

COUNTY OF SAN LUIS OBISPO HEALTH AGENCY PUBLIC HEALTH LABORATORY

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SPECIMEN COLLECTION & TRANSPORT INSTRUCTIONS

cobas® Collection Kits - Chlamydia/Gonorrhea/Trichomonas/Mycoplasma genitalium NAAT

SPECIMEN STORAGE & TRANSPORT

<u>Temperature</u>: Refrigerated or room temperature (2 °C – 30 °C / 36 °F – 86 °F) <u>Maximum Holding Time</u>: 12 months for specimens collected in cobas[®] PCR Media

<u>Exceptions</u>: For any exceptions to collection, storage, or transport conditions, please call lab first to discuss.

KIT STORAGE

Temperature: room temperature (15 °C - 30 °C / 59 °F - 86 °F)

Expiration: specimen must be collected prior to expiration date listed on kit label

ACCEPTABLE SPECIMEN TYPES

Specimen Type	Chlamydia	Gonorrhea	Trichomonas	M. gen
Urine (female/male)	✓	✓	✓	✓
Uni Swab – Vaginal (female)	✓	✓	✓	✓
Dual Swab - Endocervical (female)	✓	✓	✓	✓
Uni Swab - Anorectal (female/male)	✓	✓		
Uni Swab - Oropharyngeal (female/male)	√	✓		

TEST ORDER OPTIONS FOR THIS KIT

2900: Chlamydia Nucleic Acid Amplification Test (NAAT)

2910: Gonorrhea NAAT 2920: Trichomonas NAAT

2930: Mycoplasma genitalium NAAT

REJECTION CRITERIA

- Collection tube expired prior to date of collection
- Holding time greater than 12 months for specimens in cobas® PCR media
- Excess of blood in urine collection tube
- Specimen tube has leaked or is not sealed properly
- Urine specimens with a volume level outside the acceptable range indicated with black arrows
- Swab specimens that are missing the swab, contain multiple swabs, or contain the wrong swab
- Specimen tube not properly labeled or labeling does not match information on the requisition

Last Updated: 8/25/2022 Page 1 of 6

cobas® Collection Kits - Chlamydia/ Gonorrhea/ Trichomonas/Mycoplasma genitalium NAAT

SPECIMEN COLLECTION

- Verify that the kit is not expired.
- Use Universal Precautions when handling specimens.
- Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high
 levels of organisms. Ensure that specimen containers do not contact one another, and discard used
 materials without passing over any container. Change gloves if they come in contact with specimen.
- If tube transport media is spilled, discard and replace with a new cobas® transport tube.
- Ensure that patient information (i.e., full name, collection date) is included on the transport tube.
- Place the transport tube inside the zippered portion of the biohazard specimen bag and seal tightly.
- Fill out the requisition form completely. Fold it in half once (no staples please) and place in the **outer** pocket of the biohazard specimen bag (not inside the zippered pouch with the specimen).
- Transport to the laboratory.
- See specific instructions below for collection by specimen type.

Last Updated: 8/25/2022 Page 2 of 6

cobas® Collection Kits - Chlamydia/ Gonorrhea/ Trichomonas/Mycoplasma genitalium NAAT

Urine

Patient Instructions

- 1. Do not urinate for at least one hour prior to collection.
- 2. Do not clean genitals prior to collection.
- 3. Collect only the first, most concentrated part of the urine stream (about 10 mL to 50 mL) into a collection cup that is free of any preservatives.

Clinic Staff Instructions

- 1. Using the disposable pipette provided, transfer urine (within 24 hours) into the cobas® PCR Media tube. The correct volume has been added when the fluid level is between the two black lines on the tube label.
 - a. If the volume is outside of the acceptable range indicated with black arrows, the specimen **will be rejected**. If urine is under the line, add more. If urine is over the line, discard and replace with a new cobas® PCR media tube.
 - b. Urine specimens must be transferred into the transport tube within 24 hours of collection; however, within 2 hours is optimal.
- 2. Tightly re-cap the tube.
- 3. Invert the tube 5 times to mix.

Figure. cobas® PCR media urine sample kit.

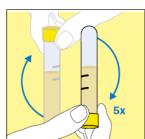


Figure. Transfer of urine into cobas® PCR Media tube.









Last Updated: 8/25/2022 Page 3 of 6

cobas® Collection Kits - Chlamydia/ Gonorrhea/ Trichomonas/Mycoplasma genitalium NAAT

Swab - Vaginal (self-collected or clinician-collected)

Note: Vaginal swabs can be collected by the patient or by the clinician. Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.

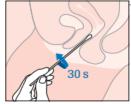
- 1. A uni swab sample kit is used for collection of a vaginal swab specimen.
- 2. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a swab from another cobas PCR Media kit.
- 3. Hold the swab in one hand and with the other hand separate the folds of skin around the vaginal opening (labia).
- 4. Insert the swab about 2 inches (5 cm) into the vaginal opening. Gently turn the swab for about 30 seconds while rubbing the swab against the wall of the vagina.
- 5. Remove the swab carefully. Do not touch the swab to any surface before placing it into the collection tube.
- 6. While holding the swab in the same hand, remove the cap from the tube.
- 7. 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.
- 8. Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
- 9. Tightly close the cobas PCR Media tube. Return the sample to your healthcare provider as instructed.

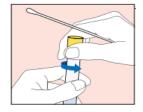
Figure. cobas® PCR Media uni swab collection kit for vaginal specimens.

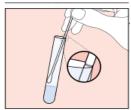


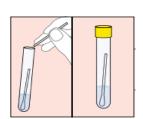
Figure. Vaginal swab sampling and collection.











Last Updated: 8/25/2022 Page 4 of 6

cobas® Collection Kits - Chlamydia/ Gonorrhea/ Trichomonas/Mycoplasma genitalium NAAT

Swab - Endocervical (clinician-collected)

- 1. A dual swab sample kit is used for collecting endocervical swab specimens.
- 2. Mucus free specimens are required for optimal test performance. Remove excess mucus from the cervical os and surrounding mucosa using the <u>woven</u> swab provided. Discard this swab. If excess mucus remains, an additional large-tipped swab (not provided) may be used for cleaning.
- 3. Insert the <u>flocked</u> swab into the cervical canal.
- 4. Gently rotate the swab 5 times in one direction and carefully withdraw, avoiding any contact with the vaginal mucosa.
- 5. Remove the cap from the cobas® PCR Media tube and lower the flocked swab specimen into the tube until the visible dark line on the swab is aligned with the tube rim.
- 6. Carefully leverage the swab against the tube rim to break the swab at the dark line; discard the top portion of the swab.
- 7. Tightly re-cap the tube. The specimen is now ready for transport.

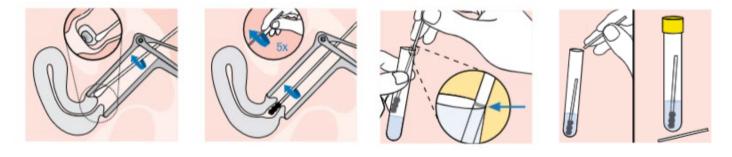
Figure. cobas® PCR Media dual swab collection kit for endocervical specimens.



Figure. Swabs in dual swab collection kit. Note: The <u>woven</u> swab is used to remove mucus; the <u>flocked</u> swab is used to sample the cervical canal.



Figure. Endocervical swab sampling and collection.



Last Updated: 8/25/2022 Page 5 of 6

cobas® Collection Kits – Chlamydia/ Gonorrhea/ Trichomonas/Mycoplasma genitalium NAAT

Swab - Oropharyngeal (throat) (clinician-collected)

- 1. A uni swab sample kit is used for collection of a throat swab specimen.
- 2. Pull the woven swab out of the package. Do not touch the soft tip or lay the swab down.
- 3. Have patient tilt head back, breathe deeply, open mouth wide and say "Ah". This serves to lift the uvula and aids in reducing the gag reflex.
- 4. Gently use tongue depressor to look for areas of inflammation (redness) and exudate (pus).
- 5. Carefully, but firmly, guide the swab over:
 - a. Several areas of inflammation or pus
 - b. The tonsils (or tonsilar crypts if tonsils have been removed)
 - c. Posterior pharynx (back of throat)
- 6. Withdraw the swab carefully. Every effort should be made to avoid touching the swabs to the tongue, teeth, roof of the mouth or the inside of the cheeks at any time.
- 7. Remove the tube cap and immediately place the specimen collection swab into the cobas® PCR Media tube.
- 8. Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
- 9. Tightly close the cobas® PCR Media tube.

Figure. cobas® PCR Media uni swab collection kit for oropharyngeal specimens.



Swab - Anorectal (clinician-collected)

- 1. A uni swab sample kit is used for collection of an anorectal swab specimen
- 2. Pull the woven swab out of the package. Do not touch the soft tip or lay the swab down.
- 3. Insert the swab approximately 1.5 to 2 inches (3-5 cm) into the rectum.
- 4. Gently rotate the swab clockwise for 2 to 3 seconds against the rectal wall; withdraw the swab carefully. Swabs that are grossly contaminated with feces should be discarded and the collection repeated.
- 5. Remove the tube cap and immediately place the specimen collection swab into the cobas® PCR Media tube.
- 6. Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
 - a. Note: Only one swab should be placed into the transport tube.
- 7. Tightly close the cobas® PCR Media tube.

Figure. cobas® PCR media uni swab collection kit for anorectal specimens.



Last Updated: 8/25/2022 Page 6 of 6