

**LIST OF RAPID DIAGNOSTIC TEST (RDT) KITS FOR MALARIA  
classified according to the Global Fund Quality Assurance Policy**

The list is an overview of malaria RDTs to assist Principal Recipients (PRs) of Global Fund grants to identify the status of Malaria RDTs according to the Global Fund Quality Assurance Policy. It includes products eligible for procurement after assessment by:

- the WHO Prequalification of Diagnostics Programme as listed by WHO (<https://extranet.who.int/prequal/vitro-diagnostics/prequalified/in-vitro-diagnostics>)

or

- Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF or WLAs within their scope of listing

or

- the Global Fund's Expert Review Panel for Diagnostics (ERPD) as described in the Global Fund Quality Assurance Policy.

The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements. The list is updated from time to time based on evidence received by the Global Fund.

"ERPD" eligibility means, that procurement with Global Fund resources of this product will be permitted / Non-Objection-Letters are required for procurement

Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
<b>For the detection of Plasmodium falciparum only (Pf)</b>							
05FK50	Bioline Malaria Ag Pf	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	WHO PQ
05FK51	Bioline Malaria Ag Pf (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	
05FK52	Bioline Malaria Ag Pf POCT (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	
05FK53	Bioline Malaria Ag P.f. POCT	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	
05FK90	Bioline Malaria Ag Pf (HRP2 / pLDH)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	WHO PQ
05FK91	Bioline Malaria Ag Pf (HRP2 / pLDH) (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	
05FK92	Bioline Malaria Ag Pf (HRP2 / pLDH) (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	
05FK93	Bioline Malaria Ag Pf (HRP2 / pLDH) POCT	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	

	Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
	05FK140	NxTek Eliminate Malaria Pf (with Assay diluent, disposable inverted cup, Alcohol Swab, sterile lancet)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25	12	1-30°C	<u>WHO PQ</u>
	05FK141	NxTek Eliminate Malaria Pf (with Assay diluent, disposable inverted cup, Alcohol Swab, safety lancet)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25	12	1-30°C	
	05FK142	NxTek Eliminate Malaria Pf (Each test with Assay diluent, disposable inverted cup, Alcohol Swab, sterile lancet)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25x 1 test per kit	12	1-30°C	
	05FK143	NxTek Eliminate Malaria Pf (Each test with Assay diluent, disposable inverted cup, Alcohol Swab, safety lancet)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25x 1 test per kit	12	1-30°C	
	00-DKM-RK-MALADX-004-025	AdvDx Malaria Pf Rapid Malaria Ag Detection Test (with Sample applicator, Alcohol Swab, Lancet, Buffer solution)	Advy Chemical Pvt Ltd Plot No.A-334,336,338 & A-337 & 339, Road no. 25 & 26, Wagle industrial Estate, Thane 400 604, INDIA	Cassette	25	24	2-40°C	<u>WHO PQ</u>
	55IC104-10	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	10	24	4-40°C	<u>WHO PQ</u>
	55IC104-25	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	25	24	4-40°C	
	55IC104-50	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	50	24	4-40°C	
	55IC116-10	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	10	24	4-40°C	
	55IC116-25	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	25	24	4-40°C	
	55IC116-50	ParaHIT® - f Ver 1.0 (Device)	Arkray Healthcare Pvt. Ltd Plot No:336-338-340, Sachin – Gujrat, India (Formerly Span Diagnostics Limited)	Cassette	50	24	4-40°C	
	W037P0022	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	25 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0028	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0030	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	25 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0024	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	25 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0033	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0035	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°C	<u>WHO PQ</u>
	W037P0042	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	100 T/k	24	1-40°C	<u>WHO PQ</u>

Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
ITPW11007-TC25	ONE STEP Malaria (Pf) Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	25	24	2-40°C	WHO PQ
ITPW11007-TC40	ONE STEP Malaria (Pf) Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	40	24	2-40°C	
ITPW11247-TC25	ONE STEP Malaria (Pf) Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	25	24	2-40°C	
ITPW11247-TC40	ONE STEP Malaria (Pf) Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	40	24	2-40°C	
302030005	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd Plot nos 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	Cassette	5	24	4-45°C	WHO PQ
302030010	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd Plot nos 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	Cassette	10	24	4-45°C	
302030025	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd Plot nos 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	Cassette	25	24	4-45°C	
302030100	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd Plot nos 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	Cassette	100	24	4-45°C	
PI13FRC25S	First Response® Malaria Ag P. falciparum (HRP2) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25x 1 test per kit	24	1-40°C	WHO PQ
PI13FRC10S	First Response® Malaria Ag P. falciparum (HRP2) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	10x 1 test per kit	24	1-40°C	
PI13FRC25	First Response® Malaria Ag P. falciparum (HRP2) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25	24	1-40°C	
PI13FRC30	First Response® Malaria Ag P. falciparum (HRP2) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	30	24	1-40°C	
09MAL10D	STANDARD Q Malaria P.f Ag Test	SD Biosensor, Inc., 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	Cassette	25	24	2-40°C	WHO PQ
C14RHA25 C14RHG25 C14RHH25	BIOCREDIT Malaria Ag Pf (pLDH)	RapiGEN Inc., 3-4F, 16, LS-ro 91 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea	Cassette	on request	on request	on request	ERPD Risk Cat 2 until 14 Jan 2026
C13RHA25 C13RHG25 C13RHH25	BIOCREDIT Malaria Ag Pf (pLDH/HRP2)	RapiGEN Inc., 3-4F, 16, LS-ro 91 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea	Cassette	on request	on request	on request	ERPD Risk Cat 2 until 14 Jan 2026
on request	on request	on request	on request	on request	on request	on request	ERPD Risk Cat 3

**For the detection of Pf and all *Plasmodium* species (Pf and Pan)**

	Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
	05FK60	Bioline Malaria Ag Pf/Pan	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40 <sup>o</sup> c	<u>WHO PQ</u>
	05FK61	Bioline Malaria Ag Pf/Pan (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40 <sup>o</sup> c	
	05FK62	Bioline Malaria Ag Pf/Pan (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40 <sup>o</sup> c	
	05FK63	Bioline Malaria Ag Pf/Pan POCT	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40 <sup>o</sup> c	
	05FK67	Bioline Malaria Ag Pf/Pan	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	30	24	1-40 <sup>o</sup> c	
	PI16FRC10S	First Response® Malaria Ag (pLDH/HRP2) Combo Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	10x 1 test per kit	24	1-40 <sup>o</sup> c	<u>WHO PQ</u>
	PI16FRC25S	First Response® Malaria Ag (pLDH/HRP2) Combo Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25x 1 test per kit	24	1-40 <sup>o</sup> c	
	PI16FRC25	First Response® Malaria Ag (pLDH/HRP2) Combo Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25	24	1-40 <sup>o</sup> c	
	PI16FRC30	First Response® Malaria Ag (pLDH/HRP2) Combo Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	30	24	1-40 <sup>o</sup> c	
	09MAL30D	STANDARD Q Malaria P.f./Pan Ag Test	SD Biosensor, Inc., 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	Cassette	25	24	2-40 <sup>o</sup> c	<u>WHO PQ</u>
	GCMAL (pf/pan)-402a-DR1	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)	Zhejiang Orient Gene Biotech Co., Ltd PRC	Cassette	25	24	1-40 <sup>o</sup> c	<u>GHTF (EU IVDR Class C)</u>
	GCMAL (pf/pan)-402a-DR2	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)	Zhejiang Orient Gene Biotech Co., Ltd PRC	Cassette	25	24	1-40 <sup>o</sup> c	
	GCMAL (pf/pan)-402a-DR3	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)	Zhejiang Orient Gene Biotech Co., Ltd PRC	Cassette	25	24	1-40 <sup>o</sup> c	
	GCMAL (pf/pan)-402a-DR4	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)	Zhejiang Orient Gene Biotech Co., Ltd PRC	Cassette	25	24	1-40 <sup>o</sup> c	
	503030010	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	4-40 <sup>o</sup> c	<u>WHO PQ</u>
	503030025	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	24	4-40 <sup>o</sup> c	
	503030050	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	50	24	4-40 <sup>o</sup> c	
	503030100	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	100	24	4-40 <sup>o</sup> c	

Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
<b>For the detection of <i>Plasmodium falciparum</i> and <i>vivax</i> (Pf and Pv/Pvom)</b>							
05FK80	Bioline Malaria Ag Pf/Pv	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	<u>WHO PQ</u>
05FK81	Bioline Malaria Ag Pf/Pv (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25	24	1-40°C	
05FK82	Bioline Malaria Ag Pf/Pv (Safety Lancet)	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	
05FK83	Bioline Malaria Ag Pf/Pv POCT	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	25x 1 test per kit	24	1-40°C	
05FK86	Bioline Malaria Ag Pf/Pv	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	10	24	1-40°C	
05FK87	Bioline Malaria Ag Pf/Pv	Abbott Diagnostics Korea Inc., #65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do,446-930, Republic of Korea	Cassette	2 Kits/8T and 1 kit 9T	24	1-40°C	
ITPW11009-TC25	ONE STEP Malaria (Pf/Pv) TriLine Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	25	24	2-40°C	<u>WHO PQ</u>
ITPW11009-TC40	ONE STEP Malaria (Pf/Pv) TriLine Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	40	24	2-40°C	
ITPW11249-TC25	ONE STEP Malaria (Pf/Pv) TriLine Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	25	24	2-40°C	
ITPW11249-TC40	ONE STEP Malaria (Pf/Pv) TriLine Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Cassette	40	24	2-40°C	
PI19FRC10s	First Response® Malaria Ag P.f./P.v. (HRP2/pLDH) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	10x 1 test per kit	24	1-40°C	<u>WHO PQ</u>
PI19FRC25s	First Response® Malaria Ag P.f./P.v. (HRP2/pLDH) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25x 1 test per kit	24	1-40°C	
PI19FRC25	First Response® Malaria Ag P.f./P.v. (HRP2/pLDH) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	25	24	1-40°C	
PI19FRC30	First Response® Malaria Ag P.f./P.v. (HRP2/pLDH) Card Test	Premier Medical Corporation Ltd Site 2: 32-35, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman - INDIA ; Site 1: A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Cassette	30	24	1-40°C	
09MAL20D	STANDARD Q Malaria P.f /P.v. Ag Test	SD Biosensor, Inc., 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	Cassette	25	24	2-40°C	<u>WHO PQ</u>
503010010	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	1-40°C	<u>WHO PQ</u>
503010025	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	24	1-40°C	
503010025(1T)	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25x 1 test per kit	24	1-40°C	

Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
503010050	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	50	24	1-40°C	
503010100	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	100	24	1-40°C	
C61RHA25 C61RHG25 C61RHH25	BIOCRECREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	RapiGEN Inc., 3-4F, 16, LS-ro 91 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea	Cassette	on request	on request	on request	<u>ERPD Risk Cat 2 until 14 Jan 2026</u>
<b>For the detection of all <i>Plasmodium</i> species (Pf, Pf and Pv)</b>							
05FK120	Bioline Malaria Ag Pf/Pf/Pv (Assay diluent vial, Disposable inverted cup, Sterile lancet, Alcohol swabs)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25	24	1-40°C	<u>WHO PQ (follow warnings in HRP2 deletion settings)</u>
05FK123	Bioline Malaria Ag Pf/Pf/Pv POCT (Each kit contains all necessary accessories)	Abbott Diagnostics Korea Inc., 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea and 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	Cassette	25x 1 test per kit (bundle kit)	24	1-40°C	
<b>For the detection of all <i>Plasmodium</i> species (Pan)</b>							
n/a	n/a	n/a	n/a	n/a	n/a	n/a	
<p>Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.</p>							

**LIST OF DIAGNOSTIC PRODUCTS RELATED MALARIA  
classified according to the Global Fund Quality Assurance Policy**

The list is an overview of malaria RDTs to assist Principal Recipients (PRs) of Global Fund grants to identify the status of Malaria RDTs according to the Global Fund Quality Assurance Policy. It includes products eligible for procurement after assessment by:

- the WHO Prequalification of Diagnostics Programme as listed by WHO (<https://extranet.who.int/prequal/vitro-diagnostics/prequalified/in-vitro-diagnostics>)

or

-Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF or WLAs within their scope of listing

or

- the Global Fund's Expert Review Panel for Diagnostics (ERPD) as described in the Global Fund Quality Assurance Policy.

The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements. The list is updated from time to time based on evidence received by the Global Fund.

"ERPD" eligibility means, that procurement with Global Fund resources of this product will be permitted / Non-Objection-Letters are required for procurement

Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
<b>For the detection of G6PD deficiency</b>							
	Standard G6PD System (Ref 02GS10)						
02GA10	Analyser	SD Biosensor Inc., 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, Republic of Korea	equipment	n/a	n/a	2-30 °C	GHTF (TGA Class C)
02G6S10	G6PD Test		tests	25	18	2-30 °C	
02G6S10A	G6PD Test		tests	10	18	2-30 °C	
02G6C10	G6PD Controls (Ref C-02GS10-1, Ref C-02GS10-2)		reagents	n/a		2-30 °C	
	Standard G6PD System (Ref 02GS11)						
02GA11	Analyser	SD Biosensor Inc., 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, Republic of Korea	equipment	n/a	n/a	2-30 °C	WHO PQ
02G6S11	G6PD Test		tests	25	18	2-30 °C	
02G6S11A	G6PD Test		tests	10	18	2-30 °C	

	Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Eligibility criteria
	02G6C11	G6PD Controls (Ref C-02GS11-1, Ref C-02GS11-2)		reagents	n/a		2-30 °C	

Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.