

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
 Sex: M
 Phone: (405) 000-0000

SPECIMEN INFORMATION

Lab Accession Number: ASL-104624
 Date Collected: 4/27/2020
 Date Received by Lab: 4/28/2020
 Date Accessioned: 4/28/2020
 Date Reported: 4/28/2020
 Faxed to: 18777966185

Controls

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

Cytomegalovirus

Collection Type: Urine clean catch

Cytomegalovirus

DETECTED - HIGH

1.00E+04

Clinic Name: Assurance Pathology Laboratory

Patient name: TEST, TEST

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.