Expanding the Use of Nucleic Acid Amplification Tests

John R Papp PhD
CDC

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

What are the different test types to detect chlamydia and gonorrhea

	Chlamydia	Gonorrhea
Culture	✓	✓
Gram Stain	✗	✓
Immunoassays	✓	✓
Nucleic Acid Genetic Transformation Test	✗	✓
Nucleic Acid Hybridization Tests	✓	✓
Signal Amplification	✓	✓
Nucleic Acid Amplification Tests	✓	✓

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What are the performance estimates* of different tests to detect chlamydia and gonorrhea

	Sensitivity	Specificity
Culture	60 – 85%	Should be 100%
Immunoassays	<65%	~95%
Nucleic Acid Hybridization Tests	60 – 78%	98 – 99%
Signal Amplification	92 – 97%	~98%
Nucleic Acid Amplification Tests	92 – 99%	98 – 100%

*Performance estimates vary widely due to differences in statistical analysis

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2002 CDC Guidelines: Screening Tests to Detect CT and GC Infections

- ☑ Recommended nucleic acid amplified tests
  - Endocervical swab
  - Urethral swab
  - Urine
- ☑ CDC will be reviewing and updating the 2002 guidelines later this year
  - Vaginal swabs
  - Rectal / oropharyngeal testing

2004 CDC / APHL Laboratory Survey

- ☑ Chlamydia Testing
  - 15 / 108 (14%) PHLs performed CT cultures
    - Approximately 0.1% of all CT tests were culture
  - NAATs were performed by 94 / 108 (87%) of PHLs
    - Approximately 64% of all CT tests were NAATs
- ☑ Gonorrhea Testing
  - 84 / 108 (78%) PHLs performed GC cultures
    - Approximately 9% of all GC tests were culture
  - NAATs were performed by 85 / 108 (78%) of PHLs
    - Approximately 61% of all GC tests were NAATs

Webster Dicker et al. Sex. Transmit. Dis. (*2007 34:41-46*)

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Considerations for using Nucleic Acid Amplification Tests

☑ Clinician and clinical staff training

- Specimen types
  - Swabs (endocervix, urethra, vagina), urine, liquid PAP (varies by test)
- Indications and limitations
  - Screening, diagnostic
- Storage and transport requirements
  - Varies from 2 to 30˚C for up to 60 days (different conditions for each test)
- RESULT INTREPRETATION
  - As with ALL LAB tests, not 100% accurate (but real close!)
  - Clinicians must understand the chance of a false positive and negative result

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Considerations for using Nucleic Acid Amplification Tests

☑ Laboratory Requirements

- Laboratory design / layout
  - Separate areas for reagent and specimen preparation, amplification and detection
  - Amplification not in a closed system must maintain a uni-directional workflow
- Laboratory protocols
  - Monitor for contamination
  - Ensure technical competence (avoid see one, do one, teach one)
- Quality assurance
  - Subscribe to an external proficiency test program
  - Monitor prevalence and develop a plan to react if significant changes are noted
- Regulatory control
  - Regulated by CLIA
  - Must be performed in a laboratory meeting federal regulations for high complexity testing (CFR 493.25)

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Importance of Chlamydia Screening

- ☑ Disease caused by infection primarily related to the host response
  - Pelvic inflammatory disease
  - Fibrosis and scarring
    - Tubal factor infertility, salpingitis, ectopic pregnancy
- ☑ Most infections are asymptomatic until sequelae becomes apparent
  - Patients have no triggers to seek care
- ☑ Chlamydia screening is a high public health priority
  - CDC, USPSTF, ACOG, AMA, AAP, ACPM

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Chlamydia Screening Coverage

- ☑ HEDIS Measure (2000 to 2004 data)
  - Commercial
    - 16 to 20 year old women ⇨ranged from 24% to 33%
    - 21 to 26 year old women ⇨ranged from 21% to 32%
  - Medicaid
    - 16 to 20 year old women ⇨ranged from 37% to 46%
    - 21 to 26 year old women ⇨ranged from 38% to 49%
- ☑ Infertility Prevention Program
  - Approximately 40% coverage of sexually active women 16 to 25 years of age

Chlamydia Screening

- ☑ The range of specimen types, transport conditions, laboratory turn-around time, and performance clearly indicates that nucleic acid amplification tests are critical in any effort to expand chlamydia screening

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