呈晖医疗
CHENGHUI MEDICAL

4 Malaria Pathogen Nucleic Acid Detection Kit (Fluorescent PCR-Chip Method)

Sample-to-Answer 4 Plasmodium Species Detection | Results in 40 Minutes

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



Detection Targets List (4 targets in Total)

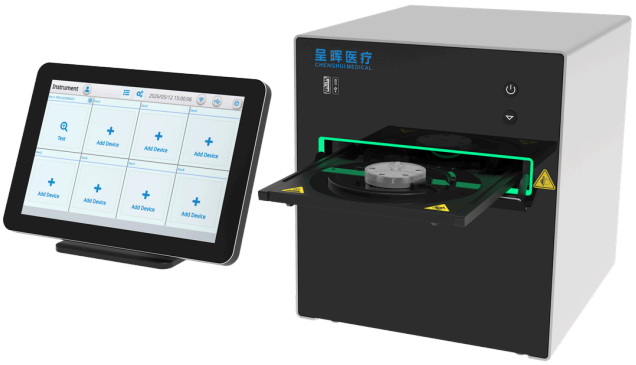
Plasmodium spp.,
Plasmodium falciparum,
Plasmodium vivax,
Plasmodium knowlesi.

Challenges

1. **Insufficient Diagnostic Accuracy & Limited Subtyping Capacity:** The traditional gold-standard microscopy relies heavily on experienced technicians, with low sensitivity for low-parasitemia infections that often cause missed diagnoses. Rapid diagnostic tests (RDTs) have limited strain differentiation capacity, and cannot accurately identify easily misdiagnosed Plasmodium knowlesi or distinguish relapsing P. vivax. This lack of precise subtyping leads to inappropriate antimalarial therapy, unaddressed relapse risks, and delayed recognition of life-threatening severe falciparum malaria.

2. **Delayed Centralized Testing Misses Critical Treatment & Quarantine Windows:** Severe P. falciparum malaria can progress to organ failure and death within hours, requiring prompt targeted intervention. Conventional nucleic acid testing relies on centralized molecular laboratories with lengthy sample transport and batch processing workflows, delaying results by hours to days. This lag directly worsens patient prognosis and slows on-site quarantine clearance at ports of entry.
3. **High Deployment Barriers & Poor Scalability Restrict Frontline Testing Access:** Standard PCR-based malaria testing requires dedicated molecular laboratories and certified technical personnel, resources largely unavailable in remote endemic regions, primary care facilities, border checkpoints and field outbreak sites. Inflexible throughput also creates a cost-capacity mismatch: high-throughput instruments incur idle costs during low-volume daily use, yet cannot handle sudden outbreak surges. Additionally, strict cold chain reliance for reagents further hinders large-scale public health deployment in remote tropical regions.

Core Benefits



1. **Precise 4-Plex Plasmodium Subtyping for Targeted Clinical Management:** A single run covers 4 targets: pan-Plasmodium genus-level screening, P. falciparum, P. vivax and P. knowlesi, delivering both infection confirmation and precise species differentiation. It clearly identifies high-lethality falciparum malaria, relapsing vivax malaria and easily misdiagnosed knowlesi malaria, enabling accurate targeted antimalarial regimen selection, reducing inappropriate medication and lowering severe disease and recurrence risks.
2. **40-Minute Rapid Turnaround to Secure Critical Intervention Windows:** With only 1 minute of hands-on sample loading, the assay delivers results in ~40 minutes, far faster than centralized workflows. It helps clinicians seize the narrow treatment window for severe malaria, and supports rapid on-site port quarantine to block transmission of imported cases.
3. **Low-Threshold POCT Deployment to Expand Frontline Testing Access:** Powered by the fully automated closed Flex-Disc platform, the assay requires no dedicated molecular laboratory or specialized technical staff, and can be operated by frontline medical workers after brief training. It can be directly deployed in infectious disease departments, primary care clinics, border quarantine stations and endemic field sites, extending high-quality molecular malaria testing to underserved settings.
4. **Flexible Modular Throughput for Dual Clinical & Public Health Use:** The independent modular design enables flexible capacity scaling: single-module setups meet routine outpatient and primary care demand, while multi-module parallel operation handles outbreak surges and mass field screening, balancing operational cost and testing capacity to align with WHO guidelines for both clinical and public health scenarios.
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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