

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-80107
 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 Gastrointestinal Panel - Bacterial Pathogens			Collection Type: Rectal Swab
Shigella spp.	DETECTED - HIGH	1.00E+06	[1/20/2020 11:34 AM] Shigella 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.
SUMMARY Gastrointestinal Panel - Viral Pathogens			Collection Type: Rectal Swab
NO PCR TARGETS DETECTED	N/A	N/A	

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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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Gastrointestinal Panel - Bacterial Pathogens			
Campylobacter coli/jejuni/lari	Not Detected	Not Detected	
Clostridium difficile	Not Detected	Not Detected	[1/20/2020 11:34 AM] • Due to the high prevalence of asymptomatic carriage of toxigenic C. difficile in infants, testing for CDI should never be routinely recommended for neonates or infants 12 months of age or younger with diarrhea • C. difficile testing should not be routinely performed in children with diarrhea who are 1–2 years of age unless other infectious or noninfectious causes have been excluded • In children 2 years of age or older, C. difficile testing is recommended for patients with prolonged or worsening diarrhea and risk factors (eg, underlying inflammatory bowel disease or immunocompromising conditions) or relevant exposures (eg, contact with the healthcare system or recent antibiotics)
--- Toxin A (tcdA)	Not Detected	Not Detected	
--- Toxin B (tcdB)	Not Detected	Not Detected	
Escherichia coli (VTEC)	Not Detected	Not Detected	
--- O157	Not Detected	Not Detected	
--- stx1	Not Detected	Not Detected	
--- stx2	Not Detected	Not Detected	
Salmonella spp.	Not Detected	Not Detected	
Sapovirus	Not Detected	Not Detected	
Shigella spp.	DETECTED - HIGH	1.00E+06	
Yersinia enterocolitica	Not Detected	Not Detected	

Gastrointestinal Panel - Viral Pathogens			
Adenovirus	Not Detected	Not Detected	
Astrovirus	Not Detected	Not Detected	
Norovirus (GI/GII)	Not Detected	Not Detected	
Rotavirus	Not Detected	Not Detected	

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