

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

Sample-to-Answer 10+1 Reproductive Tract Pathogen Panel | Results in 40 Minutes

Powered by Chenghui Flex-Disc (CH-0104) Fully Automated Molecular POCT Platform



CE IVD

10 targets CE-certified, 1 target RUO

Detection Targets List (10+1 targets in Total)

- **Mycoplasma hominis (MH),**
- **Herpes simplex virus type 2 (HSV-II),**
- **Ureaplasma urealyticum (UU),**
- **Trichomonas vaginalis (TV),**
- **Neisseria gonorrhoeae (NG),**
- **Herpes simplex virus type 1 (HSV-I),**
- **Mycoplasma genitalium (MG),**
- **Haemophilus ducreyi (HD),**
- **Gardnerella vaginalis (GV),**
- **Ureaplasma parvum (UP),**
- **Chlamydia trachomatis (CT*, RUO).**

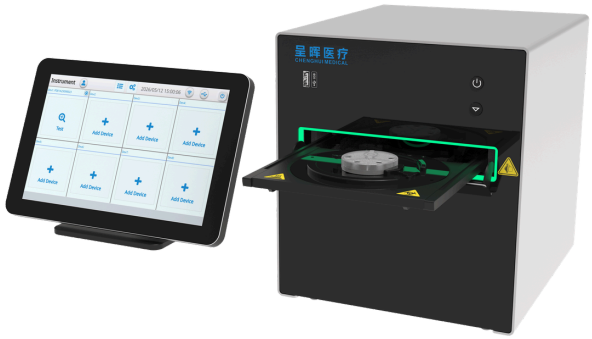
Remark: *Chlamydia trachomatis (CT) is not CE-certified and is for Research Use Only. Not for use in diagnostic procedures.

Clinical Challenges

1. **Suboptimal Diagnostic Accuracy Driving Empiric Treatment & Adverse Outcomes:** Most RTIs/STIs present with overlapping symptoms and high rates of asymptomatic infection. Traditional microscopy, culture and immunoassays have low sensitivity for fastidious pathogens such as Mycoplasma genitalium and frequently miss mixed infections, leading to widespread empiric antibiotic use, treatment failure, recurrent infections and long-term complications including infertility and pelvic inflammatory disease.

2. **Prolonged Turnaround & High Deployment Barriers Restrict Testing Access:** Conventional nucleic acid testing relies on centralized molecular laboratories with 1–3 days of turnaround, resulting in high patient loss to follow-up and delayed clinical intervention. Standard PCR assays also require dedicated labs and certified technical personnel, which are largely unavailable in community clinics and remote primary care settings, forcing sample outsourcing and further extending diagnostic cycles.
3. **Inflexible Throughput Fails to Match Variable Scenario Demands:** Daily testing volumes in primary care settings are typically low, making high-throughput PCR instruments cost-inefficient due to idle time. Meanwhile, periodic large-scale STI screening campaigns, physical examination peaks and outpatient surges require rapid capacity expansion, leaving an unmet need for a flexible, scalable testing solution.

Core Clinical Benefits



1. **Comprehensive 10-Plex Pathogen Profiling for Precision Diagnosis:** A single run covers 10 high-prevalence reproductive tract pathogens across mycoplasmas, ureaplasmas, bacteria, viruses and protozoa, with an additional Chlamydia trachomatis (CT) target available for RUO. It accurately identifies single and mixed infections to provide clear etiological evidence, reducing unnecessary antibiotic use and lowering risks of recurrent infections and long-term complications.
2. **40-Minute Rapid Turnaround for Single-Visit Treatment:** With only 1 minute of hands-on sample loading, the assay delivers full results within a single outpatient visit, enabling immediate targeted treatment, improving patient treatment compliance and significantly boosting outpatient diagnostic efficiency.
3. **Low-Threshold POCT Deployment to Expand Testing Coverage:** The fully automated closed system requires no dedicated molecular laboratory or specialized technical staff, and can be operated by frontline medical workers after brief training, supporting direct deployment in community health centers, primary care clinics, physical examination centers and remote medical sites to expand point-of-care testing access.
4. **Flexible Modular Throughput for Multi-Scenario Adaptation:** Powered by the Flex-Disc platform with independent modular design, facilities can flexibly scale testing capacity based on actual sample volume: single-module setups meet routine primary care demand, while multi-module parallel operation handles examination peaks and public health screening campaigns, balancing operational cost and testing throughput.
5. **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.
6. **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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