Xpert® Trichomonas PCR Assay

**August 2019:** Rochester Regional Health Laboratories has validated nucleic acid amplification testing (NAAT) for the diagnosis of trichomoniasis in symptomatic and asymptomatic males and females. *Trichomonas vaginalis* is a common sexually transmitted infection that can infect both men and women. There are 7.4 million cases of trichomoniasis annually in the United States. The 2015 Sexually Transmitted Diseases Treatment Guidelines discuss the use of NAAT testing for trichomoniasis in various populations.

If testing for trichomoniasis is requested, Rochester Regional Health Laboratories will perform the Cepheid Xpert® TV Assay, a qualitative in vitro diagnostic test for the detection of *Trichomonas vaginalis* genomic DNA. This is PCR method that provides greater sensitivity than culture and wet mounts for the detection of *T. vaginalis* in first catch urine samples (from males and females) and endocervical and vaginal swab (self-collected or clinician-collected) specimens. Specific collection kits are required and may be requested via the usual requisitioning process. Detailed instructions on specimen collection requirements are provided below.

The new Cepheid Xpert® TV assay (Test code: TRPCR) will replace the following tests:
- *Trichomonas Culture* (TRCUL) collected using InPouch® TV kits
- Aptima Trichomonas Vaginalis Assay (currently sent to a Reference Laboratory)

**Test Information:**

<table>
<thead>
<tr>
<th><strong>Alternate Name:</strong></th>
<th>Trichomonas by PCR, TV PCR, Trichomonas NAAT</th>
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<tbody>
<tr>
<td><strong>Test Number:</strong></td>
<td>TRPCR, 10698</td>
</tr>
<tr>
<td><strong>Department:</strong></td>
<td>Microbiology</td>
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</table>

**SPECIMEN COLLECTION REQUIREMENTS**

| **Collection Containers:** | 1) Xpert® Vaginal/Endocervical Specimen Collection Kit  
2) Xpert® Urine Specimen Collection Kit  
** Unpreserved urine may be submitted in a sterile cup, but must be sent refrigerated to the laboratory or transferred to an Xpert® Urine Collection Kit within 4 hours of collection. *** |
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<tr>
<td><strong>Collection Notes:</strong></td>
<td>Maintain proper storage conditions during specimen transport to ensure the integrity of specimen. Vaginal swabs may be clinician-collected or self-collected in a clinical setting.</td>
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</table>
| **Transport Temperature / Specimen Stability:** | Unpreserved Urine: 2-8°C (4 days), 15-30°C (4 hours)  
Urine in Xpert® Urine Transport Kit: 2-30°C (14 days)  
Vaginal/Endocervical Swabs in Kit: 2-30°C (60 days) |
| **Specimen Volume:**     | Do not remove any liquid from the Xpert® Collection Kits.  
Do not over- or under-fill Xpert® Urine Specimen Collection Kit (fill to dotted line only). |

**Also Acceptable:** All other specimen types and transports will be rejected and a recollection requested.

**TECHNICAL SPECIFICATIONS**

<table>
<thead>
<tr>
<th><strong>Performed:</strong></th>
<th>Monday-Sunday</th>
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<tbody>
<tr>
<td><strong>Reported:</strong></td>
<td>Same Day</td>
</tr>
<tr>
<td><strong>Methodology:</strong></td>
<td>Polymerase Chain Reaction (PCR)</td>
</tr>
<tr>
<td><strong>CPT:</strong></td>
<td>87661</td>
</tr>
<tr>
<td><strong>LOINC:</strong></td>
<td>69937-1</td>
</tr>
<tr>
<td><strong>Reference Range:</strong></td>
<td>Not Detected</td>
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Questions regarding this testing should be directed to Suzanne E. Dale, PhD, D(ABMM), Director, Microbiology and Molecular Diagnostics, p: (585) 429-2360.
Detailed Collection Instructions for the Xpert® Trichomonas PCR

Urine Specimens

Female or Male First Catch Collection

Note: First catch urine must be transferred to an Xpert® Urine Transport Reagent tube within 4 hours of collection.

1. The patient should not have urinated for at least 1 hour prior to collecting the specimen. Female patients should not cleanse the labial area prior to specimen collection. Male patients should not cleanse the tip of the penis prior to specimen collection.
2. Patient should collect first 20-50 mL of the initial urine stream into a sterile, plastic, preservative-free container. Collection of larger volumes may result in specimen dilution that may reduce test sensitivity.
3. Ensure the urine is mixed well in the urine cup before transferring sample to the Xpert® Urine Transport Reagent tube.
4. Using the disposable transfer pipet in the Xpert® Urine Collection kit, transfer approximately 7 mL of urine into the transport tube. The correct amount of urine has been added when the level reaches the black dashed line on the label. Urine must be transferred to the transport tube within 4 hours of collection.
5. Replace the cap on the Xpert® Urine Transport Reagent tube, tighten securely and invert 3-4 times to mix.
6. Label the transport tube with appropriate patient information.

Xpert® Urine Specimen Collection Kit
**Endocervical Specimens**

Note: Samples must be collected using the flocked collection swab and transport tube in the Cepheid Xpert® Vaginal/Endocervical collection kit.

1. Remove excess mucus from the cervical os and surrounding mucosa using the large, individually wrapped cleaning swab. Discard this large swab once cervical mucus has been removed.
2. Insert the flocked specimen collection swab (white shaft flocked swab in the package labeled FLOQSwabs) into the endocervical canal.
3. Gently rotate the swab for 10-30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully.
5. While holding the swab in the same hand, unscrew the cap from the Xpert® Swab Transport Reagent tube. (Do not spill tube contents. If the contents of the tube are spilled, then use a new collection kit).
6. Immediately place the swab in the transport reagent tube.
7. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents
8. Re-cap the swab transport reagent tube and tighten cap securely. Invert or gently shake the tube 3-4 times to elute material from this swab. Avoid foaming.
9. Ensure the transport tube is labelled with the appropriate patient information.

**Self-Collected Vaginal Specimens**

Note: Self-collected vaginal samples must be obtained in a clinical setting. Providers should instruct patients on proper collection requirements as follows:

1. Open the outer peelpack (which contains the two package kit), 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. Open the collection swab wrapper and remove the swab taking care not to touch the tip or lay it down.
3. Hold the swab shaft across the scoreline.
4. Carefully insert the swab into the vagina about 2 inches past the opening of the vagina and gently rotate the swab for 10-30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab.
5. While holding the swab in the same hand, unscrew the pink cap from the Xpert® Swab Transport Reagent tube. (Do not spill the contents! If the contents of the tube are spilled, then use a new collection kit).
6. Immediately place the swab in the transport reagent tube.
7. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents. Wash with soap and water if exposed.
8. Re-cap the swab transport tube and tighten cap securely.
9. Return the tube as instructed by lab staff or provider for appropriate patient labeling.

**Xpert® Vaginal/Endocervical Specimen Collection Kit**