SPECIMEN COLLECTION FOR THE DIAGNOSIS OF CHLAMYDIA/GONORRHOEAE NUCLEIC ACID AMPLIFICATION TESTS

Table 1: Optimal Specimen Types for Screening Asymptomatic Women

	Optimal Specimen	Alternative	Reduced sensitivity
C. trachomatis	Vaginal swab	Endocervical swab	First catch urine
N. gonorrhoeae	Vaginal swab	Endocervical swab	First catch urine

1. Routine screening recommended annually in sexually active females age ≤25 years.
2. Routine screening recommended annually in all sexually active, at-risk females (age ≤25 years, previous infection with N. gonorrhoeae, presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use).
3. Screening of extragenital sites is not currently recommended due to lack of published studies, however, available data suggests that rectal and oropharyngeal are not uncommon in women. Consider screening women with known risk factors. Extragenital sites are not FDA approved for the Cobas 4800 test system. Contact Client Support Services at (402)-354-4541 or 1-888-432-8980 for testing information on extragenital sites.

Table 2: Optimal Specimen Types for Screening Asymptomatic Men

	Optimal Specimen
C. trachomatis	First catch urine
N. gonorrhoeae	First catch urine

1. Screening of sexually active young men should be considered in clinical settings with high prevalence (adolescent clinics, STD clinics, correctional facilities).
2. Urethral swabs are a more invasive collection method and are not FDA approved for the Cobas 4800 test system.
3. Routine annual screening for all sexually active MSM is recommended since extragenital infections are common and often asymptomatic. More frequent screening recommended for MSM with multiple or anonymous sexual partners. Extragenital sites are not FDA approved for the Cobas 4800 test system. Contact Client Support Services at (402)-354-4541 or 1-888-432-8980 for testing information on extragenital sites.

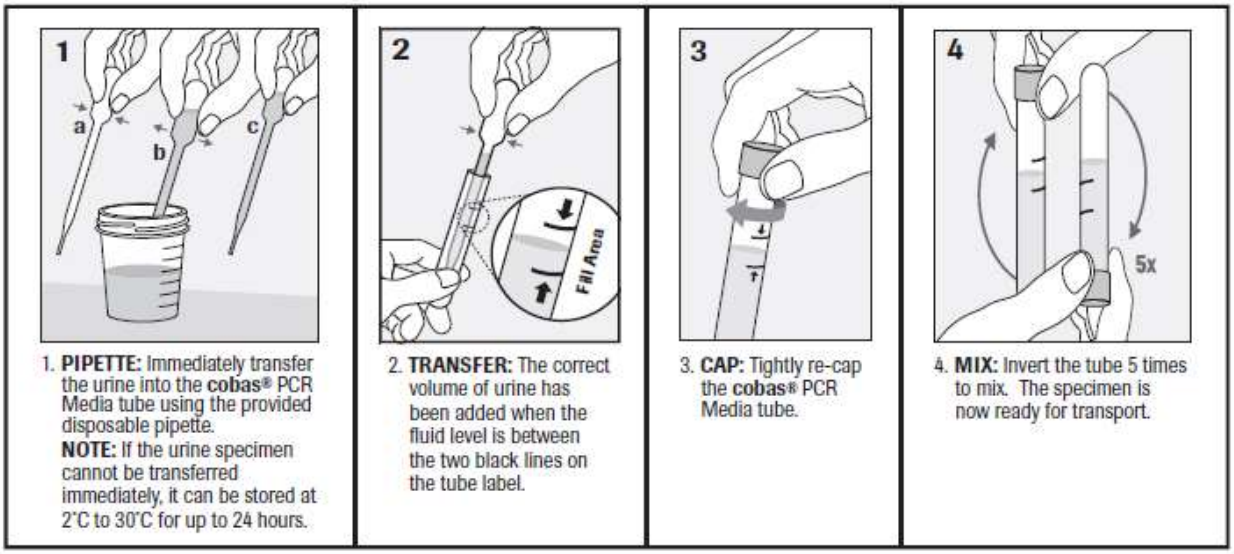
Table 3: Testing of Symptomatic Patients

	Women	Men
Urethritis	First catch urine	First catch urine
Vaginal Discharge or Cervicitis	Vaginal swab Endocervical swab First catch urine	N/A

Instructions for Specimen Collection

Urine collection protocol for male or female:

1. Patients should not have urinated for at least one hour prior to specimen collection.
2. Direct the patient to collect first-catch urine (approximately 10 to 50 mL of the initial urine stream) into a urine collection cup. The collection of larger volumes of urine may reduce test sensitivity.
3. The first catch urine should be immediately transferred into the cobas PCR Media tube using the provided disposable pipette. (Note: If the urine specimen cannot be transferred immediately, it can be stored at 2°C to 30°C for up to 24 hours.)
4. The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.
5. Tightly re-cap the cobas PCR Media tube. Store and transport at 2°C to 30°C until tested.



Handling precautions

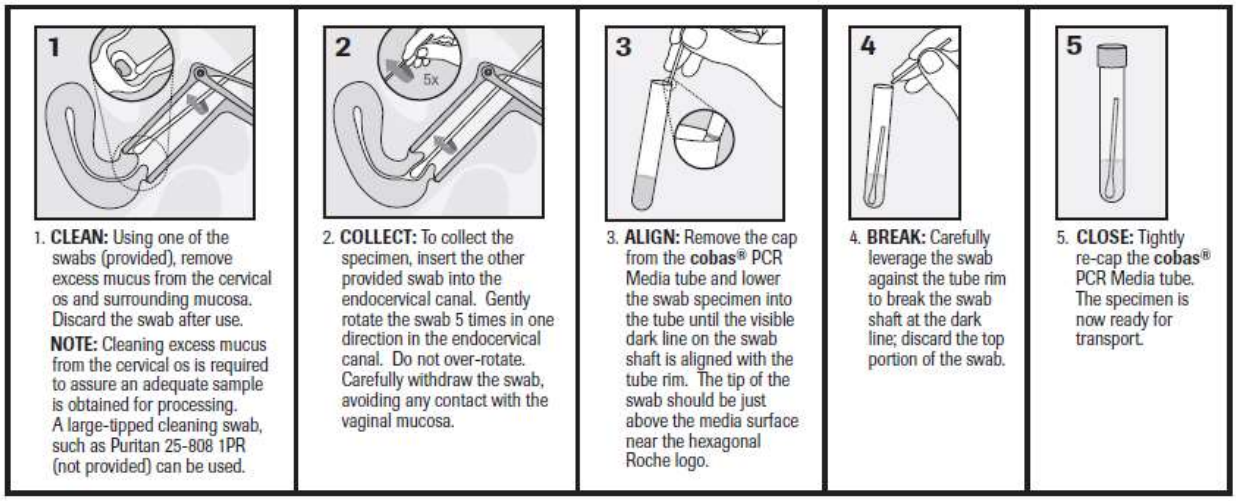
• Female patients should not cleanse the labial area prior to providing specimens.

• If the collected urine contains excess blood (specimen has a dark red or brown color) it should be discarded and not used for testing.

• Use care to avoid splashing of contents. Avoid contact of the cobas PCR Media with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water.

Female Endocervical Swab specimen collection:

1. **CLEAN:** Using one of the swabs provided, remove excess mucus from the cervical os and surrounding mucosa. Discard this swab after use.
   NOTE**:** Cleaning excess mucus from the cervical os is required to assure an adequate sample is obtained for processing. A large-tipped cleaning swab, such as Puritan 25-808 1PR (not provided) can be used.
2. **COLLECT:** Insert the other provided swab into the endocervical canal. Gently rotate the swab 5 times in one direction in the endocervical canal. DO not over-rotate. Carefully withdraw the swab, avoiding any contact with the vaginal mucosa.
3. **ALIGN:** Remove the cap from the cobas PCR Media tube and lower the swab specimen into the tube until the visible dark line on the swab shaft is aligned with the tube rim. The tip of the swab should be just above the media surface near the hexagonal Roche logo.
4. **BREAK & CAP**: Carefully leverage the swab against the tube rim to break the swab at the dark line; discard the top portion of the swab.
5. **CLOSE:** Tightly re-cap the cobas PCR Media tube. The specimen is now ready for transport. Store and transport at 2°C to 30°C until tested.



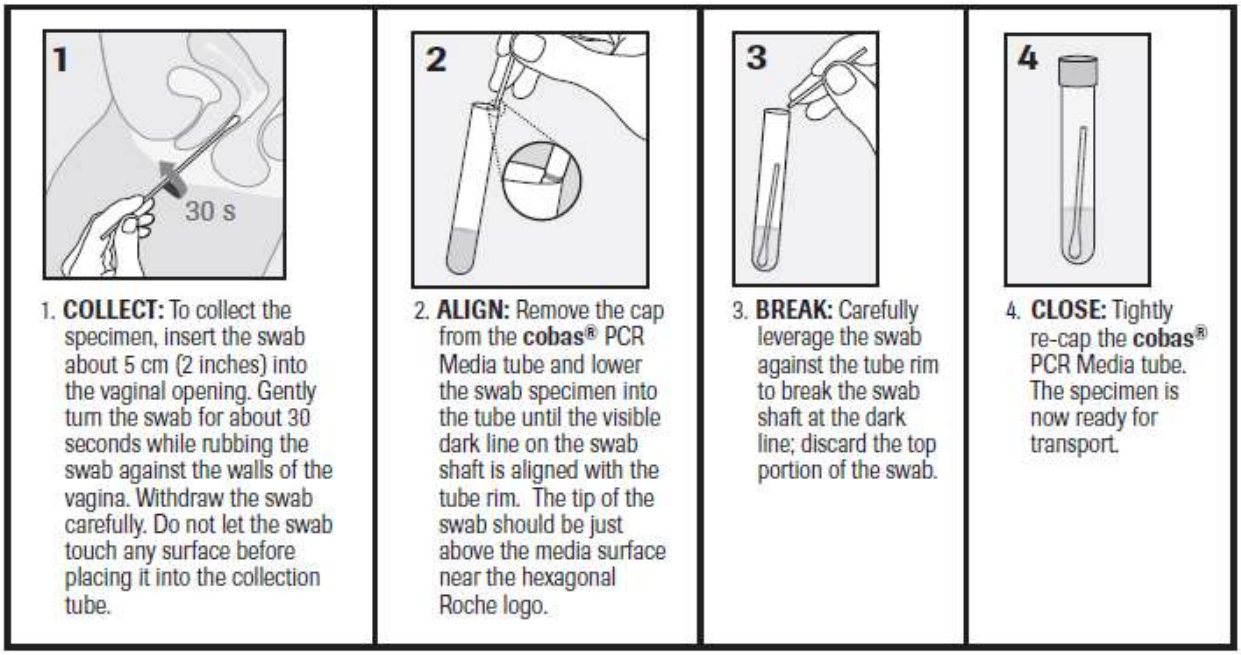
Handling precautions

• DO NOT pre-wet collection swabs with the collection media before obtaining the endocervical specimen.

• Use care to avoid splashing of contents. Avoid contact of the cobas PCR Media with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water.

Female Vaginal Swab specimen- clinician collection:

1. **COLLECT**: To collect the specimen, insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab for about 30 seconds while rubbing the swab against the walls of the vagina. Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.
2. **ALIGN**: Remove the cap from the cobas PCR Media tube and lower the swab specimen into the tube until the visible dark line on the swab shaft is aligned with the tube rim. The tip of the swab should be just above the media surface near the hexagonal Roche logo.
3. **BREAK & CAP**: Carefully leverage the swab against the tube rim to break the swab at the dark line; discard the top portion of the swab.
4. **CLOSE**: Tightly re-cap the cobas PCR Media tube. The specimen is now ready for transport. Store and transport at 2°C to 30°C until tested.



Handling precautions

• DO NOT pre-wet collection swabs with the collection media before obtaining the endocervical specimen.

• Use care to avoid splashing of contents. Avoid contact of the cobas PCR Media with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water.

VAGINAL SWAB SPECIMEN – SELF-COLLECTION IN A CLINICAL SETTING

NOTE: Ensure the patient has read and understood the following self-collection instructions before providing a collection kit.

Preparing For Sample Collection:

- Undress to expose the vaginal area.
- Put yourself in a comfortable position.
- Remove the collection tube and one swab from the collection kit.
- Discard the second swab

How to Self-Collect a vaginal swab sample:

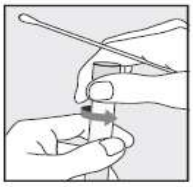
Handling Precautions:

- **Do NOT** pre-wet collection swab with the collection media or any other liquid before obtaining the vaginal sample.
- Use care to avoid splashing contents of the tube. If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube splash into your eyes, flush them with water immediately. Always notify your healthcare provider.

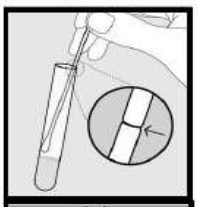
NOTE: In case the contents of the tube are accidently spilled, do not attempt to clean up. Immediately notify your healthcare provider for appropriate action.

1. POSITION: Hold the swab in one hand and with the other hand separate the folds of skin around the vaginal opening (labia).

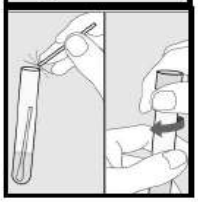
2. COLLECT: Insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab for about 30 seconds while rubbing the swab against the wall of the vagina. Remove the swab carefully. Do not touch the swab to any surface before placing it into the collection tube.



3. OPEN TUBE: While holding the swab in the same hand remove the cap from the tube as shown in the diagram.



4. ALIGN: Lower the swab into the tube until the visible dark line on the swab shaft is lined up with the tube rim. The tip of the swab should be just above the liquid in the tube.



5. BREAK: Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.

6. CLOSE: Tightly close the **cobas**® PCR Media tube. Return the sample to your healthcare provider as instructed.