Trends and Technology: Spring 2005

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ONLINE

With this issue of Trends and Technology, I decided to break with tradition – the tradition of not reviewing manufacturers' Web sites. I did not want to create the illusion of favoritism or persuasion by featuring a clinical diagnostics Web site, but after so many years of reviewing other types of sites – governmental agencies, personal lab-related Web sites, some association sites of interest, quality-related sites – I began to wonder: why not? As always, I welcome reader input about sites that may be helpful – or not so helpful – to review for other readers (send your ideas to clstt@aol.com). This time, I visited the site of Ortho-Clinical Diagnostics (www.orthoclincal.com), a subdivision of Johnson & Johnson, and found that when I answered the Web survey, I got a timely response to my query, which led to me look at the site from the standpoint of a laboratory scientist. I have to say that helpfulness is a hallmark of the Ortho-Clinical site. All of its major analyzers and other product lines are clearly labeled as links to the left on the homepage. The information under "Contact Us" is extensive and inviting, and not just an email address that is often found online. If you want to contact these folks, they make it easy. The homepage also has links to technical support (including holiday photos of these people, putting faces to the voices on the phone) and technical documentation, which brought up 123 "Instructions for Use" documents, down to the last calibrator kit. The most impressive fact of this Web site, for me, is that it is all available with a glance at the homepage, including headline news about new products. Ortho appears to be a company dedicated to customer service and response and its site is indeed user friendly.

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.

NEW PRODUCTS

The VITROS 350 Chemistry System offers easy operation, maintenance, and training. Whether you use it as a primary, STAT, or back-up to the powerful VITROS 5,1 FS, the VITROS 350 Chemistry System can perform the work. The VITROS 350 comes complete with enhanced throughput, a broad accessible menu, and new ergonomic design. "Load-and-go" reagent preparation, MicroSlide™ Technology and up to six months' calibration stability mean labor can be redeployed for value-added tasks. Minimal instrument maintenance assists with productivity and reduces costs with the system that delivers the right results the first time. Ortho-Clinical Diagnostics studies indicate that the VITROS 350 Chemistry System with enhanced software improves throughput 10% to 25% and time-to-first-result up to 12% when compared to the VITROS 250 System. Visit www.orthoclinical.com for more information on this and other products.

Ortho-Clinical VITROS 350

Maxell Corporation of America, leader in advanced recordable media products, has announced new ultra-durable and ultra-reliable DVD media designed specifically for the medical market. Maxell's new medical-grade media incorporates the innovative MAXPRO™ Hardcoat technology to produce enhanced DVD-R media that delivers the highest level of data protection for up to twice the archival shelf life. Maxell Medical DVD-R is HIPAA- and DICOM-compliant, and with its superior scratch, dust and smudge resistance and extended archival life, is ideal for critical medical images, patient records, backup, and fixed content storage. Maxell's 700 MB, 8X speed Medical DVD-R media will be available in March as a single disc in a jewel case and in 50-pack spindles with printable white surfaces

for either thermal or inkjet printers. Pricing will be affordable compared to other backup media. Contact www.maxell.com.

Healthcare organizations now have continuous access to the Joint Commission on Accreditation of Healthcare Organizations' Periodic Performance Review (PPR) on the Joint Commission's secure extranet, "JAYCO." The PPR is an integral component of the Joint Commission's accreditation process that promotes continuous standards compliance through ongoing, internal monitoring. Before making the PPR continuously available, organizations had received access to the PPR tool 15 months after its last triennial survey and had three months to complete it. Those timeframes for access have now been eliminated. The schedule for completing the PPR remains unchanged until January 2006, when organizations will be expected to update the PPR annually. For 2005, the PPR process requires each accredited organization to conduct a mid-cycle self-assessment against applicable Joint Commission standards, develop a Plan of Action to address identified areas of non-compliance and identify Measures of Success for validating resolution of the identified problem areas. Under the usual PPR process, organizations will be expected to share this information with the Joint Commission at the mid-cycle point. Contact Charlene Hill at Charlene D. Hill 630-792-5175 or email chill@jcaho.org.

Tecan introduced several new laboratory automation products at Lab Automation 2005, the pre-eminent industry meeting, held at the San Jose McEnery Convention Center. Tecan's interactive trade show booth included the latest unique robotic solutions. Tecan's participation at Lab Automation 2005 demonstrated robotic solutions that deliver speed, efficiency, and reliability for laboratories focused on clinical diagnostics, genomics, proteomics and drug discovery. Contact Greg Porter, Ph.D., at 919-361-5200.

AxSYM Anti-HCV (hepatitis C virus) is a Microparticle Enzyme Immunoassay (MEIA) for the qualitative detection of anti-HCV IgG to HCV recombinant proteins in human serum or plasma containing potassium EDTA, sodium EDTA, sodium heparin, lithium heparin, sodium citrate, or potassium oxalate. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV virus (state of infection or associated disease not determined) in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis C infection. Visit www.abbottdiagnostics.com for the 2005 product releases and listings.

FDA APPROVALS

Bayer Diagnostics has received U.S. Food and Drug Administration (FDA) approval for its automated assay for the hepatitis C virus on the ADVIA Centaur® Immunoassay System. Contact Susan Hager at 781-551-7916.

Bio-Rad Laboratories has received marketing clearance from the FDA for its new BioPlex® 2200 system, a revolutionary new immunoassay platform that employs multiplexing technology to analyze for multiple disease states from single patient samples. It is the first clinical diagnostics platform to offer multiplexing technology on a fully-automated, fully-integrated random access platform. The system was unveiled last July at the American Association of Clinical Chemistry meeting and will soon be available in the U.S. The BioPlex 2200 system is a bead-based multiplexing immunoassay platform that can deliver up to 2200 results per hour. The system will initially include a panel of assays targeting autoimmune diagnostics. Future assays in development are in the areas of serology, infectious disease, cardiac, and toxicology. Contact Gary Mantha at 510-741-4637 or email Gary_Mantha@bio-rad.com.

BioPlex 2200

Bio-Rad Laboratories recently received approval from the FDA for its new Multispot HIV-1/HIV-2 Rapid Test. This highly sensitive test kit this year became available in the U.S. and will significantly aid in the diagnosis of HIV-1/HIV-2 (human immunodeficiency virus, types 1 and 2), the virus that causes AIDS. Contact Susan Berg at 510-741-6063 or email susan_berg@bio-rad.com.

Roche announced that its first microarray-based test, the AmpliChip CYP450 Test, has been cleared by the FDA for diagnostic use in the U.S. This test, which is powered by Affymetrix microarray technology, analyses a patient's cytochrome P450, 2D6, and 2C19 genotypes from genomic DNA extracted from a blood sample. Test results will allow physicians to consider unique genetic information from patients in selecting medications and doses of medications for a wide variety of common conditions such as cardiac diseases, pain, and cancer. This new test allows physicians access to information that could help to prevent harmful drug interactions and to assure drugs are used optimally. Adverse drug reactions cause

a huge number of hospitalizations in the U.S. The new test also will, in some cases, enable patients to avoid suboptimal or even harmful treatment choices. For patients it is extremely important to know whether pain killers or anesthetics might work differently or not at all for them. More information is available at www.roche-diagnostics.com.

Dade Behring (NASDAQ: DADE) has received clearance from the FDA for the use of its Advanced D-Dimer assay as an aid in the diagnosis of venous thromboembolism (VTE), [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. The clearance included performance data with a defined cutoff value for the Dade Behring BCS® System and Sysmex® CA-1500 System. The assay is also for use on Dade Behring's BCT® System, and Sysmex® CA-7000 and CA-560 Systems.

ARRANGEMENTS

VWR International announces the recent acquisition of Alpha-Omega Calibrations, LLC. This acquisition expands VWR's service portfolio to now include instrument calibration services and repairs for customers nationwide. Alpha-Omega Calibrations' proven process includes a quality manual, well-documented standard operating procedures, a world-class training program for all their technicians, state-of-the-art facilities and equipment, and decades of gravimetric and metrology experience. Service advantages include fast turnaround times, competitive pricing, full traceability to NIST, and fulfillment of ISO and all other compliance record-keeping requirements. Contact Robin Gervasoni at 610-430-7258 or email robin_gervasoni@vwr.com.

Infotrieve Inc, a provider of content software technology and information services, has announced its acquisition of GenSys Software, Inc, provider of the GenSys/ELN™ electronic laboratory notebook for life sciences, chemistry, and other research-intensive industries. The GenSys/ELN will serve as the anchor for Infotrieve's life sciences electronic research platform, which has been designed to collectively increase the value of organizational content and improve scientists' existing workflow by enabling links from electronic laboratory notebooks to discovery tools, literature and scientific data, laboratory product information, and integrated retrieval capabilities for literature and laboratory products. Contact Infotrieve Marketing Manager Ian Palmer by phone at 310-445-3038 or via e-mail at ipalmer@infotrieve.com.

International Technidyne has struck a deal with Medical Automation Systems for the MAS RALS to integrate ITC's IRMA TRUpoint™ analyzer for point-of-care blood gas monitoring with the widely used RALS®-Plus data management system, marketed by MAS. Contact Check Weber at 847-705-1802.

Abbott and Nihon Kohden Corporation announced that they have entered into an agreement for the commercialization of automated hematology diagnostic instruments for use in hospital laboratories and physician offices. Under terms of the agreement, two 5-part differential hematology instruments, which are designed to offer red and white blood cell analysis, will be manufactured by Nihon Kohden and distributed by Abbott under the CELL-DYN Pearl™ brand name. Abbott obtains exclusive distribution rights for the two instruments in the United States and Canada and non-exclusive distribution rights for the instruments in other countries with the exception of China and Japan. Contact Amy Woodworth at 847-935-4755.

Instructions to Authors

Detailed **Instructions to Authors** can be found on the ASCLS Website (www.ascls.org) by following the Publications links or going directly to http://www.ascls.org/leadership/cls/index.htm, or obtained by contacting the Clin Lab Sci Editorial Office, PO Box 5399, Coralville, IA 52241. (319) 351-2922. cls@ia.net

Questions may be addressed to Ivan Schwabbauer, Managing Editor.