

## 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/pqweb/sites/default/files/documents/210928\\_prequalified\\_product\\_list.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/210928_prequalified_product_list.pdf))
- 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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> C	<a href="#">WHO PQ</a>
	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 <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
	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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	
	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	25	24	1-40 <sup>o</sup> C	<a href="#">ERP Risk Cat 2 until 14 Jul 2022</a>
	C13RHA25 C13RHG25 C13RHH25	BIOCREDIT Malaria Ag Pf (pLDH/HRPII)	RapiGEN Inc., 3-4F, 16, LS-ro 91 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea	Cassette	25	24	1-40 <sup>o</sup> C	<a href="#">ERP Risk Cat 2 until 14 Jul 2022</a>
	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 <sup>o</sup> C	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	<a href="#">WHO PQ</a>

	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 Pf and all <i>Plasmodium</i> species (Pf and Pan)								
	MHLRDP-02	One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag	Meril Diagnostics Pvt. Ltd., INDIA	Cassette	30	24	1-40 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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	<a href="#">WHO PQ</a>
	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	
	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	<a href="#">WHO PQ</a>
	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	
	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	<a href="#">WHO PQ</a>
	503030010	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	4-30 <sup>o</sup> c	<a href="#">WHO PQ</a>
	503030025	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	24	4-30 <sup>o</sup> c	
	503030050	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	50	24	4-30 <sup>o</sup> c	
	503030100	parascreen - Rapid test for Malaria Pan/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	100	24	4-30 <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
For the detection of <i>Plasmodiumfalciparum</i> and <i>vivax</i> (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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	
	MFLRPD-02	One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	Meril Diagnostics Pvt. Ltd., second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	Cassette	30	24	1-40 <sup>o</sup> c	<a href="#">WHO PQ</a>
	MFLRPD-03	One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	Meril Diagnostics Pvt. Ltd., second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	Cassette	25	24	1-40 <sup>o</sup> c	
	MFLRPD-04	One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	Meril Diagnostics Pvt. Ltd., second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	Cassette	50	24	1-40 <sup>o</sup> 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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	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 <sup>o</sup> 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 <sup>o</sup> 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 <sup>o</sup> c	
	C61RHA25 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	1-40 <sup>o</sup> C	<a href="#">ERPD Risk Cat 2 until 14 Jul 2022</a>
	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 <sup>o</sup> c	<a href="#">WHO PQ</a>
	503010010	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	10	24	1-40 <sup>o</sup> c	<a href="#">WHO PQ</a>
	503010025	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	25	24	1-40 <sup>o</sup> c	
	503010050	FalciVax - Rapid test for Malaria Pv/Pf	Zephyr Biomedicals - A Division of Tulip Diagnostics Ltd, India	Cassette	50	24	1-40 <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
	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 <i>Plasmodium</i> 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	<a href="#">WHO PQ (follow warnings in HRP2 deletion settings)</a>
	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 <i>Plasmodium</i> species (Pan)								
	n/a	n/a	n/a	n/a	n/a	n/a	n/a	
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.								



THE GLOBAL FUND

Version 30  
29 September 2021

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/pqweb/sites/default/files/documents/210521\\_prequalified\\_product\\_list.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/210521_prequalified_product_list.pdf) )
- 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

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For the detection of <i>G6PD deficiency</i>							
	Standard G6PD System (Ref 02GS10)	SD Biosensor Inc., 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, Republic of Korea					ERPD Risk Cat 2 until 24 July 2022
02GA10	Analyser		equipment	n/a	n/a	2-30 °C	
02G6S10	G6PD Test		tests	25	12	2-30 °C	
02G6C10	G6PD Controls (Ref C-02GS10-1, Ref C-02GS10-2)		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.

THE GLOBAL FUND

Version 30  
29 September 2021

List of Malaria RDTs removed in 2020 and 2021 from the list of eligible products.

It should be used together with the current LIST OF RAPID DIAGNOSTIC TEST (RDT) KITS FOR MALARIA classified according to the Global Fund Quality Assurance Policy

This list is not exhaustive and reflects only recent removals.

Product codes superscripted with a \* (star) mark is WHO prequalified

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Manufacturer Product Catalogue number	Product Name	Manufacturer and Manufacturing site address	Format	Number of tests per kit	Shelf life (months)	Recommended storage temperature	Removal rational
For the detection of Plasmodium falciparum only (Pf)							
RMOM-02571 * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
RMOM-02571CB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
RMOM-02571RB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
RMOM-02571RI * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
RMOM-02591 * (old product code)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
RMOM-05071 * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
RMOM-05071CB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
RMOM-05071RB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
RMOM-05071RI * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
RMOM-05091 * (old product code)	CareStart™ Malaria Pf (HRP2) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	50	30	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	Removal rational
	RMOU-02571 * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
	RMOU-02571CB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMOU-02571RB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMOU-02571RI * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMOU-02591 * (old product code)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
	RMOU-04071 * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMOU-04071CB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMOU-04071RB * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMOU-04071RI * (old product code G0141)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMOU-04091 * (old product code)	CareStart™ Malaria Pf (HRP2) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	40	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
	RMPM-02571 * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPM-02571CB * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPM-02571RB * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPM-02571RI * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPM-02591 * (old product code)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	24	1-40°C	
	RMPM-05071 * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	24	1-40°C	
	RMPM-05071CB * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	24	1-40°C	
	RMPM-05071RB * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	24	1-40°C	
	RMPM-05071RI * (old product code G0181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	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	Removal rational
	RMPM-05091 * (old product code)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	50	24	1-40°C	
	RMPU-02571 * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	<a href="#">QA Information Notice 2020-01</a>
	RMPU-02571CB * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPU-02571RB * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPU-02571RI * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	24	1-40°C	
	RMPU-02591 * (old product code)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	24	1-40°C	
	RMPU-04071 * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	24	1-40°C	
	RMPU-04071CB * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	24	1-40°C	
	RMPU-04071RB * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	24	1-40°C	
	RMPU-04071RI * (old product code Go181)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	24	1-40°C	
	RMPU-04091 * (old product code)	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	40	24	1-40°C	
For the detection of Pf and all <i>Plasmodium</i> species (Pf and Pan)								
	RMRM-02571 * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMRM-02571CB * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMRM-02571RB * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMRM-02571RI * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMRM-02591 * (old product code)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
	RMRM-05071 * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMRM-05071CB * (old product code Go131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	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	Removal rational
	RMRM-05071RB * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40 <sup>o</sup> c	<a href="#">QA Information Notice 2020-01</a>
	RMRM-05071RI * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40 <sup>o</sup> c	
	RMRM-05091 * (old product code)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	50	30	1-40 <sup>o</sup> c	
	RMRU-02571 * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> c	
	RMRU-02571CB * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> c	
	RMRU-02571RB * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> c	
	RMRU-02571RI * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> c	
	RMRU-02591 * (old product code)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40 <sup>o</sup> c	
	RMRU-04071 * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40 <sup>o</sup> c	
	RMRU-04071CB * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40 <sup>o</sup> c	
	RMRU-04071RB * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40 <sup>o</sup> c	
	RMRU-04071RI * (old product code G0131)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40 <sup>o</sup> c	
	RMRU-04091 * (old product code)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	40	30	1-40 <sup>o</sup> c	
For the detection of <i>Plasmodiumfalciparum</i> and <i>vivax</i> ( Pf and Pv/Pvom)								
	RMVM-02571 * (old product code G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> C	
	RMVM-02571CB * (old product code G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> C	
	RMVM-02571RB * (old product code G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> C	
	RMVM-02571RI * (old product code G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40 <sup>o</sup> C	
	RMVM-02591 * (old product code)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40 <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	Removal rational
	RMVM-05071 * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
	RMVM-05071CB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMVM-05071RB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMVM-05071RI * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMVM-05091 * <small>(old product code)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	50	30	1-40°C	
	RMVU-02571 * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMVU-02571CB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMVU-02571RB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMVU-02571RI * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMVU-02591 * <small>(old product code)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
	RMVU-04071 * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMVU-04071CB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMVU-04071RB * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMVU-04071RI * <small>(old product code Go161)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMVU-04091 * <small>(old product code)</small>	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	40	30	1-40°C	
For the detection of all <i>Plasmodium</i> species (Pf, Pf and Pv)								
	n/a	n/a	n/a	n/a	n/a	n/a	n/a	
For the detection of all <i>Plasmodium</i> species (Pan)								
	RMNM-02571 * <small>(old product code Go111)</small>	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	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	Removal rational
	RMNM-02571CB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
	RMNM-02571RB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNM-02571RI *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNM-02591 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
	RMNM-05071 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMNM-05071CB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMNM-05071RB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMNM-05071RI *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	50	30	1-40°C	
	RMNM-05091 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Multi Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	50	30	1-40°C	
	RMNU-02571 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNU-02571CB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNU-02571RB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNU-02571RI *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	25	30	1-40°C	
	RMNU-02591 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	25	30	1-40°C	
	RMNU-04071 *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with capped lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMNU-04071CB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with capped lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMNU-04071RB *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and bulb type specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	1-40°C	
	RMNU-04071RI *	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc 65 Clyde Rd., Suite A, Somerset, NJ 08873, USA	Cassette	40	30	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	Removal rational
	RMNU-04091 * (old product code)	CareStart™ Malaria PAN (pLDH) Ag RDT (Single Kit with retractable lancet and inverted cup specimen transfer device)	Access Bio, Inc Yeka Sub-City, Kebele 16, House No. - New Addis Ababa, Ethiopia	Cassette	40	30	1-40°C	<a href="#">QA Information Notice 2020-01</a>
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