

Aptima Combo 2 testing from extra-genital sample types

Bibliography

1. How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men? **Sexton et al. Journal of Family Practice 2013.**
“The equivalent or better detection rates [of AC2] for rectal and oral gonorrhea and chlamydia among patients suggest that patients are capable of performing their own screening for STIs, which may increase infection detection and treatment.”
2. Use of Nucleic Acid Amplification Testing for Diagnosis of Anorectal Sexually Transmitted Infections. **Consentino et al. JCM 2012.**
“These data suggest that rectal infection is common and that the AC2 is superior to SDA for the detection of C. trachomatis and N. gonorrhoeae from rectal swab samples.”
3. Comparative performance of culture using swabs transported in Amies medium and the Aptima Combo 2 nucleic acid amplification test in detection of *Neisseria gonorrhoeae* from genital and extra-genital sites: a retrospective study. **Harryman et al. Sex Transm Infect 2012.**
“The AC2 with AGC confirmation performs well at genital and extra-genital sites for detecting GC.”
4. Evaluation of Self-Collected Glans and Rectal Swabs from Men Who Have Sex with Men for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Use of Nucleic Acid Amplification Tests. **Moncada et al. JCM 2009.**
“The sensitivities of the tests with self-collected and clinician-collected rectal swab specimens were comparable (for C. trachomatis, 41% and 44%, respectively, by SDA and 82% and 71%, respectively, by AC2; for N. gonorrhoeae, 77% and 68%, respectively, by SDA and 84% and 78%, respectively, by AC2), ... far superior to culture for the detection of C. trachomatis and N. gonorrhoeae in the rectum, ... we found self-collected rectal swabs from MSM to be valid specimens for testing,”

TABLE 4. Detection of *N. gonorrhoeae* and *C. trachomatis* by NAATs with rectal swab specimens^a

Rectal swab specimen collector	Test	<i>N. gonorrhoeae</i> (n = 882)		<i>C. trachomatis</i> (n = 907)	
		Sensitivity ^d (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Self	SDA	77.1 (64/83) ^{b,c}	99.3 (793/799)	40.9 (27/66) ^c	100 (841/841)
Clinician	SDA	67.5 (56/83) ^c	100 (799/799)	43.9 (29/66) ^c	99.9 (840/841)
Self	AC2	84.3 (70/83) ^c	100 (799/799)	81.8 (54/66) ^c	100 (841/841)
Clinician	AC2	78.3 (65/83) ^c	99.8 (797/799)	71.2 (47/66) ^c	99.6 (838/841)
Clinician	Culture	34.9 (29/83)	100 (799/799)	18.2 (12/66)	100 (837/837)

^a True-positive results were defined as positivity by culture, positive results by two or more NAATs, or a positive result by a single NAAT confirmed by an alternate amplification method. The overall prevalence rates of *C. trachomatis* were 9.8% (43/438) for asymptomatic MSM and 4.9% (23/469) for symptomatic MSM. The overall prevalence rates of *N. gonorrhoeae* were 8.0% (33/413) for asymptomatic MSM and 10.7% (50/469) for symptomatic MSM.

^b The values in parentheses are the number of MSM positive/total number of MSM tested.

^c All *P* values were <0.005 by comparison with the results of culture.

5. Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in pharyngeal and rectal specimens using the BD Probetec ET system, the Gen-Probe Aptima Combo 2 assay and culture. **Ota et al. Sex Transm Infect 2009**
“The sensitivity of PT for pharyngeal GC, rectal GC, pharyngeal CT and rectal CT was 95.0%, 93.1%, 80.0% and 94.7%, respectively. The sensitivity of AC2 was 95.0% for pharyngeal GC and 100% at all other sites. Specificity was consistently above 98%. NAATs should be the method of choice for the detection of GC and CT in extragenital sites in men who have sex with men.”
6. Self-taken pharyngeal and rectal swabs are appropriate for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in asymptomatic men who have sex with men. **Alexander et al. Sex Transm Infect 2008**
“No significant difference in sensitivity was observed between the nurse-taken and the patient-taken swabs for the detection of either GC or CT in the rectum and GC in the pharynx, when using the AC2 test.”
7. Nucleic Acid Amplification Tests in the Diagnosis of Chlamydial and Gonococcal Infections of the Oropharynx and Rectum in Men Who Have Sex With Men. **Schachter et al Sex Transm Dis 2008.**
“Even so the AC2 test detected twice as many CT and GC infections from both anatomical sites as were

found by culture. It would be an important advance in the control of STDs, if manufacturers would seek US Food and Drug Administration- clearance for testing samples from these anatomical sites.”

8. Detection and Confirmation of *Neisseria gonorrhoeae* Infections in Genital and Extragenital Samples using Aptima Assays on the Panther™ Instrument. **Turra et al. J J Microbiol Pathol 2015.**
“This study demonstrates that the initial AC2 results from all sampling sites (urogenital and extragenital) can be accepted with high confidence.”

9. Use of the APTIMA Combo 2 Assay and a Secondary Algorithm to Detect and Confirm *Chlamydia trachomatis* in Rectal-Only Infections. **Pabbaraju et al. Sex Transm Dis 2016.**
“In conclusion, this study adds to the growing volume of data validating the use of NAATs [AC2 &ACT] in rectal screening for C. trachomatis. Such screening, as recommended by the US Centers for Disease Control has the potential to accurately identify asymptomatic extragenital site infections in high risk populations, thereby decreasing transmission.”