

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

2007 – December 2017

Malaria RDT lot testing results from July to December 2017 (initial testing)

Product Names	Catalog N°	Manufacturer	N° of lots tested	N° of lots passed
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	67	67
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120/123	Standard Diagnostics Inc. (Alere)	6	6
SD BIOLINE Malaria Ag Pf	05FK50/53	Standard Diagnostics Inc. (Alere)	104	104
SD BIOLINE Malaria Ag P.f/Pan	05FK60/63/67	Standard Diagnostics Inc. (Alere)	30	30
SD Bioline Malaria Ag P.f/P.v	05FK80/83/86/87	Standard Diagnostics Inc. (Alere)	36	36
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	25	25
ParaHIT f Ver.1.0	55IC104-25	Arkray Healthcare Pvt. Ltd.	2	2
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25/ I13FRC25CE	Premier Medical Corporation Ltd.	7	7
First Response Malaria Ag. P. falciparum HRP2 Card Test	PI13FRC25/26/27/28	Premier Medical Corporation Ltd.	19	19
First Response Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC25/ PI16FRC25CE	Premier Medical Corporation Ltd.	3	3
CareStart Malaria Pf/Pan (pLDH)	RMLC-02571	Access Bio Inc.	2	2
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	1	1
CareStart malaria pLDH (Pan)	RMNM-02571	Access Bio Inc.	5	5
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	90	90
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-01071/ RMRM-02571	Access Bio Inc.	31	31
CareStart™ Malaria Pf/PAN(HRP2/pLDH)Ag Combo RDT Single kits	RMRU-02571	Access Bio Inc.	4	4
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-01071/ RMVM-02571	Access Bio Inc.	9	9
Malaria Pf/Pan Antigen Whole Blood Test Cassette (Colloidal Gold)	YF503C	Innovita Biological Technology Co. Ltd.	1	0*

*Deferred during Initial Testing. No confirmatory testing result available.

Malaria RDT lot testing results from July to December 2017 (long term testing)

Product Names	Catalog N°	Manufacturer	N° of lots tested	N° of lots passed
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	2	2
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics Inc. (Alere)	43	43
SD BIOLINE Malaria Ag P.f/Pan	05FK60/67	Standard Diagnostics Inc. (Alere)	7	7
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics Inc. (Alere)	3	3
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	20	20
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	4	4
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC25	Premier Medical Corporation Ltd.	1	1
CareStart™ Malaria Pf/Pan (HRP2/pLDH) Ag Combo RDT	RMNM-02571 (G0111)	Access Bio Inc.	1	1
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571 (G0141)	Access Bio Inc.	31	31
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571 (G0131)	Access Bio Inc.	3	3
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571 (G0161)	Access Bio Inc.	8	8

Malaria RDT lot testing results – Summary 2007 to December 2017

Manufacturer	Category N°	Product name	N° of lots tested	Year(s) tested	PASS RATE (%)	Comment (s)
Access Bio Inc.	RMLC-02571/ RMLM-02571 (G0121)	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	11	2008- 2009- 2016-2017	91	Pv detection @ 200 parasites/μl failed at initial QC
Access Bio Inc.	RMOM-02571 (G0141/141- SK)	CareStart™ Malaria Pf (HRP2) Ag RDT	724	2010- 2011- 2012- 2013- 2014- 2015- 2016-2017	100	
Access Bio Inc.	RMRM- 01071/ RMRM- 02571/ RMRU-02571 (G0131/131- SK)	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	294	2007- 2008- 2009- 2010- 2011- 2012- 2013- 2014- 2015- 2016-2017	98	Pf and Pv detection @ 200 parasites/μl failed at initial QC
Access Bio Inc.	RMVM- 01071/ RMVM-02571 (G0161)	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	39	2012- 2013- 2014- 2015- 2016-2017	100	
Access Bio Inc.	G0221	CareStart™ Malaria/Pregnanc y Combo (HRP2/pLDH/HCG)	1	2015	100	
Access Bio Inc.	G0231	CareStart™ Malaria Screen	16	2008-2009	100	
Access Bio Inc.	RMNM-02571 (G0111)	CareStart™ Malaria pLDH (Pan)	29	2011- 2014- 2015- 2016-2017	100	
Access Bio Inc.	RMPC-02571 (G0181/181- ET/181-SK)	CareStart™ Malaria HRP2/ pLDH(Pf)	37	2013- 2014- 2015-2016	100	
Advy Chemical Private Limited	RK MAL 001	EzDx™ Malaria Pan/Pf Rapid test detection Kit	9	2011-2013	100	
Advy Chemical Private Limited	RK MAL 003	EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	2	2013	100	

Manufacturer	Category N°	Product name	N° of lots tested	Year(s) tested	PASS RATE (%)	Comment (s)
ARKRAY Healthcare Pvt Ltd*	55IC104-25/50	Parahit® f Ver 1.0 - Device	95	2013-2014-2015-2016-2017	100	
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	
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	
Diamed AG	710024	OptiMAL-IT	1	2008	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	Pv detection @ 200 parasites/μl failed at initial QC
ICT Diagnostics	ML02	ICT Malaria Combo Cassette Test	68	2007-2008-2009-	88	Pv detection @ 200 parasites/μl

Manufacturer	Category N°	Product name	N° of lots tested	Year(s) tested	PASS RATE (%)	Comment (s)
				2010-2011-2012		failed at initial QC
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)	1	2017	0	Deferred during Initial Testing. No confirmatory testing result available.
J. Mitra & Co. Pvt. Ltd.	IR016025	Advantage P.f. Malaria Card	14	2013-2014-2015-2017	100	
J. Mitra & Co. Pvt. Ltd.	IR211025	Advantage Malaria Card	1	2010	100	
J. Mitra & Co. Pvt. Ltd.	IR231025	Advantage Malaria Pan + Pf Card	2	2016	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	
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	
Nanong Egens Biotechnology Co., LTD.	Nil	QD Malaria Antigen P.f	1	2014	100	
Orchid Biomedical Systems (Tulip Group)	30301025/302030025	Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	1238	2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017	100	
Premier Medical Corporation Ltd.	I13FRC25/25C E/25S/30/30S/35	First Response® Malaria Ag P. falciparum (HRP2) Card Test	297	2009-2010-2011-2012-	100	

Manufacturer	Category N°	Product name	N° of lots tested	Year(s) tested	PASS RATE (%)	Comment (s)
				2013-2014-2015-2016-2017		
Premier Medical Corporation Ltd.	I16FRC25/25CE/25S/30/30s/40	First Response Malaria HRP2/pLDH(Pf/Pan)	171	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.	PI13FRC25/26/27/28	First Response Malaria Ag. P. falciparum HRP2 Card Test	26	2014-2016-2017	100	
Premier Medical Corporation Ltd.	PI16FRC25/25CE	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	5	2014-2017	100	
Premier Medical Corporation Private Ltd.	PI19FRC25	First Response® Malaria Ag. P.f./P.v. Card test	4	2014-2017	100	
SD Bio Standard Diagnostics PVT.LTD,India	05FK60I-40	SD Malaria Ag Pf/Pan	2	2010	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	Pv detection @ 200 parasites/μl failed at initial QC
Standard Diagnostics Inc.	05FK60/63/64/65/66/67	SD BIOLINE Malaria Ag P.f/Pan	713	2010-2011-2012-2013-2014-2015-2016-2017	100	
Standard Diagnostics Inc. (Alere)	05FK120/123	SD BIOLINE Malaria Ag P.f/P.f/P.v	18	2014-2015-2016-2017	100	
Standard Diagnostics Inc. (Alere)	05FK90/93	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	120	2009-2010-2012-2013-2014-	100	

Manufacturer	Category N°	Product name	N° of lots tested	Year(s) tested	PASS RATE (%)	Comment (s)
				2015-2016-2017		
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	1413	2009-2010-2011-2012-2013-2014-2015-2016-2017	100	Pf detection @200 parasites/ μ l failed at initial QC
Standard Diagnostics, Inc.	05FK80/83/85/86/87	SD Bioline Malaria Ag P.f/P.v	351	2010-2011-2012-2013-2014-2015-2016-2017	100	
Standard Diagnostics, Inc.	05FK80POCT	SD BIOLINE Malaria Ag P.f/P.v POCT	17	2012	100	
Zephyr Biomedicals	50310025	Parascreen Device Rapid Test for Malaria Pan/Pf (Device)	14	2007-2008-2009-2010	100	
Zhuhai Encode Medical Engineering Co., Ltd.	IMA432	RAPIQUICK Malaria P.f/Pan Rapid Test Device	1	2017	0	

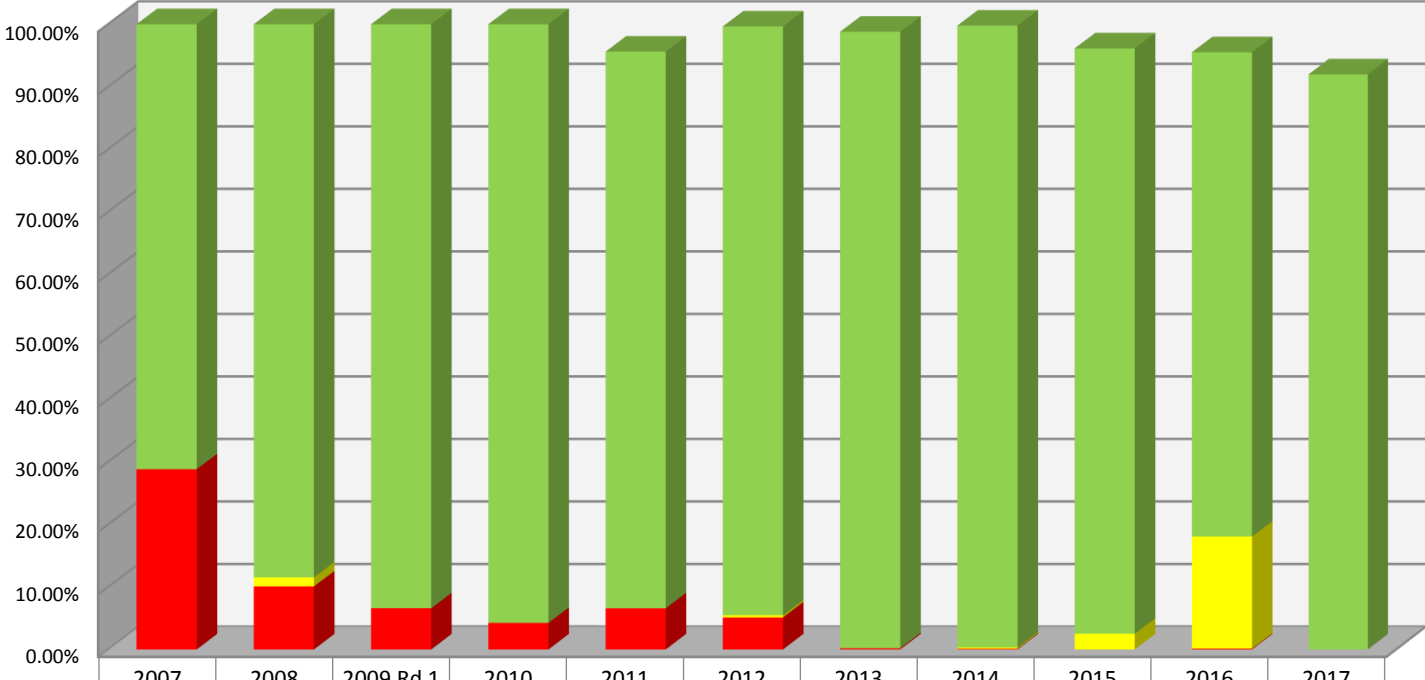
* Previously known as Span Diagnostics Ltd.

Summary of results 2007 – 2017

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	-	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	-
2017	4	2	760	1	-
Total	63	25	6055	14	19

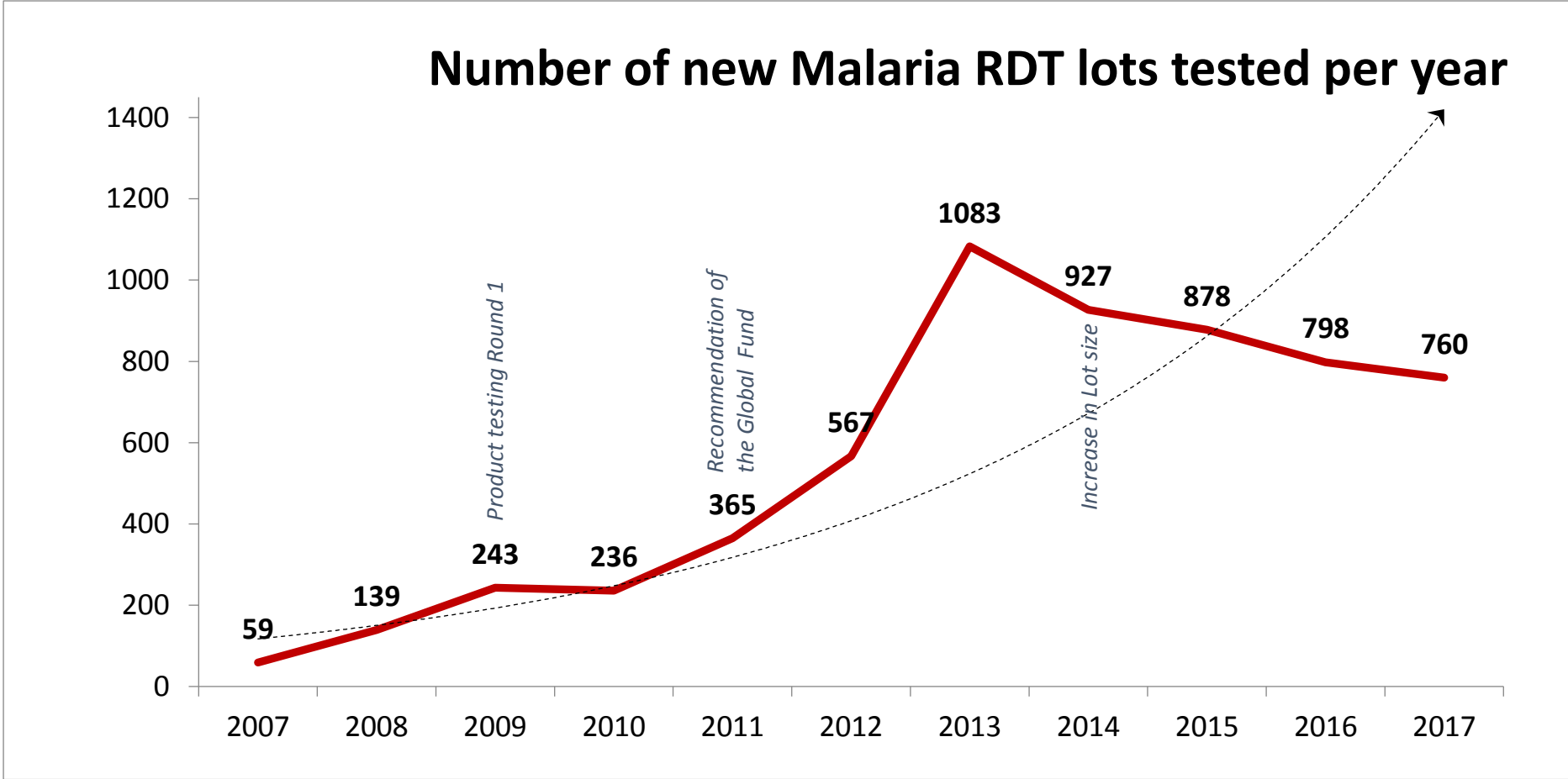
Performance of malaria RDTs submitted for lot testing from 2007 to December 2017

**Panel Detection Score (PDS)
of Malaria RDTs submitted for lot-testing**



	2007	2008	2009 Rd 1	2010	2011	2012	2013	2014	2015	2016	2017
■ PDS $\geq 75\%$ (high performance criteria)	71.19%	88.49%	93.42%	95.76%	89.04%	94.18%	98.61%	99.46%	93.63%	77.45%	91.97%
■ PDS $\geq 50\%$ (WHO medium performance criteria)	0.00%	1.44%	0.00%	0.00%	0.00%	0.35%	0.00%	0.22%	2.50%	17.94%	0.00%
■ PDS $< 50\%$ including False Positive (outside WHO criteria)	28.81%	10.07%	6.58%	4.24%	6.58%	5.11%	0.18%	0.11%	0.00%	0.12%	0.00%

Annual demand for malaria RDT lot testing



Requesters and recipient countries of lot-tested malaria RDTs – July to December 2017

