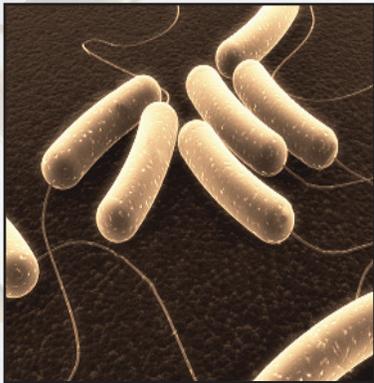


Available for patients of all ages...

INTESTINAL PATHOGEN DETECTION

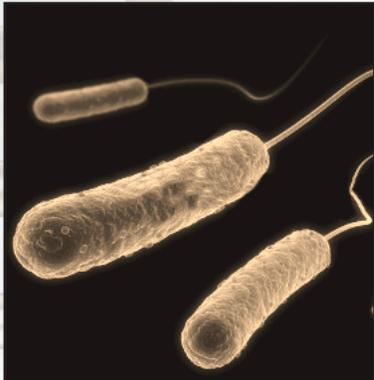


Molecular detection of intestinal pathogens is available utilizing the **OneSwab**[®] specimen collection platform. The **OneSwab**[®] platform enables non-invasive specimen collection that provides sufficient sample quantities obtained from loose stool. Testing is now available for 12 common intestinal pathogens.

- No refrigeration required before or after collection
- Test additions available for up to 30 days after collection
- Specimen viability up to five (5) days after collection

Tests currently available on the **OneSwab**[®] by Real-Time PCR

- 365 *Campylobacter jejuni*
- 162 *Clostridium difficile* (Toxins A and B)
- 371 *Cryptosporidium parvum*
- 372 *Entamoeba histolytica*
- 168 *Escherichia coli* (O157 and Shiga toxin) by Real-Time PCR
- 370 *Giardia intestinalis*
- 310 *Helicobacter pylori*
- 274 Human Rotavirus A
- 158 *Listeria monocytogenes*
- 272 Norwalk Virus
- 160 Salmonella
- 161 Shigella



Convenient specimen collection with **OneSwab**[®]

Loose stool specimen:

- Step 1.** Utilize the swab provided to obtain a sample of loose stool and insert into the vial.
- Step 2.** Snap off the shaft to fit completely in the vial.
- Step 3.** To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with patient information.



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IH0017 upd: 9/2023

365 *Campylobacter jejuni*

Clinical Significance: *Campylobacter jejuni* is a species of curved, rod-shaped, non-spore forming, Gram-negative microaerophilic, bacteria commonly found in animal feces. *C. jejuni* is the most commonly reported bacterial cause of food borne infection in the United States with an estimated 2.1 to 2.4 million cases of human campylobacteriosis occurring each year with illnesses ranging from loose stools to dysentery. *Campylobacter jejuni* results in enteritis, which is characterized by abdominal pain, cramping, diarrhea, fever, and malaise within two to five days after exposure to the organism. The diarrhea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts one week. Food poisoning caused by *Campylobacter* species in persons with compromised immune systems may spread to the bloodstream and cause a serious life-threatening infection.

162 *Clostridium difficile* (Toxins A and B)

Clinical Significance: *Clostridium difficile* is an anaerobic Gram-positive spore forming bacteria. *C. difficile* is the most serious cause of antibiotic-associated diarrhea (AAD) and can lead to pseudomembranous colitis, a severe infection of the colon, often resulting from eradication of the normal gut flora by antibiotics. *C. difficile* is frequently found in hospitals, nursing homes, extended care facilities, and nurseries for newborn infants. Found in feces, *C. difficile* is spread by ingestion of the spores from the environment which lies dormant in the body until antibiotics disrupt the normal bacteria. Then the spore becomes active and produces the active *C. difficile* bacteria. Infection can occur when someone touches items or surfaces that are contaminated with feces and then touch their mouth or mucous membranes. Healthcare workers can spread the bacteria to other patients or contaminate surfaces through hand contact. Symptoms of infection may include watery diarrhea (at least three bowel movements per day for two or more days), fever, loss of appetite, nausea, and abdominal pain/tenderness.

371 *Cryptosporidium parvum*

Clinical Significance: *Cryptosporidium parvum* is a microscopic parasite that is one of the most prevalent species that causes the diarrheal disease cryptosporidiosis. The parasite is protected by an outer shell that allows it to survive outside of the body for long periods of time and makes it very tolerant to chlorine disinfectant. The parasite is spread by ingesting contaminated water and occasionally through food sources. Outbreaks have been associated with recreational water parks, community swimming pools, and child care centers. Patients typically present with acute, watery, non-bloody diarrhea, abdominal cramps, and low-grade fever.

372 *Entamoeba histolytica*

Clinical Significance: *Entamoeba histolytica* is an anaerobic protozoan and the causative agent of amebiasis. Transmission occurs through ingestion of the infective cystic form via the fecal-oral route and is commonly associated with fecal contamination of food and water supplies. Although many infections are asymptomatic, when symptoms do occur they can vary from mild gastrointestinal distress to dysentery. Invasive extraintestinal infection can occur and may result in the abscess of hepatic, pleuropulmonary, cardiac, cerebral, renal, genitourinary, and cutaneous sites. Diagnosis can be complicated because of the similar appearance of *E. histolytica* to other parasites when visualized under a microscope.

168 *Escherichia coli* (O157 and Shiga toxin)

Clinical Significance: *Escherichia coli* (*E. coli*) is the head of the large bacterial family, *Enterobacteriaceae*, the enteric bacteria, which are facultatively anaerobic Gram-negative rods that live in the intestinal. *E. coli* serogroup O157 is largely found in cattle, but has also been isolated from sheep, goats, pigs, and turkeys. It also exists as an enterohemorrhagic pathogen in the human intestinal tract. O157 is typically contracted orally through consumption of under-cooked contaminated meat, as well as unpasteurized milk or cider, fresh vegetables, contaminated water sources, and infected persons. Symptoms of infection present as watery diarrhea, but may progress to bloody diarrhea (hemorrhagic colitis), kidney failure, anemia due to blood loss, and low platelet count (hemolytic uremic syndrome). Children and the elderly are more susceptible to the severe symptoms of infection. Real-Time PCR is a rapid and accurate method for identifying *Escherichia coli* (O157 and Shiga toxin) in loose stool swab samples.

370 *Giardia intestinalis*

Clinical significance: *Giardia intestinalis* is a microscopic, anaerobic, flagellated protozoan parasite that is the causative agent of the diarrheal illness known as giardiasis. Transmission occurs through contact with contaminated water, soil or food. The majority of infections are thought to originate from person-to-person through poor hygiene, travel in underdeveloped nations or contact with surfaces that have been contaminated with feces from infected humans or animals. Day care centers and contaminated lakes and swimming holes also serve as ready sources of infection. Because *Giardia* cysts can be excreted intermittently, it is important to use a highly sensitive and specific assay for detection. In this assay, DNA is extracted from the specimen and subjected to Real-Time PCR amplification.

310 *Helicobacter pylori*

Clinical significance: *Helicobacter pylori* resides within the mucous membrane of the gastric epithelium and occasionally the duodenal or esophageal mucosal epithelium as well. It can lead to inflammation of the mucosa and, if untreated, chronic superficial gastritis. This inflammation process has been linked to peptic ulceration and gastric cancer. *Helicobacter pylori* is now established as the most common cause of gastritis. In this procedure, we perform a PCR assay for the sensitive and specific detection of *H. pylori*. The assay is based on the DNA sequence of a species-specific protein antigen, which is present in all strains of *H. pylori* tested. The specificity of this assay and the fidelity of the chosen region was verified by the lack of cross-reactivity with other enteric bacteria (whose coding sequence did not hybridize to the DNA of numerous enteric bacteria). In this assay, DNA is extracted from the specimen and subjected to PCR amplification

274 Human Rotavirus A

Clinical Significance: Human Rotavirus is a double stranded RNA virus. Rotavirus is the single most important cause of severe gastroenteritis in infants and young children. Every year in the United States, there are an estimated 55,000 to 70,000 hospitalizations and 205,000 to 272,000 emergency department visits due to rotavirus gastroenteritis among children under the age of five. Of the seven species of Human Rotavirus (denoted A through G), species HRV A is the most common. Infection is usually through fecal-oral transmission. The incubation period is around two days followed by three to eight days of sickness. The severity of rotavirus infection ranges from asymptomatic infection to severe gastroenteritis.

158 *Listeria monocytogenes*

Clinical Significance: *Listeria monocytogenes* is a Gram-positive, facultative intracellular parasite and is the causative agent of listeriosis. *L. monocytogenes* infections can cause septicemia, encephalitis, meningitis, and gastroenteritis. The bacteria is capable of entering most cells. Transmission occurs through contaminated foods including raw meat and fish, unpasteurized dairy products, and uncooked vegetables. *L. monocytogenes* has also been found in processed foods that have become contaminated after processing such as soft cheeses, deli cold cuts, sliced or grated cheese, and ice cream. The infective dose for oral transmission is unknown but is thought to depend on the strain and the susceptibility of the person. Healthy people seem to be able to eat most *Listeria*-contaminated foods without clinical signs; however, in susceptible persons, the infective dose is probably fewer than 1,000 organisms. The incubation period in susceptible adults is 3 to 70 days, with the median incubation period estimated to be 3 weeks. *L. monocytogenes* is relatively resistant to freezing, drying and heat and can proliferate at refrigeration temperatures on contaminated foods.

272 Norwalk Virus

Clinical Significance: Norwalk Virus is a small, round, structured RNA virus of the Caliciviridae taxonomic family. This virus causes approximately 90% of epidemic non-bacterial outbreaks of gastroenteritis around the world, and may be responsible for 50% of all food-borne outbreaks of gastroenteritis in the United States. The virus is transmitted by food or water contaminated with feces and by person-to-person contact. Outbreaks of infection often occur in closed or semi-closed communities, such as long-term care facilities, hospitals, prisons, dormitories, and cruise ships where once the virus has been introduced, the infection spreads very rapidly. Usual symptoms include nausea, vomiting, diarrhea, and abdominal pain. Headache and low-grade fever may also accompany this disease. The disease is usually mild and brief. Symptoms will develop 24-48 hours after contaminated food or water is ingested and lasts for 24-60 hours. Symptoms may become life-threatening (approximately 300 cases per year) in the young, the elderly, or the immunocompromised if dehydration is ignored or not treated.

160 *Salmonella*

Clinical Significance: *Salmonella* is a genus of Gram-negative, rod-shaped motile bacilli. *Salmonella* infections cause diarrheal illness in humans. Transmission occurs through contaminated foods including raw meat and fish, unpasteurized dairy products, and uncooked vegetables. *Salmonella* has also been found in processed foods that have become contaminated after processing such as soft cheeses, deli cold cuts, sliced or grated cheese, and ice cream. The infective dose for oral transmission is unknown. Most people experience diarrhea, abdominal cramps, and fever within 8 to 72 hours after the consumption of contaminated food. Most of the symptoms disappear within 4 to 7 days without treatment of antibiotics. *Salmonella* carries the *invA* gene which is not carried by any other bacterial species and enables the bacteria to invade cells.

161 *Shigella*

Clinical Significance: *Shigella* is a genus of Gram-negative, rod-shaped bacteria including four serotypes: A (*S. dysenteriae*), B (*S. flexneri*), C (*S. boydii*), D (*S. sonnei*). *Shigella* species are the cause of shigellosis and are typically transmitted via a fecal-oral route. *Shigella* species normally cause dysentery. Most cases in adults are mild and self-limiting. In some cases, a range of antibiotics can be used to treat the infection. In more severe cases, the bacteria can produce toxins that cause hemolytic uremic syndrome.