













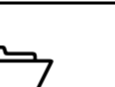



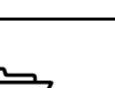


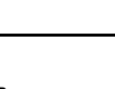
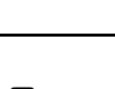
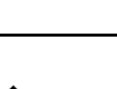
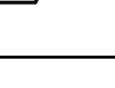
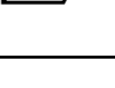
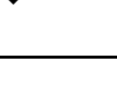
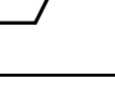


<b>R</b> information requested from manufacturer	 in process	 stage complete	<b>F</b> follow-up amendments	<b>S</b> scheduled; date confirmed
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Please note: these tables are updated regularly; while every attempt is made to provide current data, the 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: 13 September 2023**  
<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
CareStart Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571, RMWM-02571RI, RMWM-02571CB, RMWM-02571RB, RMWM-05071, RMWM-05071RI, RMWM-05071CB, RMWM-05071RB, RMWU-02571, RMWU-02571RI, RMWU-02571CB, RMWU-02571RB, RMWU-04071, RMWU-04071RI, RMWU-04071CB and RMWU-04071RB.	Access Bio Inc.	<b>R</b>				PQDx 0339-049-00
Advantage P.f Malaria Card	IRC16025	J.Mitra & Co. Pvt. Ltd.		<b>R</b>			PQDx 0472-062-00
BIOCREDIT Malaria Ag Pf (pLDH)	C14RHG25 and C14RHH25	RapiGen Inc.	<b>R</b>				PQDx 0483-160-00
BIOCREDIT Malaria Ag Pf (pLDH/ HRP II)	C13RHG25 and C13RHH25	RapiGen Inc.	<b>R</b>				PQDx 0482-160-00
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C61RHG25 and C61RHH25	RapiGen Inc.	<b>R</b>				PQDx 0478-160-00
ONE STEP Malaria (Pf) Test	ITPW11007-TC25 and ITPW11007-TC40	InTec Products, Inc.	<b>R</b>				PQDx 0626-017-00
ONE STEP Malaria (Pf/Pv) Tri-line Test	ITPW11009-TC25 and ITPW11009-TC40	InTec Products, Inc.					PQDx 0627-017-00
Wondfo Malaria P.f (HRP2/pLDH) Test	W037P0022, W037P0028, W037P0030, W037P0024, W037P0033, W037P0035 and W037P0037.	Guangzhou Wondfo Biotech Co., Ltd.	<b>R</b>				PQDx 0651-004-00
Lariacheck Pf	302090005, 302090010, 302090025 and 302090100	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd					PQDx 0694-024-00
Lariavax	503180025, 503180010, 503180025, 503180050 and 503180100	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.					PQDx 0696-025-00
Lariascreen	503190025, 503190010, 503190025, 503190050 and 503190100	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.					PQDx 0697-025-00
Plasmodium Falciparum /Plasmodium Vivax Antigen Detection Kit (Colloidal Gold)	HWTS-OT055A and HWTS-OT055B	Jiangsu Macro & Micro-Test Med-Tech Co., Ltd					PQDx 0717-248-00