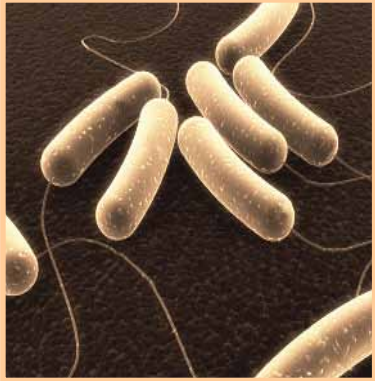


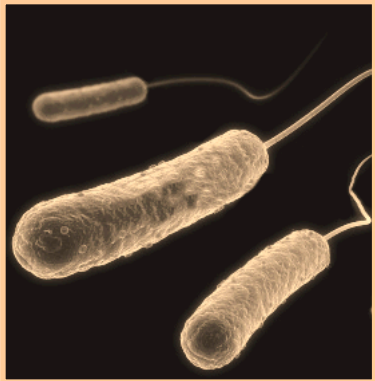
Now Available

INTESTINAL PATHOGEN DETECTION



MDL is pleased to announce the availability of molecular detection of intestinal pathogens utilizing the **OneSwab**[®] specimen collection platform. The **OneSwab**[®] platform enables non-invasive specimen collection that provides sufficient sample quantities obtained from loose stool with a rapid turnaround time of only 24 – 48 hours. Testing is now available for ten common intestinal pathogens.

- No refrigeration required before or after collection
- Rapid turnaround time of only 24-48 hours
- Test additions available for up to 30 days
- Specimen viability up to five (5) days



Tests currently available on the **OneSwab**[®]

- 365 *Campylobacter jejuni* by Real-Time PCR
- 162 *Clostridium difficile* (Toxins A and B) by Real-Time PCR
- 153 *Enterococcus faecalis* by Real-Time PCR (Reflex to vancomycin-resistant Van A & Van B by Real-Time PCR)
- 154 *Enterococcus faecium* by Real-Time PCR (Reflex to vancomycin-resistant Van A & Van B by Real-Time PCR)
- 168 Enteropathogenic *Escherichia coli* (O157:H7) by Real-Time PCR
- 274 Human Rotavirus A by Real-Time PCR
- 158 *Listeria monocytogenes* by Real-Time PCR
- 272 Norwalk Virus by Real-Time PCR
- 160 *Salmonella* by Real-Time PCR
- 161 *Shigella* spp. by Real-Time PCR



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

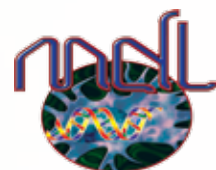
Loose stool specimen:

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.

Medical Diagnostic Laboratories, L.L.C.
www.mdlab.com • 877.269.0090



365 **Campylobacter jejuni** by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying *Campylobacter jejuni* in loose stool swab samples.

162 **Clostridium difficile** (Toxins A and B) by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying *Clostridium difficile* in loose stool swab samples.

153 **Enterococcus faecalis** by Real-Time PCR (Reflex to vancomycin-resistant Van A & Van B by Real-Time PCR)

Clinical Significance: *Enterococcus faecalis* is a Gram-positive commensal bacteria inhabiting the gastrointestinal tract. *E. faecalis* can cause life-threatening infections, especially in a nosocomial or hospital environment, where the naturally high levels of antibiotic resistance found in *E. faecalis* contribute to its pathogenicity. Enterococci are important nosocomial pathogens. Their emergence in the past two decades is in many respects attributable to their resistance to many commonly used antimicrobial agents. Vancomycin-resistant *Enterococcus* (VRE) is the name given to a group of bacterial species of the genus *Enterococcus* that are resistant to the antibiotic vancomycin. Enterococci are enteric and can be found in the digestive and urinary tracts of some humans. VRE was first discovered in 1985 and is particularly dangerous to immunocompromised individuals. While infection of healthy individuals is uncommon, it is possible for them to become colonized with newly-resistant bacteria. VRE can then be carried by healthy people who have come in contact with the bacteria, this most likely occurs in hospital settings. There are six different types of vancomycin resistance shown by *Enterococcus*: Van-A, Van-B, Van-C, Van-D, Van-E, and Van-F. Of these, only Van-A, Van-B, and Van-C have been seen in general clinical practice thus far. Real-Time PCR is a rapid and accurate method for identifying *Enterococcus faecalis* in loose stool swab samples.

154 **Enterococcus faecium** by Real-Time PCR (Reflex to vancomycin-resistant Van A & Van B by Real-Time PCR)

Clinical Significance: *Enterococcus faecium* is a Gram-positive cocci bacteria and is one of the leading causes of gastrointestinal infection worldwide. The bacteria can be commensal in the human intestines, but may also act as a pathogen causing infections similar to neonatal meningitis. Enterococcus nosocomial infections are second only to *E.coli*, and are known to cause intestinal and skin infections that can become life threatening in some instances. *E. faecium* has become a major concern in the medical community, because of the known resistant strains to many antibiotics, including penicillin and vancomycin. Real-Time PCR is a rapid and accurate method for identifying *Enterococcus faecium* in loose stool swab samples.

168 **Enteropathogenic Escherichia coli** (O157:H7) by Real-Time PCR

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 tract. *E. coli* serogroup O157:H7 is largely found in cattle, but also has been isolated from sheep, goats, pigs, and turkeys. It also exists as an enterohemorrhagic pathogen in the human intestinal tract. O157:H7 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 Enteropathogenic *Escherichia coli* (O157:H7) in loose stool swab samples.

274 **Human Rotavirus A** by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying Human Rotavirus A in loose stool swab samples.

158 **Listeria monocytogenes** by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying *Listeria monocytogenes* in loose stool swab samples.

272 **Norwalk Virus** by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying Norwalk Virus in loose stool swab samples.

160 **Salmonella** by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying Salmonella in loose stool swab samples.

161 **Shigella** spp. by Real-Time PCR

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. Real-Time PCR is a rapid and accurate method for identifying *Shigella* spp. in loose stool swab samples.