

19th

ISSTDR
QUÉBEC 2011



Québec City, CANADA
JULY 10 TO 13, 2011

Industry Sponsored
Symposia

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SUNDAY JULY 10, 2011

ROCHE SATELLITE SYMPOSIUM



Roche

12:00 – 13:30

ROOM: 200B

One step ahead in CT/NG testing – performance, populations, and preferred specimens

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) infections are widespread but treatable and controllable. Effective screening and diagnostic tools in asymptomatic and symptomatic populations are necessary to contain silent disease transmission and reduce CT and NG prevalence.

Nucleic acid amplification tests (NAATs) have demonstrated high sensitivity and specificity for detection of CT and NG. The need to test different at risk populations calls for the use of diverse specimen types from urogenital and other anatomical localizations. While screening guidelines are promoting the use of vaginal swabs in females and urine in males, other specimen types may be advisable.

Studies have shown that the **cobas®** CT/NG Test is an effective avenue to facilitate screening and diagnosis of infection with CT and NG. The Test offers flexibility in population type and specimen choice without compromising accuracy, and is validated with clinician-collected vaginal swab specimens, clinician-instructed self-collected vaginal swab specimens, male and female urine, endocervical swab specimens, and in cervical specimens for liquid based cytology.

Chair:

Barbara Van der Pol, PhD, MPH, Assistant Professor of Epidemiology and Medicine, Division of Epidemiology and Biostatistics, Indiana University, Bloomington, USA

Speakers:

Barbara Van der Pol, PhD, MPH, Assistant Professor of Epidemiology and Medicine, Division of Epidemiology and Biostatistics, Indiana University School of Medicine, Indianapolis, USA
"The female feature"

Stephanie N. Taylor, MD, Associate Professor of Medicine and Microbiology, Section of Infectious Disease, Louisiana State University School of Medicine, New Orleans, USA
"The male memoir"

Servaa Morré, PhD, Head of the Laboratory of Immunogenetics, Department of Pathology, VU University Medical Center, Amsterdam, The Netherlands
*"A European Perspective: Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from vaginal and rectal swab samples obtained from a high risk population in The Netherlands"*

MONDAY JULY 11, 2011

ABBOTT MOLECULAR SATELLITE SYMPOSIUM



7:00 – 8:30

ROOM: 200AB

Advancing Molecular Diagnostics in Sexual Health for Chlamydia, Gonorrhea, and HPV testing

According to the WHO, more than 85 million cases of Chlamydia and over 62 million cases of Gonorrhea occur worldwide annually.

Abbott's RealTime CT/NG assay is an *in vitro* polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae* in female endocervical or vaginal swab specimens, male urethral specimens, or in male or female urine specimens. The assay is designed for use on Abbott's automated molecular diagnostics system, the m2000, which utilizes real-time PCR technology for detecting and monitoring infectious diseases. Outside of the U.S, Abbott offers a separate CT and CT/NG assay available on the m2000 and the m24 systems.

HPV infections are among the most common STIs. Persistent HPV infection may result in progression to cervical cancer. Approximately 70% of invasive cervical cancer cases worldwide are caused by HPV 16 and HPV 18. The Abbott RealTime HR HPV assay is a qualitative *in vitro* test that amplifies and detects HR HPV DNA in cervical cells collected in liquid media. The detection of fourteen HR HPV genotypes (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) is achieved through a primer mix targeting a conserved region of HPV genomes and single stranded DNA probes. Specimens can be collected in PreservCyt Solution (Cytoc Corporation), SurePath Preservative Fluid (TriPath Imaging, Inc.), and the Abbott Cervi-Collect Specimen Collection Kit. The Abbott RealTime HR HPV assay is available outside of the U.S on the m2000 and the m24.

Chair:

Max Chernesky, McMaster University, Hamilton, Canada

Speakers:

Glen Hansen, Ph.D, Medical Director; Clinical Microbiology & Molecular Laboratories, Hennepin County Medical Center, Assistant Professor; Pathology & Laboratory Medicine, Assistant Professor; Medicine (infectious diseases), University of Minnesota School of Medicine, Canada

"Detection of Chlamydia trachomatis and neissera gonorrhea from throat and rectal specimens: Concepts and Considerations"

Dr Kate Cuschieri, Deputy Director, Scottish Human Papilloma Virus Reference Laboratory (SHPVRL)

Specialist Virology Centre, Royal Infirmary of Edinburgh, Edinburgh, UK

"Current HPV testing applications and the performance of Abbott RealTime HPV"

MERCK SATELLITE SYMPOSIUM



12:00 – 13:30

ROOM: 200AB

Setting New Standards for Preventing More HPV Related Diseases with the Quadrivalent HPV Vaccine

12:00	Welcome	M. Steben
12:05	HPV Burden of Disease beyond the Cervical Cancer (Men and Women)	S. Goldstone
12:25	Rational for Gender Neutral Vaccination and Long Term Studies	M. Steben
12:45	Real Life Impact of Gardasil: The Australian Experience	B. Donovan
13:05	Question and Answer	Panel
13:25	Closing Remarks	M. Steben

Chair:

Marc Steben, MD, Institut national de santé publique du Québec, Montréal, Canada

Speakers:

Marc Steben, MD, médecin conseil, Direction des risques biologiques et de la santé au travail, Institut national de santé publique du Québec, Montréal, Canada

Stephen E. Goldstone, MD, Assistant Clinical Professor of Surgery, 4, NY, USA

Basil Donovan, MB BS NSW, MD Syd, DipVen Lond, FACHSHM RACP, FAFPHM RACP, FRCPI Ire

Sexual Health Physician at the Sydney Sexual Health Centre, Sydney Hospital; and Professor and Head of the Sexual Health Program at the Kirby Institute (previous called the National Centre in HIV Epidemiology & Clinical Research), University of New South Wales, UK

TUESDAY JULY 12, 2011

GEN-PROBE SATELLITE SYMPOSIUM



7:00 – 8:30

ROOM: 200AB

“New Developments in Molecular Diagnostic Testing for *Trichomonas vaginalis*”

Trichomonas vaginalis (TV) is a sexually transmitted parasite that can cause vaginitis, urethritis, and premature membrane rupture in pregnancy; and can increase susceptibility to infection with HIV-1. The majority of *Trichomonas* testing currently centers on the diagnosis of symptomatic infections; however, it has been estimated that as many as 50% of infections in women are asymptomatic. Increases in screening of asymptomatic patients could provide a significant impact on overall health care costs by reducing the negative consequences of untreated infections and the spread of disease. Screening is enabled with the use of nucleic acid amplification tests (NAATs), which offer increased sensitivity for detection of *Trichomonas* and improved laboratory workflow.

This symposium will present data from recent clinical evaluations using the new APTIMA® *Trichomonas vaginalis* Assay that demonstrates TV prevalence nearly double that observed by conventional methods and highlights the need for increased screening for TV in at-risk populations.

Attendees of this symposium will learn about the latest developments in laboratory testing for *Trichomonas* from the following speakers:

Chair:

Max Chernesky Ph. D, Professor Emeritus, McMaster University/St. Joseph's Healthcare, Hamilton, ON Canada

Speakers:

Kimberle C. Chapin, M.D., Rhode Island Hospital, USA

*“New Approaches to Molecular Diagnostic Screening for *Trichomonas vaginalis*”*

Charlotte A. Gaydos, MS, MPH, DrPH, Johns Hopkins University, Baltimore, USA

*“Prevalence of *Trichomonas vaginalis* using the APTIMA *Trichomonas vaginalis* Assay and Co-Infection with *Chlamydia trachomatis* and *Neisseria gonorrhoea* in the United States”*

Jane R. Schwebke, M.D., University of Alabama at Birmingham, USA

*“Clinical Evaluation of the APTIMA *Trichomonas vaginalis* Assay in Asymptomatic and Symptomatic Female Subjects”*

BD SATELLITE SYMPOSIUM



12:00 – 13:00

ROOM: 200AB

New cost effective and fully automated molecular testing allows for improved typing, diagnosis and treatment of HSV 1 and HSV 2

For years laboratories have attempted to overcome the time it takes culture to produce an HSV result, the lack of sensitivity of culture and the ability to effectively type. Laboratories have developed laboratory developed tests and have used ASRs to provide faster results directed towards CSF samples. These molecular tests are not approved or cleared by any regulatory agency and are manual and labor intensive. The clinical value outweighed the process issues, yet has kept these tests from being widely adopted for HSV 1 and HSV 2 lesion samples. With the availability of antiviral therapy and the fact of varying recurrence between HSV 1 and HSV 2, different treatment modalities are recommended based on the specific type of HSV, the need for more sensitive and cost effective testing has grown. With the prevalence of HSV 2 in the genital area increasing the need to type HSV becomes more critical because of the different counseling and treatments for HSV 2 vs. more aggressive therapy for HSV 1 to reduce symptomatic episodes. BD has made available the first fully automated and cleared HSV 1 and HSV 2 assay. This assay delivers the automation and process efficiency to enable fast and highly sensitive results. This symposium will inform on the need for a more aggressive diagnosis of HSV in lesion samples and the new BD assay now available to meet this clinical demand.

Chair:

Lawrence Mahn, BD Business Manager, Women's Health and Cancer

Speakers:

Barbara Van Der Pol, Ph.D., MPH, Assistant Professor of Epidemiology and Medicine, Director, Infectious Diseases Laboratory, Indiana University, School of Health, Physical Education and Recreation, School of Medicine, Indianapolis, IN, USA
"A major advancement in the molecular diagnosis and typing of Herpes Simplex Virus infections using the BD HSV QxAssays on the BD Viper System"

Edward W. Hook, III, M.D., Professor of Medicine, Epidemiology and Microbiology, Director, Division of Infectious Diseases, University of Alabama at Birmingham, Birmingham, USA
"Variability in Clinical Genital Herpes Presentations: the Need for More Aggressive Etiologic Diagnosis"

WEDNESDAY JULY 13, 2011

SIEMENS SATELLITE SYMPOSIUM

SIEMENS

7:00 – 8:30

ROOM: 200AB

The VERSANT® CT/GC DNA 1.0 Assay (kPCR) - Combining CT/GC Detection with the Power to Do More

CT/GC NAAT assays that employ nucleic acid isolation prior to amplification have consistently been shown to be the most sensitive. Since NAAT assays are very similar in sensitivity and specificity, there are other features that should be considered as important factors in selecting the best CT/GC NAAT assay and automated system.

The Siemens VERSANT® CT/GC DNA 1.0 Assay (kPCR) is a qualitative in-vitro diagnostic assay for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC). The VERSANT CT/GC Assay is designed to detect the presence of CT and GC in both symptomatic and asymptomatic individuals from female endocervical swab specimens, male urethral swab specimens, and female and male urine specimens. Results will be presented to demonstrate that clinical performance of the VERSANT CT/GC Assay in detecting CT and GC targets in clinical specimens has excellent agreement with the Gen-Probe APTIMA Combo 2 assay.

From an operational perspective, the VERSANT CT/GC assay's workflow and time-to-result of 5.5 to 6 hours allows for the processing of large numbers of specimens in a relatively short period of time. Kinetic PCR (kPCR) DNA technology combined with Siemens' proprietary bead technology for the isolation of nucleic acids from clinical specimens and workflow performance provides a reliable and efficient CT/GC assay on the VERSANT kPCR Molecular System.

Chair:

Guido Hennig, PhD, Senior Global Scientific Marketing Manager, Siemens Healthcare Diagnostics, Eschborn, Germany

Speakers:

Charlotte A. Gaydos, MS, MPH, DrPH, Professor, Division of Infectious Disease, Medicine, Johns Hopkins University, Baltimore, MD, USA

"The Siemens VERSANT® kPCR Molecular System for Chlamydia and Gonorrhea: Workflow Studies and Assay Time Requirements"

Professor Dr. Angelika Stary, Head, Outpatients' Center for Venero-Dermatological Infections, Vienna, Austria

"MultiCenter Evaluation of the VERSANT® CT/GC DNA 1.0 Assay (kPCR) for Chlamydial and Gonococcal Diagnosis: Have We Reached the Top of the Mountain?"

Guido Hennig, PhD, Senior Global Scientific Marketing Manager, Siemens Healthcare Diagnostics, Eschborn, Germany

"VERSANT® kPCR Sample Prep: A Versatile, Fully Automated System for the Isolation of Nucleic Acids from Clinical Specimens"

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MAJOR CONTRIBUTORS



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