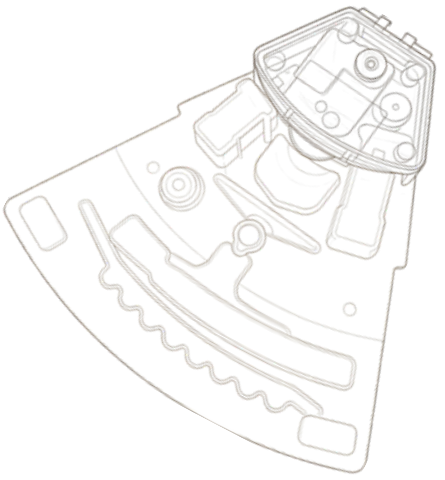
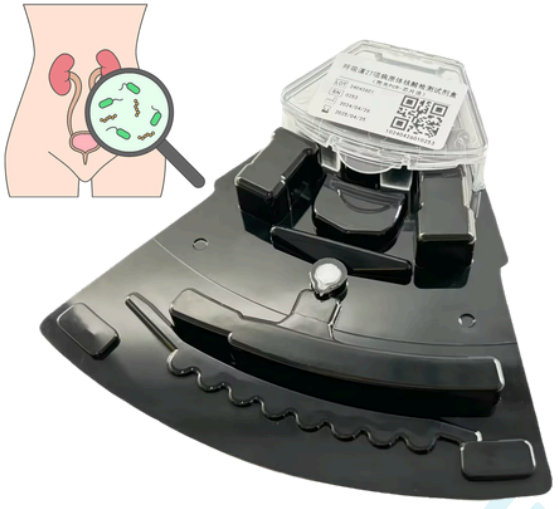
呈晖医疗
CHENGHUI MEDICAL



10 Reproductive Tract Pathogen Nucleic Acid Detection Kit (Fluorescent PCR-Chip Method)

Sample-to-Answer 10+1 Reproductive Tract Pathogen Panel | 4 Samples in 80 Minutes

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



CE
IVD

10 targets CE-certified, 1 target RUO

Detection Targets List (10+1 targets in Total)

Mycoplasma & Ureaplasma (4 CE-certified): Mycoplasma hominis (MH), Ureaplasma urealyticum (UU), Mycoplasma genitalium(MG), Ureaplasma parvum (UP).
Bacterial Pathogens (3 CE-certified + 1 RUO):Neisseria gonorrhoeae (NG), Haemophilus ducreyi (HD), Gardnerella vaginalis (GV), Chlamydia trachomatis (CT*, RUO).
Viral Pathogens (2 CE-certified):Herpes simplex virus type 1 (HSV-I), Herpes simplex virus type 2 (HSV-II).
Protozoan Pathogen (1 CE-certified): Trichomonas vaginalis (TV).

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

Clinical Challenges

1. **Complex Mixed Pathogen Spectrum Drives High Missed Diagnosis & Recurrent Infections:** Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are caused by diverse pathogens spanning bacteria, viruses, mycoplasma and protozoa, with extremely high mixed infection rates. Conventional microscopy, culture and single-target PCR have narrow coverage and low sensitivity, frequently missing atypical pathogens such as Mycoplasma genitalium, leading to unclear etiology, recurrent persistent infections and delayed targeted intervention.
2. **Prolonged Turnaround & High Deployment Barriers Raise Complication & AMR Risks:** Traditional culture-based testing takes 2–7 days, and centralized molecular workflows add extra sample transfer time. Conventional nucleic acid assays also rely on dedicated PCR labs and certified personnel, making them unavailable in gynecology, urology and inpatient wards. Delayed results force empiric therapy, which accelerates antimicrobial resistance and elevates risks of severe complications including pelvic inflammatory disease (PID), infertility and mother-to-child transmission.
3. **Inadequate Batch Throughput Fails Large-Scale Public Health Screening:** Population-level STI screening and public health surveillance require both rapid turnaround and stable batch processing capacity, which conventional testing methods cannot balance. This gap hinders efficient large-scale population screening and timely containment of infection transmission sources.

Core Clinical Benefits



1. **Comprehensive 10+1 Pathogen Profiling for Accurate Differential Diagnosis:** The clinically optimized panel covers 10 CE-marked core reproductive tract pathogens across mycoplasma, bacteria, viruses and protozoa, with an additional Chlamydia trachomatis (CT) target available for RUO. With higher sensitivity and specificity than traditional microscopy and culture methods, it accurately identifies both single and mixed infections in one run, drastically reducing missed diagnosis rates and enabling timely transition from empiric to targeted therapy to cut recurrent infection and long-term complication risks.
2. **High-Efficiency Batch Testing + Low-Threshold Deployment for Full Scenario Coverage:** Compatible with the Multi-Disc (CQ-0404) fully automated analyzer, the assay delivers complete results in ~80 minutes with only 1 minute of hands-on operation. 4 parallel samples per run significantly improves batch detection throughput, efficiently meeting both routine clinical testing and large-scale STI public health screening demands. The fully closed sample-to-result system requires no dedicated PCR lab or specialized operators, enabling direct deployment in gynecology, urology and inpatient wards to shorten total turnaround time, optimize antimicrobial stewardship and curb transmission risks.
3. **Onboard Single-Cartridge Quality Control:** Built-in internal control monitors the entire fluidic and PCR reaction process, effectively reducing the risk of false-negative results.
4. **Cold-Chain-Free Storage & Transportation:** Stable for 12 months at 4–28°C for storage and transport, no cold chain required, cutting logistics and inventory costs for healthcare facilities.

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