

RESULTS OF THE FIND-WHO LOT TESTING
PROGRAMME FOR MALARIA RAPID
DIAGNOSTIC TESTS (RDTs)

2007- End of June 2017

Contents

About	3
Malaria RDT lot testing results from January to June 2017 (initial testing).....	4
Malaria RDT lot testing results from January to June 2017 (long term testing)	5
Malaria RDT lot testing results from January to end of June 2017 (Non-routine testing)	6
Malaria RDT lot testing results – Summary 2007 to June 2017	6
Summary of results 2007 – end of June 2017	10
Performance of malaria RDTs submitted for lot testing from 2007 to June 2017	12
Annual demand for malaria RDT lot testing	13
Requesters and recipient countries of lot-tested malaria RDTs	14
Evaporation of individual buffer vial.....	15

About

The WHO-FIND 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, two regional lot-testing laboratories in Cambodia and Philippines have the capacity to evaluate RDT lots using well-characterized and standardized parasite samples for quality control of malaria RDTs.

RDTs are sent from anywhere in the world on request by Ministries of Health, national malaria control programmes, NGOs, RDT manufacturers, procurement agencies and other international organizations. Lot testing is performed at the Institut Pasteur du Cambodge (Cambodia) and the Research Institute for Tropical Medicine (The Philippines) according to procedures outlined in the Methods Manual for Laboratory QC Testing of Malaria RDTs available at <http://who.int/malaria/publications/rdt-lab-quality-manual/en/>. RDT lots are tested within five days of receipt and at six months before the expiration date to provide long term stability data after storage at high temperature and humidity conditions. Malaria RDT lot testing results provide information about adequacy of RDTs for clinical use, stability over their shelf life, 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.

Lot testing has been mandatory for all recipients of grants from the Global Fund since 2011 and has been adopted by all major procurers since then. With the support from UNITAID, WHO and FIND are decentralizing the RDT lot testing programme to provide this capacity to countries in other WHO regions.

Further information about procedures to request RDT lot testing services as well as other related resources are available at <http://www.finddx.org/quality-assurance/malaria-rdt-qa/>.

Malaria RDT lot testing results from January to end June 2017 (initial testing)

Product Names	Catalog No	Manufacturer	N° of lots tested	N° of lots passed
Advantage Pf malaria Card	IR016025	J. MITRA & CO. PVT. LTD	6	6
CareStart Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio, Inc.	68	68
CareStart malaria Pf/Pan (HRP2/pLDH) combo	RMRM-01071/02571	Access Bio, Inc.	37	37
CareStart Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571 (G0161)	Access Bio, Inc.	5	5
CareStart malaria pLDH (Pan)	RMNM-02571	Access Bio, Inc.	6	6
CareStart™ Malaria Pf/PAN(HRP2/pLDH) Ag Combo RDT Single kits	RMRU-02571	Access Bio, Inc.	1	1
CareStart™ Malaria Pf/PAN(pLDH)	RMLC-02571	Access Bio, Inc.	1	1
First Response Malaria Ag P.f. HRP2 Card test	PI13FRC25	Premier Medical Corporation Ltd.	3	3
First Response Malaria Ag. P. falciparum HRP2 Card Test	I13FRC25/I13FRC25CE	Premier Medical Corporation Limited	14	14
First Response Malaria Ag. P.f/P.v Card Test	PI19FRC25	Premier Medical Corporation Ltd.	2	2
First Response Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC25/I16FRC25CE	Premier Medical Corporation Limited	3	3
Malaria Pf/PAN Cassette Test	MAL-MD02	Deangel Biological Engineering Co. Ltd.	1	1
Malaria Pf/Pv Cassette Test	MAL-ND02	Deangel Biological Engineering Co. Ltd.	1	1
Paracheck® Pf Device	302030025	OBS (Orchid Biomedical System)	25	25
RAPIQUICK Malaria P.f/Pan Rapid Test Device	IMA432	Encode Zhuahai Pty Ltd.	1	0*
SD BIOLINE Malaria Ag P.f	05FK50	Standard Diagnostics, Inc	76	76
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc	18	18
SD BIOLINE Malaria Ag P.f/P.v	05FK80/83/86/87	Standard Diagnostics, Inc	25	25
SD BIOLINE Malaria Ag P.f/Pan	05FK60/63	Standard Diagnostics, Inc	23	23
SD BIOLINE Malaria Ag Pf/Pf/Pv	05FK120	Standard Diagnostics, Inc	2	2

*Failure with *P. vivax* samples at 200 parasites/µl of blood during initial testing.

Malaria RDT lot testing results from January to end June 2017 (long-term testing)

Long-term testing refers to the testing performed on RDTs stored at 37°C and at 6 months before the expiration date.

Product Names	Catalog No	Manufacturer	N° of lots tested	N° of lots passed
Advantage Pf Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	1	1
CareStart™ Malaria HRp2/ pLDH (Pf/PAN) COMBO	G0131	Access Bio, Inc.	28	28
CareStart™ malaria pLDH (Pan)	G0111	Access Bio, Inc.	1	1
CareStart™ Malaria/ Pregnancy Combo (HRP2/pLDH/HCG)	G0221	Access Bio, Inc.	1	1
CareStart™ Malaria HRP2 (Pf)	RMOM-02571 (G0141)	Access Bio, Inc.	24	24
CareStart™ Malaria HRP2/ pLDH(Pf)	RMPC-02571 (G0181)	Access Bio, Inc.	12	12
First Response Malaria Ag. P. falciparum HRP2 Card Test	I13FRC25	Premier Medical Corporation Ltd.	7	7
First Response Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC25	Premier Medical Corporation Ltd.	2	2
Malaria P.f/Pan (Mal Pf/Pan) Antigen Test Kit	A03-18-322	Artron Laboratories, Inc.	1	1
Malaria P.f/Pv (Mal Pf/Pv) Antigen Test Kit	A03-12-322	Artron Laboratories, Inc.	1	1
Malaria Pf/PAN Rapid Test (Cassette)	MAL-MD02	Deangel Biological Engineering Co. Ltd.	1	1
Paracheck Pf DEVICE	302030025	OBS (Orchid Biomedical System)	6	6
ParaHIT-f (device)	55IC104-50	Arkray Healthcare Pvt. Ltd.	13	13
Quick Profile Malaria Pf/Pan Antigen Test	71063	Lumiquick Diagnostics, Inc.	2	2
Quick Profile Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics, Inc.	2	2
Rapid 1-2-3 Hema Cassette Malaria (PFV)	MAL-PFV-CAS25	Hema Diagnostic Systems, LCC	1	1
SD Biline Malaria Ag P.f.	05FK50/05FK58	Standard Diagnostics, Inc.	63	63
SD Biline Malaria Ag P.f/P.v	05FK80/05FK86	Standard Diagnostics, Inc.	8	8
SD Biline Malaria Ag P.f/Pan	05FK60	Standard Diagnostics, Inc.	39	39
SD Biline Malaria Ag. P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	1	1
SD BIOLINE Malaria Antigen P.f (HRP2/pLDH) POCT	05FK93	Standard Diagnostics, Inc.	13	13

Malaria RDT lot testing results from January to end June 2017 (non-routine testing)

Non-routine testing refers to the testing of RDTs collected from lots that have been already deployed in the field.

Manufacturer	Catalog No	Product Names	N° of lots tested	N° of lots passed
Standard Diagnostics, Inc	05FK67	SD BIOLINE Malaria Ag P.f/Pan POCT	7	7

Malaria RDT lot testing results – Summary 2007 to end June 2017

Manufacturer	Cat No	Product name	N° of lots tested	Year(s) tested	PASS RATE	Comment (s)
Access Bio, Inc.	G0121	CareStart™ Malaria pLDH 3 lines Test	5	2008–2009	100%	
Access Bio, Inc.	G0221	CareStart™ Malaria/Pregnancy Combo (HRP2/pLDH/HCG)	1	2015	100%	
Access Bio, Inc.	G0231	CareStart™ Malaria Screen	16	2006–2008–2009	100%	
Access Bio, Inc.	RMLM-02571/RMLC-02571	CareStart™ Malaria Pf/PAN(pLDH)Ag RDT	3	2016–2017	66%	Pv detection @ 200 parasites/μl failed at initial QC
Access Bio, Inc.	RMOM-02571 (G0141/141-SK)	CareStart™ Malaria HRP2 (Pf)	660	2010–2011–2012–2013–2014–2015–2016–2017	100%	
Access Bio, Inc.	RMPC-02571 (G0181/181-SK)	CareStart™ Malaria HRP2/ pLDH(Pf)	37	2013–2014–2015–2016	100%	

Access Bio, Inc.	RMRM-02571 (G0131/131-SK) RMRU-02571	CareStart™ Malaria Pf/Pan (HRP2/pLDH) Ag Combo RDT	261	2006–2007–2008–2009–2010–2011–2012–2013–2014–2015–2016–2017	97.7%	Pf and Pv detection @ 200 parasites/μl failed at initial QC
Access Bio, Inc.	RMVM-01071 (G0161)	CareStart™ Malaria P.f/P.v (HRP2/pLDH) Ag Combo RDT	30	2012–2013–2014–2015–2016–2017	100%	
Access Bio, Inc.	RMNM-02571 (G0111)	CareStart™ Malaria pLDH (Pan)	25	2011–2014–2015–2016–2017	100%	
Advy Chemical Private limited, Factory, India	RK MAL 001	EzDx™ Malaria Pan/Pf Rapid test Detection Kit	9	2011–2013	100%	
Advy Chemical Private limited, Factory, India	RK MAL 003	EzDx™ Malaria Pv/Pf Rapid Test Detection Kit	2	2013	100%	
Artron Laboratories, Inc.	A03-12-322	Malaria P.f/Pv (Mal Pf/Pv) Antigen Test Kit	1	2016	100%	
Artron Laboratories, Inc.	A03-18-322	Malaria P.f/Pan (Mal Pf/Pan) Antigen Test Kit	1	2016	100%	
Artron Laboratories, Inc.						
Bio Footprints Healthcare Pvt. Ltd.	MTR00250	Mytest™ Malaria Ag Pf/Pan	2	2015	100%	
BioNote Inc. Korea	RG19-08	Bionote Malaria Pf/Pan Ag Rapid Test Kit	1	2014	100%	
BioNote Inc. Korea	RG19-11	Bionote Malaria P.f Ag Rapid Test Kit	2	2015	100%	
Clearview	VB11	Clearview Malaria Combo	1	2010	100%	
CTK Biotech, Inc.	R0112C	Onsite Malaria Pf/Pv Ag Rapid Test, Cs	8	2013–2014	100%	
CTK Biotech, Inc.	R0113C	Malaria Pf/Pan Ag Rapid Test, Cs	1	2012	100%	
CTK Biotech, Inc.	R0114C	OnSite Malaria Pf Ag Rapid Test	6	2007–2013–2014	100%	
Deangel Biological	MAL-MD02	Malaria Pf/Pan Rapid Test Device	2	2015–2017	100%	

Engineering Co., Ltd.						
Deangel Biological Engineering Co., Ltd.	MAL-ND02	Malaria Pf/Pv Rapid Test Device	1	2017	100%	
Diamed AG	710024	OptiMAL-IT	1	2008	100%	
Zhuhai Encode Medical Engineering Co., Ltd.	IMA432	RAPIQUICK Malaria P.f/Pan Rapid Test Device	1	2017	0%	
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%	Pv detection @ 200 parasites/ μ l failed at initial QC
ICT Diagnostics	ML01	ICT Malaria Pf Cassette Test	249	2007–2008–2009–2010–2014	100%	
ICT Diagnostics	ML02	ICT Malaria Combo Cassette Test	68	2007–2008–2009–2010–2011–2012	85%	Pv detection @ 200 parasites/ μ l failed at initial QC
ICT Diagnostics	ML03	ICT Diagnostics Malaria Dual	2	2012–2014	100%	
J. Mitra & Co. Pvt. Ltd.	IR231025	ADVANTAGE MALARIA PAN+PF CARD	2	2016	100%	
J. Mitra & Co. Pvt. Ltd.	IR016025	Advantage Pf malaria Card	14	2013–2014–2015–2017	100%	
J. Mitra & Co. Pvt. Ltd.	IR211025	Advantage Malaria Card	1	2010	100%	
Lumiquick Diagnostics, Inc.	71050	Quick Profile Malaria Pf/Pv Antigen Test	3	2013–2016	100%	
Lumiquick Diagnostics, Inc.	71063	Quick Profile Malaria Pf/Pan Antigen Test	2	2016	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	2012–2013	100%	

Nanong Egens Biotechnology Co., LTD.	Nil	QD Malaria Antigen P.f	1	2014	100%	
OBS (Orchid Biomedical System)	30301025/302030025	Paracheck Pf DEVICE	1183	2007–2008–2009–2010–2011–2012–2013–2014–2015–2016–2017	100%	
Premier Medical Corporation Ltd.	I13FRC25/25S/30/30S/35	First Response Malaria Ag. P. falciparum HRP2 Card Test	290	2009–2010–2012–2013–2014–2015–2016–2017	100%	
Premier Medical Corporation Ltd.	I16FRC25/25S/25CE/30/30S/40	First Response Malaria HRP2/pLDH(Pf/Pan)	170	2010–2011–2012–2013–2014–2015–2016–2017	99%	Pv detection @ 200 parasites/μl failed at initial QC
Premier Medical Corporation Ltd.	I16MCC10/25	Malacheck Malaria Ag (pLDH/HRP2) Combo Card Test	4	2012–2013	100%	
Premier Medical Corporation Ltd.	PI13FRC25	First Response Malaria Ag. P. falciparum HRP2 Card Test	7	2014–2016–2017	100%	
Premier Medical Corporation Ltd.	PI16FRC25	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	2	2014	100%	
Premier Medical Corporation Ltd.	PI19FRC25	First Response Malaria Ag. P.f./P.v. Card Test	4	2014–2017	100%	
Span Diagnostics Ltd.	55IC102-10	ParaHIT-f (device)	7	2007–2009	100%	
Span Diagnostics Ltd.	55IC104-25/50	ParaHIT f Ver.1.0	93	2013–2014–2015–2016	100%	
Span Diagnostics Ltd.	55IC201-10	ParaHIT-Total (dipstick)	1	2008	0%	Pv detection @ 200 parasites/μl failed at initial QC

Standard Diagnostics, Inc.	05FK120/123	SD Bioline Malaria Ag P.f/P.f/P.v	12	2015–2016–2017	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	1322	2009–2010–2011–2012–2013–2014–2015–2016–2017	99%	Pf detection @ 200 parasites/μl failed at initial QC
Standard Diagnostics, Inc.	05FK60/63/64/65/66/67	SD BIOLINE Malaria P.f/Pan rapid test	693	2010–2011–2012–2013–2014–2015–2016–2017	100%	
Standard Diagnostics, Inc.	05FK80/83/85/86/87	SD Bioline Malaria Ag Pf/Pv	333	2010–2011–2012–2013–2014–2015–2016–2017	100%	
Standard Diagnostics, Inc.	05FK90/93	SD BIOLINE Malaria Antigen P.f (HRP2/pLDH) POCT	95	2009–2010–2012–2013–2014–2015–2016–2017	100%	
Zephyr Biomedicals	50310025	Parascreen Device Rapid Test for Malaria Pan/Pf (Device)	14	2007–2008–2009–2010	100%	

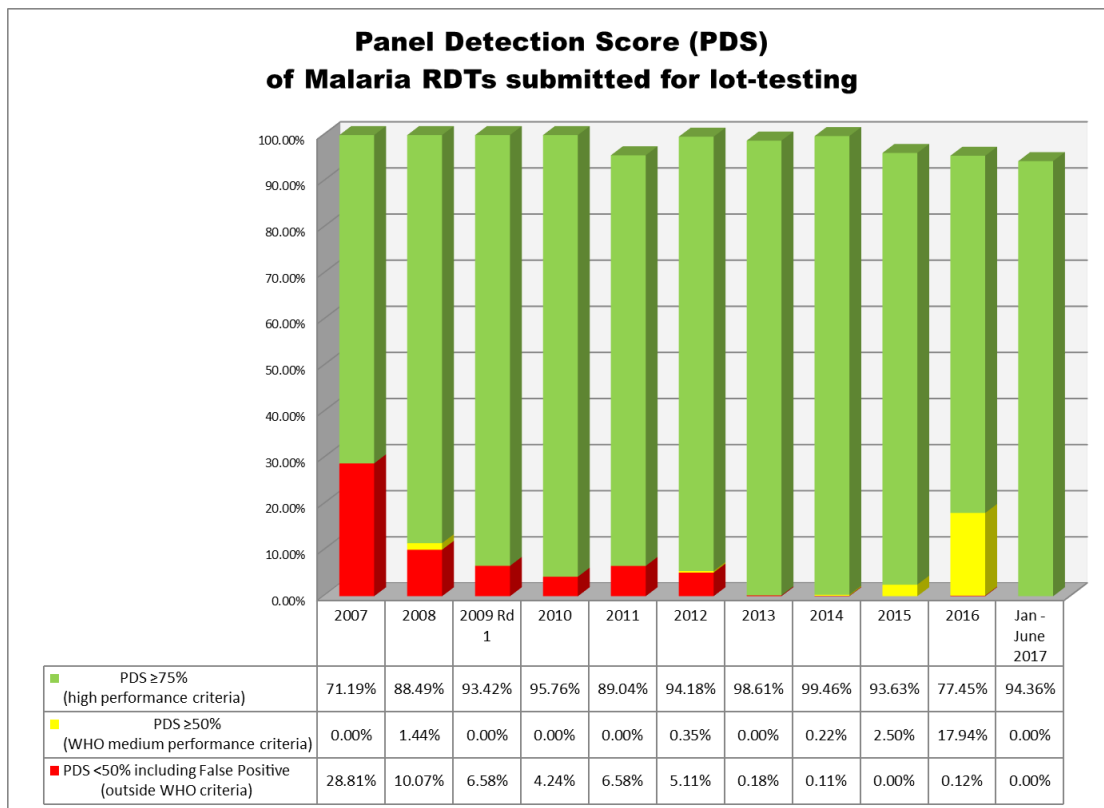
Summary of results 2007 – end of June 2017

Malaria RDT lot failures are more frequently observed close to their expiration date. Failures also occur mostly when testing RDTs on *P. vivax* samples at 200 parasites per microliter of blood, while failures on *P. falciparum* samples are relatively rare at the same parasite density.

Year	N° of new products	N° of new manufacturers	N° of RDTs lots	N° of initial failures	N° of long term failures
2007	8	7	59	1	1
2008	6	4	139	3	1
2009	2	-	243	-	2
2010	7	3	236	-	-
2011	4	2	365	2	9
2012	4	-	567	4	6
2013	6	1	1083	-	-
2014	2	1	927	-	-
2015	6	3	879	2	-
2016	14	2	797	1	-
January to end June 2017	3	1	318	1	-
Total	59	24	5713	14	19

Performance of malaria RDTs submitted for lot testing from 2007 to June 2017

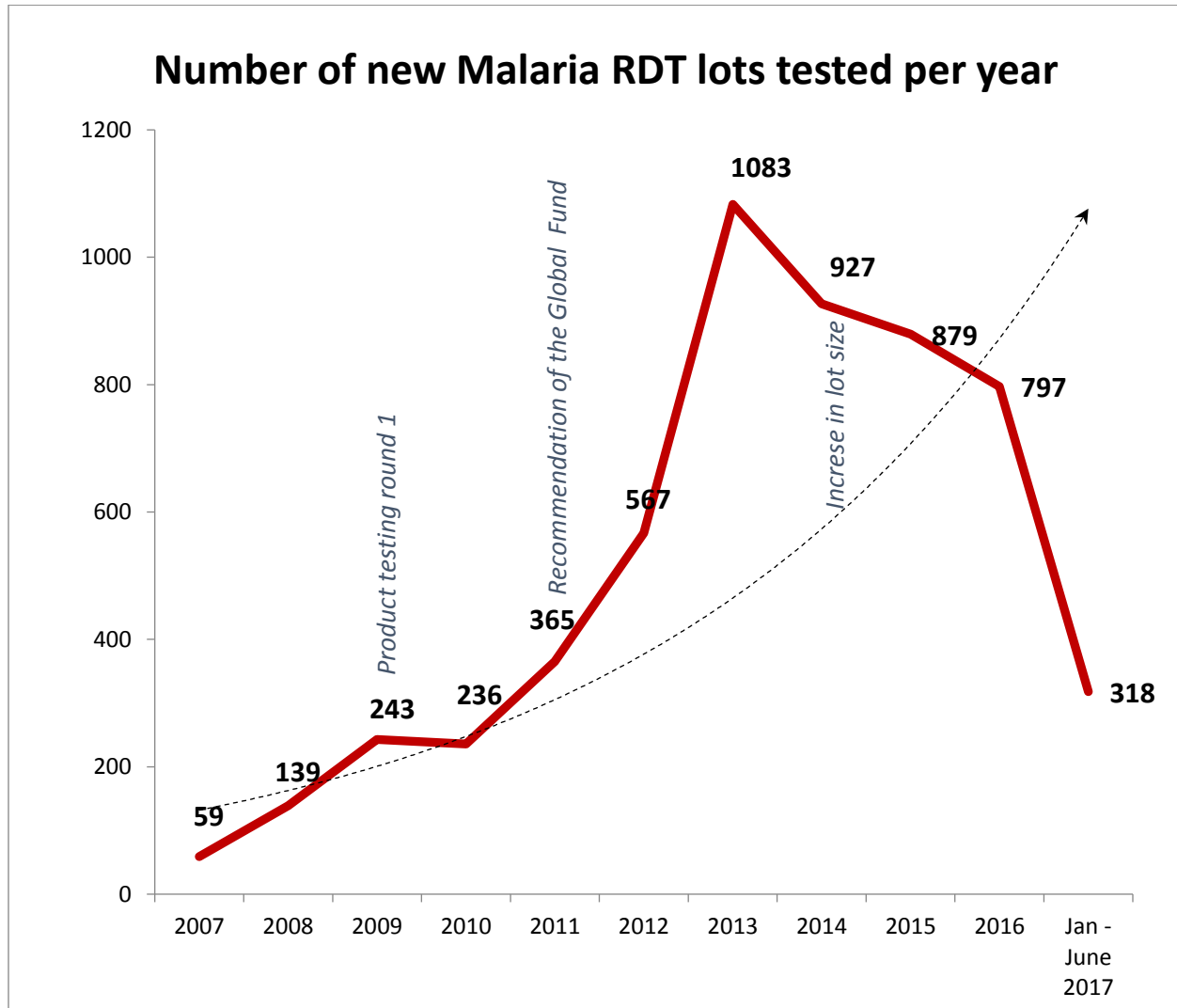
In 2007, about 30% of the lot testing requests were for RDT products that were below the threshold of performance recommend by WHO for procurement (panel detection score below 75% in the WHO-FIND malaria RDT product testing programme). In 2015 and 2016 there was an increase of lot tested RDT products that don't meet the WHO criteria. However, between January and June 2017, 94.3% of the malaria RDTs lots tested were from products with panel detection scores over 75%. The remaining 5.7% of products were not evaluated in the last three rounds of product testing. This indicates that the majority of procurers selected their RDTs according to WHO procurement criteria, based on WHO Product Testing results¹. These results also demonstrate consistency between the WHO-FIND malaria RDT product testing programme and lot testing results and a substantial increase in the quality of tests being procured.



¹ <http://www.finddx.org/quality-assurance/malaria-rdt-qa/>

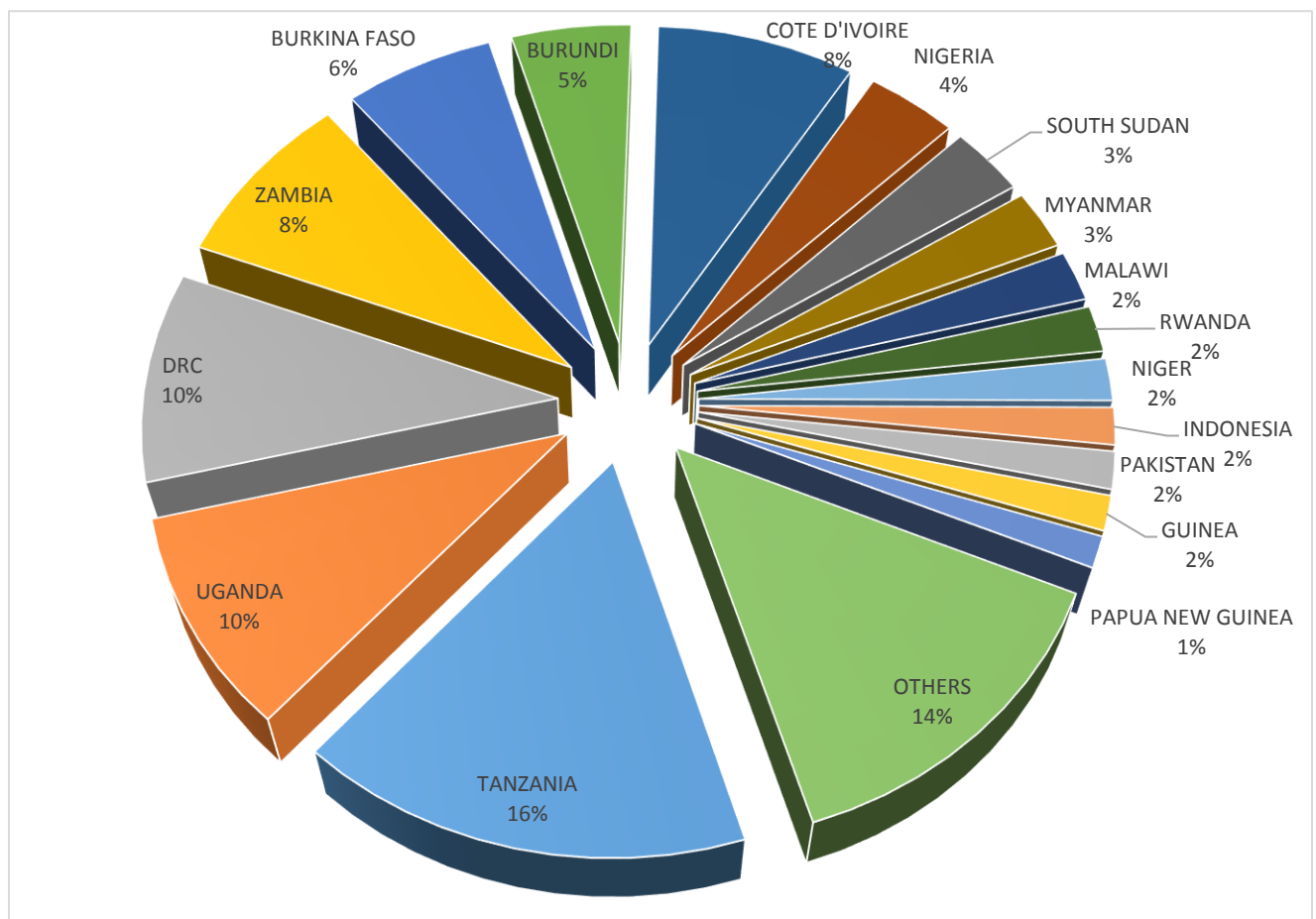
Annual demand for malaria RDT lot testing

The lot testing programme for malaria RDTs was launched in 2007. Since 2011, lot testing has been mandatory for all Global Fund grants recipients and has been adopted by all major procurers since then. This new policy adoption led to a substantial increase in demand for lot testing, reaching a peak in 2013. The apparent decrease that started in 2014 is mainly due to an increase in lot sizes, and actually corresponds to an increase in demand when considering the number of individual RDTs.



Requesters and recipient countries of lot-tested malaria RDTs

From January to June 2017, the malaria RDT lot testing service was requested by NGOs/international organizations (50%), procurement agencies (36%), and RDT manufacturers (14%). According to data collected from lot testing requesters, the RDT lots evaluated during this period represented about 90 million RDTs meant for distribution in about 39 countries (information about country distribution was not available for about 900,000 RDTs tested).



Evaporation of individual buffer vial

Since 2014, the WHO-FIND Malaria RDT lot testing programme has observed buffer evaporation in single-use buffer vials for some RDT lots after heat stability testing. Therefore, buffer volumes were insufficient to conduct long term testing. Similar observations were also reported from end users in various countries. The **WHO Prequalification of Diagnostics Programme** has since then issued an “information notice for users” and is working closely with RDT manufacturers to address this issue.

Buffer evaporation has only been noted on individual buffer vials of RDT single test kits but not on buffer bottles from multi-test kits (e.g. packs of 25, 30 or 50 RDTs). Up until the end of December 2016, 24 RDT lots from 9 different products and 6 different manufacturers could not undergo long term testing due to the insufficient volume of buffer available. From January to June 2017, buffer vials evaporation has not been observed during lot testing activities.

Below is the list of RDT products with buffer vial evaporation during long-term lot testing up to December 2016.

Product name	Catalog number	Manufacturer
SD Bioline Malaria P.f/Pan POCT Rapid Test	05FK63	Standard Diagnostics, Inc.
SD Bioline Malaria Ag P.f/P.v POCT	05FK83	Standard Diagnostics, Inc.
SD Bioline Malaria Ag P.f. (HRP2/pLDH) POCT	05FK93	Standard Diagnostics, Inc.
CareStart Malaria HRp2/pLDH (Pf/PAN) COMBO	G0131-SK	Access Bio, Inc.
First Response Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC30s	Premier Medical Corporation Ltd.