Malaria Rapid Diagnostic Test Performance

Summary Results of WHO product testing of malaria RDTs: Rounds 1 and 2 (2008-2009)

World Health Organization
FIND foundation for innovative new diagnostics
CDC
TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

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SUMMARY PEFORMANCE OF MALARIA RDTS: WHO PRODUCT TESTING: ROUNDS 1 AND 2

Introduction

The World Health Organization estimates that half the world's population are at risk of malaria, with 243 million people developing clinical malaria last year (86% in Africa), with nearly 863,000 deaths (89% in Africa, most being children). Malaria remains endemic in 108 countries, and while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly identified, resulting in over-use of anti-malarial drugs and poor disease monitoring.[1]

WHO recommends that malaria case management be based on parasite-based diagnosis in all cases[2]. The use of antigen-detecting rapid diagnostic tests (RDTs) forms a vital part of this strategy, forming the backbone of expansion of access to malaria diagnosis as they provide parasite-based diagnosis in areas where good quality microscopy can not be maintained. The number of RDTs available, and the scale of their use, has rapidly increased over the past few years. However, limitations of comparative field trials and the heterogeneous nature of malaria transmission and epidemiology has limited the availability of good quality performance data that national malaria programmes require to make informed decisions on procurement and implementation, and limits the ability to extrapolate results of field trials to different populations and time periods. To this end in 2006, the World Health Organization (WHO), Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched an evaluation programme to assess the comparative performance of commercially available malaria RDTs. This data will guide procurement decisions and help drive improvement in the quality of manufacturing. The results of the first round of Product Testing were published in April 2009, and now form the basis of procurement criteria of WHO and UN agencies and national governments.

This Summary presents an overview of the results of the first and second rounds of WHO product testing of malaria antigen-detecting RDTs completed in 2008 and 2009 respectively, and is published in conjunction with the release of the results of Round 2. The results of the two rounds of testing should be considered as a single data set, and the full reports of both Rounds 1 and 2 consulted for further detail on product performance, and on the interpretation and use of these results.

The WHO Product Testing Programme

The RDT evaluations summarized here were performed as a collaboration between WHO, TDR, FIND, the US Centers for Disease Control and Prevention (CDC) and other partners[3]. All companies manufacturing under ISO 13485:2003 Quality System Standard were invited to submit up to 3 tests for evaluation under the programme. In the first round of testing, 41 products from 21 manufacturers were evaluated against prepared blood panels of cultured *Plasmodium falciparum* parasites, while 29 products from 13 manufacturers were evaluated in Round 2. Of these products, 68 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites, and a parasite-negative panel. Thermal stability was assessed after two months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded. Of the 68 products, 22 detect *P. falciparum* alone, 39 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific), 6 detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them, and 1 product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation.

The Phase 1, *P. falciparum* cultured-parasite panel was derived from the same *P. falciparum* cultures in Rounds 1 and 2. However, the *P. falciparum* and *P. vivax* wild-type (clinical samples) panels were expanded in Round 2. More specifically, the *P. falciparum* panel was increased from 79 in Round 1 to 100 in Round 2, with 76 *P. falciparum* samples common to both rounds of testing. The *P. vivax* panel increased from 20 in Round 1 to 40 samples in Round 2, and the parasite-negative panel from 42 clean-negative samples and 48 disease or immune-factor positive samples in Round 1 to 50 of each in Round 2. The distribution of culture and wild-type sample antigen concentrations for *P. falciparum*-HRP2, *P. falciparum*-pLDH and P. vivax-pLDH were compared between the two rounds of testing to ensure consistency. The median *P. falciparum*-HRP2 and *P. falciparum*-pLDH levels were marginally lower in the Round 2 panel compared to that for Round 1; however, the difference was not statistically significant for either antigen (P>0.2; Mann-Whitney test). The median antigen concentration for *P. vivax*-pLDH, was higher

[1] *World Malaria Report 2009.* Geneva, World Health Organization, 2009.

[2] *Guidelines for the Treatment of Malaria, Second Edition.* Geneva, World Health Organization, 2010.

[3] See full reports of Rounds 1 and 2 for full list of collaborating partners.

in the Round 2 panel, but this difference was not statistically significant (P=0.68; Mann-Whitney test). The results of Round 1 and 2 are, therefore, comparable and should be viewed as a single data set for procurement purposes.

The evaluation is designed to provide comparative data on the performance of the submitted production lots of each product. Such data will be used to guide procurement decisions of WHO and other UN agencies and national governments. Product testing is part of a continuing programme of work to improve the quality of RDTs that are used, and to support broad implementation of reliable malaria diagnosis in areas where malaria is prevalent. A third round of product testing began in April 2010.

Results of the Evaluation

The results (summarized in Figures S1 and S2 and Tables S1 and S2) provide comparative data on two lots of products against a panel of parasite samples diluted to a low parasite density (200 parasites/µL) and a higher parasite density (2000 or 5000 parasites/µL). The former is below the mean parasite density found in many populations with endemic malaria, and considered close to the threshold that tests must detect to reliably identify clinical malaria in many settings.[1] For the purposes of this report, the main measure of performance is the 'panel detection score (PDS)'[2]; the percentage of malaria samples in the panel giving a positive result by two RDTs per lot at the lower parasite density, and a single RDT per lot at the higher parasite density. Thus, it is not a measure of RDT clinical sensitivity, or positivity rate against the panel but rather a combined measure of positivity rate, along with inter-test and inter-lot consistency. The figures also show the false-positive rates against blood samples containing no malaria parasites or known markers of other diseases, and the rate at which invalid results occurred.

The clinical sensitivity of an RDT to detect malaria is highly dependent on the local conditions, including parasite density in the target population, and so will vary between populations with differing levels of transmission. The results in this report show comparative performance between RDTs, and give an idea of which products are likely to provide higher sensitivity in the field, particularly in populations with low-density infections. In general, as countries reduce malaria prevalence and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the detection rate at 2000 parasites/µL indicates, the sensitivity of many of these products will be similar in populations with higher parasite densities, although a subset of any population will include vulnerable individuals who may develop illness at low parasite densities (e.g. young children, pregnant women, those well protected by bed nets) and must always be taken into account when interpreting RDT results.

Heat stability (summarized in Table S2) is vital to maintaining sensitivity of the test in the field. As a result, for procurement, it is essential that careful consideration be given to stability results to ensure that products to be used in areas with high temperatures of transport and storage have demonstrated stability in the product testing programme. Requirements will vary between countries: for example, if tests are to be deployed in areas where temperatures rarely rise above 30°C, less emphasis needs to be placed on stability at high temperatures.

Ease of use requirements will also vary, depending on the extent of training and the work environment of the end-users. Particularly in primary health care settings, the simpler the tests, the easier it will be to avoid errors in preparation and interpretation.

Detailed results of the evaluations can be found in the reports of each evaluation,[3] and at www.wpro.who.int/sites/rdt

[1] *WHO Technical Consultation on Parasitological Confirmation of Malaria Diagnosis. Report.* Geneva, World Health Organization, 2010. (Unpublished)

[2] Termed 'Detection Rate' in the full report of Round 1, published in 2009. See the Round 2 report for a full explanation of the panel detection score (PDS).

[3] *Malaria Rapid Diagnostic Test Performance : Results of WHO product testing of malaria RDTs: Round 1 (2008).* Geneva, World Health Organization, 2009. ISBN 978 92 4 1598071

Summary of outcomes

This laboratory-based evaluation provides a comparative measure of RDT performance in a standardized way to distinguish between well and poorly performing tests to inform procurement decisions of malaria control programmes and guide UN procurement policy.

Several RDTs from Rounds 1 and 2 demonstrated consistent detection of malaria at low parasite densities (200 parasites/µl), have low false positive rates, are stable at tropical temperatures, are relatively easy to use, and can detect *P. falciparum*, *P. vivax* infections, or both.

Performance between products varied widely at low parasite density (200 parasites/µl); however, most products showed a high level of detection at 2000 or 5000 parasites/µl.

P. falciparum tests targeting HRP2 antigen demonstrated the highest detection rates, but some tests targeting pLDH also exhibited high detection rates.

Test performance varied between lots, and widely between similar products, confirming the advisability of lot-testing post purchase and prior to use in the field.

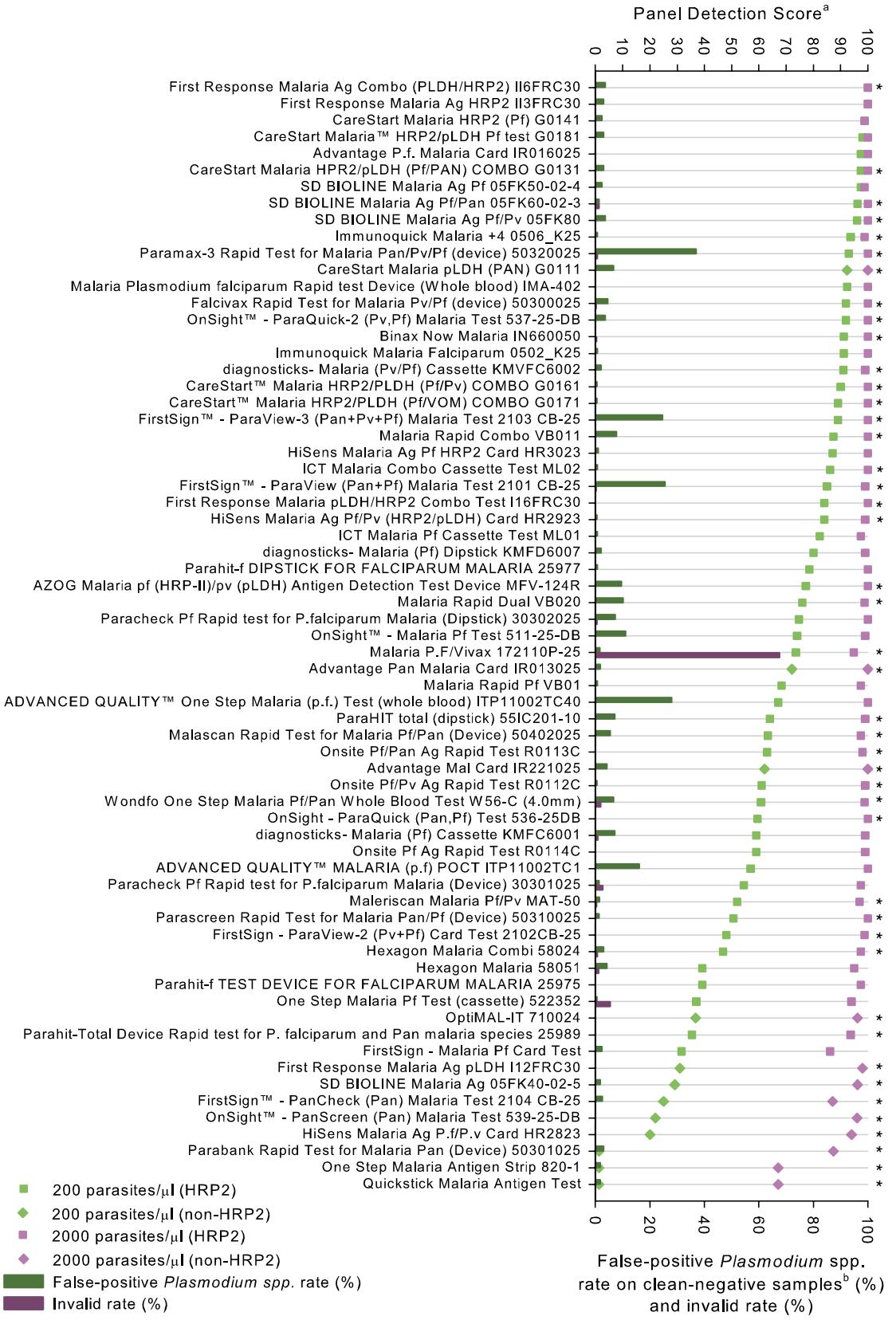
The results underscore the need for manufacturers to have adequate reference materials for product development and lot-release. The WHO-FIND malaria RDT evaluation programme, in collaboration with the CDC, offers quality standard panels to manufacturers to assist in this process.

Use of these Results

Ultimately, it is imperative that procurement decisions based on these results take into consideration local conditions of malaria transmission and illness where the tests will be used (e.g. *Plasmodium* species, target antigen variation, parasite densities, climate). Accurate diagnosis is vital to good malaria case management, whether based on microscopy or RDTs. These results should be used to short-list products for procurement for use in cases where good microscopy is not available of appropriate. Other considerations, including training and retraining requirements, are also essential components of product selection. It is recommended that each lot of RDTs is also tested in a standardized way prior to dispersal to the field, to ensure that the high performance demonstrated by the lots evaluated in the product testing programme is maintained.[1] Procurement of RDTs must not occur without programmatic and infrastructure preparation for proper use, including supply chain management, training on test usage and disposal, and training on patient management in response to results. Both reports provides an algorithm to assist in this decision-making process (Rounds 1 and 2: Annex 5).

[1] The WHO-FIND Malaria RDT Evaluation Programme provides lot-testing capacity in a number of regional laboratories free of charge, and can be accessed through *mal-rdt@wpro.who.int* and *info@finddiagnostics.org*.

Figure S1: Malaria RDT performance in Phase 2 of Rounds 1 and 2 against wild type (clinical) samples containing *P. falciparum* at low (200) and high (2000 or 5000) parasite densities (parasites/µl) and clean-negative samples

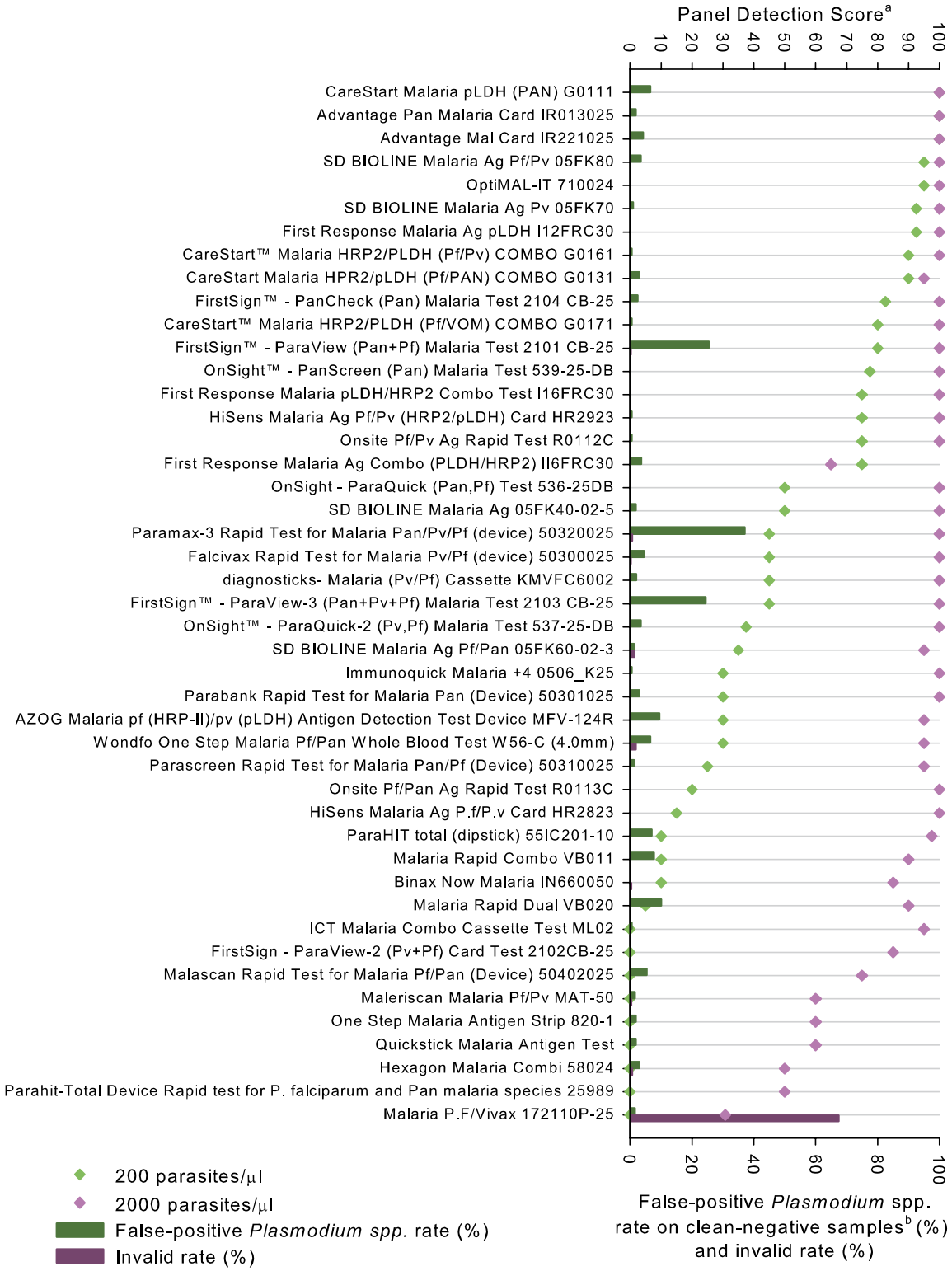


[a] panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.;

[b] clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

* indicates tests that also detect other non-*P. falciparum* parasites. (see Figure S2)

Figure S2: Malaria RDT performance in Phase 2 of Rounds 1 and 2 against wild type (clinical) samples containing *P. vivax* at low (200) and high (2000 or 5000) parasite densities (parasites/µl)) and clean-negative samples



[a] panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.

[b] clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

Pf: *Plasmodium falciparum* - Pv: *Plasmodium vivax* - pan: *Plasmodium species*

[a] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive

[b] The total number of times a positive result for malaria was generated when it should not have been

[c] Round 1, n=79; Round 2, n=100

[d] Round 1, n=20; Round 2, n=40

[e] For combination tests, Pan or Pv line, only, positive indicates a false positive *P. falciparum* infection (Round 1 n=316; Round 2, n=400)

[f] Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=80; Round 2, n=160)

[g] For combination tests, Pan or Pv line, only, positive indicates a false positive *P. falciparum* infection (Round 1, n=158, Round 2, n=200)

[h] Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=40; Round 2, n=80)

[i] Round 1, n=168; Round 2, n=200

Detection rate (%)	≥95	85-94	50-84	< 50
False positive rate (%)	<2	2-5	6 -10	>10
Invalid rate (%)	<1% of tests conducted	1-2% of tests conducted	2-5% of tests conducted	>5% of tests conducted

Table S2: Malaria RDT Rounds 1 and 2 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µl). Positivity rate at baseline, and after 60 days incubation at 35°C and 45°C

Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Number of tests positive (max. 20)			Number of tests positive (max. 20)			Number of tests positive (max. 20)			Number of tests positive (max. 20)			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf only															
ADVANCED QUALITY™ MALARIA (p.f) POCT	ITP11002TC1	InTec Products, Inc.	16	19	18	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
ADVANCED QUALITY ™ One Step Malaria (p.f.) Test (whole blood)	ITP11002TC40	InTec Products, Inc.	16	17	9	20	19	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	19	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	19	14	11	19	19	19	N/A	N/A	N/A	N/A	N/A	N/A	2
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
First Response Malaria Ag HRP2	II3FRC30	Premier Medical Corporation Ltd.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	4	3	0	20	18	19	N/A	N/A	N/A	N/A	N/A	N/A	1
Hexagon Malaria	58051	Human GmbH	10	7	12	19	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
ICT Malaria Pf Cassette Test (ML01)	ML01	ICT Diagnostics	20	20	19	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Immunoquick Malaria Falciparum	0502_K25	Biosynex	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Malaria Plasmodium falciparum Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Malaria Rapid Pf	VB01	Vision Biotech (Pty) Ltd.	20	20	17	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
One Step Malaria Pf Test (cassette)	522352	BlueCross Bio-Medical (Beijing) Co., Ltd	6	3	2	16	18	16	N/A	N/A	N/A	N/A	N/A	N/A	2
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	20	19	18	20	20	13	N/A	N/A	N/A	N/A	N/A	N/A	2
Onsite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	20	18	13	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
Paracheck Pf Rapid test for *P. falciparum* Malaria (Device)	30301025	Orchid Biomedical Systems	18	14	10	20	17	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Paracheck Pf Rapid test for *P. falciparum* Malaria (Dipstick)	30302025	Orchid Biomedical Systems	19	20	17	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Parahit-f DIPSTICK FOR FALCIPARUM MALARIA	25977	Span Diagnostics Ltd.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Parahit-f TEST DEVICE FOR FALCIPARUM MALARIA	25975	Span Diagnostics Ltd.	14	10	8	20	19	19	N/A	N/A	N/A	N/A	N/A	N/A	1
SD BIOLINE Malaria Ag Pf	05FK50-02-4	Standard Diagnostics, Inc.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	1
Pf and Pan															
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	20	20	11	19	20	19	11	9	8	20	20	20	1
AZOG Malaria pf (HRP-II) /pv (pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	12	13	7	20	20	20	8	7	5	18	14	4	1
Binax Now Malaria Test	IN660050	Inverness Medical Innovations, Inc.	20	20	20	20	20	19	1	0	0	19	19	15	1
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131	Access Bio, Inc.	20	19	20	20	20	20	20	19	20	20	20	20	1
First Response Malaria Ag Combo (PLDH/HRP2)	II6FRC30	Premier Medical Corporation Ltd.	20	20	20	20	20	20	19	14	20	20	20	20	1
First Response® Malaria pLDH/HRP2 Combo Test	I16FRC30	Premier Medical Corporation Ltd.	20	20	20	20	20	20	17	11	11	10	10	10	2
FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	Unimed International Inc.	20	20	20	20	20	20	19	8	8	10	10	10	2
Hexagon Malaria Combi	58024	Human GmbH	13	11	10	20	17	19	0	0	0	0	0	0	1
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	7	0	1	20	20	20	0	0	0	7	0	0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	20	20	20	20	20	20	20	20	19	20	20	20	2
ICT Malaria Combo Cassette Test (ML02)	ML02	ICT Diagnostics	20	20	20	20	20	20	1	1	0	18	15	15	1
Immunoquick Malaria +4	0506_K25	Biosynex	20	20	20	20	20	20	0	0	0	20	16	16	1
Malaria P.F/Vivax	172110P-25	Diagnostics Automation/Cortez Diagnostics, Inc.	13	3	4	13	9	1	0	0	0	0	0	0	1
Malaria Rapid Combo	VB011	Vision Biotech (Pty) Ltd.	20	20	20	20	20	20	3	6	0	19	20	15	1

Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Number of tests positive (max. 20)			Number of tests positive (max. 20)			Number of tests positive (max. 20)			Number of tests positive (max. 20)			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Malaria Rapid Dual	VB020	Vision Biotech (Pty) Ltd.	20	20	20	20	20	20	0	3	0	12	5	3	1
Malascan Rapid Test for Malaria Pf/Pan (Device)	50402025	Zephyr Biomedicals	19	18	17	20	20	20	0	1	0	13	11	3	1
One Step Malaria Antigen Strip	820-1	IND Diagnostic Inc.	3	0	0	13	10	0	3	0	0	13	10	1	1
OnSight™ – ParaQuick (Pan, Pf) Test	536-25DB	Amgenix International, Inc.	20	18	12	20	20	20	0	0	0	20	20	19	1
Onsite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	20	18	8	20	20	20	1	0	0	20	14	9	2
OptiMAL-IT	710024	DiaMed AG	6	2	0	20	19	0	6	3	0	20	20	2	1
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	11	17	11	20	20	19	2	0	0	10	9	14	2
Parahit-Total Device Rapid test for *P. falciparum* and Pan malarial species.	25989	Span Diagnostics Ltd.	13	15	5	19	20	20	1	0	0	0	0	0	1
Parascreen Rapid Test for Malaria Pan/Pf (Device)	50310025	Zephyr Biomedicals	19	16	9	20	20	19	1	0	0	17	14	16	1
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.	3	0	0	13	10	0	3	0	0	13	10	1	1
SD BIOLINE Malaria Ag	05FK40-02-5	Standard Diagnostics, Inc.	7	12	15	20	20	20	0	9	15	11	20	19	1
SD BIOLINE Malaria Ag Pf/Pan	05FK60-02-3	Standard Diagnostics, Inc.	20	20	20	20	20	19	0	1	16	18	9	18	1
Wondfo One Step Malaria Pf/Pan Whole Blood Test	W56-C(4.0mm)	Guangzhou Wonfo Biotech Co., Ltd	20	19	20	19	20	20	14	18	14	19	20	20	1
Pf and Pv															
CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	20	20	19	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	20	19	19	20	20	19	N/A	N/A	N/A	N/A	N/A	N/A	2
Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	Zephyr Biomedicals	20	20	20	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
FirstSign – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	19	14	0	20	19	15	N/A	N/A	N/A	N/A	N/A	N/A	1
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	20	12	6	20	18	19	N/A	N/A	N/A	N/A	N/A	N/A	2
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	20	20	20	20	20	17	N/A	N/A	N/A	N/A	N/A	N/A	2
Onsite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	20	19	9	20	20	20	N/A	N/A	N/A	N/A	N/A	N/A	2
SD BIOLINE Malaria Ag Pf/Pv	05FK80	Standard Diagnostics, Inc.	20	20	20	20	20	19	N/A	N/A	N/A	N/A	N/A	N/A	2
Pf, Pv and Pan															
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	20	20	20	20	20	20	12	10	3	20	18	20	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	20	10	10	20	20	20	20	5	6	20	19	20	2
Pan only															
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	10	13	14	20	20	20	1
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	20	20	18	20	20	20	1
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	10	16	11	20	20	20	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	N/A	N/A	N/A	N/A	N/A	N/A	5	1	2	20	20	20	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	1	7	3	20	20	20	2
Parabank Rapid Test for Malaria Pan (Device)	50301025	Zephyr Biomedicals	N/A	N/A	N/A	N/A	N/A	N/A	1	0	0	17	18	14	1
Pv only															
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2

Pf: *Plasmodium falciparum* - Pv: *Plasmodium vivax* - pan: *Plasmodium species*

TDR/World Health Organization
20, Avenue Appia
1211 Geneva 27
Switzerland

Fax: (+41) 22 791 48 54
tdr@who.int
www.who.int/tdr

FIND
71, Avenue Louis-Casaï
1216 Cointrin/Geneva
Switzerland

Fax: (+41) 22 710 05 99
info@finddiagnostics.org
www.finddiagnostics.org