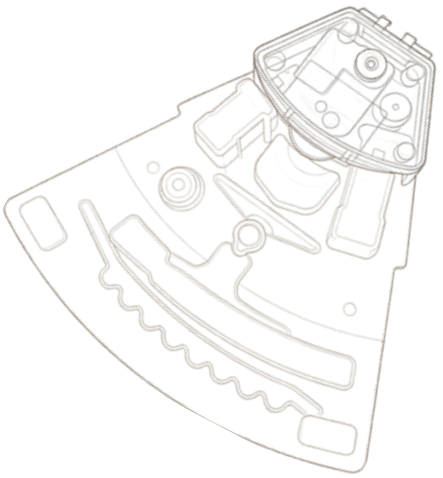
呈晖医疗
CHENGHUI MEDICAL



26 Gastrointestinal Tract Pathogen Nucleic Acid Detection Kit (Fluorescent PCR-Chip Method)

Sample-to-Answer 26 targets in One Test | 4 Samples in 80 Minutes

Powered by Chenghui Multi-Disc (CQ-0404) Fully Automated Molecular POCT Platform



CE
IVD

Detection Targets List (26 targets in Total)

Bacteria & Toxins (16): Vibrio cholerae, Vibrio parahaemolyticus, Vibrio vulnificus, Salmonella spp., Shigella/Enteroinvasive E. coli (EIEC), Campylobacter spp., Clostridioides difficile (toxin A/B), Yersinia enterocolitica, Plesiomonas shigelloides, Bacillus cereus, Shiga toxin-producing Escherichia coli (STEC) stx1, Shiga toxin-producing Escherichia coli (STEC) stx2, Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC), E. coli O157, Enteroaggregative E. coli (EAEC).

Enteric Viruses (6): Norovirus GI, Norovirus GII, Adenovirus F40/41, Astrovirus, Sapovirus, Rotavirus A.

Parasites (4): Cryptosporidium spp., Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia.

Clinical Challenges

1. **Complex Etiology & High Missed Diagnosis Risk:** Infectious diarrhea is caused by a broad spectrum of bacteria, viruses, parasites and toxigenic strains, with nearly identical symptoms of diarrhea, vomiting and fever. Mixed infections are highly prevalent, while conventional testing with narrow coverage often misses co-infections and rare pathogens, leading to delayed etiological confirmation, repeated sequential testing and widespread empiric medication.

2. **Prolonged Turnaround Delays Clinical Intervention & Outbreak Response:** Traditional culture-based methods take days to return results with low positivity, forcing clinicians to rely on empiric treatment for severe cases and increasing the risk of adverse outcomes. Slow detection also extends the response window for nosocomial Clostridioides difficile outbreaks and foodborne cluster infections, amplifying transmission risks and public health burden.
3. **High Deployment Barriers Limit Multi-Scenario Testing Access:** Standard nucleic acid testing depends on centralized PCR labs and certified technicians, failing to meet the rapid turnaround demands of emergency departments, gastroenterology wards and ICUs. It also cannot support on-site screening for foodborne events and field public health campaigns, creating gaps in both clinical care and epidemic prevention.

Core Clinical Benefits



1. **Full-Spectrum 26-Plex Profiling to Eliminate Diagnostic Gaps:** A single run covers 26 high-prevalence targets across bacteria, toxins, enteric viruses and parasites, covering over 90% of common infectious gastrointestinal pathogens. It accurately identifies both single and mixed infections in one test, drastically reducing missed diagnosis rates, eliminating the need for repeated sequential testing and providing clear etiological evidence for precise clinical decision-making.
2. **80-Minute Rapid Results to Accelerate Therapy & Outbreak Control:** With only 1 minute of hands-on operation, the assay delivers full results in ~80 minutes, rapidly distinguishing bacterial, viral and parasitic diarrhea. It enables clinicians to shift promptly from empiric therapy to targeted treatment, optimizing antimicrobial stewardship and reducing unnecessary antibiotic use. Fast detection of Clostridioides difficile and other outbreak-associated pathogens also cuts infection control response time, supporting rapid tracing and containment of nosocomial and foodborne cluster infections.
3. **High-Efficiency Batch Testing & Low-Threshold Deployment for Full Scenario Coverage:** Compatible with the Multi-Disc (CQ-0404) fully automated analyzer, 4 parallel samples per run significantly improves batch testing throughput, securing critical diagnostic windows for ICU and emergency severe patients. The closed sample-to-answer system requires no dedicated PCR lab or specialized operators, enabling flexible deployment across inpatient wards, outpatient clinics and public health field sites to fill testing gaps at every care setting.
4. **Fully Automated, Low-Threshold Workflow:** Pre-loaded nucleic acid extraction and lyophilized PCR reagents on chip. Full automation of purification, amplification and analysis after sample loading; no manual extraction, dedicated PCR lab or specialized operator required.
5. **Onboard Single-Cartridge Quality Control:** Built-in on-chip internal control monitors fluid flow and the full PCR reaction process to effectively reduce false negatives.
6. **Cold-Chain-Free Storage & Transportation:** Storable and transportable at 4–28°C with 12-month shelf life, no cold chain required, reducing logistics and inventory costs for hospitals.

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