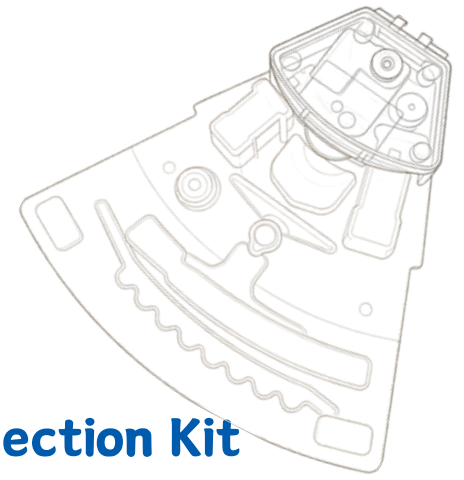


呈晖医疗
CHENGHUI MEDICAL



Meningitis Pathogen Nucleic Acid Detection Kit (Fluorescent PCR-Chip Method)

Sample-to-Answer 18+1 Meningitis Pathogen Panel | 4 Samples in 80 Minutes

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



CE
IVD

18 targets CE-certified, 1 target RUO

Detection Targets List (18+1 targets in Total)

- **Viral Pathogens (7 CE-certified + 1 RUO): Enterovirus, Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Human Parechovirus, Human Herpesvirus 6, Varicella-Zoster Virus, Toscana Virus, Cytomegalovirus* (RUO).**
- **Bacterial Pathogens (10): Haemophilus influenzae, Escherichia coli K1, Neisseria meningitidis (Encapsulated), Mycoplasma pneumoniae, Streptococcus agalactiae, Staphylococcus epidermidis, Listeria monocytogenes, Streptococcus pyogenes, Streptococcus pneumoniae, Staphylococcus aureus.**
- **Fungal Pathogens (1): Cryptococcus neoformans/gattii.**

Remark: *Cytomegalovirus is not CE-certified and is for Research Use Only. Not for use in diagnostic procedures.

Clinical Challenges

1. **Broad Pathogen Spectrum & Difficult Differential Diagnosis Carry Severe Missed Diagnosis Risks:** Acute meningitis is a life-threatening critical illness with rapid disease progression. Causative agents span viruses, bacteria and fungi with nearly identical initial symptoms, and mixed infections are common in immunocompromised patients. Conventional testing with narrow target coverage easily misses atypical pathogens, delaying precise intervention and raising mortality risk.
2. **Slow Traditional Detection Leads to Blind Empirical Therapy & Permanent Neurological Damage:** Cerebrospinal fluid (CSF) samples are often limited in volume. Traditional microbial culture takes days with low positive rates, while single-target PCR only covers a handful of pathogens. The inability to rapidly confirm etiology forces clinicians to rely on broad-spectrum empiric medication, elevating risks of treatment failure and permanent neurological sequelae such as hearing loss and brain injury.
3. **High Lab Deployment Barriers Miss the Narrow Golden Diagnostic Window:** Routine nucleic acid testing relies on centralized PCR laboratories and well-trained technicians, making it impossible to deploy at the point of care in neurology wards, emergency departments and ICUs. Long sample transport and testing cycles fail to match the narrow golden treatment window for acute meningitis, directly worsening patient outcomes.

Core Clinical Benefits



1. **Comprehensive One-Stop Pathogen Profiling to Eliminate Diagnostic Gaps:** A single CSF sample enables simultaneous detection of 18 CE-certified meningitis-related pathogens covering core viral, bacterial and fungal causative agents, plus an additional Cytomegalovirus target for RUO use. It accurately identifies both single and mixed infections in one run, drastically reducing missed diagnosis rates and eliminating the need for sequential repeated testing even with limited sample volume.
2. **Rapid 80-Min Turnaround + 4 Parallel Samples to Guide Precision Therapy & Improve Prognosis:** Compatible with the Multi-Disc (CQ-0404) fully automated analyzer, the assay requires only 1 minute of hands-on sample loading and delivers complete results in ~80 minutes. 4 parallel samples per run significantly improves batch detection throughput, securing the critical diagnostic window for critically ill patients. It supports timely regimen adjustment, reduces unnecessary empiric antibiotic use, lowers the risk of permanent neurological sequelae and effectively improves patient prognosis.
3. **Fully Automated Low-Threshold Workflow for Bedside POCT Deployment:** Pre-loaded nucleic acid extraction and lyophilized PCR reagents onboard the cartridge enable full automation of purification, amplification and analysis after sample loading. No manual extraction, dedicated PCR lab or specialized operator is required, allowing flexible on-site deployment in neurology wards, emergency departments and ICUs to fully match the urgent diagnostic needs of acute meningitis.
4. **Onboard Single-Cartridge Quality Control with Contamination Prevention:** Built-in internal control monitors the entire fluidic and PCR reaction process, effectively reducing the risk of false-negative results. The fully sealed cartridge system eliminates aerosol cross-contamination, ensuring stable and reliable results for every test.

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