identification and antimicrobial susceptibility testing.	Bacterial and yeast identification and antimicrobial susceptibility testing.	Urinary tract infection, antibiotic-resistant infections.	*Salmonella* spp., *Shigella* spp., *Campylobacter jejuni*, *E. coli*, *B. pertussis*, cfb gene of *S. agalactiae; S. aureus*, *S. lugdunensis*, mecA gene, *Staphylococcus* spp., other
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Colorimetric and turbidometric detection in a microbroth dilution format	Colorimetric and turbidometric detection in a microbroth dilution format	Standard bacterial cultures on standard media in petri dishes	PCR
Scalable with 15, 30, or 60 card capacity. Performs same day identifications and susceptibility testing	60 card capacity. Performs same day identifications and susceptibility testing	200 to 240 plates per hour.	one specimen per run, approx 90 min to result
Microbiology middleware solution provides instrument connectivity, microbiology workflow overview, data management and lab analytics to enhance microbiology workflow and provide valuable insights for increased efficiency.	Middleware solution provides instrument connectivity, microbiology workflow overview, data management and lab analytics to enhance microbiology workflow and provide valuable insights for increased efficiency.	When connected to the LIS, samples of no clinical significance can be auto validated and removed from the workflow. Machine learning algorithms remove plates with no significant growth.	All reagents and controls fully integrated; sample extraction, amplification, and detection performed on-cartridge; results interpreted and reported electronically.
1 week of hands-on training in addition to on-site training.	1 week of hands-on training in addition to on-site training.	1/2 day on-site / remote training.	1 hour
24/7 call center support. Dedicated field service engineers and application specialists. Remote diagnostics for proactive maintenance and remote updates.	24/7 call center support. Dedicated field service engineers and application specialists. Also remote access, proactive maintenance, and remote updates.	Tiered technical support tailored to requirements.	Online, chat, phone
Designed to save space while providing same-day, accurate ID/AST testing. Easy to use and intuitive icon-driven software. Advanced Expert System provides microbial phenotype match and one-click result validation. Designed for small- to mid-sized laboratories.	Designed to save space while providing same-day, accurate ID/AST testing. Easy to use and intuitive icon-driven software. Advanced Expert System provides microbial phenotype match and one-click result validation. Designed for small- to mid-sized laboratories.	The only FDA-cleared product that provides automated culture reading. Other features include compact design, ease of installation, and rapid screening of culture plates.	Sample-to-result, on-demand testing, mid-plex panels

Meridian Bioscience	Qiagen	Randox Laboratories	T2 Biosystems
Cincinnati, Ohio 513-271-3700 mbi@meridianbioscience.com www.meridianbioscience.com	Hilden, Germany 800-362-7737 www.qiagen.com	Crumlin, UK +44 (0) 28 9442 2413 www.randox.com	Lexington, Mass 781-457-1200 www.t2biosystems.com
Curian	QIAstat-Dx	Evidence Investigator	T2Dx Instrument which runs the T2Bacteria, T2Candida and T2SARS-C0V-2 Panels,
US, OUS, 2020. FDA 510(k), CE mark.	FDA emergency use authorization, 2020, for QIAstat-Dx Respiratory SARS-CoV-2 Panel	CE, Health Canada, NPMA, TGA, KSA SFDA MDMA, ANVISA, MDA	FDA, 2014
4.9 inches x 4.5 inches x 4.6 inches	9.21 inches x 12.83 inches x 20.35 inches	29.5 inches x 18.9 inches x 16.5 inches	28.5 inches x 40.5 inches x 24.5 inches
Diagnosis	In vitro diagnosis	Diagnostics across applications including clinical diagnostics, molecular, research, forensic, and veterinary testing.	Bacterial and fungal pathogen detection, with same-day results for clinically relevant fungi and bacteria species as well as SARS-CoV-2.
Stool	Nasopharyngeal swab eluted in universal transport medium liquid	Serum, plasma, whole blood, urine, tissue, cerebrospinal fluid, saliva, forensic matrices.	Whole blood, upper respiratory specimens
Helicobacter pylori	21 respiratory targets including SARS-CoV-2	Cerebral II, chronic kidney disease, cytokines, gastrointestinal, pancreatic cancer, metabolic syndrome, Alzheimer risk detection, chronic lung disease, SARS-CoV-2, others.	Sepsis-causing bacteria or fungal pathogens from whole blood; also direct detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens in transport media.
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Fluorescence technology detection	Real-time PCR technology	Immunoassay principles	The bacterial and fungal are direct from whole blood assays and are not predicated on positive growth.
Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop.	Maximum 28 samples per 8-hour shift.	Up to 44 tests per samples per hour, storing up to 20,000 sample results, reporting up to 2,376 tests per hour.	Up to 20 samples per day, with no batching required for bacterial and fungal panels. Up to 60 samples per day for SARS-CoV-2.
Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS.	Automated sample prep and detection with dry and wet reagents preloaded, onboard swab elution, mechanical cell disruption and liquefaction. Internal controls, automatic analysis, Ct values, amplification curves and seamless LIS connectivity.	Semiautomated system; on-board data analysis features; built-in Charge Coupled Device (CCD) camera, information technology compatibility; on-board storage capacity of 500,000 test results; internal QC software; LIMS integration	Configurable to report results to several LIS providers. Also equipped with internal self-diagnostics to confirm instrument performance.
30 minutes	2 hours	3 days	1 day
Phone support	Remote and on-site support	24/7 customer support, including onsite installation, training, validation	Phone, email, and in-person support
Gastrointestinal-focused immunofluorescence analyzer; simple stool sample prep device removes subjectivity in reading the colorimetric result; every assay has a simple, three-step workflow, allowing for easy training and implementation; intuitive user interface has dual-mode capability to run samples in either batch or single-patient runs.	Streamlined workflow with less than 1 minute hands-on time; detects 21 respiratory targets, including SARS-CoV-2, in about 1 hour and allows access to Ct values and amplification curves for pathogens detected.	Multiplex testing offers complete patient profiling with the most comprehensive test menu on the market. Consolidating immunoassay and molecular diagnostics on a single platform with protein and DNA biochips. Simultaneous detection of multiple biomarkers from a single patient sample ensures efficient and cost-effective testing.	Identify fungal and bacterial pathogens directly from whole blood, without the wait for a positive blood culture enabling clinicians to target therapy for sepsis patients in 3 to 5 hours.

Thermo Fisher Scientific Waltham, Mass 800-255-6730 www.thermofisher.com	**Thermo Fisher Scientific** Waltham, Mass 800-255-6730 www.thermofisher.com	**Thermo Fisher Scientific** Waltham, Mass 800-255-6730 www.thermofisher.com	**Thermo Fisher Scientific** Waltham, Mass 800-255-6730 www.thermofisher.com
Thermo Scientific Sensititre Aris HiQ system	Automated workflow: Copan Wasp Walkaway Specimen Processor with Remel Media	Full lab automation: Copan WaspLab with Remel Media	Thermo Scientific VersaTrek Automated Microbial Detection System
FDA 510(k)	N/A	N/A	FDA 510(k)
44.3 inches x 29.5 inches x 28.9 inches	76 inches x 81.5 inches x 43.5 inches	76 inches x 81.5 inches x 43.5 inches	76 inches x 52 inches x 34.75 inches
Automated organism identification and antimicrobial susceptibility testing	Automated specimen processing	Laboratory automation	Automated microbial detection, including blood culture and mycobacteria testing
Bacterial, fungal, and mycobacterial isolates	All specimen types	All specimen types	Blood and other normally sterile body fluids for cultivating and recovering microorganisms. Sterile body specimens and digested-decontaminated clinical specimens for the recovery of mycobacteria.
Bacterial identification and antimicrobial susceptibility testing.	N/A	N/A	Detection of all organism types, including common and fastidious organisms, and mycobacteria, as well as mycobacterium tuberculosis (Mtb) susceptibility testing.
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Fluorescence technology detection; broth microdilution.			
100 minimum inhibitory concentration, breakpoint, or identification plates	378 plate capacity with 9 silo carousel; throughput capacity that matches 2 to 3 full-time equivalents	378 plate capacity with 9 silo carousel; throughput capacity that matches 2 to 3 full-time equivalents; incubator capacity 854 plates for single, 1,708 plates for double	38,500 maximum annual bottle volume for 5-day blood culture and 27,500 for 7-day blood culture; 4,700 maximum annual bottle volume for myco
Automatically incubate and read microtitre plates to identify organisms and report susceptibility results with LIS connectivity, customizable Expert System, QC module, automated reports/alerts, and optional epidemiology module.	Provides full automation of pre-analytical processing for planting and streaking, Gram slide prep, and enrichment broth inoculation.	Customized for each lab, using flexible conveyors, with robotic plate management system, smart incubators, and state-of-the-art image acquisition technology.	Provides automated microbial detection with LIS connectivity and intuitive software for one-touch access to patient samples and results.
3 days	1 week	1 to 1.5 weeks	3 days for all user types/shifts
24/7	24/7	24/7	24/7
Large selection of standard and custom-made MIC plates. Earlier access to AST for new, potent antimicrobials; large and up-to-date selection of FDA-cleared antimicrobials. Scalable instrumentation to support manual or automated workflows.	Automates all aspects of specimen processing using trusted Remel media products, optimized for automation. With fully automated specimen processing, valuable resources can be redeployed to ensure optimal lab productivity.	Trusted solutions for the entire microbiology lab, from planting and streaking to AST and diagnosis.	The only system with four FDA-cleared tests on one platform (blood culture, sterile body fluids, myco detection, and Mtb susceptibilities), and the only system that can detect any gas produced or consumed by organisms, to detect a wider range of organisms. Two-bottle media system for all patients is the only media FDA-cleared for draws as low as 0.1mL