



# Performance of Nucleic Acid Amplification Tests (NAATs) for Chlamydia and Gonococcal Infections of the Oropharynx and Rectum



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## Background

- *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infect the oropharynx, cervix, urethra, rectum and other sites
- Rectal infections cause proctitis and increase HIV susceptibility
- Increase in risk behaviors and STDs in men who have sex with men

## Diagnostic Testing

- Standard for non-urogenital sites is culture
- Prior studies showed the validity and increased sensitivity of NAATs—PCR, LCR
  - Ostergaard et al, GUM, 1997
  - Page-Shafer et al, CID, 2002
  - Golden et al, JCM, 2003
  - Lister et al, STD, 2003
  - Manavi et al, Int J STD AIDS, 2004
  - Lister et al, JCM, 2004

## Pilot Study Purpose

- Determine the test performance of several NAATs versus culture for the detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* of the oropharynx and rectum

## Study Methods

- Among gay men attending STD clinic, in random order we collected multiple swabs at each anatomical site
- Specimens tested by Gen-Probe APTIMA Combo 2 TMA, BD ProbeTec SDA, Roche Amplicor PCR and culture
- True positive defined in anatomic site with positive culture or  $\geq 2$  positive NAATs

## Results

Test performance pharyngeal gonorrhea (n=205, 24 True Positive)

	PGC	Culture	SDA	TMA	PCR
<b>Sensitivity</b>		50.0%	87.5%	70.8%	62.5%
<b>Specificity</b>		100.0%	96.1%	98.9%	80.1%

Confidence limits for sensitivity +/- 20%; specificity +/- 4%  
True positive defined as culture or any 2 NAATs positive

Test performance pharyngeal chlamydia (n=203, 3 True Positive)

	PGC	Culture	SDA	TMA	PCR
<b>Sensitivity</b>		66.7%	100.0%	100.0%	33.3%
<b>Specificity</b>		100.0%	99.5%	99.5%	100.0%

Confidence limits for sensitivity +/- 70%; specificity +/- 2%  
True positive defined as culture or any 2 NAATs positive

Test performance rectal gonorrhea (n=205, 17 True Positive)

	PGC	Culture	SDA	TMA	PCR
<b>Sensitivity</b>		52.9%	94.1%	100.0%	47.1%
<b>Specificity</b>		100.0%	99.5%	98.9%	99.5%

Confidence limits for sensitivity +/- 25%; specificity +/- 3%  
True positive defined as culture or any 2 NAATs positive

Test performance rectal chlamydia (n=203, 13 True Positive)

	PGC	Culture	SDA	TMA	PCR
<b>Sensitivity</b>		46.2%	84.6%	100.0%	84.6%
<b>Specificity</b>		100.0%	99.5%	97.9%	100.0%

Confidence limits for sensitivity +/- 35%; specificity +/- 3%  
True positive defined as culture or any 2 NAATs positive

## Summary

- SDA and TMA consistently showed higher sensitivity than culture for detecting infections
- The specificity of all NAATs, except PCR for PGC, was > 95%
- PCR had < 80% performance in all infections except RCT

## Conclusions

- Certain NAATs could be considered superior to culture for detecting GC and CT infections in the oropharynx and rectum
- Additional confirmatory testing should be done to determine the test performance where only NAATs were positive

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