



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

GUAM PUBLIC HEALTH LABORATORY GUIDELINES
CT/NG URINE SPECIMEN COLLECTION

Intended Use	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 gonorrhoea</i> (NG) in first-catch male and female urine specimens from symptomatic and asymptomatic individuals.
Specimen Submission Guidelines	<ul style="list-style-type: none"> • Submit specimens to GPHL Central Laboratory daily. • 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). • 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). • Specimens for transport to the GPHL must be placed in a sealed biohazard transport bag and placed in a sealed, decontaminated primary sterile container. • Physicians/providers will be notified of the result by the GPHL Technologist once completed.
Specimen Collection Kit & Storage	<p>Xpert CT/NG Urine Specimen Collection Kits contains:</p> <ul style="list-style-type: none"> • 1 tube of Xpert CT/NG Urine Transport Reagent (yellow cap) • 1 sterile disposable transfer pipette (individually wrapped) <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>
Test Submission and Turn-Around Time	Specimens must be submitted before Thursday of each week. Batch testing is performed every Thursday and results are available within 24 hours.
Specimen Requirements	<p>Preferred specimens: 7 mL first catch male/female urine specimen.</p> <p>Notes:</p> <ul style="list-style-type: none"> • First catch female urine specimen must be transferred to the Xpert CT/NG Urine Transport Reagent tube within 24 hours of collection. • First catch male urine specimen must be transferred to the Xpert CT/NG Urine Transport Reagent tube within 3 days of collection.

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<p>Specimen Transport and Stability</p>	<p>Unpreserved Urine (Not transferred to Xpert CT/NG Transport Reagent:</p> <ul style="list-style-type: none"> • First catch male/female urine specimen is stable at 4°C for 8 days. <p>Urine transferred to Xpert CT/NG Urine Transport Reagent tube:</p> <ul style="list-style-type: none"> • Female urine: stable for 45 days at 2°C- 15°C, 3 days at 2-30°C • Male urine: stable for 45 days at 2-30°C
<p>Specimen Collection Procedure</p>	<ol style="list-style-type: none"> 1. The patient should not have urinated for at least 1 hour prior to specimen collection. Note: Female patients should not cleanse the labial area prior to collecting the specimen. Male subject should not cleanse the tip of penis prior to collecting the specimen. 2. Direct patient to provide first-catch urine (approximately 20 to 50 ml of the initial urine stream) into urine collection cup free of any preservatives. <i>Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.</i> 3. Ensure that the urine is well mixed in the urine cup before transferring a sample to the Xpert CT/NG Urine Transport Reagent tube. 4. Open the packaging of a disposable transfer pipette provided in the kit. 5. Remove the cap from the Xpert CT/NG Urine Transport Reagent tube and from the urine collection cup. 6. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7 ml of urine into the Xpert CT/NG Urine Transport Reagent tube using the disposable transfer pipette. The correct volume of urine has been added when the level reaches the black dashed line on the label of the Xpert CT/NG Urine Transport Reagent tube. 7. Replace the cap on the Xpert CT/NG Urine Transport Reagent tube and tighten securely. 8. Invert the collection tube 3-4 times to ensure that the specimen and reagent are well mixed. 9. Recap the urine cup securely. 10. Label the transport tube with sample identification information, including name, date of birth and collection date. 11. Decontaminate and dispose of all specimen materials in Biohazard bag.
<p>Specimen Transport</p>	<p>Transport specimens to Guam Public Health Laboratory (GPHL) Central Laboratory at 2°C to 30°C.</p>
<p>Specimen Rejection Criteria:</p>	<ul style="list-style-type: none"> • Bloody urine specimens. • Mucoïd, icteric and specimens contaminated with Vagisil feminine powder. • Insufficient specimen quantity to perform the test. • Specimen received in a container that is leaking or spilled.

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	<ul style="list-style-type: none">• Specimen not collected in Xpert CT/NG collection kit and/ or special handling instruction not followed.• Specimen submitted in expired transport kit.• Specimen in Xpert Transport kits collected >45 days.• Specimen collected using calcium alginate, wooden shafts, and cotton-tipped swabs.• Unlabeled specimens• Specimen label does not match the Submission form.• Incomplete patient information on the Submission form.
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