
Lab Dept: Microbiology

Test Name: Trichomonas vaginalis PCR

General Information

Lab Order Codes: TVPCR

Synonyms: Trichomonas vaginalis by Nucleic Acid Amplification, Trichomonas DNA, TV DNA

CPT Codes: 87661 – Trichomonas vaginalis, amplified probe technique

Test Includes: Detection of *Trichomonas vaginalis* (TV) DNA by PCR (Real time Polymerase Chain Reaction) in first catch urine specimens and endocervical and vaginal swabs.

Logistics

Test Indications: Useful for the detection of *Trichomonas vaginalis* DNA in urine, vaginal, and endocervical swabs.

Lab Testing Sections: Microbiology, Mpls campus only

Phone Numbers: MIN Lab: 612-813-5806

STP Lab: 651-220-6555

Test Availability: Daily, 24 hours

Turnaround Time: 3 hours from receipt in Minneapolis lab

- Special Instructions:**
- This test is approved for endocervical swabs, vaginal swabs, and male and female urine utilizing special collection kits obtainable on patient units.
 - Obtain special collection supplies based on type of specimen to be collected. Supplies are stocked on patient units.
 - Patients should not have urinated for at least 1 hour prior to urine specimen collection.
 - The first 50mls of a voided urine is used because it has the highest concentration of organisms, midstream urine is unacceptable.
 - Specimen site, date/time of collection and collector's initials are required for processing.

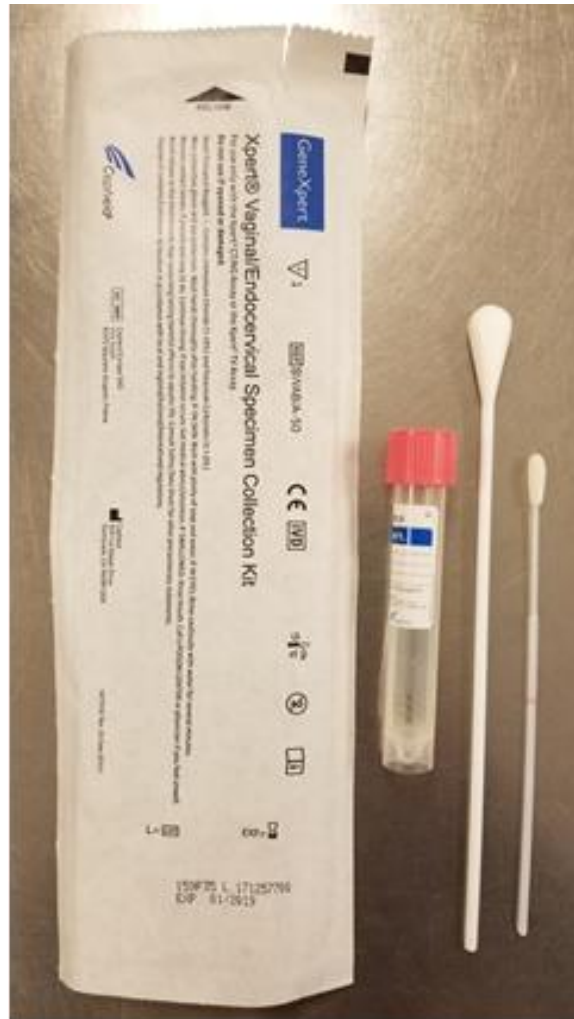
Specimen

Specimen Type: Endocervical swabs, vaginal swabs, the first 20-50ml of voided urine specimens

Container: Obtain one of the following (stocked on patient units)
Clinics: order in PeopleSoft

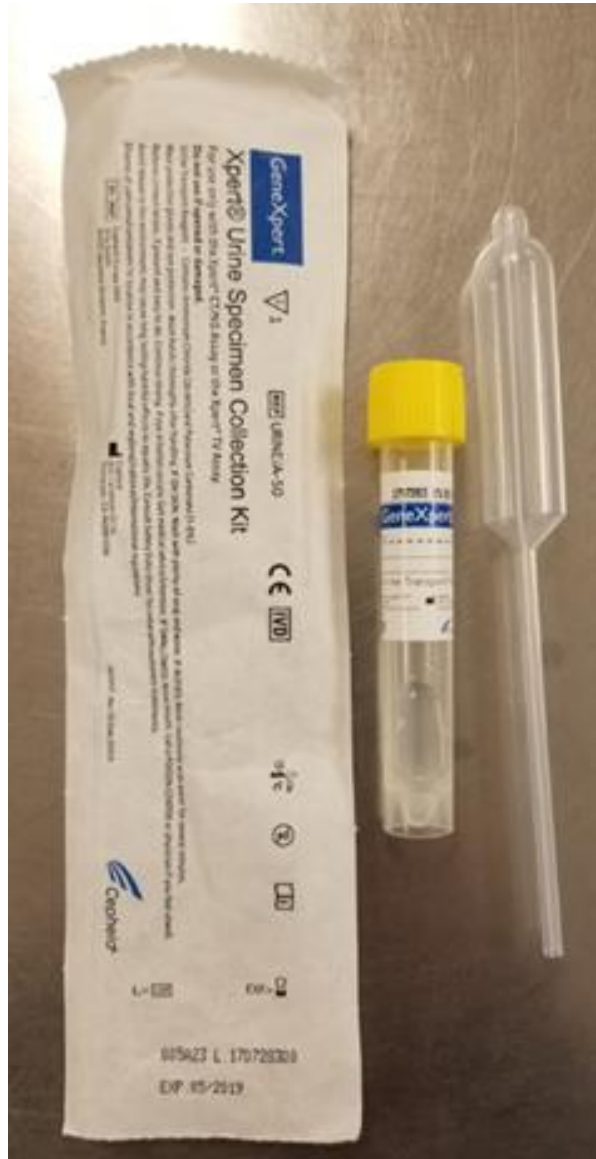
Vaginal and Endocervical:

Supply# 31654- Xpert Vaginal/Endocervical Specimen Collection Kit



Urine:

Standard sterile screw-cap urine cup
and
Supply #31655 -Xpert Urine Collection Kit



Volume:

20 ml(minimum)- 50 ml of urine or 1 swab

Collection:

Endocervical swab specimens –

Supply # 31654-Xpert Vaginal/Endocervical Specimen Collection Kit

1. Open the Xpert Vaginal/Endocervical Specimen collection kit.
 2. Use the large cleaning swab to remove excess mucus from endocervix and surrounding mucosa and discard.
 3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
 4. 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, use a new Xpert Vaginal/Endocervical Specimen Collection Kit.
 5. Insert collection swab into endocervical canal, and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.
 6. Immediately place collection swab into Xpert Swab Transport Reagent Tube (pink cap) provided in collection kit. Snap off swab at score line so swab fits into closed tube.
 7. Cap tube securely and invert the tube 3-4 times to elute material from the swab. Avoid foaming.
 8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.
 9. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.
- Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.
 - **Warning:** 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 are splashed in your eyes, immediately flush your eyes with water.

Vaginal Swab Specimen Collection

Supply # 31654-Xpert Vaginal/Endocervical Specimen Collection Kit

1. Open the Xpert Vaginal/Endocervical Specimen collection kit.
2. Discard the large cleaning swab.
3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
4. 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, use a new Xpert Vaginal/Endocervical Specimen Collection Kit.
5. Insert collection swab about 5 cm past introitus and rotate gently for 30 seconds.
6. Immediately place collection swab into Xpert Swab Transport Reagent Tube (pink cap) provided in collection kit. Snap off swab at score line so swab fits into closed tube.

7. Cap tube securely and invert the tube 3-4 times to elute material from the swab. Avoid foaming.
 8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.
 9. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.
- Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.
 - **Warning:** 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 are splashed in your eyes, immediately flush your eyes

Patient-collected Vaginal Swab Specimen Collection

Supply # 31654-Xpert Vaginal/Endocervical Specimen Collection Kit

Caution: Do NOT expose swab to Xpert Swab Transport Reagent prior to collection.

Steps For Patient To Perform

Wash your hands before starting.

1. Open the outer peel pack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
 2. 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.
 3. Open the collection swab wrapper by peeling open the top of the wrapper.
 4. 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.
 5. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.
 6. Carefully insert the swab into your vagina about 5 cm (two inches) 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.
 7. Withdraw the swab carefully and continue to hold it in your hand.
 8. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
 9. Do not spill the contents of the tube. If the contents of the tube are spilled, request a new collection kit.
- **Warning:** 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 are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the

contents of the tube are spilled, your test result may be invalidated. Do not take internally.

10. Immediately place the specimen collection swab into the transport reagent tube.
11. Identify the score line on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft.
12. Re-cap the swab transport reagent tube and tighten the cap securely.
13. Return the tube as instructed by your doctor, nurse, or care provider to complete the following steps.

Steps For Caregiver To Perform

14. Invert the tube 3-4 times to elute material from the swab. Avoid foaming.
15. Label the transport tube with the patient label including date of collection and specimen type.
16. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 3 days of collection.

Urine specimens – Screw-capped urine cup and Supply #31655 -Xpert Urine Collection Kit

- The patient should not have urinated for at least 1 hour prior to specimen collection.
 - Female patients should not cleanse the labial area prior to collecting the specimen.
 - Male patients should not cleanse the tip of the penis area prior to collecting specimen.
1. Direct patient to provide first-catch urine (approximately 20 to 50ml of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
 2. Wearing gloves swirl urine cup to mix well.
 3. Open the packaging of a disposable transfer pipette provided in the kit.
 4. Remove the cap from the Xpert GT/NG Urine Transport Reagent tube and from the urine collection cup.
 5. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7ml of urine to 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. Under or overfilling tube may affect assay performance.
 6. Replace the cap on the Xpert CT/NG Urine Transport Reagent tube and tighten securely.
 7. Invert the Xpert CT/NG Urine Transport reagent tube 3-4 times to ensure that the specimen and reagent are well mixed.
 8. Recap the urine cup securely.



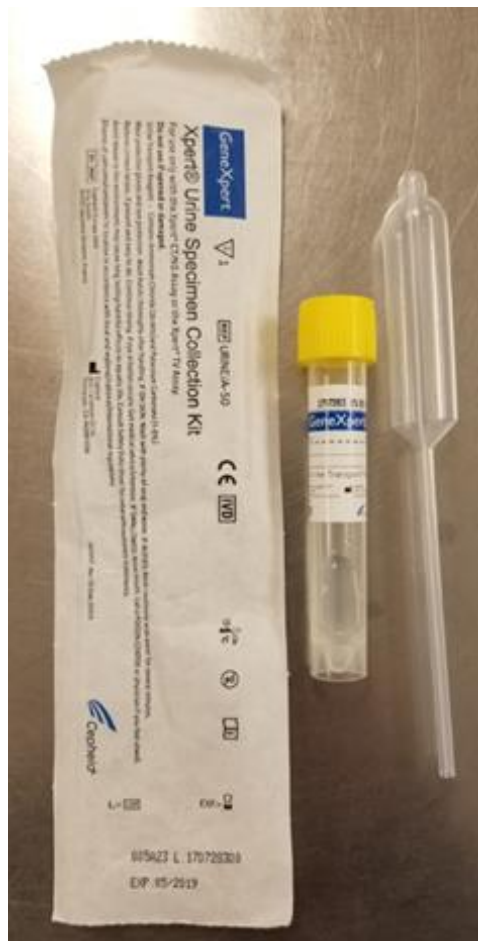
9. Label the transport tube with the patient label including the date of collection and collector's initials. Take care not to obscure the fill line on the transport tube.
10. Transport sample to the lab.

Transport/Storage:

Specimen	Transport/Storage Temperature	Specimen Stability
Urine, Unprocessed (neat) Female & Male	Refrigerated	4 Days
	Room temperature	4 Hours
Urine in Xpert Transport Tube, Female & Male	Refrigerated	28 Days
	Room temperature	14 days
Endocervical/Vaginal Swab in Xpert Transport Tube	Refrigerated or Room temperature	60 Days

Special Processing:

Lab Staff:



Neat Urine processing in the lab:

1. Process urine in the hood.
2. Put on clean gloves.
3. Place Sunquest large bar code test label aligned vertically on Xpert GT/NG Urine Transport Reagent tube with the patient's name and medical record number closest to the opening of the container. Take care not to obscure the fill line on the transport tube. Compare patient's name, medical record number, accession number and test information with the original specimen container label. Write your tech code on the bar code label.
4. Swirl urine cup to mix well.
5. Open the packaging of a disposable transfer pipette provided in the kit.
6. Remove the cap from the Xpert GT/NG Urine Transport Reagent tube and from the urine collection cup.
7. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7ml of urine to the Xpert CT/NG Urine Transport Reagent tube. 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. Under or overfilling tube may affect assay performance.
8. Replace the cap on the Xpert CT/NG Urine Transport Reagent tube and tighten securely
9. Invert the Xpert CT/NG Urine Transport reagent tube 3-4 times to ensure that the specimen and reagent are well mixed
10. Recap the urine cup securely
11. Change gloves to process another sample.

Note:

- Transfer one sample at a time with only one tube open at once.
- Previously aliquoted samples should not be returned to an original container to avoid the possibility of contamination.

Sample Rejection:

Large white swab included in Xpert Vaginal/Endocervical Specimen Collection Kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab. Specimen not submitted in appropriate transport container; improperly labeled specimen; midstream urine; cath urine, vaginal drainage, urethral swabs; insufficient volume; external contamination; specimens exceeding acceptable transport time. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range:

Negative

Unresolved results due to PCR inhibition are inconclusive. Consider repeat collection if clinically indicated.

Critical Values:

None

Limitations:

- The Xpert TV Assay has only been validated with the following specimen types, collected with the Xpert Vaginal/Endocervical Specimen Collection Kit or the Xpert Urine Specimen Collection Kit: Endocervical swabs, Patient-collected vaginal swabs, Female and male first-catch urine
- A negative test result does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, sample mix-up, or because the number of organisms in the sample is below the limit of detection of the test.
- Careful compliance with the instructions in this package insert and in the Xpert Vaginal/Endocervical Specimen Collection Kit and Xpert Urine Specimen Collection Kit package inserts is necessary to avoid erroneous results.
- The Xpert TV Assay has been validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
- Because the detection of *Trichomonas vaginalis* is dependent on the organism's DNA present in the sample, reliable results are dependent on proper sample collection, handling, and storage.
- *Trichomonas tenax* was found to cross-react with the Xpert TV Assay at levels above 1.0×10^2 cells/mL. *T. tenax* is a commensal of the oral cavity. See Xpert TV Analytical Specificity for details.
- With endocervical and patient-collected vaginal specimens, assay interference may be observed in the presence of blood (>60% v/v).
- As with many diagnostic tests, results from the Xpert TV Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- The patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated.
- The Xpert TV Assay has not been validated for use with vaginal swab specimens collected by patients at home. The patient collected vaginal swab specimen application is limited to healthcare facilities where support/counseling is available to explain procedures and precautions.
- The Xpert TV Assay provides qualitative results. No correlation can be drawn between the magnitude of the Ct value and the number of cells in an infected sample.
- The Xpert TV Assay should not be used for the evaluation of suspected sexual abuse or for other medico-legal indications.
- The predictive value of an assay depends on the prevalence of the disease in any particular population.
- Mutations or nucleotide polymorphisms in primer or probe binding regions may affect detection of new or unknown *Trichomonas vaginalis* variants resulting in a false negative result.
- Xpert TV Assay performance has not been evaluated in pregnant women, or in patients with a history of hysterectomy.
- Xpert TV Assay performance has not been evaluated in patients less than 18 years of age or older than 78 years of age. During the verification testing a total of 15 patients under the age of 18 had samples submitted for testing (10 urine and 5 vaginal). All sample results were in agreement with the comparator method, with the exception of one urine for which the arbitrated results agreed. Due to a low frequency of testing this population and availability of resources, a more thorough evaluation was not possible.

Methodology:

Real time Polymerase Chain reaction (PCR) performed on the Cepheid GeneXpert platform

References:

1. Xpert TV Package Insert 301-2887, Rev. C. Sunnyvale, CA: Cepheid; June 2019.
2. Trichomoniasis Statistics GA: CDC; [updated January 2017. Available from: <https://www.cdc.gov/std/trichomonas/stats.htm>.