

Molecular Matters

YOUR UPDATE ON THE LATEST TRENDS AND ISSUES IN MOLECULAR DIAGNOSTICS

Abbott Molecular Welcomes You to Our New Publication

A Message from Stafford O'Kelly, President of Abbott Molecular

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- FISH Continuous Quality Improvements Reach Ahead of What's Expected



Abbott Molecular is capturing the benefits of pursuing comprehensive continuous improvement (CI) in its multi-year initiative for FISH probe manufacturing and distribution functions.

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Feature Articles

- A Look at 2010 and Beyond

Molecular Diagnostics Trends: Future Growth Seen in Smaller Labs



From a remote AIDS clinic in Africa to a community hospital in Chicago, advances in molecular diagnostics are allowing clinicians to detect disease earlier, faster and with greater precision than ever.

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- Molecular Leader Spotlight

*Dr. Charlotte Gaydos:
On the Front Line in the Global Fight to Control STDs*



“Over the last 25 years, we have witnessed step-change scientific advancements in the detection and treatment of sexually transmitted diseases, namely chlamydia and gonorrhea, yet there is much more that can and must be done to raise the success bar...”

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Research and News Update

- Summary from the 2010 CROI Meeting



- Abbott Research on XMRV Featured
- High Prevalence of Variant HIV Subtypes Found in Russia
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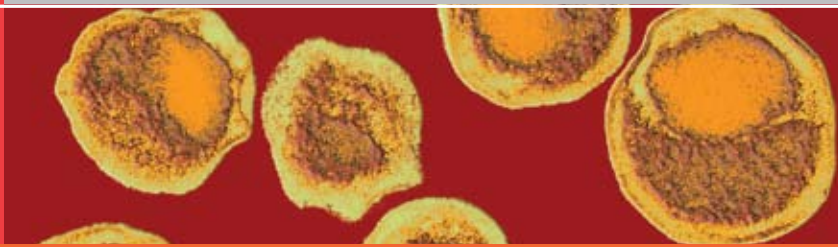
- New Gene-Based Test for Colorectal Cancer Receives EU CE Mark

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Charlotte A. Gaydos,
DrPh, MPH, MS

“Over the last 25 years, we have witnessed step-change scientific advancements in the detection and treatment of sexually transmitted diseases, namely chlamydia and gonorrhea, yet there is much more that can and must be done to raise the success bar in our global mission to control these unfortunately all too common infectious disease conditions in women and men.”

Such is the candid assessment of Charlotte A. Gaydos, DrPh, MPH, MS Professor in the Division of Infectious Diseases, Department of Medicine at Johns Hopkins University in Baltimore and an internationally known pioneer and authority in infectious disease research and medical and laboratory technology. With extensive laboratory expertise for more than 40 years in the microbiology field, Dr. Gaydos has authored 13 book chapters, in excess of 200 research articles and over 350 research abstracts and oral presentations.

When reviewing facts about chlamydia and gonorrhea, Dr. Gaydos pointed out, the data underscores the importance of continuing progress in developing even simpler, faster and more sensitive and automated diagnostic assays and instruments to more effectively and widely screen for these largely asymptomatic STDs.

Chlamydia, gonorrhea common, treatable

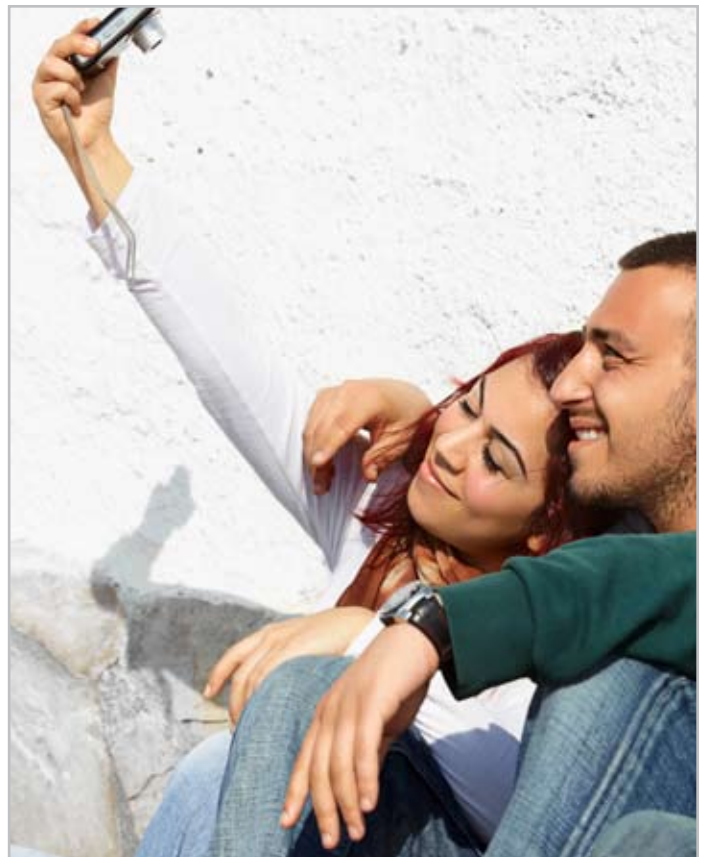
Chlamydia, caused by the bacterium *Chlamydia trachomatis*, is the most frequently reported bacterial sexually transmitted disease in the U.S. with more than one million infections reported to the Centers for Disease Control and Prevention (CDC) in 2006. Underreporting is substantial because most people with chlamydia are not aware of their infections and do not seek testing. Chlamydia is known as a “silent” disease because about three quarters of infected women and about half of infected men have no symptoms. Yet it can easily be treated and cured with antibiotics.

Gonorrhea, a very common STD triggered by the bacterium *Neisseria gonorrhoeae*, can cause serious and permanent health problems in men and women. The CDC estimates more than 700,000 persons in the U.S. contract new gonorrheal infections annually with only about half reported to the CDC. Some men with gonorrhea may have no symptoms at all; in women, symptoms are often mild, but most females who are infected have no symptoms. Several antibiotics can successfully cure gonorrhea in adolescents and adults.

For decades, Dr. Gaydos noted, culture testing for STDs was considered the “gold standard,” yet the process was slow and labor-intensive, and required maintenance of stringent laboratory conditions. Then significant diagnostic progress appeared in the late 1980s with development of two superior, non-culture methods – direct immune fluorescent antibody (DFA) tests and enzyme immunoassays (EIA) that were more sensitive, faster and easier to use.

But, unquestionably, the advent of molecular diagnostics and its subsequent, sweeping advances in assay technology and system automation has transformed the world of STD detection, starting with the first polymerase chain reaction, or PCR, test appearing in the early 1990s.

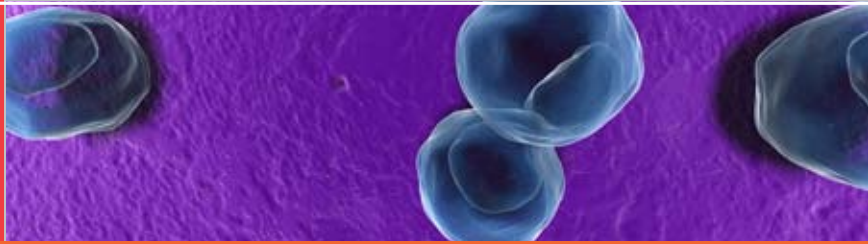
“The genetic revolution has given us significantly more sophisticated and superior molecular assays, systems and technologies for STD testing that decades ago were just a distant dream to many of us,” Dr. Gaydos said. “The pace of progress in molecular diagnostic technology in the last 15 years has been impressive and groundbreaking. Molecular methods have replaced the now tarnished culture testing while limiting the need for using EIAs.”



Chlamydia is known as a “silent” disease because for three in four women and about half of men there are no symptoms.

Today, for example, the Abbott RealTime CT/NG assay is an in vitro PCR assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae* using indicated specimens from symptomatic and asymptomatic individuals. The assay is available in the European Union and awaits clearance by the U.S. Food and Drug Administration. Its industry-proven, real-time PCR technology provides excellent performance with high specificity and sensitivity and complete automation on Abbott’s m2000 system increasing workflow and decreasing labor cost, while allowing for consolidation of multiple assays on the same platform.

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In her already hectic career where hours in a day and days in a week are at a premium, Dr. Gaydos heads a major project team of other external consultants for the CDC to develop and publish comprehensive, updated guidelines for preferred male and female specimen samples for chlamydia and gonorrhea screening assays. She is currently drafting the guidelines for preferred sample types in testing for chlamydia and gonorrhea. While estimating the revised CDC guidelines should be finalized by the end of 2010, Dr. Gaydos said the most important feature of the regulations will be that self-collected vaginal swabs will become the specimen of choice for screening women and, for men, the preferred sample will be urine. She indicated that non-amplified assays likely will no longer be acceptable for STD detection purposes.

Better STD tools needed

Looking ahead, Dr. Gaydos said, “We must develop even better tools to add to our STD toolbox if we are to see faster progress in more effective and wider detection and treatment of these infectious diseases here and in the rest of the world, where the problem is much more acute.” Perhaps the most important step, especially with public health funding levels under pressure, is to rapidly expand the means to and acceptance of home sample collections, or point-of-care tests, to send to labs for results. Dr. Gaydos, who has joint appointments at Johns Hopkins with the Department of Epidemiology, School of Hygiene and Public Health and the Department of Population, Family and Reproductive Health at the Bloomberg School of Public Health, asserts that self-collected specimens will improve and extend delivery of chlamydia screening, and her research confirms that women find self-collection easy and comfortable to complete.

“We need to obtain FDA clearance of home STD collection tests, but companies will need to complete the requisite studies to get us to that point,” said Dr. Gaydos, who co-directs the International Sexually Transmitted Diseases Research Laboratory. She leads a current Internet project for enhanced community chlamydia screening using self-administered vaginal swabs that is demonstrating an effective method for reaching women and men who may not attend clinics.

“Capture point” usage

In addition, Dr. Gaydos advocates for placing a sharper focus on the expanded use of “capture points” for mass STD screenings of individuals – such as in federal and state prisons, colleges and universities, emergency centers, Job Corps sites, juvenile detention centers and the military – so testing is more universal and can more effectively reach younger adult populations in which chlamydia and gonorrhea are markedly more prevalent.

An optimist who clearly has been a prime mover in STD progress to date, Dr. Gaydos believes the global molecular diagnostic community – health care providers, companies, scientists, researchers, clinicians – and the public health sector will forge even closer and stronger partnerships in the years ahead to achieve earlier and more widespread STD detection and control.



Public health authorities are stepping up their public awareness campaigns to alert women and men about the risks of chlamydia.

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