



GOVERNMENT OF GUAM  
**DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES**  
**DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT**

**GUAM PUBLIC HEALTH LABORATORY GUIDELINES**  
**CT/NG VAGINAL/ENDOCERVICAL SPECIMEN COLLECTION**

<b>Intended Use</b>	The Cepheid Xpert CT/NG Assay is a qualitative in vitro real-time PCR test for the detection and differentiation of genomic DNA from <i>Chlamydia trachomatis</i> (CT) and/or <i>Neisseria gonorrhoeae</i> (NG) in endocervical and vaginal specimens from symptomatic and asymptomatic individuals.
<b>Specimen Submission Guidelines</b>	<ul style="list-style-type: none"> <li>• Submit specimens to GPHL Central Laboratory daily.</li> <li>• Once vetted/approved by DPHSS, complete the specimen submission form with patient's name (last name, first name), date of birth, unique Identification (ID) number/specimen ID number, date of collection, time of collection, initial of collector (Note: Test subject to CLIA regulations and these requirements).</li> <li>• Label specimen collection tubes with patient's name (last name, first name), date of birth, unique Identification (ID) number/specimen ID number, date of collection, time of collection, initial of collector (Note: Test subject to CLIA regulations and these requirements).</li> <li>• Specimens for transport to the GPHL must be placed in a sealed biohazard transport bag and placed in a sealed, decontaminated primary sterile container.</li> <li>• Physicians/providers will be notified of the result by the GPHL Technologist once completed.</li> </ul>
<b>Specimen Collection Kit Storage</b>	<p>Xpert CT/NG Vaginal/ Endocervical Specimen Collection Kits contains:</p> <ul style="list-style-type: none"> <li>• 1 individually-wrapped sterile large cleaning swab</li> <li>• 1 package containing 1 Xpert CT/NG Swab Transport Reagent tube (pink cap) and 1 individually-wrapped sterile collection swab.</li> <li>• Visual collection instructions.</li> </ul> <p>Store collection kit(s) at 2°C to 30°C.  Note: Do not use after the expiration date clearly printed on the outer box labels.</p>
<b>Test Submission and Turn-Around Time</b>	Specimens must be submitted before Thursday of each week. Batch testing is performed every Thursday and results are available within 24 hours.
<b>Specimen Requirements</b>	<p><b>Preferred specimens:</b></p> <ol style="list-style-type: none"> <li>1. Vaginal swab (Patient-collected)</li> <li>2. Endocervical swab (Clinician-collected)</li> </ol> <p>Note: Use only the Xpert CT/NG Vaginal/Endocervical Specimen Collection kit to collect these specimens.</p>

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<b>Specimen Collection Procedure</b>	<p><b>Patient-collected vaginal swab specimen collection:</b></p> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>• Do not expose swab to Xpert CT/NG Swab Transport Reagent prior to collection.</li><li>• Wash your hand before starting.</li></ul> <ol style="list-style-type: none"><li>1. In the privacy of the examination room or restroom, undress from the waist down. Comfortably position yourself to maintain balance during the collection procedure.</li><li>2. Open the outer peel pack (which contains the two-package kit), and identify the larger cleaning swab and discard.</li><li>3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample.</li><li>4. Open the collection swab wrapper by peeling open the top of the wrapper.</li><li>5. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.</li><li>6. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft.</li><li>7. <b>Carefully insert the swab into the vagina about two inches (5cm) inside the opening of the vagina and gently rotate the swab for 10 to 30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab.</b></li><li>8. Withdraw the swab carefully.</li><li>9. While holding the swab in the same hand, unscrew the cap from the Xpert CT/NG Swab Transport Reagent Tube.</li><li>10. Do not spill the contents of the tube. If the contents spilled, request for new kit.</li><li>11. Immediately place the specimen collection swab into the transport reagent tube.</li><li>12. Identify the score line on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the score line and discard the top position of the swab shaft, use care to avoid splashing contents.</li><li>13. Re-cap the swab transport reagent tube and tighten the cap securely.</li><li>14. Invert or gently shake the tube 3-4 times to elute materials from the swab. Avoid foaming.</li><li>15. Label the transport tube with sample identification, name, date of birth, patient number and collection date.</li><li>16. Return the tube as instructed by doctor, nurse or STD/HIV staff.</li></ol> <p><b>Clinician-collected endocervical swab specimen collection:</b></p> <p><b>Note:</b> Do not expose swab to Xpert CT/NG Swab Transport Reagent prior to collection.</p>
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<p><b>(Cont.) Specimen Collection Procedure</b></p>	<ol style="list-style-type: none"> <li>1. Open the Xpert CT/NG Vaginal/Endocervical Specimen collection kit.</li> <li>2. Before collecting the endocervical specimen with the Xpert CT/NG Vaginal /Endocervical Kit, remove excess mucus from the cervical os and surrounding mucosa using the larger individually wrapped cleaning swab. Partially peel open the larger cleaning swab wrapper and remove the swab. <b>Clean the cervical os and surrounding mucosa and then discard the swab.</b></li> </ol> <p>Note: If collecting multiple specimen, excess mucus need only be removed once.</p> <ol style="list-style-type: none"> <li>3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before proceeding.</li> <li>4. Open the collection swab wrapper by peeling open the top of the wrapper.</li> <li>5. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.</li> <li>6. Insert the collection swab clockwise for 10 to 30 seconds in the endocervical canal.</li> <li>7. <b>Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canals to ensure adequate sampling.</b></li> <li>8. Withdraw the swab carefully.</li> <li>9. While holding the swab in the same hand, unscrew the cap from the Xpert CT/NG Swab kit.</li> <li>10. Do not spill the content of the tube. If the contents of the tube are soiled, request a new collection kit.</li> <li>11. Identify the score line on the collection swab shaft. 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 contents.</li> <li>12. Re-cap the swab transport reagent tube and tighten the cap securely.</li> <li>13. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.</li> <li>14. Label the tube with sample identification, name, date of birth, chart number and collection date.</li> <li>15. Decontaminate and dispose of all specimen and reagent to biohazard bag.</li> </ol>
<p><b>Specimen Transport and Stability</b></p>	<p>Specimen swab must be <b>transferred immediately to CT/NG collection transport reagent tubes.</b></p> <p>Transport specimens to Guam Public Health Laboratory (GPHL) Central Laboratory at 2°C to 30°C.</p> <p>Swab samples in Xpert CT/NG Swab Transport Reagent tubes are stable up to 60 days at 2°C to 30°C before testing with Xpert CT/NG Assay.</p>

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<p><b>Specimen Rejection Criteria:</b></p>	<ul style="list-style-type: none"> <li>• Bloody specimens.</li> <li>• Insufficient specimen quantity to perform the test.</li> <li>• Specimen received in a container that is leaking.</li> <li>• Specimen not collected in Xpert CT/NG collection kit and/ or special handling instruction not followed.</li> <li>• Specimen submitted in expired transport kit.</li> <li>• Specimen in Xpert Transport kits collected &gt;60 days.</li> <li>• Specimen collected using calcium alginate, wooden shafts, cotton-tipped swabs.</li> <li>• Very mucoid specimens</li> <li>• Unlabeled specimens</li> <li>• Specimen label does not match the Submission form.</li> <li>• Incomplete patient information on the Submission form.</li> </ul>
<p><b>Warnings</b></p>	<p>With vaginal/endocervical specimens, assay interference may be observed in the presence of blood or mucin.          To avoid <b>INVALID</b> result proper collection in rotating the swab clockwise for 10 to 30 seconds in the endocervical canals and for the swab touches the wall of the vagina so the moisture is absorbed by the swab, to ensure adequate sample collected.</p>
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