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OSPHL Instructions: Chlamydia and Gonorrhea (CT/GC) Testing

The purpose of the information below is to help facilities submitting Chlamydia and Gonorrhea specimens to the Oregon State Public Health Laboratory (OSPHL) follow the acceptable practices for ordering, collecting, storing and transporting specimens to the OSPHL. Detail is provided for each specimen type accepted by the OSPHL. Please contact the Virology section at the OSPHL with questions at 503-693-4100.

How to Order the Test

- On the Virology/Immunology Request Form (Form 42), in the CT/GC section, choose the “Chlamydia/Gonorrhea by NAAT” box.
- Choose the appropriate specimen source.

Specimen Collection and Handling

Endocervical or Urethral Specimens, clinician-collected

- Use the Hologic APTIMA Unisex Collection Kit
- Carefully follow the instructions printed on the collection kit.
    - When collecting male urethral specimens, the patient should not have urinated at least one hour prior to specimen collection.

Vaginal Specimens, clinician-collected or patient-collected

- Use the Hologic APTIMA Multitest Collection Kit
- Carefully follow the package insert instructions included with the collection kit.
    - These specimens can be either clinician collected or patient-collected at the clinic site.

Urine Specimens

- Use the Hologic APTIMA Urine Specimen Collection Kit
- Carefully follow the instructions printed on the collection kit.
    - Collect 20-30 mL of first catch urine in a sterile urine container. Patient should not have urinated for at least one hour prior to specimen collection.
    - Transfer urine to the Gen-Probe collection kit.
    - Urine level must fall between the black fill lines on the kit.

*Rectal Specimens, clinician-collected or patient-collected

- Use the Hologic APTIMA Unisex Collection Kit
- For specimen collection:
    - Insert the blue shaft swab 1 inch into the rectum and rotate against the rectal wall several times, approximately 5-10 seconds.
    - Immediately place the blue swab into the specimen transport tube. Break the swab at the score line. Recap the tube tightly.

*Pharyngeal Specimens, clinician-collected

- Use the Hologic APTIMA Unisex Collection Kit
- For specimen collection:
    - Vigorously rub the tonsils and posterior pharynx with the blue shaft swab. The use of a tongue depressor may be helpful.
    - Carefully remove the swab, not touching any area of the mouth. Immediately place the blue swab in to the specimen transport tube. Break the swab at the score line. Recap the tube tightly.

Specimen Storage and Transport Instructions

All sample types may be stored and transported at room or refrigerated temperatures (2-30°C). All sample types are stable for 30 days.

Rejection Criteria

Specimens are subject to the requirements of the OSPHL Specimen Submission Policy and Criteria, available at http://bit.ly/SpecimenCriteria.

Comments

- The performance of the Aptima Combo 2 Assay has not been evaluated in adolescents less than 14 years of age.
- First catch female urine specimens are acceptable but may detect up to 10% fewer CT/GC infections when compared with vaginal and endocervical swab specimens.
- The Aptima Combo 2 Assay has not been validated for use with vaginal swab specimens collected by patients at home. The patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain procedures and precautions.

Method Performance Specifications

Specimen Source(s)	Test	Percent Accuracy	Positive Predictive Value	Negative Predictive Value	Coefficient of Variation	Misclass-ification Rate	Sensitivity
*Clinician Collected Rectal & Pharyngeal Swabs	CT	100%	100%	100%	0	0	100%
	GC	100%	100%	100%	0	0	100%
*Patient Collected Rectal Swabs	CT	97.03%	94.44%	98.46%	0	0	97.14%
	GC	100%	100%	100%	0		100%
Urine and Urethral, Vaginal, and Endocervical Swabs	Detailed data on assay performance for this test is available from the manufacturer, Hologic at: https://www.hologic.com/package-inserts/diagnostic-products/aptima-combo-2-assay-ctng						

* The OSPHL has validated the modification of the current FDA approved procedure for CT/GC testing to include rectal and pharyngeal swabs.