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STD TESTING USING NUCLEIC ACID AMPLIFICATION TESTS-SAMPLE COLLECTION INSTRUCTIONS

Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis

Specimens should be collected and transported following the manufacturer's instructions and using the manufacturer's collection kits provided by ARUP. For FDA approved tests, use of other transport media (e.g., viral transport media) is discouraged and may result in reduced sensitivity.

Table 1: FDA Approved Collection Devices and Approved Body Sites (patients 14 years and older*)

Approved Collection Device		Body Site	C. trachomatis N. gonorrhoeae	T. vaginalis
Aptima Urine Spec Collection Kit ARUP Supply #28908/#54556		First-catch Urine (Female)	х	
	Collection Kit ARUP Supply	First-catch Urine (Male)	х	
	Aptima Multitest Swab ARUP Supply #55224/#55229	Vaginal Swab	Х	Х
Approved the second sec		Throat Swab	Х	
		Rectal Swab	Х	
HOLOGIC 23 M	Aptima Unisex Swab ARUP Supply #28907/#54555	Endocervical	Х	Х
		Male Urethral	Х	
Timper B	ThinPrep	Endocervical	х	х

*FDA approved body sites are for patients 14 years of age or older. Specimens for patients younger than 14 years old may be submitted for *C. trachomatis* and *N. gonorrhoeae* testing using the Aptima Unisex Swab (ARUP Supply #28907/#54555) for the following sources: vaginal, endocervical, throat, rectal, eye, and male urethra. First-catch urine is also acceptable.

Table 2: Optimal Specimen Types for Screening Women					
	Optimal Specimen	Alternative	Reduced Sensitivity		
C. trachomatis ¹	Vaginal Multitest swab	Endocervical Unisex swab	First-catch urine		
		Rectal Multitest swab	ThinPrep Pap Collection		
		Endocervical Unisex swab	First-catch urine		
N. gonorrhoeae ²	Vaginal Multitest swab	Rectal Multitest swab			
		Pharyngeal Multitest swab	ThinPrep Pap Collectio		
	Vaginal Multitest swab				
T. vaginalis ³	Endocervical Unisex swab	First-catch urine			
	ThinPrep Pap Collection				

¹ Routine screening is recommended annually in sexually active females 25 years or younger, all pregnant women under 25 years of age, and all pregnant women age 25 and older if at increased risk (including retesting during the third trimester). Test-of-cure is recommended in pregnant women 3-4 weeks after treatment. Retesting three months after treatment is recommended for all women with *C. trachomatis* infection.

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² Routine screening is recommended annually in sexually active females 25 years or younger, all pregnant women under 25 years of age, and all pregnant women age 25 and older if at increased risk. Retesting three months after treatment is recommended for all women with *N. gonnorrhoeae* infection.

³ Screening can be considered in women at high risk for infection (e.g., new/multiple partners, history of STDs, exchange of sex for payment, injection drug use).

Table 3: Optimal Specimen Types for Screening Men

	Optimal Specimen	Alternative	MSM ²
C. trachomatis	First-catch urine ¹	Urethral Unisex swab	Rectal Multitest swab ²
N. gonorrhoeae	First-catch urine ¹	Urethral Unisex swab	Rectal Multitest swab ²
	First-Catch unne		Pharyngeal Multitest swab ²
T. vaginalis	Urethral Unisex swab ³	First-catch urine ³	

¹ Screening of sexually active young men should be considered in clinical settings with high prevalence (e.g., adolescent clinics, STD clinics, correctional facilities).

² Routine annual screening for all sexually active MSM is recommended, as extragenital infections are common and mostly asymptomatic. Screening every 3–6 months is recommended for MSM at increased risk.

³ Nucleic acid amplification tests are more sensitive than a culture but have not been FDA approved for testing in men. Culture of urethral swabs, urine, and semen is one diagnostic option. Wet preparation lacks sensitivity with these specimens.

Table 4: ARUP Validated Options for Patients Younger Than 14

	Optimal Specimen	Alternative	Reduced Sensitivity	
C. trachomatis	Vaginal Unisex swab	Rectal Unisex swab	First-catch urine	
	Endocervical Unisex swab	Pharyngeal Unisex swab		
N. gonorrhoeae	Vaginal Unisex swab	Rectal Unisex swab	First-catch urine	
	Endocervical Unisex swab	Pharyngeal Unisex swab		
T. vaginalis	First-catch urine			

Screening recommendations from the Centers for Disease Control and Prevention can be accessed at <u>cdc.gov/std/tg2015/screening-recommendations.htm</u>.

Instructions for Specimen Collection

VAGINAL SWAB SPECIMENS

- 1. Use Aptima Multitest Swab Specimen Collection Kit (ARUP supply #55224 PK/50 or #55229 PK/10).
- 2. Partially peel open the swab package. Remove the pinkshaft specimen collection swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, use a new Aptima Multitest Swab Collection Kit.
- 3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 4. Carefully insert the pink-shaft swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
- 5. While holding the swab in the same hand, unscrew the cap from the tube. Take care not to spill the contents of

the tube. If you spill the contents of the tube, use a new Aptima Multitest Swab Specimen Collection tube.

- 6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 7. Carefully break the swab shaft at the score line against the side of the tube.
- 8. Immediately discard the top portion of the swab shaft.
- 9. Tightly screw the cap onto the tube.
- 10. Store and transport at 2°C to 30°C until tested.

FIRST-CATCH URINE COLLECTION

- 1. Use Aptima Urine Specimen Collection Kit (ARUP supply #28908 PK/50 or #54556 PK/10).
- 2. Do not urinate for at least one hour prior to collecting specimen.
- 3. Collect approximately 20-30 mL of first-catch urine (i.e., initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution, which may reduce

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test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.

- 4. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the label of the urine specimen transport tube.
- 5. Urine sample must be transferred into the Aptima Urine Specimen Collection tube within 24 hours of collection.
- 6. Recap the urine specimen transport tube tightly.
- 7. Store and transport at 2°C to 30°C until tested.

MALE URETHRAL SWAB SPECIMENS

1. Use the Aptima Unisex Swab Specimen Collection Kit (ARUP supply #28907 PK/50 or #54555 PK/10).

2. Do not urinate for at least one hour prior to collecting specimen.

3. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) 2-4 cm into the urethra.

4. Gently rotate the swab clockwise for 2-3 seconds in the urethra for adequate sampling.

5. Withdraw the swab carefully.

6. Remove the cap from the Aptima Unisex Swab Specimen Collection tube and immediately place the blue specimen collection swab into the transport tube.

7. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.

- 8. Recap the swab specimen transport tube tightly.
- 9. Store and transport at 2°C to 30°C until tested.

FEMALE ENDOCERVICAL SPECIMENS

- 1. Use the Aptima Unisex Swab Specimen Collection Kit (ARUP supply #28907 PK/50 or #54555 PK/10).
- 2. Remove excess mucus from the cervical ostium and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). Discard this swab.
- 3. Insert the specimen collection swab (blue-shaft swab in the package with the green printing) into the endocervical canal.
- 4. Gently rotate the blue swab clockwise for 10! 30 seconds in the endocervical canal to ensure adequate sampling.
- 5. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- 6. Remove the cap from the Aptima Unisex Swab Specimen Collection tube and immediately place the specimen collection swab into the transport tube.

- 7. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 8. Recap the swab specimen transport tube tightly.
- 9. Store and transport at 2°C to 30°C until tested.

ANAL/RECTAL SWABS

- Use Aptima Multitest Swab Specimen Collection Kit (ARUP supply #55224 PK/50 or #55229 PK/10).
- 2. Insert the pink-shaft specimen collection swab approximately 3-5 cm into the anal canal.
- Rotate the swab for 5-10 seconds against the rectal wall (at least three times) to sample the mucosal surface.
- 4. If the swab is grossly contaminated with feces, discard and repeat the collection.
- 5. Withdraw the swab carefully, remove the cap from the swab specimen transport tube, and immediately place the specimen collection swab into the transport tube.
- 6. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 7. Recap the swab specimen transport tube tightly.
- 8. If needed prior to insertion, the swab can be moistened with water or saline solution.

THROAT/PHARYNGEAL SWABS

- 1. Use Aptima Multitest Swab Specimen Collection Kit (ARUP supply #55224 PK/50 or #55229 PK/10).
- 2. Discard the large white-shaft cleaning swab.
- 3. Using the pink-shaft specimen collection swab, sample the bilateral posterior pharynx, both tonsils, and the uvula.
- 4. Withdraw the swab carefully, remove the cap from the swab specimen transport tube, and immediately place the specimen collection swab into the transport tube.
- 5. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 6. Recap the swab specimen transport tube tightly.