

呈晖医疗
CHENGHUI MEDICAL



26 Upper Respiratory Tract Pathogens Nucleic Acid Detection Kit (Fluorescent PCR-Chip Method)

Sample-to-Answer 26+1 Respiratory Pathogens Panel | 4 Samples in 80 Minutes

Powered by Chenghui Multi-Disc (CQ-0404) fully automated molecular POCT platform



CE
IVD

26 targets CE-certified, 1 target RUO

Detection Targets List (26+1 Pathogens in Total)

Respiratory Viruses (21 CE-certified):SARS-CoV-2, Influenza A Virus, Influenza A/H3, Influenza A H1N1 pdm09 Virus, Influenza A/H1, Influenza A/H5, Parainfluenza virus type 1-4, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Rhinovirus, Respiratory syncytial virus A, Respiratory syncytial virus B, Influenza B Yamagata, Influenza B Victoria, Bocavirus, Enterovirus, Human metapneumovirus, Adenovirus, Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Atypical Pathogens (1 CE-certified + 1 RUO):Mycoplasma pneumoniae, Chlamydia pneumoniae* (RUO).

Bacterial Pathogens (4 CE-certified): Bordetella pertussis, Bordetella parapertussis, Bordetella holmesii, Legionella pneumophila.

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

Clinical Challenges

1. **Difficult Differential Diagnosis**: Overlapping respiratory symptoms and frequent mixed infections make empirical diagnosis unreliable for severe and immunocompromised patients, hindering targeted treatment.
2. **Limited Traditional Detection Performance**: Conventional culture takes 3–7 days with only 40%–60% positivity; single-target PCR has narrow pathogen coverage. Neither detects viruses, atypical pathogens or bacteria simultaneously, leading to missed diagnosis and inappropriate antibiotic use.
3. **Cumbersome & Slow Workflow**: Traditional nucleic acid testing requires dedicated PCR labs and trained technicians, with multi-step manual operations and long turnaround, unable to meet urgent diagnostic demands of inpatient wards and ICUs.

Core Clinical Benefits



1. **Precise Etiological Diagnosis for Critical Care:** Single nasopharyngeal swab detects 26+1 respiratory pathogens covering viruses, atypical pathogens and pathogenic bacteria, guiding targeted therapy, reducing unnecessary antibiotic use and shortening hospital stays.
2. **Reliable Co-Infection & Outbreak Management:** Accurately identifies multi-pathogen mixed infections, supporting individualized treatment for severe/immunocompromised patients and rapid control of nosocomial respiratory outbreaks.
3. **High-Efficiency Inpatient Testing:** Compatible with Multi-Disc (CQ-0404) fully automated analyzer, delivers complete results in ~80 minutes. 4 parallel samples per run greatly improves batch detection efficiency, securing the critical diagnostic window.
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. **Single-Cartridge Quality Control:** Built-in on-chip internal control monitors full fluid flow and PCR reaction process, effectively reducing the risk of false-negative results.
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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