

WHO LOT TESTING PROGRAMME FOR MALARIA RAPID DIAGNOSTIC TESTS (RDTs)

2007–2022



**World Health
Organization**

WHO LOT TESTING PROGRAMME FOR MALARIA RAPID DIAGNOSTIC TESTS (RDTs)

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CONTENTS

ABOUT	1
MALARIA RDT LOT TESTING RESULTS, 2022 (INITIAL TESTING)	2
MALARIA RDT LOT TESTING RESULTS, 2022 (NON-ROUTINE TESTING)	3
MALARIA RDT LOT TESTING RESULTS, 2007 – 2022 (CUMULATIVE SUMMARY BY PRODUCT)	4
MALARIA RDT LOT TESTING RESULTS SUMMARY, 2007 – 2022	10
PRE-QUALIFIED PRODUCTS SUBMITTED FOR MALARIA RDT LOT-TESTING, 2022	11
ANNUAL DEMAND FOR MALARIA RDT LOT TESTING, 2007-2022	12
REQUESTERS AND RECIPIENT COUNTRIES OF LOT-TESTED MALARIA RDTs, 2022	14

ABOUT

The WHO lot testing programme for malaria rapid diagnostic tests (RDTs) is an independent quality control system designed to evaluate lot to lot variation in performance of malaria RDTs. The purpose of this programme is to ensure that only the highest quality malaria RDT lots are procured and used in endemic countries. Currently, the Research Institute for Tropical Medicine (RITM) (Philippines) serves as the only WHO-sponsored and monitored laboratory evaluating RDT lots according to WHO procedures, using well-characterized and standardized parasite samples for quality control of malaria RDTs. Historically, WHO has commissioned independent, external quality laboratory assessments of the National Institute of Malaria Research (NIMR), New Delhi, India and the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos, Nigeria and these laboratories have been found to be compliant with WHO malaria RDT lot testing standard operating procedures. These laboratories conduct lot verification for RDT batches imported into their respective countries and they are not accounted for in this report. Representatives from these laboratories should be contacted for information regarding their ongoing compliance with WHO procedures and availability of lot testing services (India: nks.nimr@gmail.com; Nigeria: andimalariacentre@unilag.edu.ng).

RDTs are sent from anywhere in the world to RITM on request by Ministries of Health, national malaria control programmes, NGOs, RDT manufacturers, procurement agencies and other international organizations. Lot testing is performed at RITM according to procedures outlined [Methods Manual for Laboratory Quality Control Testing of Malaria RDTs \(who.int\)](#). RDT lots are tested within fourteen days of receipt. Malaria RDT lot testing results provide information about adequacy of RDTs for clinical use, and anomalies noted during testing that can also be encountered during use in the field. Reports provided to lot testing requesters include photos of the RDTs tested, observations (e.g., red background, faint test line, invalid result, etc.), and results of the accessory assessment.

This report is updated annually by the staff of the Malaria RDT Lot Testing Laboratory, Research Institute for Tropical Medicine (RITM), Philippines (ritm.malariardtlt@gmail.com) and reviewed by the responsible WHO technical officer (malaria_rdt@who.int). Further information about procedures to request RDT lot testing services as well as other related resources are available at [Global Malaria Programme \(who.int\)](#).

MALARIA RDT LOT TESTING RESULTS, 2022 (INITIAL TESTING)

Product Names	Catalog No.	Manufacturer	No. of lots tested	No. of lots passed
Adv Dx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MAL-ADX-004-024	Advy Chemical Pvt. Ltd.	12	11
Biocredit Malaria Ag. P.f/P.v (pLDH/pLDH)	C61RHF25	Rapigen, Inc.	2	2
Bioline Malaria Ag Pf	05FK50	Abbott Diagnostics Korea, Inc.	13	13
Bioline Malaria Ag Pf POCT	05FK53		4	4
Bioline Malaria Ag. P.f/P.f/P.v	05FK63		9	9
Bioline Malaria Ag. P.f/P.v	05FK83		1	1
Bioline Malaria Ag. P.f/Pan	05FK60		3	3
EzDx Malaria Pan/Pf Rapid Test Detection Kit	00-DKM-RK-MAL-EDX-001-025		Advy Chemical Pvt. Ltd.	1
FalciVax Device Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1	1
First Response Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC25	Premier Medical Corporation Pvt. Ltd.	81	81
First Response Malaria Ag Pf/Pv Card Test	PI19FRC25		12	12
First Response Malaria Ag pLDH/HRP2 Combo Card Test	PI16FRC25		30	30
	PI16FRC25CE		3	3
	PI16FRC25s		1	1
Meriscreen Malaria P.f/P.v Ag	MFLRPD-03	Meril Diagnostics, Pvt. Ltd.	3	3
Paracheck Pf Device - Rapid Test for P. falciparum Malaria (Ver 3)	302030010	Orchid Biomedical Systems	20	20
	302030025		57	57
ParaHIT f. ver 1.0 Rapid Test for P. falciparum Malaria Device	55IC104-25	Arkray Healthcare Pvt. Ltd.	74	74
	55IC104-10		10	10
Parascreen Device Rapid Test for Malaria PAN/Pf	503030025	Zephyr Biomedicals	6	6
SD Bioline Malaria Ag P.f/P.v POCT	05FK83	Standard Diagnostics, Inc.	1	1
STANDARD Q Malaria Pf Ag	09MAL10D	SD Biosensor, Inc.	2	2
STANDARD Q Malaria Pf/PAN Ag	09MAL30D		3	3
STANDARD Q Malaria Pf/Pv Ag	09MAL20D		1	1
TOTAL			350	348

MALARIA RDT LOT TESTING RESULTS, 2022 (NON-ROUTINE TESTING)

A total of 23 lots were received for non-routine testing. Sixteen (16) of these were sent to the RITM for testing after being retrieved from field sites in Rwanda (6 lots) and health facilities in Malawi (10 lots) due to complaints on their performance. Two of the 6 lots from Rwanda failed the QC assessment due to insufficient buffer which did not allow testing. Concerning lots that originated from Malawi, 9 out of 10 lots passed the QC assessment; 1 lot returned false positive results (3/13) on negative QC samples.

The other 7 lots were for confirmatory testing after deferred QC assessment results from NIMR, India. Four (4) of the 7 lots obtained failed QC assessment results in the confirmatory testing because the lots showed negative results on *Pf* QC samples (3/4 samples), consistent with the primary testing results from NIMR.

Product Names	Catalog No.	Manufacturer	No. of lots tested	No. of lots passed
Advantage MAL Card	IRI21050	Diagnostic Enterprises	1	0
ErbaQik ® Malaria PAN Antigen Test	132213	Transasia Bio-Medicals Limited	3	0
EdgeXpress Malaria Pan Antigen Detection Test	EL011C25	EdgeLabs LLP	3	3
SD Bioline Malaria Ag <i>P.f</i> /PAN POCT	05FK67	Standard Diagnostics Inc.	6	4
First Response Malaria Ag. <i>P. falciparum</i> (HRP2) Card Test	PI13FRC25	Premier Medical Corporation Private Limited	10	9
TOTAL			23	16

MALARIA RDT LOT TESTING RESULTS, 2007 – 2022

(Cumulative summary by product)

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate† (%)	Comment (s)
Abbott Diagnostics Korea, Inc.	05FK50/53	Bioline Malaria Ag Pf	39	2021	100	
Abbott Diagnostics Korea, Inc.	05FK60/63	Bioline Malaria Ag Pf/PAN	22	2021	100	
Abbott Diagnostics Korea, Inc.	05FK83	Bioline Malaria Ag. P.f/P.v	1	2022		
Abbott Diagnostics Korea, Inc.	05FK123	Bioline Malaria Ag. P.f/P.f/P.v	9	2022		
Access Bio Inc.	RMLC-02571/RMLM-02571 (G0121)	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	11	2008-2009-2016-2017	91	1 lot failed initial testing in 2016
Access Bio Inc.	RMOM-02571/RMOU-02571 (G0141/141-SK)	CareStart™ Malaria Pf (HRP2) Ag RDT	866	2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2021	100	
Access Bio Inc.	RMRM-01071/RMRM-02571/RMRU-02571 (G0131/131-SK)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	349	2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2021	98	6 lots failed initial testing in 2016
Access Bio Inc.	RMVM-01071/RMVM-02571/RMVC-02571 (G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	57	2012-2013-2014-2015-2016-2017-2018-2019-2021	100	
Access Bio Inc.	RMWM-02571	CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	2	2018	100	
Access Bio Inc.	G0221	CareStart™ Malaria/Pregnancy Combo (HRP2/pLDH/HCG)	1	2015	100	
Access Bio Inc.	G0231	CareStart™ Malaria Screen	16	2008-2009	100	
Access Bio Inc.	RMNM-02571/RMNC-02571 (G0111)	CareStart™ Malaria pLDH (Pan)	64	2011-2014-2015-2016-2017-2018-2019-2021	100	
Access Bio Inc.	RMPC-02571 (G0181/181-ET/181-SK)	CareStart™ Malaria HRP2/ pLDH(Pf)	37	2013-2014-2015-2016	100	
Advya Chemical Private Limited	RK MAL 001	EzDx™ Malaria Pan/Pf Rapid test detection Kit	9	2011-2013	100	

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate [†] (%)	Comment (s)
Advys Chemical Private Limited	RK MAL 003	EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	2	2013	100	
Advys Chemical Private Limited	00-DKM-RK-MAL-ADX-004-025	AdvDx™ Malaria Pf Rapid Malaria Ag Detection Test	24	2020-2021-2022	96	1 lot failed initial testing in 2022.
Advys Chemical Private Limited	00-DKM-RK-MAL-EDX-001-025	EzDx Malaria Pan/Pf Rapid Test Detection Kit	1	2022	1	
ARKRAY Healthcare Pvt Ltd*	55IC104-10/25/50	Parahit® f Ver 1.0 Rapid Test for P. falciparum Malaria - Device	199	2013-2014-2015-2016-2017-2018-2019-2020-2021-2022	100	
ARKRAY Healthcare Pvt Ltd*	55IC102-10	ParaHIT-f (device)	7	2007-2009	100	
ARKRAY Healthcare Pvt Ltd*	55IC201-10	ParaHIT-Total (dipstick)	1	2008	0	1 lot failed initial testing in 2008
Artron Laboratories Inc.	A03-18-322	Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	1	2016	100	
Artron Laboratories, Inc.	A03-12-322	Malaria P.f/Pv (Mal Pf/Pv) Antigen Test Kit	1	2016	100	
Athenese-Dx Pvt. Ltd.	AR0112C	TRUSTline Malaria Pf/Pv Ag	1	2021	100	
Bio Footprints Healthcare Pvt. Ltd.	MTR00250	Mytest™ Malaria Ag Pf/Pan	2	2015	100	
BioNote Inc. Korea	RG19-11	Bionote Malaria P.f Ag Rapid Test Kit	2	2015	100	
BioNote, Inc.	RG19-08	BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	1	2014	100	
Clearview	VB11	Clearview Malaria Combo	1	2010	100	
CTK Biotech, Inc.	R0112C	OnSite Malaria Pf/Pv Ag Rapid Test	8	2013-2014	100	
CTK Biotech, Inc.	R0113C	OnSite Malaria Pf/Pan Ag Rapid Test	1	2012	100	
CTK Biotech, Inc.	R0114C	OnSite Malaria Pf Ag Rapid Test	6	2007-2013-2014	100	
Deangel Biological Engineering Co., Ltd.	MAL-MD02	Malaria Pf/Pan Rapid Test Device	2	2015-2017	100	
Deangel Biological Engineering Co., Ltd.	MAL-ND02	Malaria Pf/Pv Rapid Test Device	1	2017	100	
Diagnostic Enterprises	IRI21050	Advantage MAL Card	1	2022	0	1 lot failed RITM confirmatory testing in 2022.

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate [†] (%)	Comment (s)
Diamed AG	710024	OptiMAL-IT	1	2008	100	
EdgeLabs LLP	EL011C25	EdgeXpress Malaria Pan Antigen Detection Test	3	2022	100	
Guangzhou Wondfo Biotech Co. Ltd.	W56-C (4.0 mm)	One step Malaria Pf/Pan whole blood test	4	2008-2009	100	
Hema Diagnostic Systems, LCC	MAL-PFV-CAS25	Rapid 1-2-3 Hema Cassette Malaria (PFV)	3	2015	100	
Human GmbH	58024	Hexagon Malaria Combi	1	2008	0	1 lot failed initial testing in 2008
ICT Diagnostics	ML02	ICT Malaria Combo Cassette Test	68	2007-2008-2009-2010-2011-2012	88	8 lots failed initial testing; 2007 (1), 2008 (1), 2011 (2) & 2012 (4)
ICT INTERNATIONAL	ML01	ICT MALARIA P.F. CASSETTE TEST	249	2007-2008-2009-2010-2011-2014	100	
ICT INTERNATIONAL	ML03	ICT MALARIA DUAL TEST	2	2012-2014	100	
Innovita Biological Technology Co. Ltd.	YF503C	Malaria Pf/Pan Antigen Whole Blood Test Cassette (Colloidal Gold)	2	2017-2018	50	1 lot was deferred during initial testing in 2007. No confirmatory testing result available.
J. Mitra & Co. Pvt. Ltd.	IR016025	Advantage P.f. Malaria Card	15	2013-2014-2015-2017-2018	100	
J. Mitra & Co. Pvt. Ltd.	IR211025	Advantage Malaria Card	1	2010	100	
J. Mitra & Co. Pvt. Ltd.	IR231025	Advantage Malaria Pan + Pf Card	4	2016-2018	100	
Lumiquick Diagnostics Inc.	71050	QuickProfile™ Malaria Pf/Pv Antigen Test	3	2013-2016	100	
Lumiquick Diagnostics, Inc.	71063	QuickProfile™ Malaria Pf/Pan Test	2	2016	100	
Meril Diagnostics, Pvt. Ltd.	MFLRDP-03	MeriScreen Malaria Pf/Pv Ag	8	2020-2021-2022	100	
Nanong Egens Biotechnology Co., LTD.	Inf-73	Malaria P.f./Pv Antigen Test Cassette	2	2011-2013	100	
Nanong Egens Biotechnology Co., LTD.	Inf-76	Malaria P.f. Antigen Test Cassette	2	2011-2013	100	

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate [†] (%)	Comment (s)
Nanong Egens Biotechnology Co., LTD.	Nil	QD Malaria Antigen P.f	1	2014	100	
Orchid Biomedical Systems (Tulip Group)	30301025/30203010/302030025	Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	1507	2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2020-2021-2022	100	
Premier Medical Corporation Ltd.	I13FRC25/25CE/25S/30/30S/35	First Response® Malaria Ag P. falciparum (HRP2) Card Test	321	2009-2010-2011-2012-2013-2014-2015-2016-2017-2018-2019	100	
Premier Medical Corporation Ltd.	I16FRC25/25CE/25S/30/30s/40	First Response Malaria HRP2/pLDH(Pf/Pan)	172	2010-2011-2012-2013-2014-2015-2016-2017-2018	99	Pv detection @ 200 parasites/µl failed in 2 lots in 2015
Premier Medical Corporation Ltd.	I16MCC10/25	Malacheck Malaria Ag (pLDH/HRP2) Combo Card Test	4	2012-2013	100	
Premier Medical Corporation Ltd.	PI13FRC25/25CE/26/27/28	First Response Malaria Ag. P. falciparum HRP2 Card Test	294	2014-2016-2017-2018-2019-2020-2021-2022	100	
Premier Medical Corporation Ltd.	PI16FRC25/25CE/25S	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	112	2014-2017-2018-2019-2020-2021-2022	100	
Premier Medical Corporation Private Ltd.	PI19FRC10/10S/25/25S	First Response® Malaria Ag. P.f./P.v. Card Test	47	2014-2017-2019-2020-2021-2022	96%	
RapiGEN Inc.	C14RHG25	BIOCREDIT Malaria Ag Pf (pLDH)	1	2021	100	
RapiGEN Inc.	C32RHA25	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	4	2018-2020-2021	100	
RapiGEN Inc.	C61RHI25	BIOCREDIT Malaria Pf/Pv	3	2021-2022	100	
SD Biosensor, Inc.	09MAL10D	Standard Q Malaria Pf Ag	78	2020-2021-2022	100	
SD Biosensor, Inc.	09MAL20D	Standard Q Malaria Pf/Pv Ag	5	2020-2021-2022	100	
SD Biosensor, Inc.	09MAL30D	Standard Q Malaria Pf/PAN Ag	20	2020-2021-2022	100	
SD Bio Standard Diagnostics PVT. LTD, India	05FK60I-40	SD Malaria Ag Pf/Pan	2	2010	100	

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate [†] (%)	Comment (s)
Shenzhen Bioeasy Biotechnology Co. Ltd	YRLG0180102	Bioeasy One Step Malaria P.f/Pan Tri Line Rapid Test	1	2019	100	
Standard Diagnostics Inc.	05FK60/61/63/64/65/66/67	SD BIOLINE Malaria Ag P.f/Pan	843	2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2020-2021-2022	99	2 lots failed initial non-routine testing in 2022. No confirmatory results available.
Standard Diagnostics Inc. (Alere)	05FK120/123	SD BIOLINE Malaria Ag P.f/P.f/P.v	43	2014-2015-2016-2017-2018-2019-2020	100	
Standard Diagnostics Inc. (Alere)	05FK90/93	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	136	2009-2010-2012-2013-2014-2015-2016-2017-2018-2019	100	
Standard Diagnostics, Inc.	05FK40	SD Bioline Malaria Ag	14	2007-2008-2009-2010	100	
Standard Diagnostics, Inc.	05FK50/51/52/53/54/55/56/57/58/59	SD BIOLINE Malaria Ag Pf	1846	2009-2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2020-2021	100	2014-6 lots of 05FK57 failed interval testing due to evaporation of buffer
Standard Diagnostics, Inc.	05FK80/81/83/85/86/87	SD Bioline Malaria Ag P.f/P.v	474	2010-2011-2012-2013-2014-2015-2016-2017-2018-2019-2020-2021-2022	100	
Standard Diagnostics, Inc.	05FK140	Alere Malaria Ag Pf Ultra Sensitive	5	2019-2020	100	
Transasia Bio-Medicals Limited	132213	ErbaQik ® Malaria PAN Antigen Test	3	2022	0	3 lots failed RITM confirmatory testing in 2022.
Zephyr Biomedicals	503010025/10	Parascreen (Falcivax) Device Rapid Test for Malaria Pan/Pf (Device)	26	2007-2008-2009-2010-2020-2021	100	
Zephyr Biomedicals	503030025	ParaScreen Device Rapid Test for Malaria PAN	46	2020-2021-2022	100	
Zephyr Biomedicals	503040025	ParaBank Device Rapid Test for Malaria PAN/Pf	5	2020-2021	20	4 lots failed confirmatory testing in 2021
Zhuhai Encode Medical Engineering Co., Ltd.	IMA432	RAPIQUICK Malaria P.f/Pan Rapid Test Device	1	2017	0	1 lot failed initial testing in 2017

Manufacturer	Catalogue No.	Product name	No. lots tested	Year(s) tested	Pass Rate [†] (%)	Comment (s)
TOTAL			8129			

[†] Pass rate during routine initial testing

* Previously known as Span Diagnostics Ltd

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MALARIA RDT LOT TESTING RESULTS SUMMARY, 2007 – 2022

From 2013 up to the last long-term testing done in 2018, no lots have failed. Under initial testing, since 2017 no failures were noted until 2021. In 2022, 1 lot failed in initial testing due to unacceptably high false positive against negative QC samples. In total, 8,258 lots were initially tested with 17 failures (0.22%) recorded from 2007 to present.

Year	No. of new products	No. of new manufacturers	No. of RDTs lots	No. of initial failures	No. of long term failures
2007	8	7	59	1	1
2008	6	4	139	3	1
2009	2	-	243	0	2
2010	7	3	236	0	0
2011	4	2	365	2	9
2012	4	-	567	4	6
2013	6	1	1083	0	0
2014	2	1	927	0	0
2015	6	3	879	2	0
2016	14	2	797	1	0
2017	4	2	760	1	0
2018	2	1	592	0	0
2019	2	1	294	0	NA
2020	7	2	496	0	NA
2021	3	1	448	1	NA
2022	3	-	342	1	NA
Total	80	30	8258	1	19

PRE-QUALIFIED PRODUCTS SUBMITTED FOR MALARIA RDT LOT-TESTING, 2022

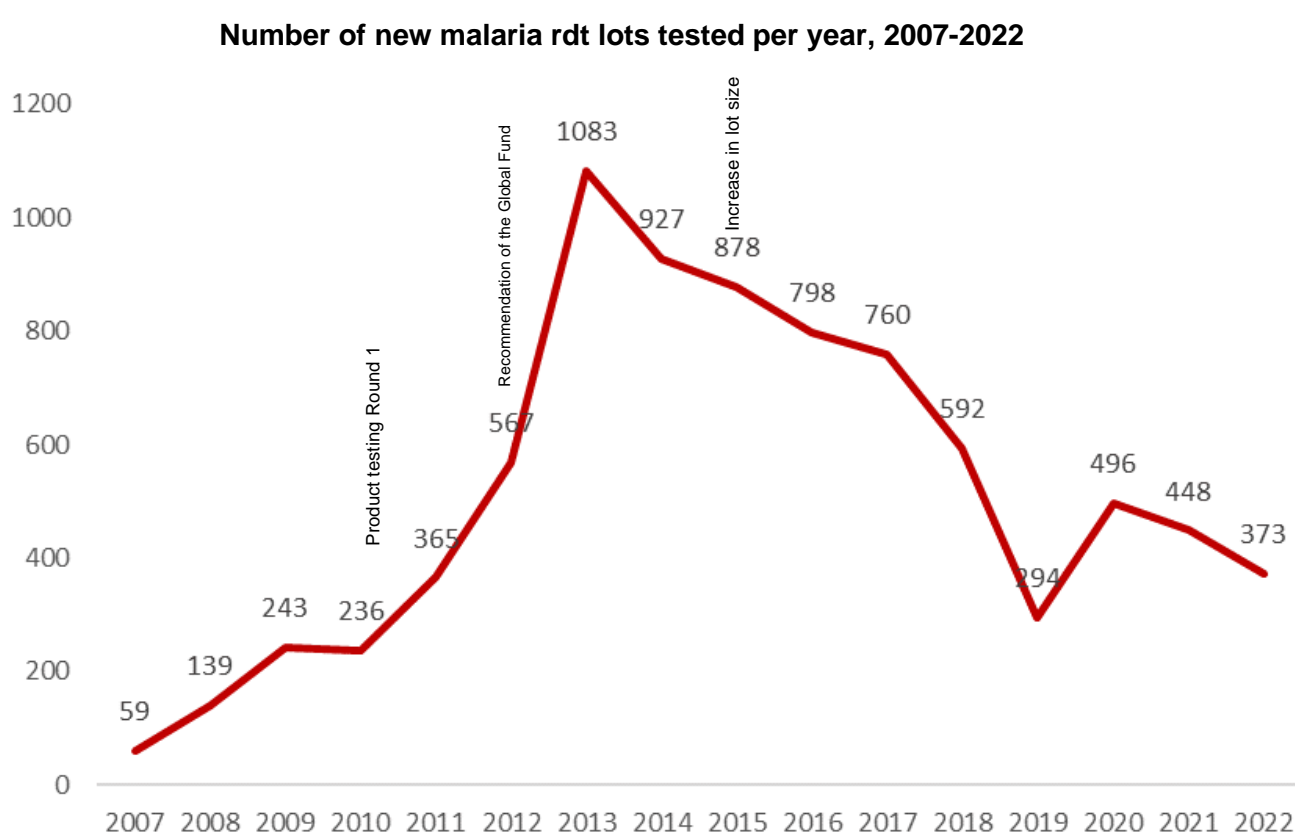
In 2022, the RITM received 10 lots from 5 different products that were not included in the WHO Pre-Qualified List of Malaria RDTs (see list below). These lots constituted almost 3% of the total lots received for the year; 7 were lot-tested for confirmatory (from NIMR) while the 3 were tested for initial testing.

1. *BIOCREDIT Malaria Ag Pf/Pv*; Catalog Number- C61RHI25; Manufacturer- RapiGEN, Inc.
2. *EzDx Malaria Pan/Pf Rapid Test Detection Kit*; Catalog Number- 00-DKM-RK-MAL-EDX-001-025; Manufacturer- Advy Chemical Private Limited.
3. *Advantage MAL Card*; Catalog Number- IRI21050; Manufacturer- Diagnostic Enterprises (Confirmatory Testing)
4. *ErbaQik ® Malaria PAN Antigen Test*; Catalog Number- AR0112C; Manufacturer- Transasia Bio-Medicals Limited (Confirmatory Testing)
5. *EdgeXpress Malaria Pan Antigen Detection Test*; Catalog Number- AR0112C; Manufacturer- EdgeLabs LLP (Confirmatory Testing)

Year	Number of Lots Tested included in the Pre-Qualified List	Percentage	Number of Lots Tested not included in the Pre-Qualified List	Percentage	Total Number of Lots Tested
2019	293	99.66%	1	0.34%	294
2020	494	99.60%	2	0.40%	496
2021	440	98.21%	8	1.79%	448
2022	332	97.08%	10	2.92%	342

ANNUAL DEMAND FOR MALARIA RDT LOT TESTING, 2007-2022

The lot testing programme for malaria RDTs was launched in 2007. Between 2011-2017, lot testing was mandatory for all Global Fund grants recipients. It was also adopted and continues to be recommended by several major procurers. To date, the peak remains in 2013 followed by a decrease in demand in the succeeding years, with a drastic drop in 2019, followed by an almost two-fold increase in the following year, 2020. In 2022, a continuing decrease in the number of lots was observed as seen in the past year.

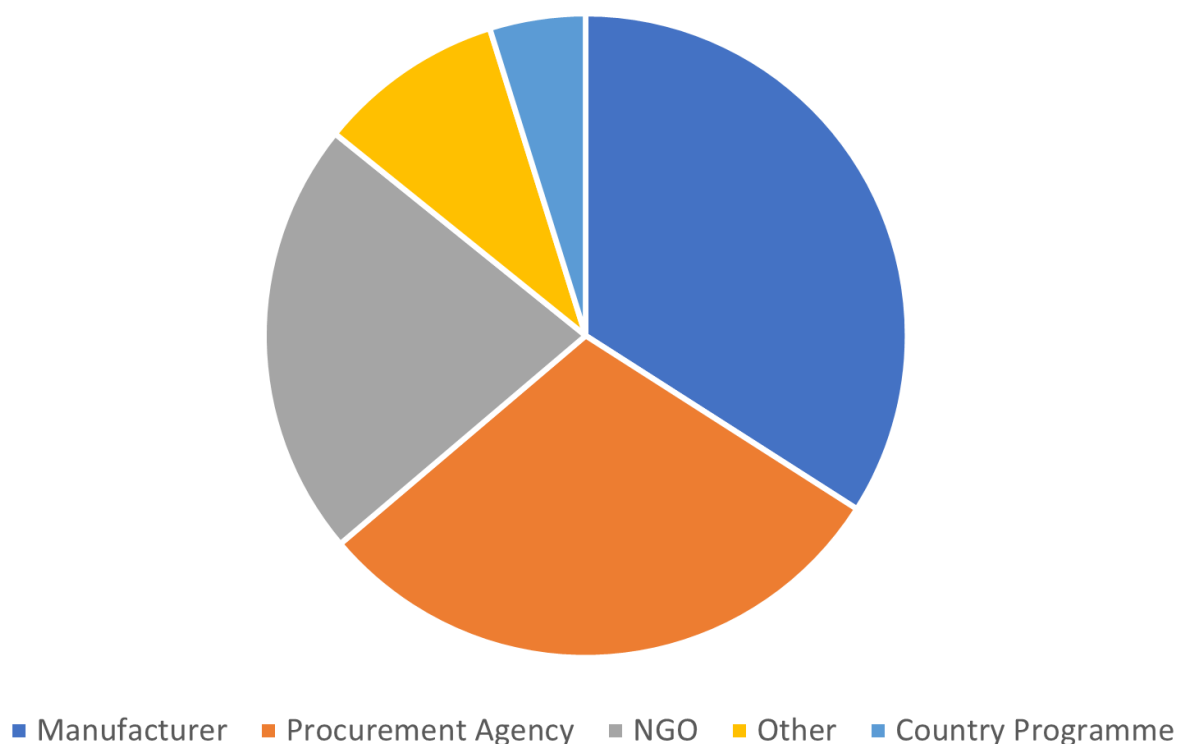


REQUESTERS AND RECIPIENT COUNTRIES OF LOT-TESTED MALARIA RDTs, 2022

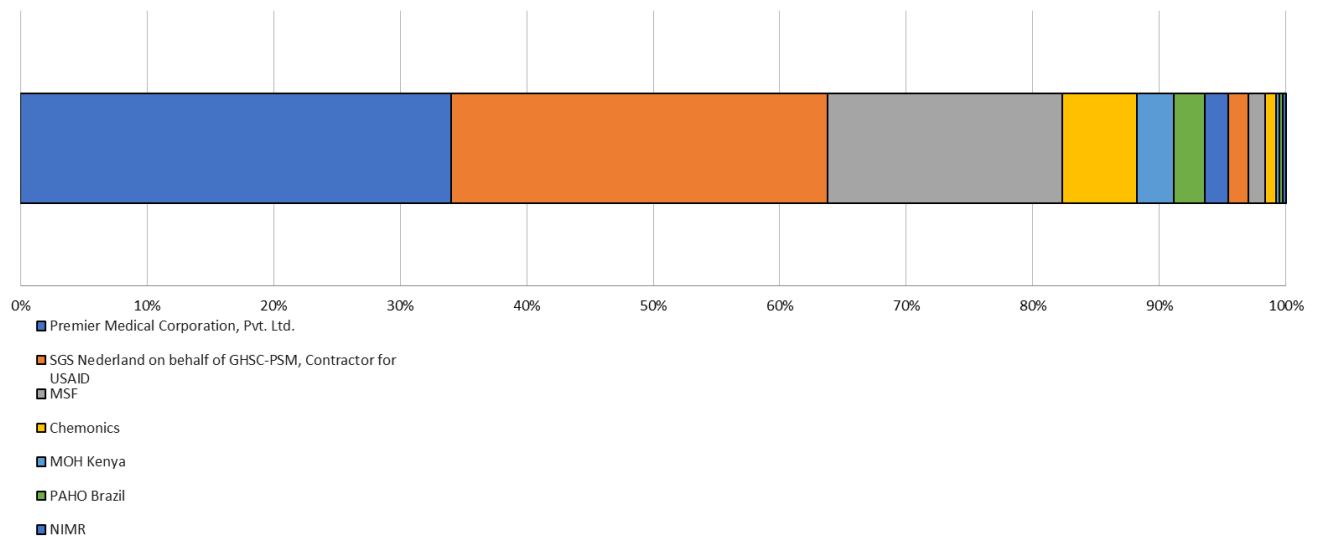
In 2022, the top requesters for lot-testing were manufacturers (34%), procurement agencies (30%), and NGOs (22%). Testing requests made by other unclassified requesters, and country programmes accounted for 9% and 5% from the total, respectively.

According to the data collected from requesters, approximately 191.4 million RDTs were distributed to 54 countries in 2022, with countries like France, Angola, and Mozambique received the bulk of the shipment. Meanwhile, no destination information was provided for over 23,768 RDTs.

Proportion of requesters requesting lot-testing, per category, 2022



Organizations/agencies requesting for lot-testing, 2022



Destination countries of lots tested at RITM, 2022

