tech guide

Microbiology Systems

	Abbott Chicago abbott.com/poct	Advanced Instruments, LLC Norwood, MA 781-320-9000 aicompanies.com	Affinity Biosensors Santa Barbara, CA 805-960-5100 www.lifescaleinstruments.com
1. What is the brand name of your company's microbiology system?	ID NOW	Anoxomat III Anaerobic Jar System	LifeScale-AST
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	2014: CE Mark, 510(k), CLIA waived		N/A
3. What are the dimensions of the named product?	8.15" W x 5.71" H x 7.64" D	Width X Depth X Height: 12 X 9 X 13 in. (30.5 X 23 X 33 cm)	18.1 inches x 28.4 inches x 28.5 inches
4. What is the intended use or primary function of the product?	A rapid, instrument-based, isothermal system for the qualitative detection of infectious diseases at the point of care.	The Anoxomat uses the McIntosh and Fildes system of evacuation and replacement to quickly create anaerobic, microaerophilic, and capnophilic environments for bacterial cultivation. The Anoxomat can create exact, repeatable conditions with gas mixtures within 0.5% of the required value.	Rapid antimicrobial susceptibility testing
5. What types of specimen/sample does the product employ?	Influenza A and B: nasal swab, nasopharyngeal swab; strep A: throat swab; RSV: nasopharyngeal swab; COVID-19: nasal swab, nasopharyngeal swab, throat swab	The Anoxomat is used to process bacterial samples prior to incubation to provide optimal growth.	Positive blood cultures
6. What types of diseases, conditions, or analytes does the system detect?	Detects influenza A and B, strep A, RSV, COVID-19 (COVID-19 assay is available in the US under the Food and Drug Administration Emergency Use Authorization [EUA]).		Bacteria resistant to antimicrobial(s) leading to, for example, sepsis
7. Which methodology or clinical standard of care does the product use?	■ Other	■ Cell lines and incubation time for virus isolation	■ Other
8. If you answered "other," explain briefly.	Utilizes isothermal technology, a proven next-generation molecular technology that uses proprietary enzymes and constant temperature, to achieve the fastest available amplification."		Minimum inhibitory concentration (MIC) for gram-negative bacteria from positive blood cultures
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	Varies by assay and patient results	Up to 144 samples can be processed at one time with the Anoxomat III.	Up to 5 x 96-well microtiter plates in an 8-hour shift
10. Briefly describe any automation or connectivity features or options	Out-of-the-box connectivity to industry leading open platform connectivity solutions	An automatic quality assurance program runs before each recipe to detect appropriate catalyst activity, eliminating guesswork and ensuring the creation of exact, repeatable environmental conditions.	Diagnostic capabilities to alert for sensor change or addition of fresh reagents. Automatically generates MIC results and clinical breakpoints.
11. What is the typical training time for the product?	CLIA-waived	Training for the instrument is typically completed in less than 2 hours.	2 days on-site training
12. What types of technical support are available?	Phone, email, in person, virtual (varies based on location)	Installation and training provided by our expert technicians is available to help your team get started with the Anoxomat. A one-year limited warranty is included with purchase of every instrument, and contract support with comprehensive preventative maintenance is offered to ensure optimal device performace.	Telephone, email, online
13. What capabilities, features, or accessories distinguish this product from others on the market?	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.	Low gas consumption with the Anoxomat delivers substantial operational savings in comparison to gas generating sachet systems and chambers, enabling a lower cost of ownership. Plates can be taken in and out of anaerobic environments in minutes instead of hours with gas generating sachet systems, expediting turnaround times.	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

Becton Dickinson Integrated Diagnostics Franklin Lakes, NJ 201-847-6800 www.bd.com	**Beckman Coulter Diagnostics** Brea, CA www.beckmancoulter.com	**Beckman Coulter Diagnostics** Brea, CA www.beckmancoulter.com	**Biomérieux** Durham, NC 919-620-2000 www.biomerieux-usa.com
BD BACTEC FX Blood Culture System	DxM MicroScan WalkAway System	MicroScan autoSCAN-4 System	VITEK MS PRIME
FDA(k), 2008; CE Mark, 2008	FDA 510(k), 1991; CE mark	FDA 510(k)1984, CE Mark	FDA 510(k), 2022 ; CE Mark 2021
Top: 37" x 24.5" x 34.25"; bottom: 78.25" x 24.5" x 34.25"	DxM 1040 MicroScan WalkAway: 29" H x 38.5" W x 34"; DxM 1096 MicroScan WalkAway: 37" H x 38.5" W x 34"	10" H x 19" W x 23" D	44" x 28" x 28"
Rapid detection of bacteria, fungi, yeast, and mycobacteria in clinical blood cultures, sterile body fluids, and platelet specimens.	In vitro identification (ID) and antimicrobial susceptibility testing (AST) patterns of microorganisms isolated from clinical specimens.	In vitro identification (ID) and antimicrobial susceptibility testing (AST) patterns of microorganisms isolated from clinical specimens.	Mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry to identify microorganisms cultured from human specimens
Blood, platelet unit, sterile body fluid	Diverse specimen types (blood, sputum, stool, tissue, urine).	Isolate testing from diverse specimen types (e.g., urine, blood, sputum, feces, sputum)	Not for direct use with clinical specimens. Isolates are taken from cultures on agar plates or cultured from solid media.
Blood stream infections caused by bacteria, fungi, yeast, or mycobacteria and platelet unit contamination caused by bacteria, fungi, or yeast.	Identification of yeast and bacteria Antimicrobial Susceptibility of bacteriaOR Aerobic, anaerobic and fastidious bacteria. Yeast.	Aerobic, anaerobic and fastidious bacteria	Organism identification for bacteria (including mycobacterium), molds, and yeasts.
■ Blood cultures ■ Other	■ Other	■ Other	■ Other
QC testing of platelet units; mycobacterial infection of sterile body fluids	Minimal inhibitory concentration (MIC) testing following FDA guidelines; identifications by classic colorimetric, chromogenic or rapid fluorescent methods	Minimal inhibitory concentration (MIC) testing following FDA guidelines; identifications by classic colorimetric or chromogenic methods	MALDI-TOF technology
Top Instrument - 200 bottle capacity, Bottom instrument - 200 bottle capacity, Stack Instrument (Combination of FX Top & Bottom) - 400 bottle capacity, FX40 Instrument - 40 bottle capacity	DxM 1096: 96 MicroScan panel (test) capacity with 96 wells per panel DxM1040: 40 MicroScan panel (test) capacity with 96 wells per panel	Single MicroScan panel (test) capacity with 96 wells per panel	768 isolates tested per equipment run
The instrument is automated and ergonomically designed, with vial-activated workflow, on board barcode scanner, integrated computer touch screen, and bottle-anywhere technology, powered by the BD Synapsys Informatics solution.	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. Networking and remote diagnostics available.	Automated read of bacterial ID/AST in seconds. Processes overnight ID, AST, and Specialty ID panels one at a time following off-line incubation. Automates detection of atypical results, epidemiology reports, quality control. Networking & remote diagnostics available.	Automated identification system with VITEK 2 compatability. Automated reports and connectivity to LIS and MYLA middleware. Results interpreted and reported electronically.
1.5 days on-site training for laboratory; in-service training for specimen collection for nurses and phlebotomists	On-demand training available 24 hours a day, 7 days a week; 3-5 days onsite training at time of installation; advanced classroom training available.	On-demand training available 24 hours a day, 7 days a week; 2-3 days onsite training at time of installation; advanced classroom training available.	2 days of on-site training. Off-site training is also available, including virtual classroom training
24/7 on-site field service support, remote system support, and remote support via mobile reality applications	24/7 call center support	24/7 call center support	24/7 support by phone, email, chat. Remote and on-site support available.
The BD BACTEC Blood Culture solution includes the scalable and modular BD BACTEC FX instrument, uniquely formulated BD BACTEC media, and the BD Synapsys Informatics Solution, a cybersecure data management system that monitors blood culture best practices and daily workflow analytics.	Simultaneous processing of conventional, rapid, and specialty panels on a single automated platform. Accurate resistance detection for the toughest pathogens. LabPro v5.0 data management provides data encryption, audit trail and other security features within guidelines set by the FDA, GDPR, and HIPAA.	Semi-automated processing of conventional and specialty panels. Accurate emerging resistance detection for the toughest pathogens. LabPro v5.0 data management provides data encryption, audit trail and other security features within guidelines set by the FDA, GDPR, and HIPAA.	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.

Biomérieux	**Biomérieux**	**Biomérieux**	**Hardy Diagnostics**
Durham, NC 919-620-2000 www.biomerieux-usa.com	Durham, NC 919-620-2000 www.biomerieux-usa.com	Durham, NC 919-620-2000 www.biomerieux-usa.com	Santa Maria, CA 800-266-2222 www.hardydiagnostics.com
Bact/Alert Virtuo	Vitek 2 Compact	Vitek 2 60	BioCode MDx-3000 by Applied BioCode
FDA 510(k), 2017; CE mark 2014	FDA 510(k), 2005	FDA 510(k), 1999	MDx-3000 System & Syndromic 17-target GPP (FDA 510(k), 2018, EU CE Mark), Syndromic 17-target RPP (FDA 510(k), 2020, EU CE Mark); SARS-CoV-2 PCR Test (FDA EUA, 2020), SARS-CoV-2 Flu Plus PCR Test (FDA EUA, 2021)
77.2" x 28.7" x 35.8"	23.6" x 28.3" x 26.8"	26" x 39" x 28"	42"W x 31"D x 61"H
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.	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.	Automated, high-throughput, multiplex, molecular diagnostic system
Blood; sterile body fluids.	All specimen types.	All specimen types.	Stool, nasopharyngeal swab, oropharyngeal, nasal swab, bronchoalveolar lavage
System is intended to provide organism recovery and detection of microorganisms from blood and other normally sterile body fluids.	Bacterial and yeast identification and antimicrobial susceptibility testing.	Bacterial and yeast identification and antimicrobial susceptibility testing.	Gastrointestinal pathogens, respiratory pathogens, SARS-CoV-2, fungal analyte specific targets.
■ Blood cultures	■ Other	■ Other	■ Other
N/A	Colorimetric and turbidometric detection in a microbroth dilution format	Colorimetric and turbidometric detection in a microbroth dilution format	Barcoded magnetic bead (BMB) technology
428 blood cultures per instrument	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	The MDx-3000 system's 96-well microplate format can process up to 188 patient samples in 8-hour shift
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.	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.	The MDx-3000 automates the PCR amplification, hybridization/target capture and detection steps of molecular testing, with automated data management through LIS connectivity.
2 days of on-site training. Off-site training is also available.	1 week of hands-on training in addition to on-site training.	1 week of hands-on training in addition to on-site training.	Applied BioCode recommends a minimum of 2 days for our on-site hands-on training. Additional training is offered to suit your lab's needs.
24/7 support by phone, email, chat. Remote and on-site support available.	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.	Supports clients with on-site field service support, remote system support, phone, and email support.
A 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.	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.	Simultaneous testing of up to three different assay panels on a single run, data masking option enables select target reporting based on clinician's order

BIOMÉRIEUX

VITEK® 2 and ETEST®

A Match Made in the Microcosmos

Together, VITEK® 2 and ETEST® provide a complete susceptibility testing solution you can trust.

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FULLY AUTOMATED

VITEK 2 offers a fully automated ID/AST system to reduce hands-on-time and intuitive software to increase productivity. With more than 25 AST cards to choose from, the VITEK 2 has you covered for nearly all susceptibility testing your lab will face.

COMPLEMENTARY

ETEST complements the VITEK 2 and adapts to your lab's needs for confirmation testing, testing pesky bugs, and using the newest drugs. There are over 75 drugs available on ETEST and two packaging formats: the Single Pack and the new M100 MULTI-PACK.

The laboratory plays a vital role in delivering timely, actionable results to physicians and pharmacists. VITEK 2 and ETEST work together to address your laboratory's susceptibility testing needs to positively impact patient care and antimicrobial stewardship programs.

Scan the QR code to learn more about VITEK 2, ETEST, and bioMerieux's total ID/AST solution.

PIONEERING DIAGNOSTICS

Meridian Bioscience	OpGen, Inc.	Randox Laboratories	Specific Diagnostics
Cincinnnati, Ohio 45244 513-271-3700 / mbi@meridianbioscience.com www.meridianbioscience.com	Gaithersburg, MD 301-869-9683 www.opgen.com	Crumlin, UK +44 (0) 28 9442 2413 www.randox.com	San Jose, CA www.specificdx.com
Curian	Unyvero	Evidence Investigator	SPECIFIC REVEAL Rapid AST System
US, OUS, 2020. FDA 510(k), CE mark.	FDA de novo 510(k), April 2018 (Unyvero System and Unyvero LRT Panel); FDA 510(k), December 2019 (Unyvero LRT BAL Panel)	CE, Health Canada, NPMA, TGA, KSA SFDA MDMA, ANVISA, MDA	CE mark 2020
4.9" x 4.5" x 4.6"	Combined Lysator, Cockpit, Analyzer 54" (H) x 47" (D) x 45" (W).	29.5"x 18.9" x 16.5"	Depth: 26.9", Width: 16.7" Height: 7.9"
Diagnosis	Automated in vitro diagnostic (IVD) system intended for use with Unyvero panels. For use in combination with application-specific Unyvero cartridges to detect multiple nucleic acid targets contained in clinical specimens.	Diagnostics across applications including clinical diagnostics, molecular, research, forensic, and veterinary testing.	Automated platform for conducting phenotypic quantitative (MIC) and qualitative (S,I,R) Antimicrobial Susceptibility Testing of most clinical and industry significant bacteria.
Stool	Endotracheal aspirates, Bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL).	Serum, plasma, whole blood, urine, tissue, cerebrospinal fluid, saliva, forensic matrices.	Positive blood cultures
Helicobacter pylori, campylobacter-specific antigen including C. jejuni, C. coli, C. upsaliensis, and C. lari	Identification of common pathogens and their associated resistance markers causing lower respiratory tract infections, direct from native specimen.	Cerebral II, chronic kidney disease, cytokines, gastrointestinal, pancreatic cancer, metabolic syndrome, Alzheimer's risk detection, chronic lung disease, SARS-CoV-2, others.	Bacterial antimicrobial susceptibility testing
■ Other	■ Other	■ Blood cultures ■ Other	■ Other
Fluorescence technology detection	PCR technology with array detection, high multiplexing capability.	Immunoassay principles	Minimum inhibitory concentration (MIC) for gram-negative bacteria from positive blood cultures, using CLSI and EUCAST guidelines.
Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop.	Random access, 2 samples per analyzer module, scalable up to 4 analyzers per cockpit, direct from native specimen 180µL, 4.5 hours run time.	Up to 44 tests per samples per hour, storing up to 20,000 sample results, reporting up to 2,376 tests per hour.	4 samples per instrument per 8 hour shift. 6 instruments can be stacked in 2 stacks (3 instruments per stack) for a capacity of 24 samples per shift.
Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS.	Automated sample-to-answer system, built-in internal controls, LIS capable	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	Automated, single shift impact, load-and-go workflow is guided by intuitive, touchscreen enabled interface. System provides real-time monitoring of MICs with bi-directional LIS integration that allows seamless integration of any ID system and SPECIFIC REVEAL. Powerful analysis dashboard enables monitoring species and antibiotic resistance trends across hospital network.
30 minutes	4.5 hours	3 days	1 day of hands-on, on-site training
Phone support	Technical support accessible 24/7 via phone and email; field service and field applications for onsite support	24/7 customer support, including onsite installation, training, validation	24/7 technical suppport by phone and email. Access to dedicated field application specialist and field service engineers for an on-site support.
Gastrointestinal-focused immunofluorescent analyzer; eliminates subjectivity commonly associated with colorimetric assays; each assay has a simple stool sample prep device with a 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	Interacts with cartridge assembly for isolation, amplification, and detection of targeted nucleic acid sequences using end-point PCR technology in a closed system. Sample to answer in 4.5 hours. Cartridges are stable at room temperature.	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.	Simple sample-to-result workflow, with less than 3 minute hands-on time, provides AST results in average of 5 hours. Assay covers wide range of antimicrobial drugs in a single panel. Modular and stakable design meets the needs of institutions of all sizes.

Thermo Fisher Scientific	Thermo Fisher Scientific	T2 Biosystems	Vela Diagnostics
Waltham, MA 800-255-6730 thermofisher.com	Waltham, MA 800-255-6730 www.thermofisher.com	Lexington, MA 781-457-1200 www.t2biosystems.com	Fairfield, NJ +1 877 593 7528 www.veladx.com
Clever Culture Systems APAS Independence	Thermo Scientific Sensititre Aris HiQ system	T2Dx Instrument which runs the T2Bacteria, T2Candida and T2SARS-C0V-2 Panels,	Sentosa® SQ HIV-1 Genotyping Assay
FDA 510(k), 2016; CE mark, 2019	FDA 510(k)	FDA, 2014	FDA, 2019
62.99" x 78.74" x 31.5"	44.3" x 29.5" x 28.9"	28.5" x 40.5" x 24.5"	26.4 x 42.2 x 24.1", 21 x 20 x 24"
Standalone automated microbiology culture plate reader that also sorts into significant and nonsignificant growth.	Automated organism identification and antimicrobial susceptibility testing	Bacterial and fungal pathogen detection, with same-day results for clinically relevant fungi and bacteria species as well as SARS-CoV-2.	Highly-automated, sample-to-result NGS-based assay for qualitative detection of drug resistant mutations (DRMs) in the pol gene of HIV-1 Group M subtypes A to K, allowing for assesment of possible drug resistances present in a particular strain of HIV-1.
Urine, infection control screening.	Bacterial, fungal, and mycobacterial isolates	Whole blood, upper respiratory specimens	EDTA Plasma
Urinary tract infection, antibiotic-resistant infections.	Bacterial identification and antimicrobial susceptibility testing.	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.	To detect DRMs in protease, reverse transcriptase and integrase regions of HIV-1 Group M subtypes A to K
■ Other	■ Other	■ Other	■ Other
Standard bacterial cultures on standard media in petri dishes	Fluorescence technology detection; broth microdilution.	The bacterial and fungal are direct from whole blood assays and are not predicated on positive growth.	Next-Generation Sequencing (NGS)
200 to 240 plates per hour.	100 minimum inhibitory concentration, breakpoint, or identification plates	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.	22 samples per run
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.	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.	Configurable to report results to several LIS providers. Also equipped with internal self-diagnostics to confirm instrument performance.	Highly-automated workflow including sample extraction, library and template preparation, data analysis and report generation. Automated reporting includes interpretation from Stanford University HIV Drug Resistance Database.
1/2 day on-site/remote training.	3 days	1 day	1 week of technical and hands-on training
Tiered technical support tailored to requirements.	24/7	Phone, email, and in-person support	Remote and on-site support
FDA-cleared product that provides automated culture reading. Other features include compact design, ease of installation, and rapid screening of culture plates.	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.	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.	FDA De Novo solution that detects DRMs in HIV-1 patient samples using NGS, giving better sensitivity than traditional Sanger sequencing. The test features a highly-automated, sample-to-result workflow that generates a comprehensive HIV Drug Resistance Interpretation Report in 2 days.