

**CDC National Infertility Prevention Project
Laboratory Update
Region IV
Charleston, South Carolina
October 8-9, 2009**

**Richard Steece, Ph.D., D(ABMM)
DrRSteece@aol.com**

Laboratory Update

- Public Health Laboratory
 - History
 - Mission
 - Core Functions
- New CT/GC Tests
- Marketing by Commercial Companies
 - Public vs. Private

Public Health Laboratory

- History
 - History of Bacteriology – Methods and Tools
 - Louis Pasteur, Robert Kock, Paul Ehrlich, Emil Behring, and others
 - Major movement in the late 1800's and the early 1900's to establish State Public Health Laboratories
 - Diphtheria
 - 1900's est. up to 200,000 case year (10-20% mortality)
 - Iditarod - 1925
 - TB
 - Food and Water

Public Health Laboratory

- **Mission:** Provide a wide range of screening, reference, diagnostic and analytical services for assessment and surveillance of infectious, communicable, genetic, chronic diseases and environmental health concerns, for the citizens of the state (city, county) and national health disease prevention programs. The Public Health Laboratory also helps to coordinate and promote quality assurance for private clinical & environmental laboratories through training, consultation, certification and quality assurance programs. In addition, the Public Health Laboratories provide scientific and managerial leadership for the development of public health policy.

Public Health Laboratory

- Core Functions (11)
 - Disease prevention, control, and surveillance
 - Integrated data management
 - Reference and specialized testing
 - Environmental health and protection
 - Food safety
 - Laboratory improvement and regulation
 - Policy development
 - Emergency response
 - Public health-related research
 - Training and education
 - Partnerships and communication

Public Health Laboratory

- Disease prevention, control, and surveillance
 - Provide accurate and precise analytical results in a timely manner for different diagnostic and analytical functions for assessment and surveillance of infectious, communicable, genetic, and chronic diseases, and environmental exposures
 - Serve as a first line of defense in rapidly recognizing and preventing the spread of communicable diseases by:
 - examining specimens for identifying disease outbreaks
 - isolating and identifying the causative agent
 - determining the source of infection
 - identifying carriers and locating sources of infection in the environment.

Public Health Laboratory

- Disease prevention, control, and surveillance (cont.)
 - Serve as a center of expertise for the detection and identification of biologic agents of significance in human disease; as such, ensure access to laboratory expertise and capabilities in the disciplines of bacteriology, virology, mycobacteriology, and etc.
 - Provide specialized tests for low-incidence, high-risk diseases (e.g., tuberculosis, rabies, botulism, and plague); detect epidemiologic shifts (influenza); and detect newly emerging pathogens (SARS), and etc.

Public Health Laboratory

- Disease prevention, control, and surveillance (cont.)
 - Provide population surveillance, or screening, for conditions of interest to the public health community, including screening for inherited neonatal metabolic disorders, environmental toxins, immune status, risk factors, chronic blood diseases, blood lead, and antibiotic resistance.
 - Perform tests to meet specific program needs of public health agencies.



New CT/GC Tests

- New Nucleic Acid Amplification Tests (NAATs) for Chlamydia and Gonorrhea
 - Abbott RealTime CT/NG
 - BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay
 - BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

Abbott RealTime CT/NG

- Technology

- Multiplex, PCR technology with homogenous real-time fluorescence detection

- Target Regions

- C. trachomatis*: Cyptic plasmid
- N. gonorrhoeae*: Opa gene

- Specimen Types

- Male: urine and urethral swab
- Female: urine, vaginal (clinician or self collected)



Abbott RealTime CT/NG

- Collection Device

- Abbott multi-collection specimen collection kit
- 14 days, 2-30⁰ C

- Internal Control

- Sensitivity

- Limit of detection 320 copies of CT target DNA

- Specificity

- No cross reactivity to 111 organisms that are related to CT and NG and those found in the urogenital tract. No cross reactivity to non-pathogenic *Neisseria* strains



BD ProbeTec™ Q^x Amplified DNA Assay

- Technology

- BD Viper Automated System with XTR Technology, FOX Extraction, Strand Displacement Amplification

- Target Regions

- C. trachomatis*: Cyptic plasmid
- N. gonorrhoeae*: Opa gene

- Specimen Types

- Male: urine and urethral swab
- Female: urine, vaginal (self collected), endocervical



BD ProbeTec™ Q^x Amplified DNA Assay

- Collection Device

- Specific specimen collection kit
- 14 - 30 Days, 2-30⁰ C

- Internal Control

- Sensitivity

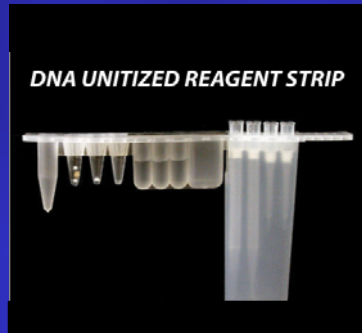
- Limit of detection 15 to 30 elementary bodies (EB)

- Specificity

- No cross reactivity to 141 organisms for CT. Two *N. cinerea* and two *N. lactamica* strains were shown to cross-react in the GC assay ($\geq 1 \times 10^8$ cells/mL)

Future Nucleic Acid Amplification Tests (NAATs) for Chlamydia and Gonorrhea

- HandyLab
- Cepheid
- GenProbe
- Others



Public vs. Private

Privatization

- **ADVANTAGES**
 - Lower Costs

Privatization

- **ADVANTAGES**
 - Lower Costs?

Privatization

- **ADVANTAGES**

- **Lower Costs?**

- **Remember the private laboratory is in business to make \$\$\$**

Privatization

- **DISADVANTAGES**

- **Lost Leader – Cheap the first year**
- **Cost of Contracting (10-20% of the value of the contract)**
- **Cost of Monitoring QA**
- **Repeat test, e.g. questionable results**
- **Specimens available for special studies, evaluations**
- **Technology changes – stuck with contract**

Privatization

- **DISADVANTAGES**

- **Manufacturers go out of business (Abbott)**
- **Need additional information, e.g. new data request from CDC**
- **Laboratory costs can rise for other tests**
- **Public Standards - Watchdog**
- **Public Health Team vs. \$\$\$**
- **Maintain Core Public Health Infrastructure**

QUESTIONS?