MDH Laboratories Administration
The J. Mehsen Joseph Public Health Laboratory
1770 Ashland Avenue, Baltimore MD 21205
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TEST:	***Chlamydia trachomatis* and *Neisseria gonorrhoeae* Nucleic Acid Amplification Test (NAAT)**
Synonym:	Hologic Panther® Aptima® Combo 2 Assay
Laboratory/Phone:	Chlamydia Laboratory / 443-681-3937
Turnaround Time:	Within 7 business days
Specimen Required:	Endocervical swab Male urethral swab Rectal Swab Vaginal self-collected swab Vaginal clinician-collected swab Pharyngeal Swab Male and female urine (first of the void)
Specimen identification:	Label specimen with the full name exactly matching test requisition and date of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Swab: Tube, Prefilled with 2.9 ml of preservation media. Urine: Optimal quality specimen is 20-30 ml of "first of the void" urine collected in a plastic collection cup. Swirl to mix. Using a sterile transfer pipette, transfer 2 ml from cup into labeled Hologic urine transport tube, prefilled with 2.0 ml of preservation media so volume falls between the two fill lines on the tube. Do not surpass the fill line.
Specimen Volume (Minimum):	Swab: Tube, Prefilled with 2.9 ml of preservation media. Urine: Collect a minimum of 4ml (20-30 best) in a plastic collection cup. Using a sterile transfer pipette, transfer 2 ml from cup into labeled HOLOGIC urine tube prefilled with 2.0 ml of preservation media so volume falls between the two fill lines on the tube. Volume must be above the lower fill line.
Collect:	Swab: HOLOGIC Unisex Collection Kit or Vaginal collection kit for HOLOGIC Aptima 2 Urine: Sterile, preservative-free, leakproof, plastic specimen collection cup. **The patient should not have urinated for at least 1 hour prior to specimen collection.** Collect 20-30 ml of "first of the void urine." Transfer 2ml of swirled neat urine into the HOLOGIC collection tube between the two fill lines. Replace cap tightly.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777) **Indicate specimen type next to test requested using the "Specimen Code" on form.**
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). ***Refer to current Federal regulations for specific shipping requirements.**
Transport Conditions:	Endocervical or Male Urethral Swab: 2-30°C. Must test within 60 days of collection. Vaginal Self-collected or clinician-collected Swab: 2-30°C. Must test within 60 days of collection. Rectal and Pharyngeal Swab: 2-30°C. Must test within 7 days of collection. Urine: 2-30°C. Must be in urine transport tube containing preservation media within 24 hours. Must test within 30 days of collection.
Specimen Rejection Criteria:	Too old, No patient ID on specimen, >30 ml of collected urine, leaked, quantity not sufficient, no swab, two swabs, expired transport, out of temp. range, no specimen received, broken, improper swab or collection kit, improper collection site, thick mucus, illegible ID, missing or incomplete lab slip (no site, date, gender, patient info., submitter info.), mismatched patient ID.
Availability:	Monday-Friday
Results and Interpretation:	▪ *Chlamydia trachomatis* RNA was DETECTED by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method. ▪ *Chlamydia trachomatis RNA was not detected by Nucleic Acid Amplification* using the Transcription Mediated Amplification (TMA) method.

	▪ *The specimen was Equivocal for Chlamydia trachomatis by Nucleic Acid Amplification* using the Transcription Mediated Amplification (TMA) method. Specimen recollection is required for accurate determination. ▪ *Neisseria gonorrhoeae was detected by Nucleic Acid Amplification* using the Transcription Mediated Amplification (TMA) method. ▪ *Neisseria gonorrhoeae was not detected by Nucleic Acid Amplification* using the Transcription Mediated Amplification (TMA) method. ▪ *The specimen was Equivocal for Neisseria gonorrhoeae by Nucleic Acid Amplification* using the Transcription Mediated Amplification (TMA) method. Specimen recollection is required for accurate determination. ▪ *Specimen failed in assay.* Specimen recollection is required for accurate determination. ▪ *Instrument failure.*
Reference Range:	Not applicable.
Additional Information:	Restricted testing (preapproved submitters only, call 443-681-3937)
Purpose of Test:	Direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* RNA .
Method:	Transcription Mediated Amplification (TMA)
Interfering Substances/Limitations:	Interfering substances: None Limitations: Assay cannot determine specimen adequacy. Proper collection is imperative. A negative test result does not exclude the possibility of infection. Interpret result in conjunction with other information. Therapeutic failure or success cannot be determined with the Aptima Combo 2 Assay since nucleic acid may persist following appropriate antimicrobial therapy Only cell culture isolation should be used when testing for the evaluation of suggested sexual abuse or other medico-legal purposes. The Aptima Combo 2 Assay provides qualitative results. Therefore, a correlation cannot be drawn between the magnitude of a positive assay signal and the number of organisms in a specimen. Performance of this assay has not been evaluated for patients less than 14 years old. Vaginal self-collected specimens are not approved for home use or outside clinical setting. The presence of mucus inhibits the proper sampling of columnar epithelial cells in endocervical specimens.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	**Rectal and pharyngeal specimens are not an FDA approved specimen type for the Hologic® Aptima® Combo 2 Assay. Performance characteristics of the assay using rectal and pharyngeal specimens were validated by the MDH Laboratories.**