

CDC National Infertility Prevention Project Laboratory Update

Region II
May 13-15, 2009

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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, 2-30° 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™ Qx 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™ Qx Amplified DNA Assay

- Collection Device
 - Specific specimen collection kit
 - 14 - 30 Days, 2-30° 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

Laboratory Guidelines for the identification of *Chlamydia trachomatis*/*Neisseria gonorrhoeae*

Expert Panel Meeting
CDC Atlanta GA
January 13-15, 2009
