CLIA ID: 05D2068632
LAB ID: GENEX-LPC

Patient **Jane Doe**
Accession ACN-17-04-00722

Medical Director **Dr. Haleh Farzanmehr M.D.,**
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13766 Alton Pkwy, Suite 144 Irvine, CA 92618

GPP-Luminex Report

PATIENT

Name	**Jane Doe**
DOB	**Feb 12, 1970** Age**(47)**
Gender	**Female**
MRN	

Diagnosis Codes
R19.4 Change in bowel habit
R19.7

ACCESSION

Accession	ACN-17-04-00722
Report Date	Apr 02, 2017 21:22
Report Version	Final Report

Specimen Used
Specimen : Fresh Stool
Specimen ID: 591
Collected: Apr 01, 2017
Received: Apr 02, 2017

PROVIDER

Name	Doctor Doctor
Phone	
Fax	

Lab Results

Test	Result	Note
Bacterial pathogens		
Campylobacter	Negative	
Clostridium difficile (C. difficile) toxin A/B	**Positive**	Comment: Three samples were processed from two vials submitted, along with two negative and three positive controls. The results were positive for Clostridium difficile toxin A/B in all three samples. (Raw data are attached for confirmation). As with any other infectious molecular testing, confirmed positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. This test is a qualitative test and does not provide the quantitative value of detected organism present in the sample. The xTAG GPP is not intended to monitor or guide treatment for C.difficile infections.
Enterotoxigenic E. coli	Negative	
Escherichia coli (E. coli) O157	Negative	
Salmonella	Negative	
Shiga-like Toxin producing E. col	Negative	
Shigella	Negative	
Vibrio cholerae (V. cholerae) cholera toxin gene (ctx)	Negative	
Parasites		
Cryptosporidium	Negative	
Entamoeba histolytica	Negative	
Giardia	Negative	
Viral pathogens		
Adenovirus40/41	Negative	
Norovirus GI/GII	Negative	
Rotavirus	Negative	

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Additional Notes

xTAG GPP is not intended to monitor or guide treatment for C. difficile infections. This test is a qualitative test and does not provide the quantitative value of detected organism present. This test is not validated for E.Histolytica and therefore the results for this pathogen should be considered research use only. All results should be used and interpreted in the context of a full clinical evaluation as an aid in the diagnosis of gastrointestinal infection. This test has been validated at Genex Laboratory Professional Corporation according to guidelines.

Notes

Comment: Three samples were processed from two vials submitted, along with two negative and three positive controls. The results were positive for Clostridium difficile toxin A/B in all three samples. (Raw data are attached for confirmation). As with any other infectious molecular testing, confirmed positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. This test is a qualitative test and does not provide the quantitative value of detected organism present in the sample. The xTAG GPP is not intended to monitor or guide treatment for C.difficile infections.

Methodology & Limitations

The Gastrointestinal Pathogen Panel incorporates multiplex reverse-transcriptase polymerase chain reaction (RT-PCR) with Luminex's proprietary universal tag sorting system on the Luminex platform.

For each sample, extracted nucleic acid is amplified in a single multiplex RT-PCR/ PCR reaction, then added to a hybridization/detection reaction and finally a signal or median fluorescence intensity (MFI) is generated for each bead population. These fluorescence values are analyzed to establish the presence or absence of bacterial, viral or parasitic targets and/or controls in each sample against an analyte-specific cut-off. A single multiplex reaction identifies all targets. The Data is then analyzed to provide a report summarizing which pathogens are present.

The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Confirmed positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Negative xTAGÂ® Gastrointestinal Pathogen Panel results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

References

1. Application of Luminex Gastrointestinal Pathogen Panel to human stool samples from CÃ´te d'Ivoire. J Infect Dev Ctries. 2015 Aug 29;9(8):884-9. doi: 10.3855/jidc.6460. PMID:26322882
2. A comparison of Luminex xTAGÂ® Gastrointestinal Pathogen Panel (xTAG GPP) and routine tests for the detection of enteropathogens circulating in Southern China. Diagn Microbiol Infect Dis. 2015 Nov;83(3):325-30. doi: 10.1016/j.diagmicrobio.2015.07.024. Epub 2015 Jul 30. PMID:26318973
3. Can the Luminex xTAG gastrointestinal pathogen panel really save money? J Infect. 2015 Oct;71(4):498-9. doi: 10.1016/j.jinf.2015.06.008. Epub 2015 Jun 21. PMID:26102456
4. Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis.Clin Lab Med. 2015 Jun;35(2):461-86. doi: 10.1016/j.cll.2015.02.006. Epub 2015 Apr 4. PMID:26004652
5. A cost benefit analysis of the Luminex xTAG Gastrointestinal Pathogen Panel for detection of infectious gastroenteritis in hospitalised patients. J Infect. 2015 May;70(5):504-11. doi: 10.1016/j.jinf.2014.11.009. Epub 2014 Nov 29.PMID:25449904
6. Luminex(Â®) multiplex bead suspension arrays for the detection and serotyping of Salmonella spp. Methods Mol Biol. 2015;1225:1-27. doi: 10.1007/978-1-4939-1625-2_1. PMID:25253245
7. Comparative evaluation of two commercial multiplex panels for detection of gastrointestinal pathogens by use of clinical stool specimens. J Clin Microbiol. 2014 Oct;52(10):3667-73. doi: 10.1128/JCM.01637-14. Epub 2014 Aug 6.
8. Evaluation of a multiplex PCR assay for simultaneous detection of bacterial and viral enteropathogens in stool samples of paediatric patients. Diagn Microbiol Infect Dis. 2014 Jun;79(2):149-54. doi: 10.1016/j.diagmicrobio.2014.02.004. Epub 2014 Feb 22.
9. Evaluation of Luminex xTAG Gastrointestinal Pathogen Analyte-Specific Reagents for High-Throughput, Simultaneous Detection of Bacteria, Viruses, and Parasites of Clinical and Public Health Importance. J Clin Microbiol. 2013 Sep; 51(9): 3018?3024.doi: 10.1128/JCM.00896-13 PMCID: PMC3754681

Electronically Signed By:

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Haleh Farzanmehr,MD

Moleuclar Genetic Pathologist

On Apr 02, 2017 21:22:56