



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Molecular

Collected: 07/28/2023 08:47 Received: 07/28/2023 08:47

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Trichomonas vaginalis Testing by PCR, Specimen Source, First catch urine, WMRL. Row 2: Trichomonas vaginalis, Not detected, WMRL.

This test utilizes a Transcription Mediated Amplification (TMA) and Hybridization Protection Assay to amplify and detect specific ribosomal RNA sequences in Trichomonas vaginalis strains. The analytical sensitivity of this assay is 0.1 T. vaginalis organisms per milliliter. A "Not detected" result does not rule out infection.

Therapeutic success or failure cannot be determined by this assay because nucleic acids may persist following appropriate antimicrobial therapy.

This test has been cleared by the FDA for the detection of T. vaginalis organisms in clinical specimens, but this specimen type has not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test was performed using the Alinity m STI in vitro PCR assay (Abbott Molecular, Inc.). This test is approved for testing endocervical, vaginal, and first-catch urine. The use of this test for other specimens and/or sites has not been validated. The analytical sensitivity of this assay is 0.1 organisms per mL. This test is only intended for clinical monitoring of patients and should not be used for medical-legal purposes. A negative result does not exclude the possibility of infection with T. vaginalis.

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

Reported Date: 2023.07.28 8:48 TVPCR

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F12800003 Ordered By: KAJAL SITWALA, MD, PhD
WX0000003827 WX00000000002354
Printed D&T: 07/28/23 08:48

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
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