

Enteric Pathogens, Isolation and Identification

Use

For evaluation of stool samples from individuals exhibiting signs and symptoms of infectious colitis or gastroenteritis. Testing includes potential identification of *Salmonella* spp., *Shigella* spp., *Escherichia coli* O157, non-O157 shiga-like toxin-producing *E. coli* (STEC), enterotoxigenic *E. coli* (EPEC), *Campylobacter* spp., *Yersinia* spp., *Vibrio* spp., *Aeromonas* spp., *Plesiomonas shigelloides*, Adenovirus, Norovirus, Rotavirus A, *Cryptosporidium* spp., and *Giardia lamblia*.

Refer to *Enteric Pathogen, Isolate Identification* test to submit pure *isolates* for pathogen identification.

Clinical Significance

The CDC estimates that each year 48 million Americans develop foodborne illnesses that result in 128,000 hospitalizations and 3000 deaths and costs the U. S. economy an estimated 8.4 billion dollars in lost productivity. Considering the large impact on public health, it is critically important that these infections be identified, and the isolates characterized as quickly as possible. Prompt identification of the causal agent can not only aid in diagnosis and implementation of individual patient management plans, but also ultimately reduce the number of infections in outbreak situations.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services [website](#).

Methodology

Specimens are initially screened using a PCR amplification assay (xTAG® Gastrointestinal Pathogen Panel (GPP)) that detects multiple bacterial, viral and protozoan enteric pathogens. All specimens negative by GPP are subject to limited culture to screen for potential common enteric pathogens not detected by GPP. Attempts are made to confirm GPP-positive specimens by routine culture and biochemical testing, and mass spectroscopy, as necessary; however, confirmation of certain GPP-positive results (e.g., ETEC, rotavirus, Norovirus, Adenovirus, *Cryptosporidium*, *Giardia*) will be beyond the testing capabilities of the OSDH PHL and may require specimen referral by the submitter, as clinically appropriate. [PulseNet-reportable organisms](#), as defined by the CDC, are subjected to whole genome sequencing.

Specimen Type

Solid or liquid feces in Cary-Blair Transport Media (enteric kit)

Minimum Volume/Size

Solid, 2 grams; Liquid, 5-10 mL

Collection Instructions

Stool specimens should be collected according to the submitting institution's standard procedure. Enteric pathogen detection depends on the collection of high-quality specimens, which involves the transfer of stool to transport media as soon as possible after collection, rapid transport to the testing laboratory and appropriate storage before testing. Training in specimen collection/processing is highly recommended due to the importance of specimen quality.

- See [Guidance for Provider Processing of Stool Samples](#) (Specimen-specific Guidance)
- See [Guidance for Patients Collecting Stool Samples](#) (Specimen-specific Guidance)

Note: GPP results will not be reported for specimens received > 48 hours from time of collection. Specimens received > 96 hours (> 4 days) from time of collection will be tested for surveillance purposes only (results not reported to submitter).

Common Causes for Rejection

- Raw stool (not in Cary-Blair Transport Media)
- Rectal swabs
- > 7 days from date of collection
- Frozen specimen

Shipping

Store and ship at refrigerated (2-8°C) as soon as possible. Place each specimen in an individually sealed bag with sufficient absorbent material to absorb the contents of the vial in case of a spill in transit.

Turn-around Time

A preliminary report based on GPP results is issued within 4 working days from receipt, followed by a final report upon completion of other testing; usually within 21 working days from specimen receipt.

Reference Range

Pathogen Not Detected

Reportable Results

- Pathogen Detected (Genus or Genus/species/targeted genes/serotype, as relevant)
- Evidence of (Genus or Genus/species/targeted genes/serotype, as relevant), unable to isolate
- Pathogen Not Detected

Note: *Whole genome sequencing is not validated for clinical reporting.*

Interpretation

GPP results alone are considered presumptive and confirmation by other laboratory methods is recommended. Laboratory confirmation of pathogens in fecal specimens from symptomatic individuals is evidence of fecal-oral contamination via food, water, fomites or the hands. Detection of stx1 and/or stx2 in *E. coli* isolates indicates the presence of an STEC strain. Non-O157 STEC strains that produce only stx2 are more often associated with HUS than strains that produce only stx1 or both stx1 and stx2.

Limitations/Interferences

Negative results do not exclude the presence of enteric pathogens; numbers of organisms may be too low to allow for detection. Test results may be affected by improper specimen collection or transport, presence of inhibitors, and technical errors. Positive results do not rule out co-infection with other potentially clinically relevant pathogens not detected by this test. Specimen type is not suitable for microscopic parasite examination.

CPT Code

CPT codes will vary depending on the organism identified and methods used. GPP: 87801; Culture: 87045, 87046 (x3), 87077

Notes

These are laboratory-developed tests; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. These tests have not been cleared or approved by the U.S. Food and Drug Administration. Results of the whole genome sequencing are for epidemiological purposes only and are not reported to the submitter or patient.