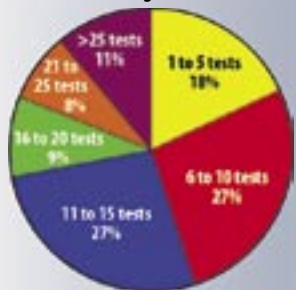


MOLECULAR DIAGNOSTICS SHOWS STRONG GROWTH

The results of a newly completed survey of 107 U.S. molecular diagnostic labs—71 in hospitals, 15 privately-held, and 21 in the public health service sector—indicate continued strong growth in the use of molecular diagnostic testing. The survey, covering four areas of discipline where molecular diagnostic methods are used—infectious diseases, inherited genetic diseases, coagulation/hematological disorders, and cancer—found a 14% increase for 2002 in overall testing volume. Labs participating in the study also reported that they expect their test volume growth would be even greater in 2003.

The purpose of the survey, conducted by Enterprise Analysis Corporation (Stamford, Conn.), a health care consulting firm, was to explore topics such as: type of tests performed; annual test volume and growth; and use of FDA-approved products, analyte specific reagents (ASRs), and home brew tests. The survey also explored test methods used, type of instrumentation used, sample extraction methods, manufacturer market shares and recent or planned additions to test menus.

Number of Assays Offered by Molecular Diagnostic Labs



Average assays per lab = 14

Source: EAC

At the top of the list were tests for infectious diseases, representing 78% of all molecular diagnostic tests performed in 2002. Tests for inherited genetic diseases represent 15% of the total test volume, while tests for coagulation/hematology disorders and cancer assays account for the balance.

EAC also found that molecular diagnostic labs offer an average of 14 different assays, with a range of 11% offering more than 25 types of tests (see figure). Testing for cystic fibrosis topped the list of genetic tests with 28% of the labs offering the test, and Fragile X testing was a close second with 25%.

Significantly, 76% of labs surveyed said they have added new tests to their menus in the past 12 months, and 83% plan to add new tests in the coming 12 months. "Home brew" methods are still widely used, with 85% of the labs reporting at least one assay performed using a home brew method. At the same time, the use of ASRs is growing with 41% of labs surveyed now using them.

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Increasing the Visibility of Lab Tests and Lab Professionals

Raising Public Awareness of the Lab's Value

BY SUE AUXTER-PARHAM

Clinical laboratory professionals have traditionally been the "silent" partners of clinicians in the diagnosis, monitoring, and treatment of disease, performing much of their work in areas of the hospital that patients never see, or in reference labs or core labs that patients never visit. Because consumers do not generally interact directly with lab professionals—with the exception of having their blood drawn by a phlebotomist—many of them tend to overlook the essential role lab professionals play in providing and improving health care, and this lack of recognition may be a contributing factor in some of the problems labs face today.

"Patients rarely know much about the laboratory professional who produced their lab reports, but they know the physician or the nurse who are there at the bedside during the diagnosis and treatment processes," explained Thomas Moyer, PhD, President of AACC, Professor of Laboratory Medicine at Mayo Medical School, and Director of the Drug Laboratory at Mayo Clinic in Rochester, Minn. In this issue of *CLN*, Moyer writes about the important role every lab professional can play in promoting the value of laboratory testing (see the President's Message, page 4). "The clinicians can't do their jobs without the lab, but the lab can't do its job without receiving some recognition for the role it plays in helping physicians and nurses," he said.



See **Lab Visibility**, continued on page 6

FDA to Once Again Assume Waiver Criteria Development Responsibility

Agency Will Wait for CLIAC Recommendations

BY SUE AUXTER-PARHAM

Last month, the Department of Health and Human Services (HHS) returned the responsibility for developing final CLIA '88 waiver criteria to the Food and Drug Administration (FDA), where it had resided in 2000 and 2001 before being reassigned to the Centers for Medicare and Medicaid Services (CMS). This recent switch actually marks the third time the responsibility for developing waiver criteria has been reassigned—initially, before the FDA was charged with the task the first time, it rested with the Centers for Disease Control and Prevention (CDC). It now appears, however, that the FDA will be the one and only entity to promulgate the waiver criteria, which is one of the few CLIA '88 rules that have never been finalized.

"In the near future, there will be an official *Federal Register* notice or another public notification that states the delegation of authority for developing the waiver criteria will be transferred from CMS back to FDA," confirmed Steven Gutman, MD, Director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD). He indicated that before taking any action to institute new waiver criteria, or to institute the draft guidance document the agency had published in 2001, the OIVD will wait for a Work Group on waiver criteria formed by the Clinical Laboratory Improvement Advisory Committee (CLIAC)

See **Waiver Criteria**, continued on page 3

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Recognizing the Lab's Value

Lab Visibility, from page 1

Why is recognition so important? At the most basic level, human beings derive satisfaction from being recognized for performing their jobs well, and lack of recognition for laboratory professionals has been cited as one of the contributing factors to laboratory labor shortages by members of the Coordinating Council on the Clinical Laboratory Workforce (CCCLW). The CCCLW, a coalition of lab organizations and others, has been formed in part to enhance the visibility of the clinical laboratory professions, and to generate awareness of the clinical lab workforce shortage among the public, hospital administrators, human resource managers, the in vitro diagnostic (IVD) industry, and policy-makers.

Recently, the CCCLW issued a press release to the popular media in an effort to heighten public awareness of the labor shortage and to build consumer recognition of the value lab professionals bring to health care. The hope is that greater consumer awareness of what lab professionals do will generate more interest in the profession. "Respect for the profession is essential to attract new people into the laboratory workforce. We must become much more proactive about promoting the fact that there are people behind the laboratory reports clinicians and patients see," opined Moyer.

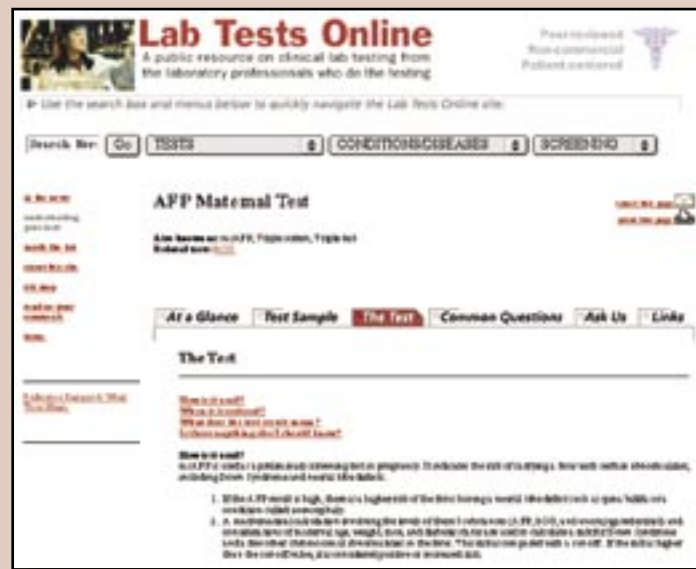
Consumer recognition is also important in that it could contribute to greater financial stability in labs long-term. As consumers assume a greater role in directing and purchasing their own health care, they are increasingly influencing what parts of health care are financed. "Because we tend to be very much behind the scenes, labs often find themselves in situations where they are losing a small fraction of their budget each year, and as that occurs year after year, laborato-

ries are steadily falling behind the rest of the practice of medicine," Moyer added. "If we were to do a better job of informing the public of what goes on behind those laboratory doors, I think we could reverse that process."

With more financial resources at their disposal, laboratory professionals could play a larger role in researching new technologies, and lab employees could potentially receive higher salaries, which the CCCLW says is essential in bringing more people into the profession. "Employers need to recognize that low salaries for laboratory personnel are one of the major factors contributing to the shortage of qualified clinical laboratory personnel," wrote the CCCLW in a November 3 press release. "Further, there are disparities in salaries earned by clinical laboratory personnel compared to their counterparts in other health professions that require college degrees, specialized training and shared responsibility for patients' care."

Building Relationships— And a Consumer Web Site

Improving the visibility of the lab is not a task that can be accomplished through a single effort, however, and lab professionals have joined with members of the IVD industry to actively build relationships at the national level that will foster greater recognition of lab testing and the laboratory professional's value in health care. The CCCLW is one example of how people from different laboratory disciplines are working together to make laboratory testing more visible to consumers, but the largest partnering effort of this kind to date is the one that supports Lab Tests Online (www.labtestsonline.org). A consumer Web site sponsored by more than twenty-five IVD companies and reference labs, with content developed by representatives from fourteen different collaborating lab organization partners, Lab Tests Online



Lab Tests Online Gains Recognition as Award-Winning Consumer Web Site

Last year was a banner-year for the lab industry's consumer Web site, Lab Tests Online. Aside from generating an average of 225,000 hits per month, Lab Tests Online won the Award of Excellence in the 2003 Associations Advance America Awards program, a national competition sponsored by the American Society of Association Executives (ASAE). The prestigious award put the site in the running to receive an ASAE Summit Award, which the Web site won in October. The Summit Awards recognized the Web site and five other projects for "innovative contributions" that have enhanced American society. Lab Tests Online also won a Gold Award for Best Health/Healthcare Content in the fourth annual eHealthcare Leadership Awards, which recognize the best Web sites from health care organizations, online health companies, pharmaceutical firms, and business improvement initiatives. Other winners of eHealthcare Leadership awards include site like WebMD, the CMS Web site, and BreastCancer.org. To learn more about the eHealthcare Leadership Award winners, go to: www.strategichealthcare.com/AwardWinnersHealthContent.html.

may be the best communication mechanism clinical labs have right now to build visibility for lab testing among consumers.

As more coverage of Lab Tests Online has appeared in the popular press, such as *The Wall Street Journal*, *Newsweek*, and major women's magazines like *Glamour* and *Shape*, the Web site has been growing by leaps and bounds since its launch in July 2001. "Recently, the Laboratory Healthcare Partnership, another group of individuals from laboratory organizations and IVD companies, paid for an article about Lab Tests Online that was distributed to the popular press. We estimate that it reached over 10 million people in several publications," noted David Sundwall, MD, Senior Medical and Scientific Officer of the American Clinical Laboratory Association and a member of Lab Tests Online's editorial board since its inception.

Currently, visitors to Lab Tests Online average about 225,000 per month, and the site has won a number of prestigious mainstream awards—most recently the gold e-Healthcare Leadership Award for best health/healthcare content (see box). In addition, 77 NIH sites, the FDA Consumer Web site, and more than 1000 other Web sites link to Lab Tests Online, fostering greater consumer awareness of laboratory testing. "I think it's an accessible, understandable source of information about lab testing in a world that's increasingly complicated and confusing," explained Sundwall, who believes that the site also has value for physicians who can use it to refresh their memories about

the functions of various laboratory tests.

According to Sundwall, lab groups and IVD companies aren't stopping at the CCCLW and Lab Tests Online—they're partnering to make the lab more visible to national policy-makers as well. "Another activity of the Laboratory Healthcare Partnership was to fund a study by the National Committee on Quality Assurance. The study identifies what kinds of laboratory data are used in HEDIS indicators, which are quality monitors for health plans. There are about 16 lab-specific HEDIS indicators, and the study also identified the barriers to such data being effectively used as quality indicators," said Sundwall. Removing these barriers is key in establishing a permanent lab testing presence in the national health care quality movement.

In addition, laboratory professionals, through groups like the National Academy of Clinical Biochemistry (NACB) are partnering with physician specialty groups and other health care professional groups to develop clinical practice guidelines. These activities elevate the visibility and status of lab professionals among other health care professionals. "I think the old adage about getting respect the old-fashioned way—earning it—rings true, and that's what we're trying to do," said Robert Christenson, PhD, AACC Secretary and Director of Rapid Response Laboratories at the University of Maryland Medical Systems in Baltimore, Md. Christenson, who serves as Chair of AACC's Evidence-Based Medicine Com-



Promote Lab Professionals During National Medical Laboratory Week April 18–24, 2004

One of the best ways for laboratorians to herald the value of lab testing is to celebrate National Medical Laboratory Week (NMLW), a special time set aside annually to recognize medical laboratory professionals. In 2004, National Medical Laboratory Week will be held April 18–24, so it's not too early to start planning! NMLW is an excellent opportunity to promote medical laboratory professions, to recruit students to the field, to thank technologists and technicians, build morale, and gain visibility for the laboratory throughout the institution and the community. This year's theme is "Laboratory Professionals: Working with You for Better Health." More information on NMLW can be found on the ASCP Web site at: www.ascp.org/general/labweek/.

mittee, is also chairing an NACB committee that's currently developing a cardiac markers guideline, but points to a number of other recent activities that have elevated the status of lab professionals in national policy-making. "AACC has worked with the Agency for Healthcare Research and Quality (AHRQ) on several different technical assessments and evidence reports, along with other experts in health care, and has established a relationship with AHRQ," he said. "The next time AHRQ needs advice on lab-related issues, we hope they'll come to us, and in this way, we're building recognition at AHRQ that lab professionals can contribute to evidence-based medicine."

In addition, AACC and other laboratory groups have worked together in efforts to effect change in lab reimbursement policy, most recently defeating an effort to impose a 20% co-payment for Medicare part B laboratory testing. Lab groups also work together with agencies like the Centers for Medicare and Medicaid Services (CMS) on certification and reimbursement issues, the Food and Drug Administration on in vitro diagnostic (IVD) device issues, and with the Centers for Disease Control and Prevention (CDC) on a number of test standardization efforts.

Making Labs More Visible— A Role for the IVD Industry?

According to Moyer, bringing more recognition to laboratory professionals and more visibility to laboratory testing is not something that the lab community can do by itself—he believes that the IVD industry must play a role. "As an industry, we must band together to create a public awareness campaign that promotes the value of laboratory service. Individual companies have ad campaigns that sell specific IVD products, but we need ads that sell the laboratory service, not a specific product," noted Moyer. For example, he said, General Electric has commercials that highlight the importance of MRIs, but doesn't sell a particular MRI instrument. "Those commercials tell you how valuable imaging is in the diagnostic process. We need to communicate how valuable the laboratory report—and the people behind the report—are in the diagnostic process," he said.

Mary Lou Gantzer, PhD, Director of Clinical and Scientific Affairs at Dade Behring (Deerfield, Ind.) believes that the IVD industry is aware that greater visibility needs to be generated for both laboratory and IVD professionals, and says that there are plans in the works to address the issue. "Everybody, whether they are in a hospital lab or in the IVD industry, knows that people do not know and understand what we do," said Gantzer. "We've certainly come some distance with Lab Tests Online in terms of educating consumers about what a specific test is and what the results mean, but they still don't necessarily understand what the IVD and lab industry is, and they don't understand how important the laboratory testing component is to proper diagnosis and treatment," she said.

Both Gantzer and Moyer believe that the terminology IVD and laboratory professionals use to communicate with consumers could be part of the problem. "Maybe the issue is that for so long, we have used terms that are too technical—like in vitro diagnostics. If you say in vitro diagnostics, people don't generally understand what that is, but if you tell them that you make the lab tests

their doctor orders, then they understand," said Gantzer.

One specific activity that IVD professionals will be involved in is the development of a new institute that will perform studies addressing the value of using particular in vitro and in vivo medical devices. The institute will be run by AdvaMed, a non-profit organization comprised mainly of health industry manufacturers. "Until they have everybody on board, it's difficult to know where the institute's priorities will be, but one of the reasons the institute was formed was to examine the value that medical device technology brings to health care," said Gantzer.

What Labs Can Do at the Local Level

Although increasing the visibility of the lab on a large scale can only be done at the national level, there are things lab professionals can do locally to promote laboratory

testing. Becoming involved in laboratory professional organizations is a great way to contribute, but the best way to promote the value of the lab locally is to tell friends, family, and co-workers about your work on a regular basis. "Laboratorians must be prepared to talk about what they do in a dynamic way in social settings to raise the interest of the general public to the important role the laboratory plays in the health care process," said Moyer. "We must be comfortable and prepared to speak up on behalf of the clinical laboratory when the time is appropriate."

Lab professionals can also use institutional communication tools to promote the value of lab testing to their colleagues and to the public. Participating in National Medical Laboratory Week (see box) is also a good way to increase the visibility of the lab. Performing lab tests at health fairs and offering wellness screening is yet another way to

make a direct connection with the public.

One of the most effective ways to promote the lab to consumers at the moment, however, may be to send them to Lab Tests Online, and to encourage physicians to send their patients to Lab Tests Online. Experts estimate that about five million people currently access the Internet every day looking for health care information, and it would be great for the lab and IVD communities if all of them were visiting Lab Tests Online.

"Lab Tests Online is really just the beginning—it's brought together the whole industry, and we have to continue working together to get the message out about the value of laboratory testing," Gantzer concluded. "It's really in the best interests of all segments of the laboratory and IVD communities to increase the public's awareness of the value that we bring to health care, and I think we're going to be most successful if everyone is pulling together." CLN

EMERGING DIAGNOSTIC TECHNOLOGIES

CONFERENCE PROGRAM

SPEAKERS

Defined Protein Assemblies as Diagnostic Reagents
J. Russell
Abbott Laboratories

Antibody Microarray Quantitation with Resonance Light-Scattering Particles
B.H. Geierstanger
Genomics Institute of the Novartis Research Foundation

Directed Evolution of Antibody Affinity and Specificity
B. Iverson
University of Texas at Austin

Diagnostic System Platforms Using an Expanded Genetic Code
J. Prudent
EraGen Biosciences

Bioarray Technology: New Horizons
J. Mooney
Corning

Analysis of Complex Mixtures for Disease Detection and Prevention
L. Zeller
Lawrence Livermore National Laboratories


Nanoelectronics: Prospects and Possibilities
G. Frazier
Raytheon

Photonic Crystal Sensing for POC Analytes
S. Asher
University of Pittsburgh

Ultrasensitive Label-free Electronic Chips for DNA/RNA Analysis
J. Li
NASA

A New Chip Concept for Measuring Proteins and DNA in Blood
P. Warthoe
Atonomics

Development of a Real-time Glucose Monitor Using Fusion Proteins
J. Schultz
University of California at Riverside



Thursday and Friday

April 29 & 30, 2004

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Pushing the Technology Envelope

An Exploration of the Future of Clinical Laboratory Testing

KEYNOTE PRESENTATION

Impact of Novel Mass Spectrometry Technologies in Discovery, Diagnosis, and Treatment of Disease

Richard Caprioli, Vanderbilt University
Stanley Cohen Professor of Biochemistry,
Director of the Mass Spectrometry Research Center

A leader in the development and application of modern mass spectrometric techniques, Dr. Caprioli will describe work on the development of imaging mass spectrometry, a technique whereby molecular images of proteins and drugs can be localized in tissue sections with molecular weight specificity. Application of the technology to questions about spatial distributions of molecules within specific tissues, including mapping proteins in cancer tissue, will be highlighted.

In addition to the invited speakers, the conference will feature oral presentations of selected abstracts, a poster session, networking breaks, and a reception.

REGISTRATION FEES

(Includes breakfast, lunch, breaks, and reception)

	Early-bird (By April 5)	Regular (After April 5)
AACC Member	\$575	\$675
Non-Member	\$760	\$860
Student/Emeritus Member	\$250	\$300

To qualify for the early-bird registration fee, we must receive full payment no later than April 5, 2004.

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