

Guidelines for the Laboratory Detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Treponema pallidum* Testing

Recommendations from the an expert
consultation meeting held at CDC
January 13-15, 2009

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention

Framework

- Experts:
 - Public Health Laboratory Directors
 - STD Program Directors
 - STD Clinicians
 - STD Laboratory Researchers
 - FDA and CMS
- Target Audience:
 - Laboratory Directors, technicians, clinicians and disease control personnel
- Key Questions:
 - Refinements or gaps from the 2002 “Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections”
 - Reviewed literature and prepared tables of evidence prior to consultation meeting at CDC

Overview of Key Questions

1) Performance Characteristics:

- Sensitivity and specificity of reported tests stratified by anatomic site

2) Screening Applications:

- Optimal specimen type
- Economic considerations

3) Laboratory Confirmation:

- Repeat testing
- Medico-legal issues

Meeting Summary:

Performance Characteristics

- All culture and non-culture tests may generate false-positive results
 - Clinician education
- Nucleic acid amplification tests (NAATs) have superior performance to all other tests
 - Performance characteristics comparisons will be based on published data
 - These are the tests labs should be using to detect CT and GC regardless of presentation
- Culture is still useful in certain circumstances
 - GC susceptibility testing
 - Detect mutant strains
 - Should be maintained but how (\$\$\$)

Meeting Summary: Performance Characteristics

- Serology
 - Should not be used for the Dx of non-LGV CT infections
 - Should not be used for the Dx of LGV rectal infections
 - Useful for the Dx of inguinal LGV infections
- Direct Detection of LGV
 - All FDA cleared NAATs detect LGV and non-LGV CT but are unable to distinguish the strains
 - Homebrew assays have been reported for the direct detection of LGV but the data are insufficient to make a recommendation on their utility

Meeting Summary: Performance Characteristics

- Need for additional data:
 - Utility of LGV specific tests
 - Clinical and laboratory
 - Studies on the length of time that newer NAATs will remain positive due to the presence residual nucleic acid after treatment
 - Performance of NAATs with ocular specimens

Meeting Summary: Screening Applications

- Vaginal swabs are the optimal specimen type for use with NAATs
 - Studies demonstrate equal performance to endocervical swabs and slightly better performance than urine
 - Ease of collection and transport

Meeting Summary: Screening Applications

- Vaginal swabs are the optimal specimen type for use with NAATs
 - Studies demonstrate equal performance to endocervical swabs and slightly better performance than urine
 - Ease of collection and transport
- Urine is the preferred specimen type for testing males with NAATs

Meeting Summary: Screening Applications

- NAATs have superior performance to culture for the detection of rectal CT and GC infections
 - NAATs are not cleared for rectal specimens by the FDA
 - CDC setting up a external specimen bank to facilitate an off-label establishment study
 - Protocol and guidelines will be reviewed for acceptability by CMS

Meeting Summary: Screening Applications

- NAATs have superior performance to culture for the detection of pharyngeal GC infections
 - Too few pharyngeal CT infections for a meaningful comparison
 - Some NAATs report cross-reaction and these may require repeat testing by an alternative method
 - NAATs are not cleared for rectal specimens by the FDA
 - CDC setting up a external specimen bank to facilitate an off-label establishment study
 - Protocol and guidelines will be reviewed for acceptability by CMS

Meeting Summary: Screening Applications

- Pooling specimens for testing with NAATs is an acceptable method to reduce costs without compromising performance

Meeting Summary: Laboratory Confirmation

- Routine repeat testing of NAAT positive specimens is not recommended for CT
- Routine repeat testing of NAAT positive specimens is not recommended for GC unless there are a significant number of false-positive test results due to cross-reaction with non-gonococcal *Neisseria* species

Meeting Summary: Laboratory Confirmation

- Medico-legal issues
 - Data supports the use of NAATs in adult cases of sexual abuse
 - Waiting to review data that has apparently been submitted for publication on the use of NAATs in cases involving children
 - Product inserts currently restrict NAAT use in cases of sexual abuse

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- **Next Steps**

- Meeting summary will be available on APHL website in the next few months
- Submit 2 key sections for publication in the MMWR weekly series this summer
 - Updated Guidelines for the Use of Nucleic Acid Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*
 - Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in the Rectum and Oro pharynx
- Publish background papers in a journal supplement (papers are due October 1)
- Publish the entire revised laboratory guidelines document as a Reports and Recommendations supplement in MMWR early 2010