THE GLOBAL FUND

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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
			For the detection of Plasmodium falciparum only (Pf)					
	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	
	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	

	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
	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	WHO PQ
	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-MAL-ADX-004-001	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 industial Estate, Thane 400 604, INDIA	Cassette	1	24	2-40°C	WHO PQ
	00-DKM-RK-MAL-ADX-004-010	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 industial Estate, Thane 400 604, INDIA	Cassette	10	24	2-40°C	WHO PQ
	00-DKM-RK-MAL-ADX-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 industial Estate, Thane 400 604, INDIA	Cassette	25	24	2-40°C	WHO PQ
	00-DKM-RK-MAL-ADX-004-050	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 industial Estate, Thane 400 604, INDIA	Cassette	50	24	2-40°C	WHO PQ
	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	
	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	WHO PQ
	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	WHO PQ
	W037P0028	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°c	WHO PQ
	W037P0030	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	25 T/k	24	1-40°c	WHO PQ
	W037P0024	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	25 T/k	24	1-40°c	WHO PQ
	W037P0033	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°c	WHO PQ

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
W037P0035	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	40 T/k	24	1-40°c	WHO PQ
W037P0042	Wondfo Malaria P.f (HRP2/pLDH) Test	Guangzhou Wondfo Biotech Co., Ltd PRC	Cassette	100 T/k	24	1-40°c	WHO PQ
ITPW11007-TC25	ONE STEP Malaria (Pf) Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	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	Casette	30	24	1-40°c	
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	Casette	25	24	2-40°c	WHO PQ
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	Casette	25	24	2-40°c	WHO PQ
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

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°c	WHO PQ
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°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°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°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°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	Casette	10x 1 test per kit	24	1-40°c	WHO PQ
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	Casette	25x 1 test per kit	24	1-40°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	Casette	25	24	1-40°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	Casette	30	24	1-40°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°c	WHO PQ
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°c	GHTF (EU IVDR Class C)
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°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°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°c	
50303025(1T)	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25x 1 test per kit	24	4-40°c	WHO PQ
503030010	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	4-40°c	
503030025	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	24	4-40°c	
503030050	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	50	24	4-40°c	
503030100	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	100	24	4-40°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
For the detection of *Plasmodium falciparum* and *vivax* (Pf and Pv/Pvom)								
	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	WHO PQ
	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	Casette	25	24	2-40°c	WHO PQ
	ITPW11009-TC40	ONE STEP Malaria (Pf/Pv) TriLine Test	InTec Products, Inc. 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China	Casette	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	Casette	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	Casette	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	Casette	10x 1 test per kit	24	1-40°c	WHO PQ
	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	Casette	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	Casette	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	Casette	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	WHO PQ
	C61RHG25 C61RHH25	BIOCREDIT 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	Casette	25	24	2-40°c	WHO PQ
	503010010	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	1-40°c	
	503010025	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	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
	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	WHO PQ
	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	
	For the detection of all *Plasmodium* species (Pf, Pf and Pv)							
	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	WHO PQ (follow warnings in HRP2 deletion settings)
	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	
	For the detection of all *Plasmodium* species (Pan)							
	n/a	n/a	n/a	n/a	n/a	n/a	n/a	

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THE GLOBAL FUND

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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
		For the detection of *G6PD deficiency*						
		Standard G6PD System (Ref 02GS10)	SD Biosensor Inc., 16, Deogyeong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, Republic of Korea					GHTF (TGA Class C)
	02GA10	Analyser		equipment	n/a	n/a	2-30 °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)	SD Biosensor Inc., 16, Deogyeong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, Republic of Korea					WHO PQ
	02GA11	Analyser		equipment	n/a	n/a	2-30 °C	
	02G6S11	G6PD Test		tests	25	18	2-30 °C	
	02G6S11A	G6PD Test		tests	10	18	2-30 °C	
	02G6C11	G6PD Controls (Ref C-02GS11-1, Ref C-02GS11-2)		reagents	n/a		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
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.								