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Specimen Collection Instructions for Chlamydia and Gonorrhea PCR Testing

Vaginal swab collection with the cobas® PCR Dual Swab sample kit

- DO NO COLLECT IF PATIENT IS MENSTRUATING.
- DO NOT PRE-WET THE SWAB IN cobas® PCR MEDIA PRIOR TO COLLECTION.

1. Discard the flocked swab.
2. Insert the woven swab about 5 cm (2 inches) into the vaginal opening.
3. Gently turn the swab for about 30 seconds while rubbing the swab against the wall of the vagina.
4. Remove the swab carefully. Do not touch the swab to any surface before placing it into the collection tube.
5. 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.
6. Carefully leverage the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
7. Tightly re-cap the cobas® PCR Media tube.
8. Label the transport tube with two patient identifiers and date of collection.
9. Transport and store the collected specimen at 2°C to 30°C.
10. Specimens stabilized in cobas® PCR Media may be stored at 2–30°C for up to 12 months.

Endocervical swab collection with the cobas® PCR Dual Swab sample kit

- DO NOT COLLECT IF PATIENT IS MENSTRUATING.
- DO NOT PRE-WET THE SWAB IN cobas® PCR MEDIA PRIOR TO COLLECTION.

1. Using the woven cleaning swab, remove excess mucus from the cervical os and surrounding mucosa.
    a. DISCARD THE WOVEN CLEANING SWAB AFTER USE.
    b. NOTE: Cleaning excess mucus from the cervical os is required to assure an adequate sample is obtained for processing.
2. Insert the flocked swab into the endocervical canal.
3. Gently rotate the swab 5 times in one direction in the endocervical canal. Do not over-rotate.
4. Carefully withdraw the swab, avoiding any contact with the vaginal mucosa.
5. 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.
6. Carefully leverage the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
7. Tightly re-cap the cobas® PCR Media tube.
8. Label the transport tube with two patient identifiers and date of collection.
9. Transport and store the collected specimen at 2°C to 30°C.
10. Specimens stabilized in cobas® PCR Media may be stored at 2–30°C for up to 12 months.

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Male/Female urine collection with the cobas® PCR Urine sample kit

- PATIENTS SHOULD NOT HAVE URINATED FOR AT LEAST ONE HOUR PRIOR TO SPECIMEN COLLECTION.
- PATIENTS SHOULD NOT CLEANSE THE GENITAL AREA PRIOR TO PROVIDING THE SPECIMEN.
- DO NOT COLLECT IF PATIENT IS MENSTRUATING.
- MID-STREAM CLEAN-CATCH URINES CANNOT BE USED FOR THIS TEST.

1. Direct the patient to provide first-catch urine (approximately 10 to 50 mL of the initial urine stream) into a urine collection cup free of any preservatives.
2. Immediately transfer the urine into the cobas® PCR Media tube using the provided disposable pipette. The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.
3. Tightly re-cap the cobas® PCR Media tube.
4. Invert the tube 5 times to mix.
5. Label the transport tube with two patient identifiers and date of collection.
6. Transport and store the collected specimen at 2°C to 30°C.
7. Specimens stabilized in cobas® PCR Media may be stored at 2–30°C for up to 12 months.
   NOTE: Urine specimens should be transferred in to the cobas® PCR Media tube immediately to stabilize. If this is not possible, neat urine may be stored at 2°C to 30°C for up to 24 hours. It MUST be transferred into a cobas® urine collection transport tube within that time.

ThinPrep® Plastic Spatula and Endocervical Brush Protocol

- THIS COLLECTION DEVICE SHOULD ONLY BE USED WHEN A THINPREP® PAP TEST IS ALSO ORDERED.
- DO NOT COLLECT IF PATIENT IS MENSTRUATING.

1. Obtain an adequate sample for the ectocervix using a plastic spatula. Select the contoured end of the plastic spatula and rotate it 360º in a clockwise direction around the entire ectocervix, while maintaining tight contact with ectocervical surface.
2. Rinse the plastic spatula immediately into the vial by swirling the spatula vigorously in the vial 10 times.
3. Discard the plastic spatula.
4. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the Cytobrush into the endocervical canal until only the bottom-most bristles are exposed. Slowly rotate ¼ or ½ turn in one direction. Do not over-rotate the brush.
5. Rinse the endocervical brush immediately in the same vial by rotating the device in the solution 10 times while pushing it against the vial wall. As a final step, swirl the brush vigorously to further release material. Discard the brush.
6. Tighten the cap so that the torque line on the cap passes the torque line on the vial. Do not over-tighten.
7. Label the vial with two patient identifiers and date of collection.
8. Transport and store the collected specimen at 2°C to 30°C.
9. Specimens in ThinPrep® PreservCyt® Media are stable at 2°C to 30°C for up to 12 months.

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ThinPrep® Cervical Sampler Broom Protocol

- THIS COLLECTION DEVICE SHOULD ONLY BE USED WHEN A THINPREP® PAP TEST IS ALSO ORDERED.
- DO NOT COLLECT IF PATIENT IS MENSTRUATING.

1. Obtain an adequate sample from the transformation zone of the cervix using a cervical sampler (broom-like device). Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the brush 360º in a clockwise direction 3 to 5 times.
2. Rinse the cervical sampler immediately into the vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. Swirl the brush vigorously to further release material. Visually inspect the cervical sampler to ensure that no material remains attached.
3. Discard the collection device. Do not leave the head of the cervical sampler in the vial.
4. Tighten the cap so that the black torque line on the cap passes the black torque line on the vial. Do not over-tighten.
5. Label the vial with two patient identifiers and date of collection.
6. Transport and store the collected specimen at 2°C to 30°C.
7. Specimens in ThinPrep® PreservCyt® Media are stable at 2°C to 30°C for up to 12 months.

Causes for Rejection

- Swab collected in any collection device other than the cobas® PCR Swab Sample Kit
  - *This test methodology is only FDA approved for vaginal and/or endocervical swabs in cobas® PCR Media.*
- Two swabs or NO swabs in cobas® PCR Media tube.
  - *This indicates improper collection which can lead to potential erroneous results.*
- Clean catch urine
  - *Chlamydia and Gonorrhea infect the columnar epithelial cells in the urethra and may not be present in a mid-stream, clean-catch urine which can lead to false negative results.*
- Urine not transferred into the cobas® PCR Media tube within 24 hours and/or not filled with a volume that falls between the two marked fill lines on the container.
  - *This indicates improper specimen handling which can lead to potential erroneous results.*
- >50 mL of dirty urine in original collection container.
  - *Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.*
- Specimens that appear bloody or are dark brown in color.
  - *Blood can cause polymerase inhibition which can lead to invalid or false negative results.*

1/15/18