MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT
MML NEW ENGLAND
NOTIFICATION DATE: September 24, 2013
EFFECTIVE DATE: October 1, 2013

TRICHOMONAS VAGINALIS BY NUCLEIC ACID AMPLIFICATION
Test ID: TVRNA

USEFUL FOR: Detection of *Trichomonas vaginalis*

METHODOLOGY: Transcription Mediated Amplification

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS:
- This test is performed only on female patients
- Specific specimen source is required. Submit only 1 of the following specimens:

NOTE: Swab specimens must be collected using an APTIMA collection Unisex Swab (Supply T583) or APTIMA Collection Vaginal Swab (Supply T584). These swabs are contained in the APTIMA Collection Kit. Specimens sent with no swab, two swabs, or non Gen-Probe swabs will not be accepted. For endocervical specimens, cervical mucus should first be removed using the cleaning swab. The endocervical sample is then obtained using the sample swab. Specimens sent with the cleaning swab will not be accepted.

SPECIMEN TYPE: ENDOCERVIX
Container/Tube**:** APTIMA Collection Unisex Swab (Supply T583)
Specimen Volume: Swab

SPECIMEN TYPE: VAGINAL
Container/Tube: APTIMA Collection Vaginal Swab (Supply T584)
Specimen Volume: Swab

SPECIMEN TYPE: URINE
Container/Tube: APTIMA Urine Specimen Transport Tube (Supply T582)
Specimen Volume: 15-20 mL
1. Patients should not have urinated for at least 1 hour prior to specimen collection.
2. Patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.
3. Transfer 2 mLs of urine into the APTIMA Urine Specimen collection Kit within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the APTIMA urine transport tube.

SPECIMEN TYPE: THINPREP SPECIMEN (ENDOCERVIX)
Container/Tube**:** ThinPrep (also called PreservCyt) Collection Kit
Specimen Volume: 1 mL
Aliquot ThinPrep specimen for *Trichomonas* and/or *Chlamydia* and/or *Neisseria* testing before processing for Pap smear. For each specimen, use a new pair of clean gloves.
1. Vortex ThinPrep/PreservCyt vial 3 – 10 seconds. Within 1 minute of vortexing:
2. Transfer 1 mL of specimen into the APTIMA Specimen Transfer Tube (Supply T652) using a disposable transfer pipette.

3. Process only 1 ThinPrep and transfer tube set at a time.
4. Recap APTIMA Specimen Transfer Tube tightly and gently invert 3 times to mix.
5. Label ATIMA transfer tube with appropriate label.
6. Use remainder of ThinPrep specimen for Pap testing.

CAUTIONS:
The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of Trichomonas vaginalis.

To ensure proper endocervical sampling, excess mucus should first be removed.

Urine, vaginal swab, and PreservCyt solution liquid Pap specimen sampling is not designed to replace cervical exams and endocervical specimens for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.

This assay has only been approved by the FDA for the specimen types indicated. Performance with other specimen types has not been evaluated by the manufacturer. Reliable results are dependent on adequate specimen collection. Because the transport system used for this assay does not permit microscopic assessment of specimen adequacy, proper specimen collection techniques is necessary.

Therapeutic failure or success cannot be determined with the APTIMA *Trichomonas vaginalis* Assay since nucleic acid may persist following appropriate antimicrobial therapy

Results from the APTIMA *Trichomonas vaginalis* Assays should be interpreted in conjunction with other clinical data and symptoms.

A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, pre-analytical errors, technical errors, or target levels below the assay limit of detection. Furthermore, a negative results does not preclude a possible infection because the presence of *Trichomonas tenax* or *Pentatrichomonas hominis* in a specimen may affect the ability to detect *Trichomonas vaginalis* rRNA.

The APTIMA Trichomonas vaginalis assay has not been validated for use with vaginal swab specimens collected by patients. Performance of the vaginal swab specimen has not been evaluated in pregnant women or in women <14 years of age.

CPT CODE: 87798

DAY(S) SET UP: Monday – Friday, 1st shift **ANALYTIC TIME**: 1 day

NOTE: The following referral test code(s) will become obsolete effective October 31, 2013.

Test Name	Test ID	Referral Lab Code	Referral Lab
Trichomonas vaginalis RNA, Qualitative TMA, Females	ZW131	19550X	Quest Diagnostics Nichols Institute
Trichomonas vaginalis, NAA	ZW76	188052	Lab-Crop

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Rita M. Baird, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710