

### CLINIC INFORMATION

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

### PATIENT INFORMATION

Name: TEST, TEST  
 DOB: 5/12/1965  
 Gender: M

### SPECIMEN INFORMATION

Lab Accession Number: ASL-80106  
 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 <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. 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 Sexually Transmitted Infection Pathogens			Collection Type: Urine
Chlamydia trachomatis	DETECTED - HIGH	1.00E+06	[1/20/2020 11:12 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.
Neisseria gonorrhoeae	DETECTED - MEDIUM	1.00E+03	[1/20/2020 11:12 AM] N. gonorrhoeae 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.

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Lab Director: Ty Thomas, MD

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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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Sexually Transmitted Infection Pathogens			
Atopobium vaginae	Not Detected	Not Detected	
<b>Chlamydia trachomatis</b>	<b>DETECTED - HIGH</b>	<b>1.00E+06</b>	
Gardnerella vaginalis	Not Detected	Not Detected	
HHV-1 (Herpes Simplex Virus)	Not Detected	Not Detected	
HHV-2 (Herpes Simplex Virus)	Not Detected	Not Detected	
<b>Neisseria gonorrhoeae</b>	<b>DETECTED - MEDIUM</b>	<b>1.00E+03</b>	
Treponema pallidum	Not Detected	Not Detected	
Trichomonas vaginalis	Not Detected	Not Detected	
Haemophilus ducreyi	Not Detected	Not Detected	

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