

Chlamydia & Gonorrhea Nucleic Acid Amplification Test

Revised 10/15/2019

Test description	Qualitative detection and differentiation of ribosomal RNA (rRNA) from <i>Chlamydia trachomatis</i> and/or <i>Neisseria gonorrhoeae</i> in genital, extra genital and urine specimens.
Test use	As an aid to the diagnosis of chlamydial and gonococcal disease in symptomatic or asymptomatic individuals.
Test Department	Sexually Transmitted Diseases Molecular Diagnostics Phone: (860) 920-6696; Fax: (860) 920-6721
Methodology	Target amplification nucleic acid probe test (Aptima Combo 2 [®] Assay)
Availability	Daily, Monday - Friday
Specimen Requirements	Specimens must be tested by the laboratory within 30 days of collection for urine and within 60 days of collection for rectal, throat, vaginal, endocervical and male urethral swabs.
Collection Kit/Container	<ul style="list-style-type: none"> <u>Urine</u>: Aptima[®] Urine Specimen Collection Kit; <u>Rectal, throat and vaginal swabs</u>: Aptima[®] Multitest Swab Specimen Collection Kit; <u>Endocervical and male urethral swabs</u>: Aptima[®] Unisex Swab Specimen Collection Kit. To obtain collection kits, refer to Collection Kit Ordering Information. Store collection kits at room temperature prior to use.
Collection instructions	<ul style="list-style-type: none"> Follow instructions provided with each specific collection kit. <u>Rectal, throat, endocervical & male urethral swabs</u> : clinician-collected ONLY. <u>Vaginal swabs</u> : clinician-collected OR patient-collected (not for home use). <ul style="list-style-type: none"> Specimen must be collected before the expiration date on the collection kit.
Specimen Handling & Transport	Once collected, transport and store the specimens at 2°C-30°C (36°F -86°F). Avoid temperature extremes.
Unacceptable Conditions	Unlabeled specimens. Specimens that have leaked or containers that have broken in transit. Specimens received beyond acceptable holding times (see Specimen Requirements). Specimens collected after the expiration date on the collection kit. Specimens collected in collection devices from other manufacturers. Incorrect volume of urine in urine transport tube.
Requisition Form	Clinical Test Requisition (select Chlamydia & Gonorrhea Nucleic Acid Amplification Test).
Required Information	Name and address of submitter (and/or Horizon profile #). Patient name or identifier, town of residence (city, state, zip), date of birth. Specimen source/type, date collected and test requested.
Limitations	The test is not intended for the evaluation of suspected sexual abuse or for other medico-legal indications. Therapeutic failure or success cannot be determined with this test since nucleic acid may persist following appropriate antimicrobial therapy. Test results should be interpreted in conjunction with all other laboratory and clinical data available to the clinician.