MAYO
Mayo Medical Laboratories
1-800-533-1710

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

TRICHOMONAS VAGINALIS, MISCELLANEOUS SITES, BY NUCLEIC ACID AMPLIFICATION

Test ID: MTRNA

USEFUL FOR: Detection of *Trichomonas vaginalis*

METHODOLOGY: Transcription Mediated Amplification

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS:

- This test is performed only on male 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). These swabs are contained in the APTIMA Collection Kit.

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 transport tube 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: URINE (FOLLOWING PROSTATIC MASSAGE)
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 void a small amount of urine prior to prostatic massage. Pre-massage urine can be discarded or submitted for other testing as applicable.
3. Patient then ceases voiding and a prostatic massage is performed by the urologist or other health care professional.
4. Collect post-massage urine into a sterile, plastic preservative-free container.
5. Transfer 2 mLs of post-massage urine specimen into the APTIMA urine specimen transport tube 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: URETHRA
Container/Tube**:** APTIMA Collection Unisex Swab (Supply T583)
Specimen Volume: Swab

1. Patient should not have urinated for at least 1 hour prior to collection.
2. With a rotating movement, insert swab (blue shaft) 2 to 4 cm into urethra
3. Once inserted, rotate swab gently at least 1 full rotation using sufficient pressure to ensure swab comes into contact with all urethral surfaces. Allow swab to remain inserted for 2 to 3 seconds.
4. Place swab in the APTIMA transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
5. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

CAUTIONS:
This assay is not FDA approved for specimens collected from male patients. However, the performance characteristics of this test have been established by Mayo Medical Laboratories in accordance with CLIA-guidelines**.**

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 are 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.

CPT CODE: 87798

DAY(S) SET UP: Monday – Saturday **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, Males	ZW131	90801	Quest Diagnostics Nichols Institute
Trichomonas vaginalis, NAA	ZW76	188052	Lab-Corp

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Kim J. Baker, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710