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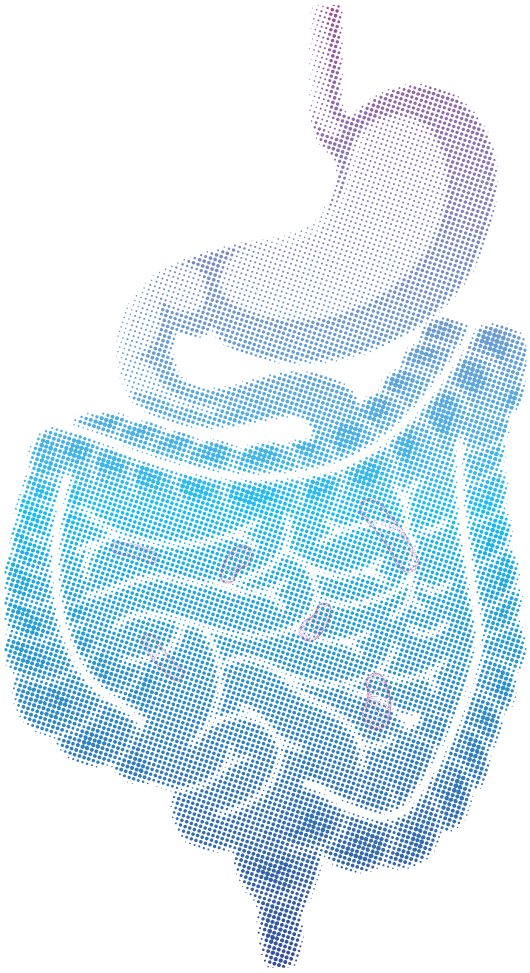
Infectious Disease Genetics

MEDGENOME

Gastrointestinal Pathogen Multiplex PCR Panel

The advantages of Molecular GI Testing



Overview

Gastrointestinal disease is a major cause of morbidity and mortality worldwide, especially among young children and immunocompromised patients. According to WHO, globally, there are nearly 1.7 billion cases of childhood diarrhoeal disease each year and it kills around 525,000 children under five every year.[1] Gastroenteritis is a common condition that affects the gut. It refers to the inflammation of the gastrointestinal tract that includes the stomach and the intestines.

Causative organisms

Gastrointestinal infections can be caused by a variety of different pathogens including viruses, bacteria, and parasites.

Symptoms and diagnostic dilemma

- Symptoms include diarrhoea, vomiting, and abdominal pain. Due to similar clinical signs and symptoms, diagnosis of the causative pathogens can be difficult, and conventional diagnostic tests can take several days to provide results.
- Most gastrointestinal infections are self-limited and resolve within a few days. However, in a healthcare setting and in specific populations (new-borns/infants, immunocompromised patients, or elderly populations), they are potentially serious.

Conventional testing

Traditional microbiological testing requires multiple steps, including bacterial culture, enzyme-linked immunosorbent assay (ELISA), microscopy, single PCR test (table 1) which are done usually sequentially.[2]

Table 1. Comparison of conventional stool tests with molecular techniques

Methods	Tests for	Turnaround Time
Conventional techniques		
Stool Culture	One to a few bacterial pathogens per test	2-3 days
Microscopy for Ova and Parasite	Only Parasitic pathogens	Multiple specimens to be collected for several days for final diagnosis
ELISA (Antigen & Antibody test)	Single pathogen per test	6-24 hours
Rapid lateral flow test	Single pathogen per test	20-30 mins
Molecular techniques		
Single Plex PCR	Single pathogen per test	NA
Multiplex Real time PCR*	Multiple pathogen & virulence genes per test	Less than 2 days

* Gastrointestinal Pathogen Panel

- The conventional tests are time consuming, labour intensive, and exhibit varying clinical performance.
- This could adversely affect patient management decisions and possible lead to inappropriate treatment.

Gastrointestinal Pathogen Panel

Gastrointestinal Pathogen Panel is a qualitative multiplex PCR-based test to detect and differentiate 9 species/groups of bacteria, 4 parasites and 5 viruses that can all cause gastroenteritis in humans (table 2). It is a CE-IVD real-time PCR-based assay.

Table 2: Target pathogens

Bacteria	Parasites	Viruses
Campylobacter spp.	*Entamoeba histolytica*	*Norovirus (GI/GII/GIV)*
Salmonella spp.	*Giardia lamblia*	*Rotavirus (A)*
Yersinia enterocolitica	*Cryptosporidium spp.*	*Adenovirus (40/41)*
Clostridium difficile toxin A	*Dientamoeba fragilis*	*Astrovirus*
Clostridium difficile toxin B		*Sapovirus (GI/GII/GIV/GV)*
Shiga toxin producing E. coli (STEC), stx1/stx2		
Enteropathogenic E. coli (EPEC), eae		
Enterotoxigenic E. coli (ETEC), elt/est		
Shigella/enteroinvasive E. coli (EIEC), ipaH		

Advantages

1. Detects **18 different pathogens** in a single tube unlike Seegene Allplex™ Gastrointestinal Panel Assays which have separate panels for bacteria, virus and parasite.
2. **Fresh or frozen stool specimens** can be used, wherein pre-treatment of stool is optional and transport media is not required.
3. **Extensively validated** with potentially cross-reactive pathogens.
4. **Internal validation at MedGenome** demonstrated 100% sensitivity and specificity.
5. Robust identification of **co-infections** which is very common in gastrointestinal pathogens.

Multiplex Real time PCR -gastrointestinal panel

Nucleic acid amplification tests (NAATs) for enteric pathogens allow for the syndromic testing of stool for multiple pathogens simultaneously[3,4]. It is rapid and accurate method.

Clinical benefits:

1	2	3	4
Aids in decision-making in terms of treatment, isolation, management in the community or hospital, and further investigations for non-infectious causes of diarrhoea.	Treatment with appropriate antimicrobials or to avoid them if they are not indicated.	Reduce downstream procedures such as endoscopies and abdominal imaging.	The high negative predictive value of this test is a valuable screening tool in outbreaks.

Workflow Benefits

- Reduces the number of laboratory tests.
- Increases the throughput and volume of information.
- Decreases the reporting times to ≤2 days.
- Superior sensitivity

Who Should Be Tested?

Individual with;

Sample collection and transportation

- Collect stool (pea sized or 2ml of unformed stool) in sterile wide mouth container.
- Avoid contaminating the stool with urine and water.
- If not processed immediately, the specimens should be stored at 4 °C and transported at the same temperature.
- If specimens cannot be processed within 48 hours, they should be kept frozen at or below -20°C, preferably -70°C then transported at the same temperature.

Test details

MedGenome offers	Test Code	Test Sample requirements	TAT
Gastrointestinal Pathogen Panel	MGM1728	Stool	**2 Working days** Post sample receipt at the lab

References:

1. www.who.int/news-room/fact-sheets/detail/diarrhoeal-disease
2. Yalamanchili H, Dandachi D, Okhuysen PC. Use and Interpretation of Enteropathogen Multiplex Nucleic Acid Amplification Tests in Patients With Suspected Infectious Diarrhea. Gastroenterol Hepatol (N Y). 2018 Nov;14(11):646-652. PMID: 30538605; PMCID: PMC6284344
3. Muhammad Amjad, "An Overview of the Molecular Methods in the Diagnosis of Gastrointestinal Infectious Diseases", International Journal of Microbiology, vol. 2020, Article ID 8135724, 13 pages, 2020. https://doi.org/10.1155/2020/8135724
4. Zhang H, Morrison S, Tang YW. Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis. Clin Lab Med. 2015;35(2):461-486. doi:10.1016/j.cll.2015.02.006

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MEDGENOME

Micra by MedGenome offers advanced

genetic and molecular tests in infectious diseases

COVID-19

COVID-19 (SARS-CoV2) RT-PCR Test

Tuberculosis

- Conventional Tests
- Molecular Tests
- SPIT SEQ (Whole genome sequencing)

CNS Infections

- Meningitis
- Meningo-encephalitis
- Acute Encephalitis Syndrome

Systemic Infections

- Respiratory Infections
- Febrile Neutropenia
- Pneumonia
- Sepsis

Eye Infections

- Endophthalmitis
- Uveitis
- Fuch's Disease
- Retinitis

Gastrointestinal Infections

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