[tech] guide

Microbiology Testing Products

	BioFire Diagnostics	bioMérieux	bioMérieux
	Salt Lake City **(801) 736-6354;** **www.biofiredx.com**	**Durham, NC** **(919) 620-2000;** **www.biomerieux.com**	**Durham, NC** **(919) 620-2000;** **www.biomerieux.com**
1) What is the name of your company's microbiology testing product?	FilmArray Blood Culture Identification (BCID) Panel	Vitek MS	Vitek 2
2) What year did it first appear on the market?	2013	2013	1999
3) What main function does it perform?	Automated multiplex pathogen and antibiotic resistance gene detection.	Automated mass spectrometry (MALDI-TOF) microbial identification system.	Automated pathogen detection and antibiotic susceptibility testing.
4) Which methodology or clinical standard of care is used?	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ■ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)
5) This test is used for (check all that apply):	❑ POC testing ■ Clinical lab testing (including molecular testing) ❑ HIV antibody testing ❑ Rapid influenza diagnosis	❑ POC testing ■ Clinical lab testing (including molecular testing) ❑ HIV antibody testing ❑ Rapid influenza diagnosis	❑ POC testing ■ Clinical lab testing (including molecular testing) ❑ HIV antibody testing ❑ Rapid influenza diagnosis
6) Is this product FDA cleared (510(k)) or approved (PMA)?	Yes	Yes	Yes
7) Briefly describe the product's automation features or options, if any.	The BCID panel is run on the FilmArray system, which integrates sample preparation, amplification, detection, and analysis into one simple system. Requiring only 2 minutes of hands-on time, the multiplexed PCR panel is automated and user-friendly.	Vitek MS is designed specifically for optimized workflow in the microbiology laboratory. Its four-slide capacity enables parallel preparation of samples by four different technologists at separate workstations, with placement on the instrument at the same time. With 48 sample spots per target slide, 192 isolates can be tested per run.	Vitek 2's advanced expert system analyzes minimum inhibitory concentration (MIC) patterns and detects phenotypes for most organisms tested, helping optimize efficiency for lean lab management. Rapid results enable clinicians to discontinue empiric therapy and prescribe targeted therapy, resulting in improved patient outcomes and enhanced antibiotic stewardship.
8) Briefly describe any additional test functionality.	In about an hour, and with over 97% sensitivity and 99% specificity, the panel is capable of simultaneous detection and identification of 27 gram-positive and gram-negative bacteria, yeast, and antibiotic resistance genes from a positive blood culture.	Vitek MS provides complete traceability and flexibility, contributing to overall lab efficiency and confidence. Reagents and disposables are barcoded for ease of use and to provide traceability, connecting the microbial identification and antibiotic susceptibility test (ID/AST) results for individual isolates. Verification of operation, tuning, and alignment is totally automatic and transparent to the user.	Vitek 2 systems use advanced colorimetry, an identification technology that enables identification of routine clinical isolates. Advanced colorimetry provides high discrimination between species, low rate of multiple choice and misidentified species, and minimal number of offline tests.
9) Does this product interface with the LIS or middleware?	No	Yes	Yes
10) How can this product be acquired?	Directly through BioFire Diagnostics	Directly through bioMérieux	Directly through bioMérieux
11) Briefly describe the features that distinguish this product from others on the market.	With 27 targets (gram-positive and gram-negative bacteria, yeast, and genetic determinants of antimicrobial resistance) combined into one panel, the panel tests pathogen identification from positive blood cultures. It is the only multiplexed PCR system to integrate sample preparation, amplification, detection, and analysis into one system.	Vitek MS is an automated microbial identification system that uses MALDI-TOF mass spectrometry to produce pathogen identification results in minutes. The synergy of Vitek MS, Vitek 2, Etest, and Myla represents a comprehensive solution for ID/AST. The integration of systems ensures optimal efficiency, full sample traceability, and quality results.	Vitek 2 technology with the advanced expert system offers a knowledge base developed from more than 100,000 references, 2,000 described phenotypes, 20,000 MIC distributions, 100 resistance mechanisms detected, and 99 organisms. On average, it provides a resulting range of five to seven MIC-doubling dilutions per antibiotic.

GG&B Company **Wichita Falls, Tex (800) 295-9588; www.quickslide.com**	GG&B Company **Wichita Falls, Tex (800) 295-9588; www.quickslide.com**	Roche Diagnostics **Indianapolis (317) 521-2000; www.mylabonline.com**
AGS-1000 Gram Stainer	MGS-80 High Volume Gram Stainer	LightCycler MRSA Advanced Test
2008	2014	2010
Hands-free Gram staining at 15 to 17 slides per hour, regardless of sample thickness or type.	Hands-free gram staining at 80+ slides per hour, true walk-away instrument, low waste, continuous load, color LCD screen prompts operator, reduces errors.	Qualitative in vitro diagnostic test for the direct detection of nasal colonization with bacterial methycillin-resistant *Staphylococcus aureus* (MRSA).
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Not Required	Not Required	Yes
The AGS-1000 is ready without warm-up 24/7. The operator places a slide in a cuvette, pushes the button, and the system stains, counterstains, and rinses. It stirs reagents, uses fresh reagents for every slide, distinguishes between thick and thin specimens, calibrates after every test, signals when complete, and goes to sleep when not in use. It has an automatic clean cycle, and tests-remaining counter. The unit saves energy, and reduces lab waste.	True walk-away instrument with continuous loading plus stat drawer. Color touch screen controls real-time response of all operations. Prompts operator on reagent levels and when to change reagent, waste levels sensor if capturing in vessel, automatic fluid fill level sensors, slide in process sensors, prompts for hands-free cleaning function.	Automated PCR amplification and detection; automated-results report generation.
All instrument functions controlled and viewed from LCD soft-touch keypad and display.	All instrument functions controlled and viewed from color touch screen. Updates and upgrades are done via Internet using secure Ethernet connection.	N/A
No	Optional feature to be offered later.	No
Purchase from GG&B; extended warranties available.	Direct sale only through GG&B; extended warranties available.	Available for purchase; lease; per-use payment or ASP.
The system is low maintenance, easy to operate, not technique-dependent, and alerts when to change reagents or tubing or to run the clean cycle. It features a small footprint, an EPA-approved waste vessel, and self diagnostics. Run any sample type for consistent Gram stain. Superior after-sale service, free tech support.	The MGS-80 produces quality slide staining regardless of who processes the slide. The system improves workflow, and reduces batching or waiting. Slides can be processed as soon as they arrive in the lab, regardless of quantity or type of sample. The unit boasts low daily maintenance, low waste, and no cross-contamination. Stain results are 100% in agreement in organism stain reaction as compared to a manual stain.	The Roche LightCycler MRSA advanced test offers a simple, flexible, and reliable way to incorporate molecular MRSA surveillance into a hospital's infection control program. Performed on the LightCycler 2.0 instrument, the real-time PCR test delivers rapid results (within 2 hours) for batches of one to 30 samples, and has high relative sensitivity and specificity compared to direct culture-based methods.

Upcoming Tech Guides

Each month, *CLP* invites leading IVD manufacturers and clinical laboratory suppliers to complete a standarized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future issues of *CLP:*

MAY
Point-of-Care Testing Products

JUNE
Controls

JULY
Prenatal Testing Products

AUGUST
Molecular Testing

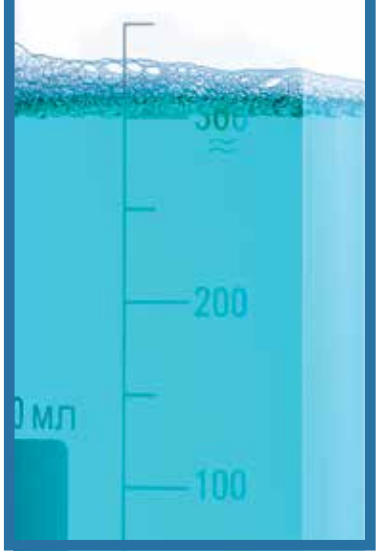
SEPTEMBER
Blood Banking Products

OCTOBER
Flu/Respiratory Virus Testing

NOVEMBER
Cardiovascular Testing Products

DECEMBER
Buyer's Guide

To be considered for inclusion, contact associate editor Jenny Lower at jlower@allied360.com



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	Roche Diagnostics	Siemens Healthcare Diagnostics	Siemens Healthcare Diagnostics
	Indianapolis (317) 521-2000; www.mylabonline.com	**Tarrytown, NY (800) 677-7226; www.usa.siemens.com/diagnostics**	**Tarrytown, NY (800) 677-7226; www.usa.siemens.com/diagnostics**
1) What is the name of your company's microbiology testing product?	MagNA Pure 96 instrument	MicroScan WalkAway plus System	Copan WASPLab System
2) What year did it first appear on the market?	2011	2005	2013
3) What main function does it perform?	Automated high-throughput nucleic acid purification.	Automated microbial identification and antibiotic susceptibility testing using MicroScan panels.	Automated specimen culturing, gram-slide preparation, and enrichment broth inoculation with robotic incubators and digital imagery for reading cultures.
4) Which methodology or clinical standard of care is used?	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)	❑ Sputum adequacy by Gram stain ❑ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)	❑ Sputum adequacy by Gram stain ■ Enrichment cultures ❑ Blood cultures ❑ Fluorochrome staining for AFB ❑ % parasitemia ❑ Cell lines and incubation time for virus isolation ❑ Statistics for molecular tests (summarizes all specimen types)
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6) Is this product FDA cleared (510(k)) or approved (PMA)?	Yes	Yes	N/A
7) Briefly describe the product's automation features or options, if any.	Automated sample-extraction process, utilizing ready-to-use reagents.	Automates microbial identification and antibiotic susceptibility testing (ID/AST) panel incubation, test interpretation, and reagent control. LabPro software simplifies workflow and minimizes technologist interaction. LabPro Alert software eliminates manual review for unusual conditions or results, and integrates staff instructions into lab workflows for consistent results and compliance.	Automates most specimens, including feces. Inoculum is standardized and verified, reducing plating errors and variability. Plates are conveyed to incubators and kept in the optimum growing environment. Digital photos are taken at time zero and scheduled intervals thereafter, and presented digitally for greater productivity and reduced turnaround time.
8) Briefly describe any additional test functionality.	N/A	LabPro Connect, an optional networking module, is designed to enhance workflow and reporting efficiency by bringing ID/AST results to the technologist's bench or supervisor's office. It also facilitates consolidation of results from multiple WalkAway systems for epidemiology and other management reports.	WASPLab is custom-built to a laboratory's needs. Different modules may be mixed and matched to find the perfect balance of improved productivity versus investment.
9) Does this product interface with the LIS or middleware?	Yes	Yes	Yes
10) How can this product be acquired?	Available for purchase or lease.	Contact Siemens sales representative.	Contact Siemens sales representative.
11) Briefly describe the features that distinguish this product from others on the market.	This automated solution combines high-quality performance with high throughput to help labs significantly increase productivity. It can be used to purify DNA, RNA, and viral nucleic acids from a broad range of sample types in approximately 50 to 90 minutes—including instrument setup. The system processes up to 96 samples simultaneously, using proven magnetic glass particle technology and barcoded, prefilled trays with ready-to-use reagents, and is designed for use in downstream diagnostic applications.	The fourth generation of proven WalkAway technology and reliability combines fluid-level detection with a directional LED system, showing when and where maintenance is needed. Advanced minimum inhibitory concentration (MIC) technology detects emerging resistance as it occurs, providing accurate results without reliance on historical data or virtual MIC.	WASPLab is the only system to apply labels to slides and broth tubes, preventing labeling errors. By mimicking manual processes, training is minimized and quantitation methods are unchanged. The highest-definition images, taken over time, optimize turnaround time. The modular design allows gradual implementation while protecting investment.