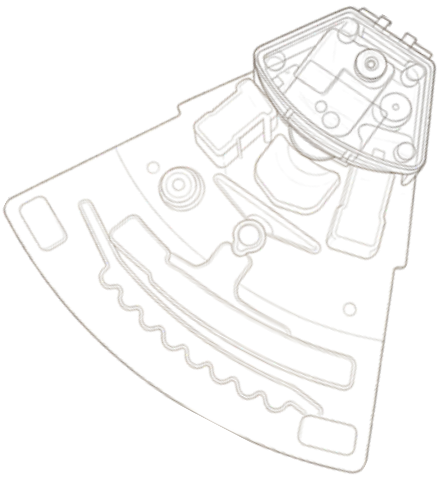
呈晖医疗
CHENGHUI MEDICAL



Human Papillomavirus (HPV) Nucleic Acid Typing Detection Kit

Sample-to-Answer 15 High-Risk HPV Genotyping Panel | 4 Samples in 80 Minutes

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



CE
IVD

Detection Targets List (15 targets in Total)

15 WHO-Recognized High-Risk HPV Genotypes: HPV 16, HPV 18, HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 53, HPV 56, HPV 58, HPV 59, HPV 66, HPV 68.

Clinical Challenges

1. **Insufficient Detection Accuracy & Weak Risk Stratification Lead to Clinical Mismanagement:** Cytology-based tests (e.g., Pap smear, TCT) have low sensitivity and high false-negative rates, while most routine HPV assays only distinguish high-risk from low-risk types without precise genotyping. This fails to stratify patients carrying high-carcinogenic genotypes such as HPV 16 and 18, resulting in either missed early diagnosis of cervical lesions or unnecessary over-treatment, especially in primary care settings with limited specialist resources.

2. **Prolonged Centralized Turnaround & High Deployment Barriers Reduce Patient Compliance:** Conventional HPV nucleic acid testing relies on centralized molecular laboratories with complex workflows, taking 3–7 days to issue reports and causing high patient loss to follow-up due to repeated return visits. It also requires standardized PCR labs and certified technical personnel, making it impossible to deploy in gynecology outpatient departments, inpatient wards or grassroots maternal and child health facilities, delaying clinical intervention.
3. **Cold Chain Reliance & Inflexible Throughput Constrain Large-Scale Screening Coverage:** Population-level cervical cancer screening requires processing large volumes of samples, while traditional reagents depend on strict cold-chain storage and transportation as well as professional operation teams. Inflexible throughput of conventional instruments also fails to balance daily routine testing and peak screening demand, limiting screening coverage in remote areas and dragging down overall public health prevention efficiency.

Core Clinical Benefits



1. **Precise 15-Genotype Profiling for Standardized Clinical Risk Stratification:** A single run achieves qualitative detection and genotyping of 15 WHO-recognized high-risk HPV genotypes, including the highest-risk HPV 16 and 18, providing clear evidence for clinical risk stratification, colposcopy referral and post-treatment follow-up, standardizing cervical cancer diagnosis and management pathways even in primary care settings. With total testing time of around 80 minutes and only 1 minute of hands-on operation, full genotyping reports are available the same day, improving patient follow-up compliance and supporting rapid outpatient testing and inpatient pre-admission screening.
2. **Low-Barrier POCT Deployment & 4-Sample Batch Testing for Multi-Scenario Adaptation:** Powered by the fully automated closed Multi-Disc (CQ-0404) platform, the assay requires no standardized molecular laboratory or specialized technical staff, and can be directly deployed in gynecology departments, physical examination centers and primary care facilities to expand diagnostic accessibility. 4 parallel samples per run significantly improves batch testing throughput, efficiently balancing daily outpatient routine testing, inpatient pre-admission screening and large-scale public health screening demands.
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 to Cut Screening Operational Costs:** Stable for 12 months at 4–28°C for storage and transport, no cold chain required, cutting logistics and inventory costs for healthcare facilities, lowering the deployment threshold of large-scale cervical cancer screening and expanding population-level screening coverage in underserved areas.

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