R	🗁	◆	F	S
information requested from manufacturer	in process	stage complete	follow-up amendments	scheduled; date confirmed

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: 27 June 2025
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	Quality Management System 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
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	🗁				PQDx 12442-12940-00
BIOCREDIT Malaria Ag Pf (pLDH/HRPII)	C13RHG25 and C13RHH25	RapiGen Inc	🗁	🗁	◆		PQDx 13193-160-00
STANDARD Q hs-Malaria P.f/P.v Ag Test	09MAL70D	SD Biosensor, Inc.	R				PQDx 13200-117-00
Lariacheck Pf	302100025, 302100100, 302100025(1T), 302100005, and 302100010	Orchid Biomedical Systems_Division of Tulip Diagnostics (P) Ltd	🗁	◆	◆	🗁	PQDx 0694-024-00
ErbaQik Malaria Ag Pf/Pan	135343 and 135342	Transasia Diagnostic Pvt Ltd.	R				PQDx 12405-12158-00
ErbaQik Malaria Ag Pf/Pv	135346 and 135347	Transasia Diagnostic Pvt Ltd.	🗁				PQDx 12409-12158-00
MERISCREEN Malaria Pf HRP-II/pLDH Ag	RWPFDH-09, RWPFDH-01, RWPFDH-02, RWPFDH-03, RWPFDH-04, RWPFDH-05, RWPFDH-06, RWPFDH-07, RWPFDH-08, RWPFDH-10, RWPFDH-11, RWPFDH-12, RWPFDH-13, and RWPFDH-14	Meril Diagnostics Pvt. Ldt.	R	◆			PQDx 13179-074-00
STANDARD Q hs-Malaria P.f Ag Test	09MAL60D	SD Biosensor, Inc.	R				PQDx 13199-117-00