

CLINIC INFORMATION

Name: Assurance Pathology
 Laboratory
 Address: 2868 Acton Road
 Suite 207
 BIRMINGHAM, AL 35243
 Provider: Doctor Test

PATIENT INFORMATION

Name: TEST, TEST
 DOB: 11/10/1962
 Gender: F

SPECIMEN INFORMATION

Lab Accession Number: ASL-80104
 Date Collected: 1/19/2020
 Date Received by Lab: 1/20/2020
 Date Accessioned: 1/20/2020
 Date Reported: 1/20/2020
 Faxed to: 18777966185

Controls

Patient Extraction Control ¹	PASS
Endogenous Positive Control ¹	PASS
Pathogen Positive Control ²	PASS
Pathogen Negative Control ³	PASS

- (1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity
- (2) Positive control is synthetic inactive pathogen
- (3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template
- (4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff. Assay cutoff is represented by CFU (bacteria), PFU (viruses) or Copy Number (DNA)

Test Performed	Lab Result(4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
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SUMMARY Vaginitis Pathogens			Collection Type: Vaginal Swab
Chlamydia trachomatis	DETECTED - MEDIUM	1.00E+03	[1/20/2020 9:57 AM] C.trachomatis was detected by PCR and is a Notifiable Pathogen per ADPH. The required time to notify ADPH is within 5 days from receipt of report.
Prevotella bivia	DETECTED - HIGH	1.00E+06	
Ureaplasma urealyticum	DETECTED - HIGH	1.00E+06	

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Page: 1

This test detects the presence of pathogen and must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved.

Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.

Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive.

In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Test Performed	Lab Result(4) (Low/Medium/High)	DNA Copy Number	Comments
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Vaginitis Pathogens			
Test Performed	Lab Result(4) (Low/Medium/High)	DNA Copy Number	Comments
Atopobium vaginae	Not Detected	Not Detected	
Bacteroides fragilis	Not Detected	Not Detected	
BVAB-2	Not Detected	Not Detected	
Candida albicans	Not Detected	Not Detected	
Candida dubliniensis	Not Detected	Not Detected	
Candida glabrata	Not Detected	Not Detected	
Candida krusei	Not Detected	Not Detected	
Candida lusitanae	Not Detected	Not Detected	
Candida parapsilosis	Not Detected	Not Detected	
Candida tropicalis	Not Detected	Not Detected	
Chlamydia trachomatis	DETECTED - MEDIUM	1.00E+03	
Enterococcus spp.	Not Detected	Not Detected	
Escherichia coli	Not Detected	Not Detected	
Gardnerella vaginalis	Not Detected	Not Detected	
Haemophilus ducreyi	Not Detected	Not Detected	
HHV-1 (Herpes Simplex Virus)	Not Detected	Not Detected	
HHV-2 (Herpes Simplex Virus)	Not Detected	Not Detected	
Lactobacillus crispatus	Not Detected	Not Detected	
Lactobacillus gasseri	Not Detected	Not Detected	
Lactobacillus iners	Not Detected	Not Detected	
Lactobacillus jensenii	Not Detected	Not Detected	
Megasphaera Type 1	Not Detected	Not Detected	
Megasphaera Type 2	Not Detected	Not Detected	
Mobiluncus curtisii	Not Detected	Not Detected	
Mobiluncus mulieris	Not Detected	Not Detected	
Mycoplasma genitalium	Not Detected	Not Detected	
Mycoplasma hominis	Not Detected	Not Detected	
Neisseria gonorrhoeae	Not Detected	Not Detected	
Prevotella bivia	DETECTED - HIGH	1.00E+06	
Staphylococcus aureus	Not Detected	Not Detected	
Streptococcus agalactiae (GBS)	Not Detected	Not Detected	
Treponema pallidum	Not Detected	Not Detected	
Trichomonas vaginalis	Not Detected	Not Detected	
Ureaplasma urealyticum	DETECTED - HIGH	1.00E+06	

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Page: 2

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