

Human Papillomavirus (HPV) Nucleic Acid Typing Detection Kit

Sample-to-Answer 15 High-Risk HPV Genotypes | Results in 40 Minutes

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



CE
IVD

Detection Targets List (15 targets in Total)

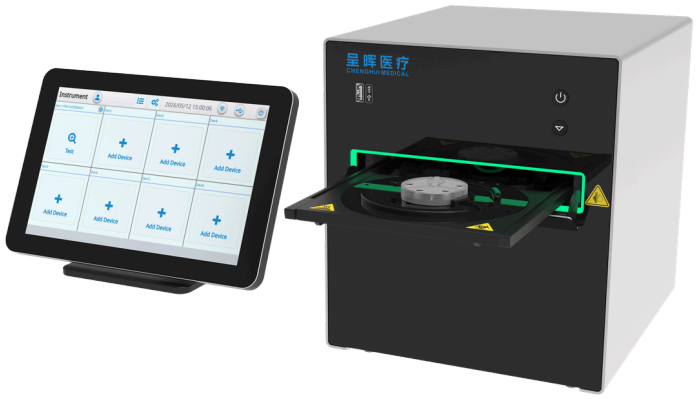
- **HPV 16,**
- **HPV 18,**
- **HPV 31,**
- **HPV 33,**
- **HPV 35,**
- **HPV 39,**
- **HPV 45,**
- **HPV 51,**
- **HPV 52,**
- **HPV 53,**
- **HPV 56,**
- **HPV 58,**
- **HPV 59,**
- **HPV 66,**
- **HPV 68.**

Clinical Challenges

1. **Insufficient Detection Accuracy & Weak Risk Stratification:** Cytology-based tests (e.g., Pap smear, TCT) have low sensitivity and high false-negative rates, leading to missed diagnoses. Most basic HPV assays only differentiate high/low-risk types without precise genotyping, failing to stratify patients with high-carcinogenic genotypes like HPV 16/18, which often causes over-treatment or inadequate intervention, especially in resource-limited primary care settings.

2. **Long Centralized Testing Turnaround & High Deployment Thresholds:** Traditional HPV nucleic acid testing relies on centralized molecular labs with batch processing, taking 3–7 days to report results and causing high patient loss to follow-up due to repeated visits. It also requires standardized PCR labs and certified technicians, which are unavailable in most community health centers, primary maternal and child health facilities and remote sites; long-distance sample transport further raises costs and sample degradation risks.
3. **Inflexible Throughput & Cold Chain Dependence Limit Screening Scale:** Primary care facilities have low daily testing volumes, making high-throughput PCR instruments cost-inefficient with long idle time, while fixed-throughput solutions cannot handle sample surges during large-scale public health screening. Cold chain reliance for conventional reagents further restricts deployment in remote areas, limiting population-level cervical cancer screening coverage.

Core Clinical Benefits



1. **Precise 15-Genotype Identification for Standardized Decision-Making:** Single-run 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 even in primary care settings.
2. **40-Minute Rapid Turnaround for Single-Visit Diagnosis:** 1-minute hands-on sample loading and ~40-minute total testing time enable full genotyping reports within a single outpatient visit, eliminating return trips, improving patient follow-up compliance, and supporting same-day on-site screening to boost clinical and public health efficiency.
3. **Low-Threshold POCT Deployment to Expand Screening Coverage:** Powered by the fully automated closed Flex-Disc platform, the assay requires no standardized molecular lab or specialized technicians; frontline medical staff can operate it after brief training. It can be deployed directly in gynecology clinics, community health centers, primary maternal and child health facilities and physical examination centers, bringing precise HPV genotyping to underserved settings.
4. **Flexible Modular Throughput Balances Cost & Capacity:** The independent modular design enables scalable testing capacity: a single module meets routine outpatient demand, while multi-module parallel operation supports large-scale public health screening, balancing daily operational cost and peak testing demand.
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.

CONTACT US:

Website: https://en.chenghuimed.com/
General Inquiries: info@chenghuimed.com
Sales: sales@chenghuimed.com
Service & Support: service@chenghuimed.com
Address: 12th Floor, North Zone, Building 2B, Skyworth Innovation Valley, No. 8 Tangtou 1st Road, Shiyan Street, Bao'an District, Shenzhen, Guangdong Province, China