



New Molecular Enteric Pathogen Panel Test for Detecting Common Viral and Bacterial Agents of Diarrhea

Note: This assay cannot be used as a test of cure.

Please order the Sal, Shig, Enterohemorrhagic Escherichia coli (EHEC) Culture.

Effective October 5, 2015, the Microbiology department of Laboratory Alliance of CNY is pleased to announce the availability of a non-cultural, molecular-based, multiplex assay for detecting the most common causes of bacterial and viral diarrhea. The new Enteric Pathogen Panel test will be replacing our conventional culture and EIA methods. The Enteric Pathogen Panel test is considerably more sensitive than the previously used methods and allows for a much shorter time to final result.

Clinical Significance

Acute diarrhea is an extremely common infectious disease second in incidence only to upper respiratory tract infections and, as such, represents a significant worldwide healthcare problem. The World Health Organization estimates that diarrhea causes or is a major contributor to approximately 25% of all post-neonatal childhood deaths.¹ In the United States, the Centers for Disease Control and Prevention estimates that 1.4 episodes of diarrhea occur per person per year² while the incidence in third world countries is considerably higher. Although most of the common bacterial and viral agents responsible for diarrheal infection cause self-limiting, non-life-threatening disease, some enteric infections may require therapeutic intervention. More serious illness may require hospitalization that could result in death.

Since clinical treatment decisions are often based on determining the identity of the infecting pathogen or the presence of a virulence gene marker, it is important to generate laboratory test results quickly and reliably. The Enteric Pathogen Panel test uses a reverse transcription, polymerase chain reaction (i.e., PCR) technology coupled with a nanoparticle-mediated microarray hybridization to detect the presence of specific nucleic acid gene sequences for the common viruses and bacteria responsible for diarrheal disease. The microarray assay detects the presence of the following enteric bacteria: *Campylobacter* group (consisting of *Campylobacter jejuni*, *Campylobacter coli*, and *Campylobacter lari*), *Salmonella* species, *Shigella* species (consisting of *Shigella dysenteriae*, *Shigella boydii*, *Shigella sonnei*, and *Shigella flexneri*), *Vibrio*

group (consisting of *Vibrio cholerae* and *Vibrio parahaemolyticus*), and *Yersinia enterocolitica*. The Enteric Pathogen Panel test also screens for the virulence gene markers for Shiga toxin 1 and Shiga toxin 2 that are responsible for hemorrhagic *Escherichia coli* disease. In addition, the new molecular-based assay also detects norovirus GI/GII and rotavirus A, the two most common agents of viral enteritis. The availability of this new molecular-based Enteric Pathogen Panel test will allow for the detection of a larger number of the more common viral and bacterial causes of enteric disease with increased sensitivity and a much shorter time to final result.

IMPORTANT: Because the Enteric Pathogen Panel test is a molecular-based assay, it cannot be used for the followup evaluation of patients for Test of Cure (TOC) because residual nucleic acids may persist in the stool specimen that may give false-positive results. In such cases, health care providers must notify the Microbiology laboratory when a TOC stool specimen is being submitted for analysis so that conventional cultural and EIA methods can be used. Please do not hesitate to contact the Microbiology Laboratory at 315-410-7067 if additional information is needed.

Test:	Enteric Pathogens By PCR
Test Code:	EPPCR
Method:	Polymerase Chain Reaction (PCR) and Nanoparticle-Mediated Microarray
Specimen Requirement:	Stool in Cary Blair type transport media preferred, unpreserved stool also acceptable
Unacceptable Specimens:	Swab specimens, frozen specimens, or unpreserved over 24 hours
Storage and Transport:	Unpreserved 24 hr refrigerated, preserved in Cary Blair 48 hr refrigerated
Schedule of Testing:	Monday – Sunday
CPT4 Code:	87506
Billing Code:	3010450
Reference Interval:	Negative for the following: 1. enteric bacteria: <i>Campylobacter</i> group (consisting of <i>Campylobacter jejuni</i> , <i>Campylobacter coli</i> , and <i>Campylobacter lari</i>), <i>Salmonella</i> species, <i>Shigella</i> species (consisting of <i>Shigella dysenteriae</i> , <i>Shigella boydii</i> , <i>Shigella sonnei</i> , and <i>Shigella flexneri</i>), <i>Vibrio</i> group (consisting of <i>Vibrio cholerae</i> and <i>Vibrio parahaemolyticus</i>), and <i>Yersinia enterocolitica</i> , 2. virulence gene markers: Shiga toxin 1 and Shiga toxin 2 that are responsible for hemorrhagic <i>Escherichia coli</i> disease, and 3. Viral enteritis: norovirus GI/GII and rotavirus A.



For Test of Cure (TOC) order:

Test:	Sal, Shig, EHEC Culture. Alternate name: Salmonella, Shigella, EHEC Culture
Test Code:	EPSSE
Method:	Culture, ELISA
Specimen Requirement:	Stool in Cary Blair type transport media, rectal swab using ESwab collector, unpreserved stool in sterile leak-proof container
Unacceptable Specimens:	Frozen specimens, or unpreserved over 24 hours room temp or over 48 hours refrigerated
Storage and Transport:	24 hr room temp, 48 hr refrigerated
Schedule of Testing:	Monday - Sunday
CPT4 Code:	87045,87427 x2
Billing Code:	3010451
Reference Interval:	No Salmonella or Shigella isolated. No Shiga Like (VERO) Toxin detected by immunoassay.

References

1. Bryce J, Boschi-Pinto C, Shibuya K, et al. 2005. WHO estimates of the causes of death in children. *Lancet*. 365:1147-1152.
2. Herikstad H, Yang S, Van Gilder TJ, et al. 2002. A population-based estimate of the burden of diarrhoeal illness in the United States: FoodNet, 1996-7. *Epidemiol. Infect.* 129:9-17.