

### CLINIC INFORMATION

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

### PATIENT INFORMATION

Name: Test, Copia  
 DOB: 10/28/2000 Sex: M  
 Phone: (999)999-9999  
 Address: 123 Test St BIRMINGHAM, AL 35243

### SPECIMEN INFORMATION

Lab Accession Number: ASL-12102110195  
 Date Collected: 12/09/21 1:47:00 PM  
 Date Accessioned: 12/10/2021  
 Date Reported: 12/10/2021  
 Faxed to: 18777966185

### Controls

Patient Extraction Control <sup>1</sup>	PASS
Endogenous Positive Control <sup>1</sup>	PASS
Pathogen Positive Control <sup>2</sup>	PASS
Pathogen Negative Control <sup>3</sup>	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.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
<b>SUMMARY Vaginitis Pathogens</b>		<b>Collection Type: Not Specified</b>	
Candida dubliniensis	DETECTED - HIGH	1.00E+05	
Candida tropicalis	DETECTED - LOW	1.00E+02	
Lactobacillus crispatus	DETECTED - MEDIUM	8.90E+02	
Lactobacillus gasseri	DETECTED - HIGH	8.37E+03	
Lactobacillus iners	DETECTED - LOW	1.83E+02	

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Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated.  
 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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<b>Vaginitis Pathogens</b>			
<b>Collection Type: Not Specified</b>			
Atopobium vaginae	Not Detected	Not Detected	
Bacteroides fragilis	Not Detected	Not Detected	
BVAB-2	Not Detected	Not Detected	
Candida albicans	Not Detected	Not Detected	
<b>Candida dubliniensis</b>	<b>DETECTED - HIGH</b>	<b>1.00E+05</b>	
Candida glabrata	Not Detected	Not Detected	
Candida krusei	Not Detected	Not Detected	
Candida lusitanae	Not Detected	Not Detected	
Candida parapsilosis	Not Detected	Not Detected	
<b>Candida tropicalis</b>	<b>DETECTED - LOW</b>	<b>1.00E+02</b>	
Chlamydia trachomatis	Not Detected	Not Detected	
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	
<b>Lactobacillus crispatus</b>	<b>DETECTED - MEDIUM</b>	<b>8.90E+02</b>	
<b>Lactobacillus gasseri</b>	<b>DETECTED - HIGH</b>	<b>8.37E+03</b>	
<b>Lactobacillus iners</b>	<b>DETECTED - LOW</b>	<b>1.83E+02</b>	
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	Not Detected	Not Detected	
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	

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Ureaplasma urealyticum	Not Detected	Not Detected	

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