

Recommendations for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) Testing in Pediatric Populations

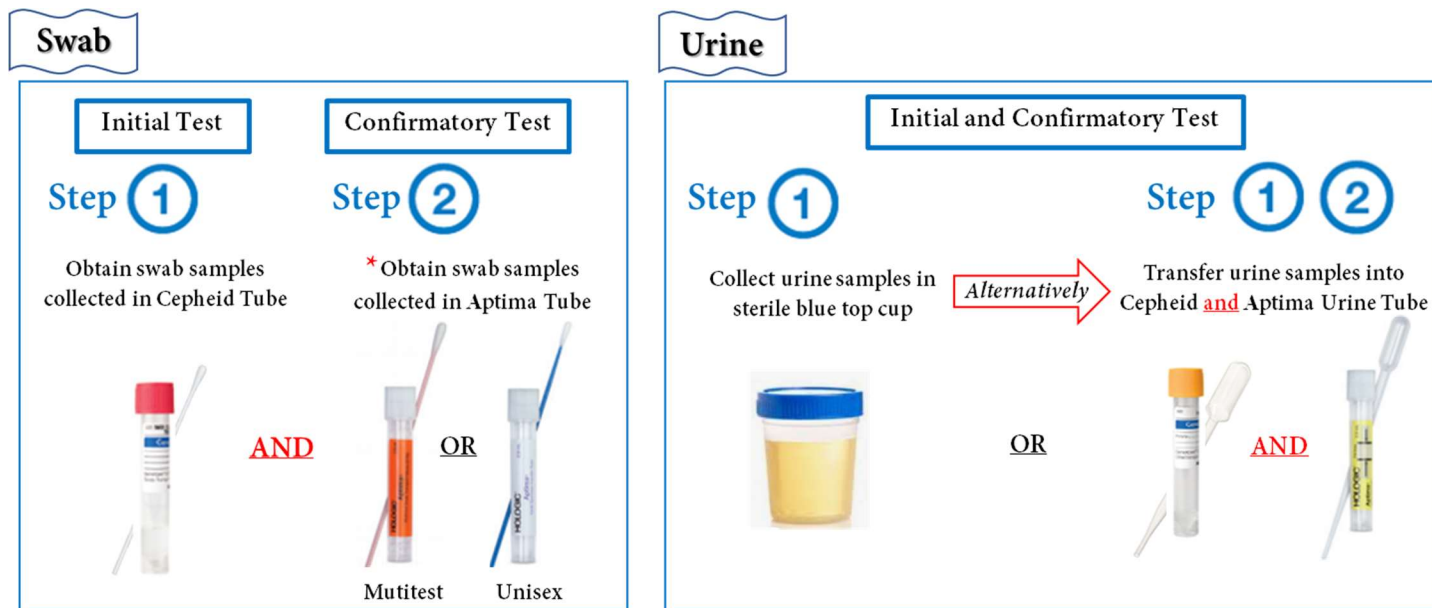
Nucleic acid amplification testing (NAAT) is the recommended test method for the diagnosis of chlamydia and gonorrhea infection due to superior performance in sensitivity, specificity, and specimen stability. However, *N. gonorrhoeae* culture collection is still needed for evaluating suspected cases of treatment failure and monitoring antimicrobial susceptibility (order GC screen culture). If multiple specimens are being collected from an anatomic site, *N. gonorrhoeae* culture specimens should be obtained first; this sequence maximizes the load collected, which increases the likelihood of a successful culture. Test of cure is unnecessary for most uncomplicated STIs and should be done only when clinically indicated (i.e., not part of routine care). This assay should not be used to monitor initial therapeutic success or failure as residual target nucleic acid from non-viable organism may persist up to 3 weeks following infection.

Due to the low prevalence and potential for false positive results of CT/NG in pediatric populations, **initial positive results will reflex to confirmation by an alternative nucleic acid target methodology** to increase the positive predictive value.

This will require a **2-step collection and test process**. See **Table 1**

EXCEPTION: A single first-catch urine cup collection can be submitted for both initial and confirmatory testing.

Table 1: Specimen Type Initial and Confirmatory Test Collection Guide



*Choice of Aptima swab collection is specimen type and age specific.

See **Table 3** for detailed instruction.

Specimen Collection Summary:

Specimen Types	Total # Collection Devices	Minimum Volume	Specimen Transport	Notes
Urine, First Catch Single, sterile cup <i>or</i> Split into 2 tubes	1 sterile screwcap cup	10 mL	2-30 °C	Optimal volume 15-20 mL
	<i>Alternatively transfer to:</i> 2: 1 Cepheid tube; 1 Aptima tube	~7 mL Cepheid ~2 mL Aptima	2-30 °C	Do not over/under fill. Fill to indicated fill lines.
Vaginal Swab	2: 1 Cepheid tube; 1 Aptima tube	N/A	2-30 °C	See Table 3 for specimen type and age specific requirements for confirmatory testing with Aptima swab collection tubes.
Throat Swab	2: 1 Cepheid tube; 1 Aptima tube	N/A	2-30 °C	
Rectal Swab	2: 1 Cepheid tube; 1 Aptima tube	N/A	2-30 °C	
Endocervical Swab	2: 1 Cepheid tube; 1 Aptima tube	N/A	2-30 °C	
Conjunctival Swab	2: 1 Cepheid tube; 1 Aptima tube	N/A	2-30 °C	

For urine specimens: see **Table 2**

Special Instructions: patient should not have urinated for at least 1 hour prior to sampling.




Step 1 (initial & confirmation): submit urine samples in single, sterile screw-cap cup (primary container). Min. volume: 10 mL.

Alternatively

Step 1 (initial): transfer 7 mL of urine sample into Cepheid Urine Collection Kit filling up to dotted black lines.

Step 2 (confirmation): transfer 2 mL of urine sample into Aptima Urine Collection Kit filling in-between black lines.

Table 2: Urine Specimen Collection Guide

Patients any age			
Approved Collection Devices – Urine			
Sterile Screw-cap Cup Minimum volume: 10 mL 			
Submit 10-20 mL first void (not mid-stream or clean-catch) urine in a sterile, screw-cap container free of any preservatives. Collection of larger volumes (>50 mL) of urine results in specimen dilution that may reduce test sensitivity.			
*Note: Initial and Confirmatory testing can be completed from a single, sterile screw-cap cup submission containing a minimum volume of 10 mL. Optimal volume: 20 mL			
Alternatively, transfer 7 mL to Cepheid Tube and 2 mL to Aptima Urine Tube			
Step 1: Initial Test Performed by PCH		Step 2: Confirmatory Test Performed by Reference Laboratory	
Cepheid Urine Kit Volume: 7 mL Fill until level reaches black dotted line		Aptima Urine Kit Volume: 2 mL Fill until level is between solid black lines.	




For swab specimens: see Table 3

Step 1 (initial): collect swab samples with Cepheid Swab Collection Kit (pink top tube) [single swab for all specimen types / ages].



Step 2 (confirmation): collect swab samples with Aptima Swab Collection Kit – **choice of swab is specimen type and age specific**.

See Table 3 for details regarding age and specimen type collection.

Table 3: Swab Specimen Collection Guide – confirmatory swab collection choice is based on age.

Patients 14 years and older (≥ 14 yrs)			
Approved Collection Devices – Swabs			
Step 1: Initial Test Performed by PCH Microbiology Laboratory		Step 2: Confirmatory Test Performed by Reference Laboratory	
Cepheid Swab Kit Pink top tube (white swab) 	Vaginal Throat Rectal Endocervical Conjunctival	Aptima Multitest Kit Orange tube (pink swab) 	Vaginal Throat Rectal
		Aptima Unisex Kit White tube (blue swab) 	Endocervical Conjunctival *Male urethral

*Collect Male Urethral Swabs with Aptima Unisex Kit Only. Not validated for in-house testing.




Patients 13 years and younger (≤ 13 yrs)			
Approved Collection Devices – Swabs			
Step 1: Initial Test Performed by PCH Microbiology Laboratory		Step 2: Confirmatory Test Performed by Reference Laboratory	
Cepheid Swab Kit Pink top tube (white swab) 	Vaginal Throat Rectal Endocervical Conjunctival	Aptima Unisex Kit White tube (blue swab) 	Vaginal Throat Rectal Endocervical Conjunctival *Male urethral

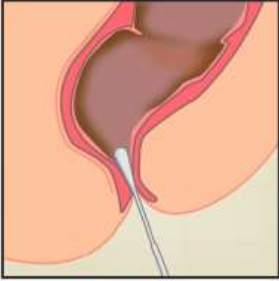
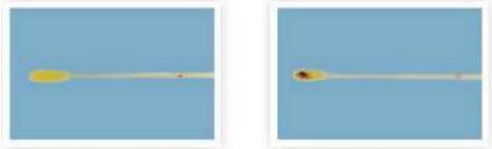
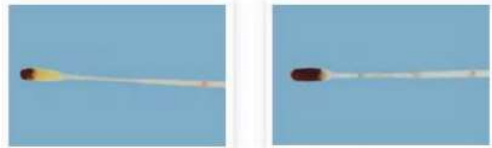

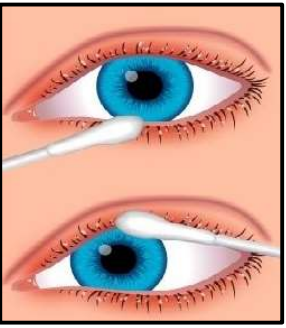
*Collect Male Urethral Swabs with Aptima Unisex Kit Only. Not validated for in-house testing.

IMPORTANT: Swab-based testing requires collection of 2 swabs (1 Cepheid, 1 Aptima) at the time of specimen collection. Initial testing is performed in-house by PCH Microbiology Laboratory (Cepheid platform). If initial testing is positive, then confirmatory testing will be performed by Reference Laboratory using alternative nucleic acid methodology (Aptima platform).

Note: Please ensure that collection tubes are submitted with the appropriate swab. Cepheid swabs are white (placed into pink top tube). Aptima swabs are pink (placed into orange tube) or blue (placed into purple lettering tube).

Specimen Collection Instructions:

Specimen Type	Specimen collection	Notes
Urine, female or male 	<p>Collect “first catch” urine, not mid-stream or clean catch.</p> <p>Submit single sterile cup (min. vol. 10 mL) or transfer to 2 secondary collection tube (see Table 2) containing stabilizing agents to prolong specimen stability for long transport times.</p>	<p>Transport specimen at 2-30 °C</p> <p>First catch is expected to contain greatest organism burden, thus yielding best sensitivity.</p> <p>Large volume collections (i.e. >50 mL) can reduce test sensitivity.</p>
Vaginal Swab 	<p>Vaginal collection includes careful insertion of swab approximately 2 inches into the vaginal opening and gently rubbing the swab against the vaginal wall for 30 seconds followed by swab removal and insertion into respective collection tubes.</p> <p>Carefully break the swab shaft at the score line; avoid splashing contents.</p> <p>Recap the swab specimen transport tube tightly and gently mix by inversion 3-4 times. Avoid foaming.</p>	<p>Transport specimen at 2-30 °C</p> <p>After swab collection, take care not to touch the swab to any surface prior to placing into collection tube.</p> <p>Vaginal swabs are the CDC preferred specimen type for females.</p> <p>While both <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> infect columnar epithelial cells of the endocervix and urethra, exfoliated organisms and debris from infected cervix and urethra are detected in vaginal specimens.</p>
Throat Swab 	<p>Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth (can use tongue depressor if needed). Swab areas of the pharynx (tonsil, posterior wall, uvula, posterior wall).</p> <p>Carefully break the swab shaft at the score line.</p> <p>Recap the swab specimen transport tube tightly and gently mix by inversion 3-4 times. Avoid foaming.</p>	<p>Transport specimen at 2-30 °C</p> <p>After swab collection, take care not to touch the swab to any surface prior to placing into collection tube.</p>

Specimen Type	Specimen collection	Notes
Rectal Swab 	<p>Carefully insert swab approximately 1 cm beyond the anal sphincter (so that the fiber tips are no longer visible) and rotate gently.</p> <p>Carefully break the swab shaft at the score line.</p> <p>Recap the swab specimen transport tube tightly and gently mix by inversion 3-4 times. Avoid foaming.</p>	<p>Transport specimen at 2-30 °C</p>  <p>Figure 1. Examples of Acceptable Rectal Swabs</p>  <p>Figure 2. Examples of Unacceptable Rectal Swabs</p>
Endocervical Swab 	<p>Remove excess mucus from the cervix and surrounding mucosa using the Large individually wrapped cleaning swab. Discard the swab.</p> <p>Insert the collection swab into the endocervical canal. Gently rotate the swab clockwise for 10-30 seconds in the endocervical canal.</p> <p>Carefully break the swab shaft at the score line.</p> <p>Recap the swab specimen transport tube tightly and gently mix by inversion 3-4 times. Avoid foaming.</p>	<p>Transport specimen at 2-30 °C</p> <p>After swab collection, take care not to touch the swab to any surface prior to placing into collection tube.</p>
Conjunctival / Eye Swab 	<p>Thoroughly swab the lower, then the upper conjunctiva, two to three times. Remove the cap from the swab specimen transport tube, and immediately place the specimen collection swab into the transport tube.</p> <p>Carefully break the swab shaft at the score line.</p> <p>Recap the swab specimen transport tube tightly and gently mix by inversion 3-4 times. Avoid foaming.</p>	<p>Transport specimen at 2-30 °C</p> <p>If multiple eye specimens are being collected, <i>N. gonorrhoeae</i> and/or bacterial culture specimens should be obtained first (Stuart or Amies media acceptable).</p> <p>For CT/NG NAAT, swab the lower and upper conjunctiva (preferred). Alternatively, swab of purulent discharge acceptable (Refer to Table 3 for acceptable collection media).</p>