

R information requested from manufacturer	 in process	 stage complete	F follow-up amendments	S scheduled; date confirmed
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Please note: these tables are updated regularly; while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement. Information may not yet be reflected here.
Last update: 30 March 2026
<https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment>
 # The product was prequalified and a change request was submitted and accepted to add an intended use claim.

Malaria Rapid Diagnostic Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	Product performance evaluation	Labelling review	Application number
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C61RHG25 and C61RHH25	RapiGen Inc		◆	◆	PQDx 13194-160-00
BIOCREDIT Malaria Ag Pf (pLDH)	C14RHG25 and C14RHH25	RapiGen Inc		◆	◆	PQDx 13192-160-00
BIOCREDIT Malaria Ag Pf (pLDH/HRPII)	C13RHG25 and C13RHH25	RapiGen Inc	R	◆	◆	PQDx 13193-160-00
Malaria P.f. Ag Rapid Test Cassette (Whole Blood)	GCMAL (pf)- 402a-1T, GCMAL (pf)-402a-25TX, and GCMAL (pf)-402a-25TD	Zhejiang Orient Gene Biotech Co., LTD	◆		R	PQDx 12442-12940-00
STANDARD Q hs-Malaria P.f./P.v Ag Test	09MAL70D	SD Biosensor, Inc.	◆			PQDx 13200-117-00
STANDARD Q hs-Malaria P.f Ag Test	09MAL60D	SD Biosensor, Inc.	◆			PQDx 13199-117-00
First Response Malaria Ag. P. falciparum (HRP2/pLDH) Combo Card Test	PI25FRC05, PI25FRC10, PI25FRC25, PI25FRC30, PI25FRC10s, and PI25FRC25s,	Premier Medical Corporation Private Limited				PQDx 13764-010-00