tech guide
Microbiology Systems

	Beckman Coulter Brea, Calif www.beckmancoulter.com	Becton Dickinson Integrated Diagnostics Franklin Lakes, NJ (201) 847-6800 www.bd.com/en-us	ChromaCode Carlsbad, Calif (442) 244-4370 www.chromacode.com
1. What is the brand name of your company's microbiology system?	DxM 1040 MicroScan WalkAway system	Phoenix identification and susceptibility testing system	High-Definition PCR (HDPCR) multiplexing technology
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 1991; CE mark, 2018.	FDA 510(k), 2013; CE mark, 2016.	Research use only.
3. What are the dimensions of the named product (H x W x D)?	29 inches x 38.5 inches x 34 inches.	21 inches x 32 inches x 30 inches.	No instrumentation.
4. What is the intended use or primary function of the product?	A diagnostic tool for determining the in vitro identification (ID) and antimicrobic susceptibility testing (AST) patterns of microorganisms isolated from clinical specimens.	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.	Research use only reagents for the multiplex detection of tick-borne pathogens and multidrug resistance markers.
5. What types of specimen/sample does the product employ?	Diverse specimen types (blood, sputum, stool, tissue, urine).	Not for direct use with clinical specimens; analyzes pure isolates of clinically significant bacteria from all sample types.	Homogenized tick, pure colonies, rectal/perirectal swabs in liquid transport, synovial fluid, tissue, whole blood.
6. What types of diseases, conditions, or analytes does the system detect?	Aerobic, anaerobic, and fastidious bacteria.	Identification and susceptibility information to help support patient management decisions.	Research use only reagents for the multiplex detection of tick-borne pathogens and multidrug resistance markers.
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.	Minimal inhibitory concentration (MIC) testing following CLSI guidelines.	Bacteria or yeast that have been obtained from clinical specimens.	Blood smears, immunoassays, PCR.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	40 MicroScan panel (test) capacity with 96 wells per panel.	One instrument can hold 50 panels; two instruments can be stacked for capacity of 100 panels per day.	Panels test 90 multiplex samples per 96-well plate.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	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 system diagnostics available.	System has self-calibration and self-diagnostic capabilities and alerts may be generated to recommend spare part replacement. Panels are autodetected by the system when loaded. The system is compatible with BD remote support services.	ChromaCode Cloud is a Web-based software for end-to-end support of HDPCR assays; the software is intuitive, user-friendly, HIPAA compliant, and does not receive or store protected health information.
11. What is the typical training time for the product?	On-demand training available 24 hours a day, 7 days a week.	3 days onsite training.	1- to 2-day onsite training, requiring less than 2 hours hands-on time.
12. What types of technical support are available?	24/7 call center support.	24/7 tech support by phone, email, and chat.	24/7 technical support available.
13. What capabilities, features, or accessories distinguish this product from others on the market?	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.	Utilizes 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.	HDPCR couples widely used, low-cost TaqMan chemistry with proprietary data-science algorithms to perform low-cost multiplex testing. HDPCR reengineers the qPCR curve to eliminate all unwanted variability from hardware, chemistries, and clinical samples.

Curetis USA	**Great Basin Scientific**	**Qiagen**	**Thermo Fisher Scientific**
San Diego (619) 452-3644 www.curetisusa.com	West Valley City, Utah (888) 320-7636 www.gbscience.com	Hilden, Germany (800) 362-7737 www.qiagen.com	Waltham, Mass (800) 255-6730 www.thermofisher.com/AST
Unyvero LRT BAL panel	Great Basin Scientific	QIAstat Dx	Thermo Scientific Sensititre Aris HiQ system
FDA 510(k), 2019.	FDA 510(k), 2012.	FDA 510(k), 2019.	FDA 510(k).
21 inches x 20 inches x 20 inches.	6.3 inches x 17.2 inches x 21.4 inches.	9.21 inches x 12.83 inches x 20.35 inches.	44 inches x 29.5 inches x 29 inches.
Diagnosis of lower respiratory tract infections.	Infectious disease diagnosis.	Intended for in vitro diagnostic (IVD) syndromic testing.	Automated organism identification (ID) and antimicrobial susceptibility testing (AST).
Bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL).	Nasopharyngeal swab preserved and eluted; positive blood culture; stool in Cary-Blair or C&S media; vaginal/rectal swab in LIM broth.	Nasopharyngeal swab eluted in universal transport medium.	Bacterial, fungal, and mycobacterial isolates.
Lower respiratory tract infections (ie, pneumonia).	*B. pertussis* IS481; *Campylobacter jejuni; E. coli* serotype O157; *Salmonella* spp.; Shiga toxins 1 and 2; *Shigella* spp.; *S. agalactiae* cfb gene*; S. aureus, S. lugdunensis,* mecA gene; *Staphylococcus* spp.	Respiratory infections.	Bacterial ID/AST.
❑ 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	❑ 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
PCR technology with array detection; high multiplexing capability.	PCR.	Real-time PCR technology.	Fluorescence technology detection; broth microdilution.
Random access; two samples per analyzer module, scalable up to four analyzers; direct analysis from 180 µL specimen.	One specimen per run; approximately 90 minutes to first result.	Scales up to four analytical modules with one operational module. Maximum throughput is seven samples per analyzer per 8-hour shift, or 28 samples per 8-hour shift when fully scaled.	Handles 100 minimum inhibitory concentration (MIC) breakpoint or identification plates, for a combination of a possible 300 tests on one instrument.
Laboratory information system capable, built-in controls.	All reagents and controls fully integrated; sample extraction, amplification, and detection performed on cartridge; results interpreted and reported electronically.	Automated sample preparation and detection with preloaded wet and dry reagents; onboard swab elution, mechanical cell disruption, and liquefaction. Internal controls, automatic analysis, Ct values, amplification curves, and seamless LIS connectivity.	Automatically incubates and reads microtiter plates to identify organisms and report susceptibility results; LIS connectivity; customizable expert system; QC module; automated reports/alerts; optional epidemiology module.
1 to 2 hours.	1 hour.	2 hours.	3 days.
24/7 phone; onsite as scheduled.	Online, chat, phone.	Remote support and onsite support.	24/7.
FDA-cleared panel that detects *Pneumocystis jirovecii* in addition to a broad spectrum of clinically relevant bacterial pathogens (including atypicals) and antibiotic resistance markers associated with pneumonia. Enables rapid diagnosis and earlier selection of optimal antibiotics.	Sample-to-result, on-demand testing, featuring mid-plex panels.	Streamlined workflow with less than 1 minute hands-on time; detects 20+ respiratory targets in about 1 hour and provides Ct values and amplification curves, allowing for greater insight into results.	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.

Our Mission

AP-Visions was founded in 2011 to bring quality, cost effective clinical laboratory software data management and connectivity solutions to today's laboratories. Our flagship product, ***xLab***™ is the result.
All of our Software is: developed, written, deployed and supported by Laboratory people for Laboratory people.

What makes us different?

All of our Team are the owners of AP-Visions and are involved in the daily operation. Each of us has a vested interest in assuring that your expectations are met including; understanding your work flow, delivery of the right product that meets your needs, ensuring your people are properly trained, supporting you over the long term, and constantly updating our software to meet new and changing industry needs.

Meet The Team

Neal P. Flora, Managing Partner and Founder: Mr. Flora has over 30 years experience in developing and delivering Clinical Laboratory Software solutions to the Clinical Laboratory. As CEO, and one of the Founders of Fletcher-Flora Healthcare System Inc., Mr. Flora brought both the LabPak™ LIS and the Merge™ LIS to our industry. ***xLab***™, our flagship LIS, is the 4th generation LIS system developed and delivered by Mr. Flora.

Christopher Floyd – VP Deployment Services: Mr. Floyd has over 20 years of lab-centric hands-on experience in a multitude of laboratory modalities including: workflow analysis, general lab, toxicology lab, pharmacogenetics and considerable experience with a variety of clinical instruments. Mr. Floyd will ensure that installation, training and support of your AP-Visions product meets your expectations.

Software Development Team: Our software development and design team are all US based and have extensive experience in software development for hospitals, reference laboratories, physician office laboratories, toxicology laboratories, and connectivity with: laboratory instrumentation, EHR/EMR and billing systems.

Debra A Flora – VP Administrative Services: Ms. Flora has over 15 years experience assisting clinical lab customers with the financial aspects of: purchasing products, keeping their support agreements current and helping resolve financial issues.

Sales Team: All of our Sales Team have years of consultive sales experience in the lab, specifically with Laboratory Data Management and laboratory instrumentation. "Meet the customers' expectations" is their primary goal and if AP-Visions does not have the product that will meet those expectations, they can and will direct you to who can.

Contact us today and see how AP-Visions can: improve your work flow, bring new modalities to your lab, and help you achieve your patient care and financial goals!

AP-Visions, LLC 935 Sundrop Ct.
Marco Island, Florida 34145-2339

xLab Laboratory Information System

xLab™ Modalities and Interfacing

Modalities: **General Lab, Toxicology, Pharmacogenetics, Microbiology, Web Portal**
Interfacing: **Instruments, Pharmacogenomic, Reference Lab, EHR/EMR, Billing**

What some others are saying

"**Amazing**! It was installed, we got trained, and now it just works! We were expecting a long drawn out process to get our old LIS replaced but nothing could have been easier. AP-Visions' team configured our xLab as we needed it, installed the software, helped us validate all of our interfaces, and provided training consistent with our schedule. Best of all, when training was done and we started using xLab, **it just works**!"

"**Thanks** to AP Visions, our pain management (confirmatory lab) can provide our physician clients with fast and accurate reporting. We love the **personal attention** to the details for our specific laboratory and the issues we are faced with daily. xLAB is easy for us to use and **offers the right reports** that our customers need to provide better healthcare to their patients. It's compatible with everything! When you call the company you get to speak with a live person and they **have been very receptive to our needs.**"

"It is **refreshing** to speak immediately with someone who can answer my questions without being routed to half a dozen people. AP Visions has greatly reduced the time it takes to manage our laboratory operations. The reports we generate from xLAB LIS are critical communication tools used in management's decisions with regard to patient treatments and improved healthcare."

"With over 250 samples a day, our lab needed a system that could meet the challenge and work with our EMR Vendor to make it happen. **AP-Visions met that challenge** and more." They not only worked with our EMR Vendor to make it happen, they actually had the vendor make changes that allowed an efficient work flow to happen for receiving samples."

"I was amazed to see that **software developers actually listens to their clients!** We had some special unique needs for our lab and the AP-Visions development team made it happen! And, even though our requirements were unique, they did it at no charge and delivered in a matter of weeks. Way to go. Tell the team thank you."

"After taking a new position as lab manager, my first order of business was to **replace a troublesome LIS**. I reached out to some older industry contacts to see if I could purchase a **LabPak**™ (loved it from my previous lab). Found out that it was no longer available; however, the same people that brought us LabPak™ had a new LIS, ***xLab***™, with the same ease-of-use and significantly improved features. So I purchased it. I could not be happier! Same ease-of-use and much improved features. It was installed in short order and the staff immediately saw the benefits over the previous LIS. Thanks AP-Visions!"

Sales@ap-visions.com **866-526-7099**
www.ap-visions.com