

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-12102110194
 Date Collected: 12/09/21 1:46:00 PM
 Date Accessioned: 12/10/2021
 Date Reported: 12/10/2021
 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.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
SUMMARY Sexually Transmitted Infection Pathogens		Collection Type: Urine clean catch	
<i>Atopobium vaginae</i>	DETECTED - HIGH	1.00E+06	
HHV-1 (Herpes Simplex Virus)	DETECTED - MEDIUM	1.00E+03	[12/10/21 2:47:40 PM] HHV-1 assay may also detect HHV-2 due to sequence homology; therefore, a positive result may be interpreted as HHV-1 or HHV-2 infection. The patient should be treated based on the clinical presentation of symptoms.

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Sexually Transmitted Infection Pathogens		Collection Type: Urine clean catch	
<i>Atopobium vaginae</i>	DETECTED - HIGH	1.00E+06	
<i>Chlamydia trachomatis</i>	Not Detected	Not Detected	
<i>Gardnerella vaginalis</i>	Not Detected	Not Detected	
<i>Haemophilus ducreyi</i>	Not Detected	Not Detected	
HHV-1 (Herpes Simplex Virus)	DETECTED - MEDIUM	1.00E+03	[12/10/21 2:47:40 PM] HHV-1 assay may also detect HHV-2 due to sequence homology; therefore, a positive result may be interpreted as HHV-1 or HHV-2 infection. The patient should be treated based on the clinical presentation of symptoms.
HHV-2 (Herpes Simplex Virus)	Not Detected	Not Detected	
<i>Neisseria gonorrhoeae</i>	Not Detected	Not Detected	
<i>Treponema pallidum</i>	Not Detected	Not Detected	
<i>Trichomonas vaginalis</i>	Not Detected	Not Detected	

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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.