R information requested from manufacturer

in process stage complete

follow-up amendments

S 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: 16 July 2024

https://extranet.wo.in/poweb/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
Wondfo Malaria P.f (HRP2/pLDH) Test	W037P0022, W037P0028, W037P0030, W037P0024, W037P0033, W037P0035 and W037P0037.	Guangzhou Wondfo Biotech Co., Ltd.		<b>*</b>	•	<b>*</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.		<b>*</b>	•		PQDx 0696-025-00
Lariascreen	503190025, 503190010, 503190025, 503190050 and 503190100	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.		<b>*</b>	•		PQDx 0697-025-00