<table>
<thead>
<tr>
<th>bioMérieux</th>
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<th>bioMérieux</th>
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</thead>
<tbody>
<tr>
<td>Durham, NC</td>
<td>Durham, NC</td>
<td>Durham, NC</td>
</tr>
</tbody>
</table>

1) What is the name of your company’s microbiology testing product?  
2) What main function does it perform?  
3) Which methodology or clinical standard of care is used?  
4) Is this test used for:  
5) Is this product FDA cleared?  
6) Very briefly, note any additional test functionality.  
7) Does this product include automation features or options? If yes, describe very briefly.  
8) Does this product interface with the LIS or middleware?  
9) What is the cost per platform and per test?  
10) How can this product be acquired?  
11) Very briefly describe what makes this product unique from others on the market.

<table>
<thead>
<tr>
<th>VITEK 2</th>
<th>Myla</th>
<th>Prev I SOLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated pathogen detection and antibiotic susceptibility testing</td>
<td>Intelligent microbiology middleware solution</td>
<td>Automated specimen inoculation</td>
</tr>
</tbody>
</table>
| - 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  
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- Cell lines and incubation time for virus isolation  
- Statistics for molecular tests (summarizes all specimen types) |
| - 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 |

Yes | Yes | Yes |

Yes | Yes | Yes |

Contact a bioMérieux representative | Contact a bioMérieux representative | Contact a bioMérieux representative |

Directly through bioMérieux | Directly through bioMérieux | Directly through bioMérieux |

Helping the clinician select the best treatment fast based on the right identification and resistance information is crucial. 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, this provides a resulting range of five to seven MIC doubling dilutions per antibiotic; and much more.

Inefficiencies in the microbiology lab can lead to slower response, higher costs, and decisions made with incomplete information—impacting patient care. Clearly, the performance of the microbiology lab can significantly influence a hospital’s reputation. Myla, a truly intelligent middleware, addresses the complexities inherent in the microbiology laboratory environment by improving connectivity, workflow, and information management.

PREVI Isola combines the comb applicator with advanced robotics and software to precisely gauge the speed and pressure of the application to maximize the growth of bacteria or other pathogens that might be in a human fluid sample, such as blood or urine. This gives scientists superior numbers of distinct bacterial colonies and, hence, the opportunity to identify more of the varieties that are present.

PREVI Isola provides a superior quality of inoculation versus the traditional method of streaking. Colonies are well isolated, which provides easy-to-read results. This means technicians save valuable reading time and there is less need for subculture. PREVI Isola offers full traceability of specimens and plates, saving you time, particularly for accreditation purposes. The instrument’s software tracks plate-lot numbers, expiration dates, consumption levels, and what specimen was used on which plate.
## GG&B Company

Wichita Falls, Tex  
(800) 295-9588  
www.quickslide.com

<table>
<thead>
<tr>
<th>AFB Acid Fast Stainer</th>
<th>AGS-1000 Gram Stainer</th>
<th>MGS-80 Gram Stainer</th>
<th>LightCycler MRSA Advanced Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-quality florescent acid fast stains</td>
<td>Gram stains</td>
<td>High-quality Gram stains</td>
<td>Qualitative in vitro diagnostic test for the direct detection of nasal colonization with bacterial MRSA</td>
</tr>
</tbody>
</table>

- 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)

### GG&B Company

Wichita Falls, Tex  
(800) 295-9588  
www.quickslide.com

<table>
<thead>
<tr>
<th>Not required</th>
<th>Not required</th>
<th>Not required</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not required</td>
<td>Processes slides at rate of 15 to 17 per hour</td>
<td>Multislide MGS-80 processes slides at rate of 60 per hour. Has stat-slide capability; load slides and walk-away.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- POC testing
- Clinical lab testing (including molecular testing)
- HIV antibody testing
- Rapid influenza diagnosis

### Roche Diagnostics

Indianapolis  
(317) 521-2000  
www.mylabonline.com

<table>
<thead>
<tr>
<th>Approximately $3,500 delivered</th>
<th>Approximately $11,000 delivered</th>
<th>Approximately $25,000, available summer 2013</th>
<th>Contact a Roche representative for pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase</td>
<td>Lease</td>
<td>Purchase</td>
<td>Lease</td>
</tr>
<tr>
<td>Per-use payment or ASP</td>
<td></td>
<td>Per-use payment or ASP</td>
<td>Per-use payment or ASP</td>
</tr>
</tbody>
</table>

### Initial cost and speed of test. Rapid Stain rated best by major clinical study. Company ISO9001-2008 quality management system-approved, so it is constantly improving products and service for the end user. All stainers and stain are made in the United States.

Gram Stainer has patented “Electro-optical Eye,” for precise decolorization, proprietary stain for clean slides, instrument not based on time or fixed settings but what is your slide regardless of specimen thickness. This unit is designed to eliminate consistence issues and is user-friendly. GG&B Co is ISO9001-2008 quality management system-approved so it is constantly improving products and service for the end user. All stainers and stain are made in the United States.

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.
Plate Management System

Comb-based streaking tool provides optimal placement

The PREVI™ Isola from bioMérieux Inc, Durham, NC, is a high-throughput specimen and agar plate management system. It performs the task of streaking a clinical sample (e.g., urine) onto an agar plate. The device provides consistent, quality plate streaking. The comb-based streaking tool results in ideal placement for optimal colonization, with an increased number of isolated colonies, saving time and reducing repeat cultures. The innovation behind this system is the multitined applicator. Clinical studies have demonstrated that this instrument can inoculate and spread samples over a greater proportion of the agar plate surface than is typically achieved using the handheld loop-to-plate method, according to the company.

bioMérieux Inc
(919) 479-3637; www.biomerieux-usa.com

Microbiology Middleware Product

Gives comprehensive picture of all testing activity

Myla from bioMérieux Inc, Durham, NC, is a middleware software solution that has been designed by microbiologists for microbiologists. It plays a central role in the pathway from sample collection to patient decision, helping labs achieve the most out of their existing instrumentation and staff. Myla helps provide an actionable, comprehensive picture of all testing activity in the lab, allowing for a faster, freer flow of information.

bioMérieux Inc
(919) 479-3637; www.biomerieux-usa.com

Automated Gram Stainer

For all types of specimens

Previ Color Gram from bioMérieux Inc, Durham, NC, is an automated gram stainer, part of the company’s Full Microbiology Lab Automation (FMLA) line of products. The stainer system is for all types of specimens and provides accurate, standardized results. Its spray nozzles dispense the same reagent volume. There is no cross contamination—each slide is separated and a fresh staining reagent is used each time. The system provides improved microorganism differentiation in comparison with manual and bath staining results, the company says. It is particularly useful when performing stainings from the bioMérieux BacT/ALERT bottles, since it can clearly and easily differentiate Gram-positive from Gram-negative cells.

bioMérieux Inc
(919) 479-3637; www.biomerieux-usa.com

Sample Processing Systems

Streamlines pre- and post-analytical processes

The AutoMate 1200 and 2500 sample processing systems from Beckman Coulter Inc, Brea, Calif, help optimize laboratory workflow by streamlining pre- and post-analytical processes, and position the lab for optimal performance and labor usage. The systems feature sorting speeds of up to 1,200 tubes per hour and single-point-of-entry technology for efficient tube management, while advanced automated sample loading and sorting minimizes manual handling. An optional recapper delivers safe and convenient transfer of the tube to the archiving stage and for error prevention, cap-color analysis validates sample type against test ordered. The systems feature intuitive software to facilitate ease of use. Intelligent aliquotting and tube labeling eliminate manual sample-preparation errors and ensure faster, more accurate secondary tube preparation.

Beckman Coulter Inc
(800) 586-3821; www.beckmancoulter.com

Automated Microbiology Specimen Processor

Streaking method offers consistency

The Kiestra InoqulA automated microbiology specimen processor from BD Diagnostics, Sparks, Md, automates the processing of both liquid and non-liquid bacteriology specimens on one integrated platform. Available in July, the InoqulA’s streaking method uses magnetic rolling bead technology to offer more consistent colony isolation and less subculturing over manual methods, allowing for faster and more accurate results, the company says. The setup of urines, ESWabs, and other liquid specimens is fully automated with this bar code-driven process, including sample agitation, decapping, and recapping, as well as automatic inoculation of plates, slides, and broth tubes according to user-defined protocols. Designed for speed, the system can streak five plates at once.

BD Diagnostics
(410) 316-4000; www.bd.com/ds

Microbiology Specimen Processor

Modular design, small footprint

WASPLab, a sophisticated bar code-driven microbiology specimen processor and workup system from Copan Diagnostics Inc, Murrieta, Calif, connects with WASP using a conveyor track. It moves any sample from front-end processing to full specimen management, automated incubation, and digital microbiology. The modular design and small footprint allows laboratories to customize WASPLab for their unique needs.

Copan Diagnostics Inc
(800) 216-4016; www.copanusa.com

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Beckman Coulter Inc
(800) 586-3821; www.beckmancoulter.com


**Product Spotlight**

**Work Cell Automation**

**Small foot print**

The BD Kiestra WCA (Work Cell Automation) from BD Diagnostics, Sparks, Md, is a modular solution designed for labs of all sizes that enables the integration of automated specimen processing, plate transportation, incubation, and digital imaging systems in a compact footprint. Scheduled to be released at the end of the year, this scalable solution helps to increase productivity and allow your staff to focus more on making clinical decisions and impacting patient care. This solution offers all of the benefits of the BD InoquA automated microbiology specimen processor while taking advantage of the integrated plate track system that connects the InoquA to the company’s ReadA Compact automated plate incubation and imaging system. After specimen processing is complete, immediate and automatic transportation of plates to the appropriate incubation condition in BD’s second-generation automated incubators allows for dynamic plate imaging with high-resolution cameras and multiple-light settings for optimal plate-reading conditions.

**BD Diagnostics**
(410) 316-4000; www.bd.com/ds

**Microbiology Lab Automation**

**Modular design for maximum flexibility**

The BD Kiestra TLA (Total Lab Automation) system from BD Diagnostics, Sparks, Md, offers complete microbiology lab automation. This solution incorporates automated specimen processing, flexible tracks with two-way plate transportation, automated plate incubation and imaging, integrated ergonomic workbenches, and reading stations with digital plate-reading software. This modular design can be scaled to include two BD InoquA automated specimen processors connected to six ReadA Compact automated incubator and imaging systems, as well as 10 inline Ergonomic workbenches with reading stations to accommodate a wide range of volume needs. By automating and integrating each of these phases of the microbiology testing process together on one streamlined platform, the system is designed to increase productivity, improve efficiency, and help produce more reliable and timely results.

**BD Diagnostics**
(410) 316-4000; www.bd.com/ds

**Pre- and Postanalytical Processing System**

Can be customized for each facility

The Sarstedt PVS 1625 from Sarstedt Inc, Newton, NC, is a comprehensive, modular laboratory automation system for pre- and postanalytical processing. Independent from an analytical platform, the system is customized per facility needs with available modules for loading, identification, decapping, sorting, aliquoting, and recapping. A new screw-cap recapper module is now available that places a screw cap onto Sarstedt aliquot tubes. Aliquots can be made directly into compatible screw-cap tubes and immediately recapped for send-outs or capped postanalysis for archiving. The system is compatible with most analyzer racks and common tube types and dimensions.

**Sarstedt Inc**
(800) 257-5101; www.sarstedt.com

**Automated Body Fluid Cell Count Control**

Three-level spinal and body fluid control

Cell-Chex Auto from Streck, Omaha, Neb, is the first automated body fluid cell count control for Abbott, Beckman Coulter, and Sysmex hematology instruments. It is a three-level spinal and body fluid control for evaluating the accuracy and precision of hematology instruments that measures blood cell counts in patient body fluid samples. The assay provides total red blood cell and white blood cell values for the following: Abbott CELL-DYN 3200, Sapphire, and Ruby; Beckman Coulter LH 750/LH 755, LH 780, and UniCel DxH 800; and Sysmex XE-2100, XE-5000, XT-2000i, XT-1800i, and XT-4000i instruments. Two-part WBC differential values are also provided for the Sysmex XE-5000 and the XT-4000i. Cell-Chex Auto is packaged in a plastic 3.0-mL vial with a pierceable cap and has 75-day closed-vial stability and a 30-day open-vial stability.

**Streck**
(800) 843-0912; www.streck.com

**Automated Recapper**

Speeds of up to 1,200 tubes per hour

The KapSafe Automated Recapping System from LGP Consulting Inc, Wood River, Ill, is now available to recap tubes in ADVIA Centaur racks, Beckman AU racks, Roche Cobas racks, and Abbott ARCHITECT racks. KapSafe is an automated, pneumatics-free, high-speed, benchtop recapper designed to safely and automatically recap tubes for storage or archiving. The system has a small footprint and automatically recaps all standard vacuum collection tubes at speeds of up to 1,200 tubes per hour. It protects lab workers from repetitive motion injuries associated with manual recapping. The archiving caps fit tubes from 13 mm to 16 mm in diameter, and enable repeated automated decapping and recapping. The system provides walkaway operations with a hopper capacity of 4,200 archiving caps and an input capacity of up to 20 multiple types of racks with multiple-sized tubes in each rack.

**LGP Consulting Inc**
(618) 251-9246; www.lgpconsulting.com
High-Speed Sorter
Benchtop or stand-alone units

The Sarstedt High Speed Sorter (HSS) from Sarstedt Inc, Newton, NC, is a modular front- and back-end system that automates time-consuming laboratory processes. Options include identification, sorting, decapping, aliquoting, recapping, and the new bulk-loading module, which eliminates the preracking of incoming specimens. Tubes are simply “dumped” into a hopper for walkaway processing. Two components of the system, the Decapper DC 1200 and Recapper RC 1200, are available as benchtop or stand-alone units that process up to 1,200 screw-cap, push-cap, or evacuated tubes per hour.

Sarstedt Inc
(800) 257-5101; www.sarstedt.com

Sample Track System
Processes 3,600 samples per hour

The Accelerator a3600 from Abbott Diagnostics, Abbott Park, Ill, is a new sample track system to help enhance efficiency, productivity, and patient safety for laboratories. Introduced in April, the automated system can increase a lab’s workload capacity and improve result turnaround times by reducing possibilities for testing errors associated with sample handling and by providing performance consistency. It can process up to 3,600 samples per hour; handle multiple tube sizes and types simultaneously; and is designed to automate preanalytical and post-analytical processing, sample-handling, and processing in the lab. The system can be configured to support a lab’s testing volumes, offering the capability to install up to 99 combined analyzers and modules on a single system. Through communication connections among the automation system, analyzers, and the laboratory information system (LIS), and middleware, the system’s automation software provides workload and sample-order management, as well as instrument operational status monitoring. The Accelerator p540 is a stand-alone nontrack based, automation platform for smaller labs.

Abbott Diagnostics
(847) 937-6100; www.abbottdiagnostics.com

Accessioning and Sorting Instrument
Used with any analytical platform

The Sarstedt BL 1200 ID from Sarstedt Inc, Newton, NC, is a stand-alone accessioning and sorting instrument that can be used in conjunction with any analytical platform. The unit features a bulk loader that eliminates manual sorting and preracking. Multiple tube sizes are accepted, and capped tubes are simply dumped into the loader for walkaway processing. Tubes are automatically singularized, and the tube type and bar code are identified. Sort and distribution rules are customized to targeted analyzer racks, centrifuge adapters, and generic and/or archiving racks on the custom sorting platform(s). Up to 1,200 tubes can be processed per hour.

Sarstedt Inc
(800) 257-5101; www.sarstedt.com
Automation System
Circular track, modular design

The Aptio Automation system from Siemens Healthcare Diagnostics, Tarrytown, NY, is a unified solution combining peak performance, adaptability, and intelligent technologies to seamlessly orchestrate sample and information flow in the laboratory. With every lab configured differently and floor space at a premium, the system’s circular track and modular design ensure it can adapt to nearly any lab or testing environment. It also offers connectivity to the company’s portfolio of automation-ready analyzers, thus facilitating a multidisciplinary approach to testing. The system’s point-in-space aspiration feature helps streamline workflow by reducing the need to aliquot (or divide) samples, and its puck-based system with RFID enables individual sample routing and tracking, along with STAT prioritization. It also delivers comprehensive analytics via powerful, centralized information technology, while having the flexibility to provide pre- and post-analytical capabilities.

Siemens Healthcare Diagnostics
(888) 826-9702; www.usa.healthcare.siemens.com/laboratory-diagnostics

Sysmex WAM and WAM Select
Centralized database manages rules configuration

WAM and WAM Select middleware solutions from Sysmex, Lincolnshire, Ill, support LEAN hematology processes with decision rules that are specifically designed for the needs of the hematology laboratory. These systems are designed to drive reflex and repeat decisions on Sysmex automation and yield unprecedented efficiency in workflow and results management. These scalable middleware solutions can help labs achieve autovalidation rates greater than 85%. WAM provides IHNs with multisite, multi-LIS connectivity, and system-wide rules for rerun/reflex testing and delta checking. WAM centralized QC review and management reports help achieve the most challenging productivity goals. WAM Select connects up to two Sysmex analyzers and a slidemaker/stainer with a centralized database and rules engine so users only configure rules once, rather than individually by analyzer.

Sysmex America Inc
(800) 379-7639; www.sysmex.com/us

Advanced Clinical Parameters
Provides reportable, direct measurements of immature cells

Sysmex, Lincolnshire, Ill, makes advanced clinical hematology parameters available to labs of any size. The Sysmex XN-Series analyzers leverage fluorescent flow cytometry to help labs offer more value on the routine CBC. These systems provide reportable, direct measurements of immature cells in peripheral blood. Immature Granulocyte counts, provided with every WBC differential, can provide insight to physicians about leukopoiesis. Indicators of erythropoiesis, including an NRBC with every CRC, Immature Reticulocyte Fraction, and Reticulocyte Hemoglobin yield information that physicians can use to manage anemia. The Immature Platelet Fraction (IPF) can help physicians make a differential diagnosis of thrombocytopenia. The expansion of the definition of the routine CBC can not only aid in the physician’s diagnosis and monitoring of diseases, but can also enhance the understanding of underlying physiological mechanisms of the disorders.

Sysmex America Inc
(800) 379-7639; www.sysmex.com/us

System to Connect Two Stand-Alone Analyzers
Robotic system features automatic routing

The VersaCell System from Siemens Healthcare Diagnostics, Tarrytown, NY, is a compact, robotic system that connects up to two stand-alone analyzers in flexible configurations. Its unique sample-management technology features automatic routing that eliminates time-consuming preanalytical sorting and extends a sample tube’s menu testing capabilities. The system enables labs to manage large sample peaks with high-throughput instrument connectivity options. Labs can choose the connectivity options that best meet their testing needs. Currently, the VersaCell System has connectivity to a range of the company’s immunoassay, chemistry, and integrated systems, including the ADVIA 1800 Chemistry System, ADVIA Centaur XP System, IMMULITE 2000 XPI System, and Dimension EXL Integrated Chemistry Systems.

Siemens Healthcare Diagnostics
(888) 826-9702; http://usa.healthcare.siemens.com/laboratory-diagnostics

Automated Hematology Analyzers
Automatically manages more than 90% of EDTA samples

The configurable XN-Series portfolio from Sysmex, Lincolnshire, Ill, realizes the goal of putting more hematology automation in every-sized lab, regardless of test volume. The analyzers share common modules, allowing labs to increase efficiency by selecting the configuration that fits the scale of their laboratory. The XN-9000 integrates up to nine XN modules, tube management, on-demand HBA1c, concentrated reagent, and slidemaker/stainers. This Lavender Top Management solution automatically manages more than 90% of all EDTA samples. Sysmex WAM decision-support software for the clinical lab can be integrated to achieve autovalidation rates greater than 85%. The series includes the XN-1000, with one analytical module; the XN-2000, with two co-primary analytical modules; and the XN-3000 with two co-primary analytical modules and an SP-10 slidemaker/stainer.

Sysmex America Inc
(800) 379-7639; www.sysmex.com/us
Iceless Cooling Container
Uses ceramic-coated aluminum beads

New from Dynalon, Rochester, NY, the DyNAQube is ideal for incubating up to 20 samples at 0°C to 4°C or ambient to 5°C for long periods of time. It chills while keeping everything dry and in place, removing the inconvenience of melted ice, contamination, or losing track of samples. The ceramic-coated aluminum beads provided with each unit help maintain the chilled sample temperature while supporting the vessels for as long as necessary. The beads are chemically resistant and, if required, can be autoclaved. The beads can also be prechilled by placing them in a Dynalon plastic beaker and incubated at refrigerated temperatures.

Dynalon
(800) 334-7585; www.dynalon.com

Thermal Cyclers
Designed for all lab sizes

Dynalon, Rochester, NY, introduces a new line of PCR thermal cyclers, called DyNAcyclers, designed with today’s labs—small, medium, and large—in mind. DyNAcycler DCL, with 20, 25, 30, and 48 array, has a small footprint and user-friendly programming. It holds 0.2-mL and 0.5-mL microtubes, and is backed with a 4-year warranty.

Dynalon
(800) 334-7585; www.dynalon.com

Lab Information Technology Gains Certification
Compliant with the ONC 2014 edition criteria

Sunquest Laboratory version 7.0.1003 from Sunquest Information Systems Inc, Tuscon, Ariz, is compliant with the ONC 2014 Edition criteria and was recently certified as an EHR Module by the Certification Commission for Health Information Technology (CCHIT), an ONC-ACB, in accordance with applicable hospital criteria adopted by HHS. The ONC 2014 Edition criteria supports both Stage 1 and 2 Meaningful Use measures required to qualify eligible providers and hospitals for funding under the American Recovery and Reinvestment Act (ARRA). Adding the Meaningful Use 2014 Incorporate and Reportable module to Sunquest Laboratory provides a way to demonstrate Meaningful Use of the Reportable Results criteria by expertly implementing public health reporting from the laboratory.

Sunquest Information Systems Inc
(520) 570-2000; www.sunquestinfo.com

Courier Management System
Tracks status of deliveries

The Laboratory Courier Management module from Path-Tec, Columbus, Ga, represents part of a web-based solution that helps labs manage critical specimen collection functions, including courier scheduling, route management, supply tracking, specimen tracking, and reporting. The module shows the location of couriers, generates summary reports, and updated arrival/departure information. The module also has an app for mobile devices.

Path-Tec
(706) 569-6368; www.path-tec.com

Performance Enhancements
Quicker results, automatic inventory

Abbott, Abbott Park, Ill, introduces a new capability for its RealTime m2000 system: enhancing the system’s flexibility and making molecular testing easier and more efficient. The new mPlus makes it possible for labs of any size to perform molecular diagnostic tests for infectious disease detection and therapy monitoring. It allows labs to process samples when they are ready rather than holding them for larger batch runs, providing faster results to physicians and patients. mPlus capability will also optimize reagent use, reduce lab cost of operations, and offer a new automatic inventory feature to improve system ease-of-use. mPlus capability is currently available for Abbott’s RealTime HIV, HCV, HBV, CT/NG, and CT assays outside the United States and for the RealTime CT/NG assay within the United States.

Abbott
(847) 937-6100; www.abbott.com
New Instrument/Gastrointestinal Pathogen Panel

Performs qualitative and quantitative analysis

Luminex Corp, Austin, Tex, has received FDA clearance for its Magpix instrument, with its xTAG Gastrointestinal Pathogen Panel (xTAG GPP). This is the first clinical assay to be cleared on Magpix. xTAG GPP can simultaneously detect 11 common viral, bacterial, and parasitic causes of infectious gastroenteritis from a single patient sample. Based on the company’s xMAP technology, the Magpix instrument is a versatile multiplexing platform capable of performing qualitative and quantitative analysis of proteins and nucleic acids in a variety of sample matrices. Its compact size makes it attractive to labs with limited bench space. This system can perform up to 50 different tests in a single reaction volume, reducing sample input, reagents, and labor while improving productivity.

Luminex Corp
(888) 219-8020; www.luminexcorp.com

Rapid Strip-Based Test for Hemoglobin

Quick, easy determination of anemia

EKF Diagnostics, UK, introduces a new strip-based test for quick and easy hemoglobin analysis for anemia determination. STAT-Site M Hgb, a handheld analyzer that combines low cost per test with portability, reliably delivers accurate hemoglobin analysis results within 30 seconds from 15 μL of finger-prick whole blood. Intuitive, step-by-step on-screen instructions minimize training and ensure ease of use.

EKF Diagnostics
(800) 531-5535; www.ekfdiagnostics.com

Molecular Pathology Solution

Deliver integrated cell-capturing solution

Applied Spectral Imaging Inc (ASI), Carlsbad, Calif, and WaveSense Inc, Irvine, Calif, are integrating their platforms to provide a newly optimized molecular pathology solution. ASI’s GenASiS imaging and analysis instrument will be paired with WaveSense’s EpiSEP cell recovery and enrichment solution to deliver an integrated cell-capturing solution and computerized instrument to detect, image, and analyze the captured cells. The combined solution is effective in performing semiautomated FISH analysis of paramagnetic labeled target cells. Target cells may be retrieved, enriched, imaged, and analyzed in urine, bone marrow, blood, needle aspiration, abdominal ascites, lymph node, culture, and pleural effusion specimens. GenASiS is FDA-cleared for FISH clinical applications such as ALK, UroVysion, HER2/neu, CEP XY, and karyotyping.

Applied Spectral Imaging Inc
(800) 611-3466; www.spectral-imaging.com
Benchtop Hematology Analyzer
Reduces manual review rates and processes

Beckman Coulter Inc, Brea, Calif, a wholly owned subsidiary of Danaher Corp, introduces a new benchtop hematology analyzer for mid- to high-volume laboratories. The new UniCel DxH 600 Coulter cellular analysis system provides labs with quality results, improved first-pass accuracy, and automatic rerun and reflex testing. By reducing manual differential rates, the new analyzer frees labs to focus time on quickly and accurately reporting patient results. The software saves time by allowing labs to partially release patient results manually or automatically via decision rules. In addition, users now have the ability to create and edit decision rules during instrument operation and use pre-defined decision rules via Cell Population Data.

Beckman Coulter Inc
(800) 526-3821; www.beckmancoulter.com

Blood Culture Identification Panel Provides automatic results

BioFire Diagnostics Inc, Salt Lake City, has submitted the FilmArray Blood Culture Identification (BCID) Panel to the FDA for 510(k) clearance. The panel provides automatic results for the most common infectious causes of sepsis, a significant cause of mortality and morbidity in adults, children, and infants. Using an easy procedure requiring only 2 to 3 minutes of hands-on time, the BCID Panel simultaneously tests positive blood cultures for approximately 90% of the gram-positive bacteria, gram-negative bacteria, and yeast microbes that cause bloodstream infections. The panel also tests for common antimicrobial resistance genes associated with Methicillin-resistant Staphylococcus aureus, Vancomycin-resistant Enterococci, and the newly emerging Carbapenem-resistant Enterobacteriaceae.

BioFire Diagnostics
(801) 736-6354; www.biofiredx.com

Contains Vitamin D
Our Acusera Immunoassay Premium Control is manufactured to stringent quality regulations and contains only 100% human material which prevents interference with antibody related tests, unlike sera with animal components which may experience shifting targets with changes of reagent batch.

Included in the 51 analytes within this true third party control is 25-OH-Vitamin D, a parameter used in the monitoring of bone weakness or bone malformation conditions and in diseases such as cystic fibrosis and Crohn’s disease.

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33% of forgotten tourniquets are left on patients for more than two hours, and some for up to 18 hours. PlatinumCode offers latex-free, bright-colored tourniquet bands to help your facility reduce the risk of accidents. PlatinumCode tourniquets are offered in four bright colors, two surface textures and four packaging options.

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HTLV-I/II Assay
Tests blood and plasma specimens
The Avioq HTLV-I/II test from Avioq Inc., Research Triangle Park, NC, is an assay for the qualitative detection of antibodies to Human T Lymphotropic Virus Type I (HTLV-I) and Type II (HTLV-II) in serum or plasma. It is intended for screening individual human donors, including volunteer donors of whole blood and blood components, and for use in clinical diagnosis of HTLV-I or HTLV-II infection and related diseases. It is also used in testing blood and plasma specimens to screen organ donors. The assay features a user-friendly microplate design suitable for various testing volumes and automation.

Avioq Inc (919) 314-5535; www.avioq.com

Synthetic Cannabinoid Test
Detects more than 55 types
Randox Toxicology, Kearneysville, WV, has developed an ELISA targeting UR-144, XLR-11, and additional synthetic cannabinoid compounds commonly found in new Spice and K2 blends. Together with its JWH/AM2201 Synthetic Cannabinoids ELISA, the new UR-144/XLR-11 ELISA provides a comprehensive solution for the rapid detection of more than 55 current synthetic cannabinoids in urine, blood, and oral fluid. UR-144 and XLR-11 are chemically different structures than earlier generations of synthetic cannabinoids such as JWH-018, JWH-073, and AM-2201.

Randox Toxicology (866) 472-6369; www.randoxtoxicology.com

Inherited Cardiovascular Disease Genetic Test Menu
Available for individual and familial settings
Aviir Inc, Irvine, Calif, will be extending its offered services with a comprehensive inherited cardiovascular disease genetic test menu. The newly validated tests cover the major causes of cardiomyopathies, arrhythmia disorders, and other genetically transmitted diseases that affect the heart and vasculature. Each test is available for testing in both individual and familial settings. Two comprehensive panels are available to check for undiagnosed arrhythmia or cardiomyopathy.

Aviir Inc (888) 287-4217; www.aviir.com

Beta-Hydroxybutyric Acid Linearity
Open-vial stability of 7 days
Audit MicroControls Inc, Carlsbad, Calif, has added the Beta-Hydroxybutyric Acid Linearity, 5 levels, to its line of calibration verification/linearity products. It is intended to simulate human patient serum samples for the purpose of determining linearity, calibration verification, and verification of reportable range for Beta-Hydroxybutyric Acid. Packaged as 5 x 1 mL, this liquid product has a shelf life of 2 years and an open-vial stability of 7 days when stored at 2°C to 8°C.

Audit MicroControls Inc (866) 252-8942; www.auditmicro.com

Multibiomarker Blood Test
Measures disease activity in RA
Crescendo Bioscience, South San Francisco, offers Vectra DA, a multibiomarker blood test that measures disease activity in rheumatoid arthritis (RA) by integrating 12 key proteins consistently associated with the biology of RA into one single, objective, and quantitative score to help physicians make more informed patient-management decisions. The Wadsworth Center at the New York Department of Health recently issued a laboratory permit to the company to provide services to physicians in New York. With this clearance, Vectra DA is now available in all 50 states.

Crescendo Bioscience (877) 743-8639; www.crescendobio.com

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ARUP Expert Drills Down on ACOs

Tracking Developments and Strategies for Labs

By Kurt Woock

In the fall of 2011, Joe Miles, MT(ASCP), MHS, sat down with CLP. Then, Miles, senior consultant, outreach development, ARUP Laboratories, Salt Lake City, discussed the introduction of accountable care organizations (ACOs) and how clinical labs were changing. Now, 18 months later, there are nearly 260 Medicare ACOs that provide coverage for an estimated four million Medicare beneficiaries, and labs are understanding their new role, often at the center of care. CLP circled back with Miles to track developments on these and other subjects.

CLP: Tell us about your background and current role at ARUP.

Miles: For more than 20 years, I was a laboratory manager in a large, public health system, a new suburban hospital, and a sole-provider, community hospital. For 9 years prior to joining ARUP, I served as the general manager of a network of hospital-based laboratories formed primarily to secure managed care contracts. With ARUP, I work in a consultative role helping our clients who are engaged in or developing outreach programs. In addition, I have been working with the business innovations team on the development of tools to support our clients in the areas of decision support, formulary development, and informatics.

CLP: What are the most significant developments in the evolution of diagnostic labs since late 2011 under the ACO model?

Miles: Forward-looking laboratories have begun focusing on providing services and test results in ambulatory settings. Many laboratories are working with affiliated physicians by enhancing their abilities to communicate electronically with physician-practice EMRs, mobile physicians, and even patients. This development is not universal, however, and we see many hospital-based laboratories still struggling to gain the commitment and investment funding needed to support outreach developments.

There is a strong awareness among laboratory management that the future of diagnostic testing in terms of access points and volumes will be in ambulatory care settings. That being said, many health systems are still grappling with their strategies for comprehensive diagnostic services. In addition, current estimates indicate there are almost 260 Medicare ACOs that provide coverage for an estimated four million Medicare beneficiaries. With rapid adoption of this new model of integrated health care, clinical laboratories and pathology groups need to proactively develop strategies to sell the value of laboratory services to ACOs in their local markets.

CLP: One of the shifts you discussed earlier concerned labs playing a larger role in the decision-making process/test selection. Has this trend continued? To what effect?

Miles: We see more laboratory professionals getting involved with the development of CPOE order sets and test algorithms that guide the selection of appropriate tests at the appropriate time. The rate of adoption of physician electronic order entry has passed a tipping point. As a result, one of the easiest ways to influence test selection is through built-in electronic prompts and well-constructed order pathways. Software vendors are becoming aware of the need for this kind of built-in functionality. The trend continues to advance, and we now see institutions developing lab formulary policies.

Lab formulary development has the potential to manage utilization of diagnostics in a way that we have not seen before. Access to ordering privileges, approval of reference laboratories, authorization of standing orders, certification of new test developments (and retirement of antiquated tests), and development of test algorithms are a few areas in which institutions are beginning to establish policy.

CLP: The last time we spoke, you suggested labs look to establish new relationships with health care providers across the continuum of care. During the past 18 months, has this idea progressed? Do you have any examples of particularly innovative or successful solutions/relationships?

Miles: With the creation of accountable care organizations, health systems are beginning to do more vertical integration and create services across the entire continuum of care. As a result, many hospital-based laboratories are moving into the nursing home business again. Decisions to re-enter the nursing home theater are not often financial around times, cost, etc.

In our practice, we see academic medical centers and specialty tertiary facilities teaming with their oncology departments to create personalized medicine programs. The goal in these centers is genetic testing that results in more precise diagnoses accompanied by individualized treatment options.