Lab Dept: Microbiology/Virology

Test Name: CHLAMYDIA /GC AMPLIFIED RNA ASSAY, MISCELLANEOUS SITES

General Information

Lab Order Codes: MCTGC

Synonyms: Chlamydia trachomatis/ Neisseria gonorrhoea by Nucleic Acid Amplification (Gen-Probe), oral/throat, ocular (corneal/conjunctiva), anal/rectal, peritoneal fluid

CPT Codes: 87491 – Chlamydia trachomatis, amplified probe technique
87591 – Neisseria gonorrhoeae, amplified probe technique

Test Includes: Combination order code for both Chlamydia trachomatis and Neisseria gonorrhoea from one specimen. Target capture, transcription-mediated amplification, and dual kinetic assay. The detection of rRNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes are labeled and combine with amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer.

Logistics

Test Indications: Detection of Chlamydia trachomatis and Neisseria gonorrhoeae in non-FDA-approved specimen types

Lab Testing Sections: Virology - Sendouts

Referred to: Mayo Medical Laboratories (MML Test: MCTGC)

Phone Numbers:
MIN Lab: 612-813-6280
STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 3 days, performed daily

Special Instructions:
- Obtain special collection supplies based on type of specimen to be collected. Kits are stocked on patient units. See Container

- Specimen site and date/time of collection are required for processing.
Specimen

Specimen Type: Oral/throat, ocular (corneal/conjunctiva), rectal/anal, peritoneal fluid

Obtain the following (stocked on patient units):

<table>
<thead>
<tr>
<th>Container</th>
<th>CHC# 24789 – Aptima Unisex swab specimen collection system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral/throat</td>
<td></td>
</tr>
<tr>
<td>Ocular (corneal/conjunctiva)</td>
<td></td>
</tr>
<tr>
<td>Rectal/anal</td>
<td></td>
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<tr>
<td>Peritoneal fluid</td>
<td></td>
</tr>
</tbody>
</table>

Volume: 1 swab from Mayo supply kit T583 (CHC# 24789)

Collection:

Miscellaneous Sources:

1. Swab site.
2. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
3. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
4. Re-cap the swab specimen transport tube tightly.
5. Label tube with 2 identifiers, including patient’s entire name, source, and date and time of collection

Transport/Storage: Transport swabs at 2-27°C to the Laboratory. Once in the lab, refrigerate swab and forward to Mayo.

Special Processing:

Lab Staff:

**Oral/throat, ocular (corneal/conjunctiva), rectal/anal, peritoneal fluid swabs:** Store at refrigerated temperatures and forward to Mayo for testing.

Sample Rejection:

Specimen not submitted in appropriate transport container; improperly labeled specimen; external contamination. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range:

No Chlamydia trachomatis detected
No Neisseria gonnorhea detected
Limitations:

- This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications.
- Appropriate specimen collection and handling is necessary for optimal assay performance.
- Results should be interpreted in conjunction with other laboratory and clinical information.
- A negative test result does not exclude the possibility of infection. Improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or low numbers of organisms in the specimen (ie, below the sensitivity of the test) may cause false-negative results.
- In low prevalence populations, positive results must be interpreted carefully as false-positive results may occur more frequently than true positive results in this setting.
- This assay cannot be used to assess therapeutic success or failure, since nucleic acids from these organisms may persist following antimicrobial therapy.
- No interference is expected due to blood (urine and swab) specimens or lubricants and spermicides (swab).
- The effects of use of tampons, douching, specimen types other than those listed and specimen collection variables have not been determined.
- This assay does detect plasmid-free variants of Chlamydia trachomatis.
- This assay does not detect Chlamydia pneumoniae.

Methodology:

Transcription Mediated Amplification (Gen-Probe)

References:

Mayo Medical Laboratories April 2018