

Chlamydia and Gonorrhea Screening – Test Performance information for Clinicians

The *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) test performed at Alberta Precision Labs is the Hologic Aptima Combo2 Assay nucleic acid amplification test (NAAT). The assay simultaneously tests for both CT and GC using transcription mediated amplification and is highly sensitive and specific for both targets.

Table 1. Test performance of Hologic Aptima Combo2 Assay for CT and GC, as reported by the manufacturer (% (95% CI))^{1,2}

Specimen type	Chlamydia		Gonorrhea	
	Sensitivity	Specificity	Sensitivity	Specificity
Endocervical swab¹	94.2 (90.1-97.0)	97.6 (96.6-98.4)	99.2 (95.7-100)	98.7 (98.0-99.3)
Vaginal swab –				
Clinician collect¹	96.6 (92.7-98.7)	96.8 (95.6-97.7)	96.0 (88.8-99.2)	99.2 (98.6-99.6)
Patient self-collect²	98.4 (91.2-100)	96.8 (95.0-98.1)	100 (95.1-100)	99.4 (98.8-99.7)
Urine (first-void)¹				
Female	94.7 (90.7-97.3)	98.9 (93.1-99.4)	91.3 (85.0-95.6)	99.3 (98.6-99.6)
Male	97.9 (95.4-99.2)	98.5 (97.4-99.2)	98.5 (96.5-99.5)	99.6 (98.9-99.9)
Male Urethral swab¹	95.9 (92.9-98.0)	97.5 (96.1-98.5)	99.1 (97.3-99.8)	97.8 (96.5-98.7)
Throat²	88.2(76.6-94.5)	99.7 (99.4-99.8)	96.1(92.4-98.0)	98.9 (98.5-99.3)
Rectal²	91.6 (87.2-94.6)	98.9 (98.4-99.3)	97.5 (94.2-98.9)	99.5 (99.1-99.7)

¹Aptima Combo 2 assay Package Insert AW-20536-001 Rev. 003 2021-09

<https://www.hologic.com/file/50601/download?token=WYIK-Of4>

²Aptima Combo 2 assay (Panther System) Package Insert AW-25929-001 Rev. 002 2023-06

<https://www.hologic.com/file/202586/download?token=Qjkvy22C>

However, as with all laboratory tests, false-positive results may occur when screening a low prevalence population.

If a false-positive result is suspected based on a patient's individual history, repeat testing should be considered; a subsequent negative result is reassuring, given the high negative predictive value of nucleic acid amplification tests in this context. Clinicians may call the Microbiologist on-call for further discussion.