

Rapigen Secures WHO Prequalification for Three pLDH-Based Malaria Rapid Diagnostic Tests

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/EINPresswire.com/ -- pLDH-Based Diagnostic Technology Addresses Growing Threat of HRP2 Gene Deletions — Enabling Expanded Access to Global Malaria Diagnostics Markets

Rapigen, Inc., an in vitro diagnostics company specializing in rapid diagnostic tests, announced that three of its malaria rapid diagnostic tests (RDTs) — BIOCREREDIT Malaria Ag Pf (pLDH), BIOCREREDIT Malaria Ag Pf (pLDH/HRPII), and BIOCREREDIT Malaria Ag Pf/Pv (pLDH/pLDH) — were officially added to the World Health Organization (WHO) Prequalification (PQ) product list on April 14, 2025. With this listing, Rapigen becomes eligible for UN procurement channels and global public health supply programs.

WHO Prequalification is an internationally recognized certification program that evaluates whether medical products — including medicines, diagnostics, and vaccines — meet WHO standards for quality, safety, and performance. Products listed under WHO PQ are deemed suitable for public procurement by international agencies and are a key eligibility requirement for access to global health supply markets.

A particularly noteworthy aspect of this listing is that all three products are built on pLDH (Plasmodium lactate dehydrogenase) technology. The majority of malaria RDTs currently in widespread global use rely on HRP2 (Histidine-rich protein 2), a protein produced by



Plasmodium falciparum as the primary diagnostic target. However, growing reports of *pfrp2/3* gene deletion mutations — documented in the Horn of Africa (Ethiopia, Eritrea, Djibouti), parts of South America, and Southeast Asia — have raised serious concerns about false-negative results in HRP2-based RDTs.

In response, WHO's Malaria Policy Advisory Group (MPAG) issued guidance in 2021 recommending that countries where *pfrp2/3* gene deletion prevalence exceeds 5% transition to non-HRP2-based diagnostic strategies. pLDH, an enzyme expressed across all *Plasmodium* species regardless of gene deletion status, has emerged as a critical alternative detection target — and is explicitly cited by WHO as the representative non-HRP2 antigen for such transitions.

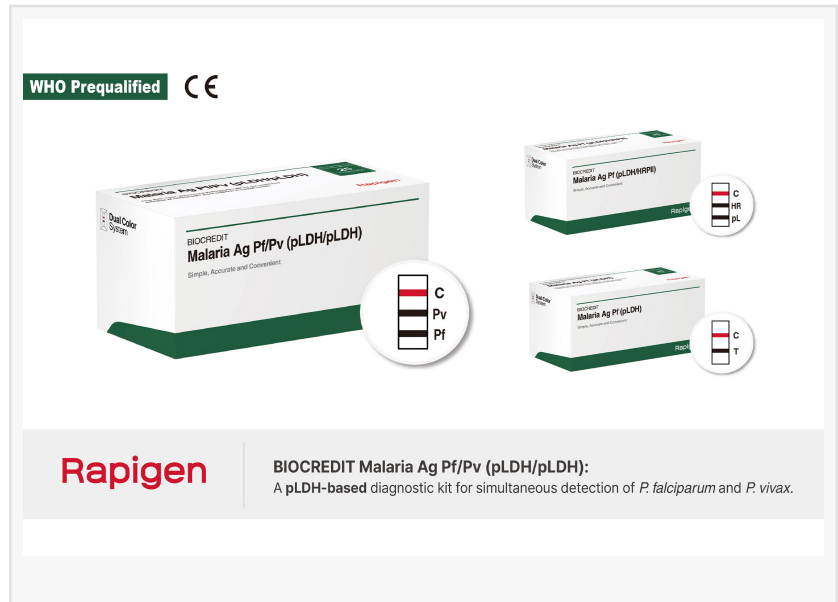
The three WHO PQ-listed Rapigen products and their WHO Product IDs are:

- BIOCREDIT Malaria Ag Pf (pLDH) — WHO Product ID: 13192-160-00
- BIOCREDIT Malaria Ag Pf (pLDH/HRPII) — WHO Product ID: 13193-160-00
- BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) — WHO Product ID: 13194-160-00

The BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) test is capable of simultaneously detecting both *P. falciparum* and *P. vivax*, making it well-suited for deployment across a wide range of malaria-endemic settings. Additionally, the BIOCREDIT Malaria Ag Pf (pLDH) was directly utilized as a comparative diagnostic tool in a peer-reviewed, WHO-supported surveillance study on *pfrp2* gene deletions conducted across 100 health facilities in Tanzania (Scientific Reports, 2024), providing independent real-world validation of the product's performance and operational reliability.

"This WHO PQ listing for three malaria products is a significant milestone that confirms Rapigen's diagnostic innovation and quality standards on the international stage," said a Rapigen spokesperson. "Our pLDH-based platform represents a key solution to the expanding global threat posed by *pfrp2/3* gene deletions, and we are confident it will contribute meaningfully to improving access to accurate malaria diagnosis and advancing global public health."

Building on this WHO PQ achievement, Rapigen plans to accelerate its global business expansion, with a particular focus on malaria-endemic regions across Africa, Southeast Asia, and Latin America. The company will pursue this growth through international procurement mechanisms and national public health programs.



Key References

- WHO List of Prequalified IVD Products
- WHO Statement by the Malaria Policy Advisory Group on the urgent need to address the high prevalence of pfhrp2/3 gene deletions in the Horn of Africa and beyond, 28 May 2021
- WHO Malaria Policy Advisory Group(MPAG) Meeting Documentation, April 2021
- Rogier E. et al. (2024): pfhrp2/pfhrp3 gene deletions in Tanzania — Scientific Reports(BIOCREDIT Malaria Ag Pf (pLDH) utilized as comparative diagnostic tool)
- WHO Surveillance Template Protocol for pfhrp2/pfhrp3 Gene Deletions, 2nd edition (2024)

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