# tech guide

Microbiology Systems

| | Affinity Biosensors<br><br>Santa Barbara, CA<br>805-960-5100<br>www.affinitybio.com | Beckman Coulter Diagnostics<br><br>Brea, CA<br>www.beckmancoulter.com | Becton Dickinson Integrated Diagnostics<br><br>Franklin Lakes, NJ<br>201-847-6800<br>www.bd.com |
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| 1. What is the brand name of your company's microbiology system? | LifeScale AST | DxM MicroScan WalkAway System | BD Phoenix M50 Automated Microbiology System |
| 2. Specify the authorizing agency, type, and year of the product's regulatory authorizations. | | FDA 510(k), 1991; CE mark (IVDR 2022) | FDA 2016, CE 2016 |
| 3. What are the dimensions of the named product? | 18.1" x 28.4" x 28.5" | DxM 1040 MicroScan WalkAway: 29" H x 38.5" W x 34"; DxM 1096 MicroScan WalkAway: 37" H x 38.5" W x 34" | 21" x 32" x 30" |
| 4. What is the intended use or primary function of the product? | Rapid antimicrobial susceptibility testing | Diagnostic tools for determining the microbial identification (ID) and antimicrobial agent susceptibility (AST) patterns of microorganisms isolated from clinical specimens, by trained laboratory personnel. | Rapid identification (ID) bacteria/yeast and antimicrobial susceptibility testing (AST) of clinically significant bacteria. |
| 5. What types of specimen/sample does the product employ? | Positive blood cultures | Isolate testing from diverse specimen types (e.g., urine, blood, sputum, feces) | Pure culture isolates of aerobic and/or facultatively anaerobic Gram-negative organisms |
| 6. What types of diseases, conditions, or analytes does the system detect? | Bacteria resistant to antimicrobial(s) leading to, for example, sepsis | Identification of yeast and bacteria; antimicrobial susceptibility of bacteria | The system can provide identification and susceptibility results of most clinically significant Gram-negative and Gram-positive bacteria, as well as identification results of yeast. |
| 7. Which methodology or clinical standard of care does the product use? | ■ Other | ■ Other | ■ Other |
| 8. If you answered "other," explain briefly. | Minimum inhibitory concentration (MIC) for Gram-negative bacteria from positive blood cultures (CLSI, FDA) by exploiting the company's Resonant Mass Measurement technology | Minimal inhibitory concentration (MIC) testing; identifications by classic colorimetric, chromogenic, or rapid fluorescent methods | BD Phoenix System utilizes an optimized colorimetric redox indicator for AST, and a variety of colorimetric and fluorometric indicators for ID. |
| 9. What are the product's maximum specimen capacity and throughput under ideal conditions? | LifeScale-AST can measure up to 5 x 96-well microtitre plates containing 14 antimicrobials in an 8-hour shift | DxM 1096: 96 MicroScan panel (test) capacity with 96 wells per panel; DxM1040: 40 MicroScan panel (test) capacity with 96 wells per panel | 50 identification and antimicrobial susceptibility tests can be performed at a time. The instrument is compact and stackable, allowing for increased testing volumes by doubling capacity within the same footprint. |
| 10. Briefly describe any automation or connectivity features or options | 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 simultaneously. Automates detection of atypical results, epidemiology reports, quality control. Networking and remote diagnostics available. | The BD EpiCenter data management system interfaces with the BD Phoenix M50 and provides intuitive, on-demand antibiogram generation and flexible reporting options. |
| 11. What is the typical training time for the product? | | 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. | 2.5 days |
| 12. What types of technical support are available? | Telephone, e-mail, online | 24/7 call center support | 24/7 on-site field service support, remote system support, and remote support via merged 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 5 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. LabPro v5.0 data management provides data encryption, audit trail, and other security features within guidelines set by the FDA, GDPR, and HIPAA. | True MIC derived from dilutions using doubling antibiotic concentrations. Growth determined by redox and turbidity measurement. |



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| **BioMérieux** | **DiaSorin Inc** | **DiaSorin Inc** | **Karius Inc.** |
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| Salt Lake City, UT<br>919-620-2000<br>www.biomerieux-usa.com | Stillwater, MN<br>www.diasorin.com | Stillwater, MN<br>www.diasorin.com | Redwood City, CA<br>866-452-7487<br>www.kariusdx.com |
| VITEK MS PRIME | LIAISON XL | LIAISON XS | The Karius Test |
| FDA 510(k), 2022 ; CE Mark 2021 | FDA 510(k), 2011; CE Mark 2010 | FDA 510(k), 2021; CE Mark 2019 | N/A |
| 44" x 28" x 28" | 59" H x 59" W x 36" D | 28" H x 47" W x 30" D | Send-out kits include BD Vacutainer Plasma Preparation Tubes (PPT). Tube size: 13x100mm with draw volume 5ML |
| Mass spectrometry system using matrix-assisted laser desorption/ ionization time of flight mass spectrometry to identify microorganisms cultured from human specimens | High-volume, random access chemiluminescence immunoassay floor model analyzer that automates and consolidates specialty testing | Low- to mid-volume, random access chemiluminescence immunoassay benchtop analyzer that automates and consolidates specialty testing | Provides the ability to use only a single blood draw to rapidly, and with high accuracy, detect more than 1,000 clinically relevant pathogens. |
| Not for direct use with clinical specimens. Isolates are taken from cultures on agar plates or cultured from solid media. | Serum, plasma, urine, stool | Serum, plasma, urine, stool | Blood |
| Organism identification for bacteria (including mycobacterium), molds, and yeasts. | Infection management, latent tuberculosis, infectious disease, metabolics, gastrointestinal, hepatitis + HIV, endocrine | Infection management, latent tuberculosis, infectious disease, metabolics, gastrointestinal, hepatitis + HIV, endocrine | Help physicians diagnose infections in immunocompromised patients that include over 1,000 clinicaly relevant pathogens (bacteria, fungi/molds, DNA viruses, other eukaryotes, archea) causing deep-seated and blood stream infections. Also helps diagnose pneumonia, invasive fungal infections, culture-negative endocarditis, opportunistic infections, and infectious causes of neutropenic fever |
| ■ Other | ■ Other | ■ Other | ■ Other |
| MALDI-TOF technology | Chemiluminescent immunoassay | Chemiluminescent immunoassay | Next-generation sequencing of microbial cell-free DNA |
| 768 isolates tested per equipment run | 120 samples, up to 171 tests per hour | 48 samples, up to 85 tests per hour | N/A |
| Automated identification system with VITEK 2 compatability. Automated reports and connectivity to LIS and MYLA middleware. Results interpreted and reported electronically. | Laboratory automation system (track) ready, connectivity to LIS (host) and/or Middleware, integrated QC software, remote access, traceability via RFID technology | Connectivity to LIS (host) and/ or middleware, integrated QC software, remote access, traceability via RFID technology, programmable automated daily priming | Access to results (fax, mobile app, online portal, text notification) |
| 2 days of on-site training. Off-site training is also available, including virtual classroom training | 2 days on-site training; advanced customer training offerred at vendor site | 2 days on-site training | CLIA-waived |
| 24/7 support by phone, email, chat. Remote and on-site support available. | 24/7 phone support, remote, and on-site support available | 24/7 phone support, remote, and on-site support available | Clinician support (24/7 phone, text, email support, consultation with Karius infectious disease physician) |
| 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. | Automated specialty testing consolidation and continuous monitoring of processes, reagents, and consumables empowers timely and reliable results for better patient care. | Automated specialty testing consolidation and continuous monitoring of processes, reagents, and consumables empowers timely and reliable results for better patient care. | Non-invasive liquid biopsy needing only a single blood sample to rapidly detect over 1,000 pathogens. Helps clinicians avoid invasive, low-yield, and sequential diagnostic tests that can delay treatment for the most vulnerable hospitalized patients by speeding up diagnosis with a 1-day turnaround time. |



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| | Meridian Bioscience | Qiagen Inc. | Randox Laboratories Ltd. |
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| | Cincinnnati, OH<br>513-271-3700<br>mbi@meridianbioscience.com<br>www.meridianbioscience.com | Germantown, MD<br>Tracy Gambrell<br>240-751-0276<br>www.qiagen.com/neumodx | Kearneysville, WV<br>304-728-2890<br>www.randox.com |
| 1. What is the brand name of your company's microbiology system? | Curian | NeuMoDx 96, NeuMoDx 288 | Qnostics Meningitis/Encephalitis (ME) Evaluation Panel |
| 2. Specify the authorizing agency, type, and year of the product's regulatory authorizations. | US, OUS, 2020. FDA 510(k), CE mark. | The NeuMoDx SARS-CoV-2 Assay: EUA in the United States - 2020; The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay: EUA in the United States - 2021. | RUO |
| 3. What are the dimensions of the named product? | 4.9" x 4.5" x 4.6" | NeuMoDx 96: Height: 43", 54", 43"; NeuMoDx 288: 75", 72", 43" | |
| 4. What is the intended use or primary function of the product? | Diagnosis & eradication | Infectious disease molecular diagnostics—IVD and self-developed assays | Dedicated evaluation panel for validating a new meningitis/encephalitis (ME) assay or instrument to ensure that everything is working as expected |
| 5. What types of specimen/sample does the product employ? | Stool | Plasma, serum, universal/viral transport media, CSF, whole-blood, growth media, cytology media, saliva, nasopharyngeal, oropharyngeal, nasal swabs and bronchoalveolar lavage | Qnostics offer exclusively whole pathogen control material which contains the full organism genome and is designed to mimic the performance of a patient sample. |
| 6. What types of diseases, conditions, or analytes does the system detect? | Helicobacter pylori, Campylobacter-specific antigen (including C. jejuni, C. coli, C. upsaliensis, C. lari), and Shiga-toxin producing E. coli with detection and differentiation of Shiga toxin 1 and Shiga toxin 2. | Respiratory - blood-borne pathogens, transplant, sexual reproductive health, vector-borne pathogens | Escherichia coli, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, Cytomegalovirus, Enterovirus, Herpes Simplex Virus 1, Herpes Simplex Virus 2, Human Herpes Virus 6, Human Parechovirus, Varicella Zoster virus, Cryptococcus neoforman/gattii |
| 7. Which methodology or clinical standard of care does the product use? | ■ Other | ■ Other | ■ Other |
| 8. If you answered "other," explain briefly. | Fluorescent immunoassay | Real Time PCR | Designed to provide a quality control solution for molecular infectious disease testing in molecular diagnostics laboratories and laboratories carrying out nucleic acid testing (NAT) |
| 9. What are the product's maximum specimen capacity and throughput under ideal conditions? | Incubate and analyze mode incubates one specimen at a time; analyze now mode allows for batching of multiple specimens incubated on the benchtop. | The NeuModDx 96—Up to 144 samples in an 8-hour shift. The NeuMoDx 288—Up to 288 samples in an 8-hour shift. | |
| 10. Briefly describe any automation or connectivity features or options | Walkaway processing; analyzer automatically counts down and reads results when the incubation period is complete; autodetection of test type; interface with LIS. | Seamless bidirectional LIS integration with ASTM and HL7 protocols. Remote access allows monitoring for improved service and support. | Connects to Acusera 24.7—our interlaboratory data management software. With the ability to generate real time peer group data while also automatically calculating measurement uncertainty. |
| 11. What is the typical training time for the product? | 30 minutes | On-site 3-day training by a QIAGEN field application specialist (FAS) and ongoing field support once live. | Minimal preparation and training time required |
| 12. What types of technical support are available? | Phone support, virtual training modules available, on-site training as requested | Phone, email, and chat technical service support. Field application specialist team provides on-site training. Provides on-site install IQ/OQ and preventative maintenance. | 24/7 phone and email support, online educational material and references, on-site support (available in certain circumstances) |
| 13. What capabilities, features, or accessories distinguish this product from others on the market? | 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. | Easy to learn, easy to use, easy to maintain. Intuitive software and simple loading workflow. Reagents that are ready-to-use, room temperature and with month-long on-deck stability. Adaptable to evolving needs - batch, random access and STAT loading options. Consolidation to a single platform. Seamless combination of self-developed and IVD tests. | Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This ME Evaluation Panel has been designed with known performance on the BioFire FilmArray platform and is intended to be used with BioFire's verification pooling scheme for the FilmArray ME assay, but may also be used with other molecular diagnostic platforms. |



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| Thermo Fisher Scientific | Thermo Fisher Scientific | T2 Biosystems |
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| Waltham, MA<br>800-255-6730<br>thermofisher.com | Waltham, MA<br>800-255-6730<br>thermofisher.com | Lexington, MA<br>781-457-1200<br>www.t2biosystems.com |
| Clever Culture Systems APAS Independence | Thermo Scientific Sensititre Aris HiQ system | T2Dx Instrument which runs the T2Bacteria, T2Candida, and T2SARS-C0V-2 Panels |
| FDA 510(k), 2016; CE mark, 2019; CE mark under IVDR, 2023 | FDA 510(k) | FDA, 2014 |
| 62.99" x 78.74" x 31.5" | 44.3" x 29.5" x 28.9" | 28.5" H x 40.5" W x 24.5" D |
| Standalone automated microbiology culture plate reader that also sorts into significant and nonsignificant growth. | Automated organism identification and antimicrobial susceptibility testing | Direct-from-blood bacterial and fungal pathogen detection assays, providing same-day results directly from a whole blood specimen for the most clinically relevant fungi and bacteria species. |
| Urine, infection control screening. | Bacterial, fungal, and mycobacterial isolates | K2EDTA whole blood (T2Bacteria and T2Candida) |
| Urinary tract infection, antibiotic-resistant infections. | Bacterial identification and antimicrobial susceptibility testing. | T2Bacteria: identifies sepsis-causing bacteria directly from whole blood. T2Candida: identifies sepsis-causing fungal pathogens from whole blood. |
| ■ Other | ■ Other | ■ Other |
| Standard bacterial cultures on standard media in petri dishes | Fluorescence technology detection; broth microdilution. | Direct from whole blood assays and are not predicated on positive culture growth. Both assays received unique product codes from FDA upon clearance as they define their own standard of care classification. |
| 200 to 240 plates per hour. | 100 minimum inhibitory concentration, breakpoint, or identification plates | T2Bacteria and T2Candida: 7 individual, random access drawers can be loaded at any time. Up to 20 samples/day. No batching is required. |
| 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. | T2Dx Instrument can be confirgured to report results to several well known LIS providers to support general laboratory workflows. In addition, it is also equipped with internal self diagnostics to confirm instrument performance to augment standard QC routines. |
| 1/2 day on-site/remote training. | 3 days | 1 day |
| Tiered technical support tailored to requirements. | 24/7 | Phone, email, and in person 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. | T2Bacteria and T2Candida panels identify causative pathogens directly from whole blood, without the wait for a positive blood culture, enabling clinicians to target therapy for their sepsis patients in 3-5 hours, often before the second dose of antibiotics is administered. |



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