

Trends and Technology: Winter 2003

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Trends and Technology welcomes releases and information about new products, services, Web sites, trends, and upcoming events. If your company has a Web site that you would like for us to review, please send us news for our Online section, or tell us about sites that would interest clinical laboratory scientists (CLSs). These sites, as well as the new product information, are offered for reader information only. We cannot vouch for them and their presence here does not constitute an endorsement by CLS or ASCLS.

ONLINE

Labexplorer.com (www.labexplorer.com) really does live up to its name. It is the equivalent, to my thinking, of a great Table of Contents to the laboratory universe – it may not have all of the meaty information, but it is a useful index in many cases. GLP Webmedia, which is a Kentucky-based Web information technology company, maintains the site. “Our core competency is to link the labo-

The Trends and Technology section seeks to publish product and technology information (including black-and-white glossy photographs), news items (such as FDA approvals), and information about laboratory resources of all kinds. The intent of this section is to provide a cutting-edge, one-stop shop tailored to the current practical needs and concerns of clinical laboratory practitioners. Let us hear from you with suggestions on how to improve this section. Direct inquiries and information to Mary Jane Gore, CLS Trends and Technology Editor, c/o ASCLS, 6701 Democracy Blvd., Suite 300, Bethesda, MD 20814, clstt@aol.com. Please send all materials clearly marked NEW PRODUCTS.

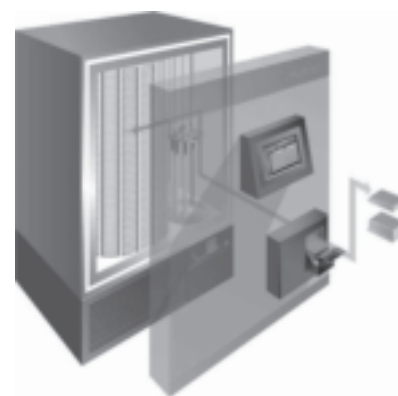
ratorian to laboratory specific information”, the site reads. “Our site concentrates on assembling everything relevant to the laboratory profession. By bringing together multiple resources for the Web integration of laboratory medicine, Labexplorer.com enables our visitors to rapidly locate laboratory specific information.”

I don't know how new the site is, but it has a way to go before it is comprehensive. In terms of the articles it offers (written by interested CLSs), the offerings were only four works, on topics from “Phlebotomy” to “Edward Jenner.” The phlebotomy article dealt with the national trend toward nurses taking over this traditional laboratory function, and certification and safety issues. The site makes it clear that scientists with an area of expertise are encouraged to contribute articles; at this time, the pickings are slim. Here's a chance for publication in an area of interest.

The site includes links to a monitored chat room, links to laboratory organization sites, links to vendor sites, a meetings calendar (that did not go much past April 2003 when I checked in the mid-fall), current news geared toward medicine and hospital news in general (but up to the minute), a laboratory history page, job ads, an education page, and a very limited disease page (which also asked for contributions). With time and contributions, Labexplorer.com will become a more valuable resource, but for now, it remains a central place to go for laboratory-related links—and some in-depth laboratory information.

NEW PRODUCTS

BIOPHILE, Inc. supplies fully automated sample storage systems that operate at -80°C , -40°C and -20°C , while providing sample validation, and group and individual sample security and integrity. The system's software interface is convenient and simple to use for cataloging samples and tracking chain-of-custody, and it complies with FDA 21 CFR Part 11 guidelines. It provides touch screen accessibility for laboratory users and administrators, while insuring secure access through username and password protocols. Recently, Emory University installed its new fully automated BIOPHILE™ ultra-low temperature sample storage system at the University's Center for Medical Genomics. The BIOPHILE storage system is designed for use in clinical laboratories, as well as in genomics, proteomics, DNA forensics, and drug discovery laboratories. Contact (434) 245-4053, x117 or visit BIOPHILE's web site at www.BIOPHILEinc.com.



BIOPHILE storage system

Olympus Diagnostics Systems Group has introduced its new HDL and LDL Cholesterol Direct reagents, customized for use on the Olympus AU 400, AU600, AU 640, AU 2700 and AU 5400 chemistry-immuno analyzers. These reagents can be used with fasting and non-fasting samples with no significant interference from triglycerides (up to 1,000 mg/dL). For more information, contact Carole Dauscher at (800) 223-0125 or visit www.olympus.com.

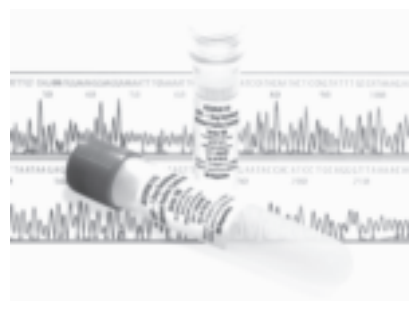


Olympus Diagnostics Reagents

Extending Dade Behring's commitment to provide solutions to the diagnostic industry, the company has added two new products to its Dimension® RxL clinical chemistry diagnostic instrumentation: RxL Max™ and Max Suite™. RxL Max features hardware and software enhancements to its Dimension instrument line: With the RxL Max, a new touch screen Operator Interface adds a 'smart' feature to existing monitor/keyboard arrangements, and provides immediate access to sample information for STATs and abnormal specimens, each of which can be of particular importance for requests from the Emergency Department or intensive care units. The screen includes visual early warning alerts for reagent inventory, calibration, and supply needs, which is a workflow benefit to laboratories. Additionally, the enhanced software gives laboratorians the

ability to electronically store maintenance and QC (quality control) logs. Additional company information is available at www.dadebehring.com.

Boston Biomedica now offers ACCURUN® 515 HIV-1 Drug Resistant Mutant Positive Control. This is designed specifically for laboratories performing HIV genotyping assays for detection of drug-resistant strains of virus. Contact Alan Doty at (508) 580-1900.



Boston Biomedica's Positive Control

Quater Research & Development has announced an advanced new micropositioner that provides high-precision motion control – in three dimensions – by remote control. The new Quater Model XYZ-500 MIMT is motorized and may be controlled either by computer or joystick. It utilizes three high-precision stepping motors that are attached to precise gear heads driving high thread-count screws. As a result, ultra-fine motion control can be achieved – with resolutions of from 0.48µm per step down to 0.0105µm per step, depending upon the gearbox ratio that is ordered. This positioner addresses a wide spectrum of analytical, test, instrumentation, and production equipment applications – automating the positioning of probes, test heads, lasers, optics, and numerous other system components. For more information, contact Keith Riehl at (503) 247-7131.

APPROVAL NEWS

Bayer Diagnostics announced today that it received U.S. Food and Drug Administration approval for VERSANT® HIV-1 RNA 3.0 Assay (bDNA), its nucleic acid probe diagnostic assay for the quantitation of HIV-1 RNA in the plasma of people living with HIV. The test is for in vitro diagnostic use only by clinical laboratory professionals in the direct quantitation of human immunodeficiency virus type 1 (HIV-1) in plasma of HIV-1 infected individuals. The Bayer bDNA viral load system is the first FDA-approved viral load test that automates critical assay steps and includes approved software for automatic results generation. The VERSANT HIV-1 RNA 3.0 Assay directly measures HIV-1 viral levels in plasma using novel branched DNA (bDNA) signal amplification technology. It detects and quantifies all major HIV-1 subtypes (Group M, types A-G). The VERSANT assay's precision makes it the only FDA-approved test capable of reliably detecting significant (three-fold) changes in viral load throughout its entire quantitation range. Contact (978) 462-0412 for more information.

Health Canada Therapeutic Products Directorate has granted a Class III in vitro diagnostics medical device license for the detection of Ischemia Modified Albumin (IMA™) by the Albumin Cobalt Binding (ACB®) test. The test is currently available for sale in Europe, with U.S. regulatory submission in process. Contact Donna Edmonds, at (720) 540-0200 or company president Peter Crosby at pcrosby@ischemia.com.

TRENDS AND TECHNOLOGY

ACCREDITATION

Joint Commission Resources (JCR) today announced the publication of *From Practice to Paper: Survey Documentation for Laboratories*. JCR is a subsidiary of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). This book helps laboratory professionals comply with JCAHO standards by demonstrating how to benchmark documentation practices and improve them. The book provides sample documentation for each functional chapter of the *2002-2003 Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services*, including abridged versions of documents used by laboratory professionals to demonstrate compliance with the standards. Readers also learn what role documents play in the survey process. *From Practice to Paper: Survey Documentation for Laboratories* is available for \$95 using order code SDFL-01. To order, call the Customer Service Center toll free at (877) 223-6866, 8 A.M. to 8 P.M. Central Time, weekdays, or visit Infomart at www.jcrinc.com.

Likewise, JCR recently announced the publication of *Joint Commission International Accreditation Standards for Clinical Laboratories*. The publication includes standards, intent statements, and measurable elements, plus policies

for accreditation of international laboratories. Standards are grouped into five key chapters. The standards are available for \$95 using order code JCIS-100. To order, call the Customer Service Center toll-free at 877-223-6866, 8 A.M. to 5 P.M. Central Time, weekdays, or visit Infomart at www.jcrinc.com.

A special 16-page edition of *Perspectives*, the Joint Commission's official newsletter, takes an in-depth look at the new, national JCAHO accreditation process. Over the next one-and-one-half to two years, the initiative, "Shared Visions – New Pathways," will progressively sharpen the focus of the accreditation process on care systems critical to the safety and quality of patient care. The 16-page publication is available at Joint Commission Resources' Website at www.jcrinc.com/perspectives. Contact Charlene D Hill at (630) 792-5175 for more information.

BUSINESS NEWS

Nikon Instruments, Inc., the world leader in precision optics manufacturing, today announced that it has formed two new business Divisions – Microscopy Sales and Microscopy Product/Marketing. The focus will be on expanding Nikon's position in microscopy. This new organizational framework will streamline the company's operations, allowing

greater flexibility in responding to market and customer needs.

Cholestech Corporation (Nasdaq: CTEC) announced today that it has been included in Forbes' comprehensive annual list of the 200 Best Small Companies, published in the October 28, 2002 issue. Cholestech was ranked 83rd overall on Forbes' list, which is a compilation of financially strong small cap businesses. Cholestech's Diagnostic Products and WellCheck™ business units offer efficient and economic diagnostic screening for cholesterol, blood sugar and liver function at the point of care.

Dade Behring has successfully consummated its debt restructuring, establishing a sound capital structure to support the long-term growth potential of its consistently strong operating business, the company announced. Jim Reid-Anderson, President and Chief Executive Officer of Dade Behring notes: "(Our customers' and suppliers') confidence in Dade Behring underscores the enduring strengths of our business and the means by which we deliver value – service, trust, quality, and 'lab-smart' innovation."