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.
Clinical Significance: Campylobacter jejuni is a species of curved, rod-shaped, non-slore 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. Enterococcal 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. fecium 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.

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

Clinical Significance: Enteropathogenic 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.

157 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 2 days followed by a week of severe illness. 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 can also be 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 7 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.

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 diarrheal illnesses 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.

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