

WHO public announcement to rapid diagnostic test manufacturers, procurement agencies and national malaria control programmes

WHO, through its WHO Prequalification Team and Global Malaria Programme, would like to announce changes to the WHO criteria used to determine procurement eligibility for antigen-detecting malaria rapid diagnostic tests (RDTs).

Since 2009, the [WHO recommendations](#) on malaria RDT procurement are based on product performance in the WHO Malaria RDT Product Testing Programme, coordinated by the WHO Global Malaria Programme, in collaboration with FIND and the US Centers for Disease Control and Prevention. It constitutes the laboratory evaluation component of the [WHO Prequalification](#) of malaria RDTs which is additionally comprised of a standardized dossier review and a manufacturing site inspection to provide comprehensive assurance of safety, quality and performance. Established in 2008, WHO prequalification of IVDs is used across the UN agencies to determine procurement eligibility of HIV, Hepatitis B and C and syphilis tests and by national authorities as a complement to their national regulatory approvals. WHO Prequalification will also become the determinant of procurement eligibility of malaria RDTs as of 31 December 2017. The results of the WHO Product Testing scheme will continue to be used as the independent performance laboratory evaluation component of the prequalification process.

To facilitate this transition, manufacturers with products that currently meet procurement criteria (Table 1) and future expressions of interest for participation in WHO Product Testing (ie. Round 8) are required to submit applications to WHO prequalification and pay associated fees according to the timelines outlined below. Only those products that meet WHO prequalification requirements by 31 December 2017 will be eligible for WHO procurement. Currently, 12 malaria RDTs from four manufacturers are WHO prequalified (Table 1). Seven are intended to detect *P.falciparum*-only; four detect and distinguish between *P.falciparum* and non-falciparum and one detects all species but does not distinguish between them. Applications for RDT combination tests and tests that target antigens other than HRP2 for detection of *P.falciparum* are encouraged and will be prioritized.

RDT procurers and National Malaria Control Programmes are encouraged to review their procurement policies for malaria RDTs and seriously consider bringing them in line with these revised WHO recommendations.

Timelines:

1. For products that are currently eligible for WHO procurement, manufacturers must submit a [WHO PQ pre-submission form](#) to WHO PQT by 31 July, 2016.
2. For products that are new to WHO processes or for products that are due for compulsory resubmission to Product Testing, manufacturers must submit to the revised EOI for Round 8, in quarter 4 of 2016.
3. Manufacturers are expected to have submitted a complete dossier for each product to WHO PQT by 31 December, 2016.
4. Manufacturers are expected to complete full prequalification by 31 December, 2017. Beyond this date only prequalified products will be recommended and eligible for WHO procurement.

Table 1: Malaria RDTs that meet current WHO recommended procurement criteria including those that are WHO prequalified

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
<p>A: <i>P. falciparum</i> panel detection score \geq 75% at 200 parasites/μL; B: <i>P. vivax</i> panel detection score \geq 75% at 200 parasites/μL; C: false-positive rate against clean negatives < 10%; D: invalid rate < 5%</p>								
Pf only								
Advantage P.f. Malaria Card ^a	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	0.0	0.0	5	No
BIONOTE MALARIA P.f. Ag Rapid Test Kit ^a	RG19-11	Bionote, Inc.	88.0	NA	0.5	0.0	6	No
CareStart™ Malaria HRP2 (Pf) ^a	RMOM(U)-XXX7X/RMOM(U)-XXX9X ^{b,c}	Access Bio, Inc.	91.0	NA	0.9	0.0	5	Yes
CareStart™ Malaria HRP2/pLDH Pf test	RMPM(U)-XXX7X/RMPM(U)-XXX9X ^{b,d}	Access Bio, Inc.	91.0	NA	0.0	0.0	6	Yes
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	1.0 (198)	0.3	3	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
First Response® Malaria Ag P. falciparum (HRP2) Card Test ^a	I13FRC25	Premier Medical Corporation Ltd.	95.0	NA	0.4	0.0	5	Yes
First Response® Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	1.0	0.0	6	No
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	2.2 (231)	0.2	4	No
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	1.4	0.0	6	No
ICT Diagnostics Malaria P.f. ^a	ML01	ICT INTERNATIONAL	86.9	NA	0.0	0.0	3	No
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	NA	4.0 (199)	0.3	3	No
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	91.0	NA	1.0	0.0	6	No
Maleriscan® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (P) Ltd.	83.7	NA	0.4	0.2	4	No
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	0.0	0.3	3	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
One Step Malaria P.f Whole blood Test ^a	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	NA	0.0	0.0	6	No
One Step Malaria P.F Test (Cassette) ^a	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	1.3	0	4	No
OnSite Malaria Pf Ag Rapid Test ^a	R0114C	CTK Biotech, Inc.	75.0	NA	0.0	0.2	6	No
Paracheck [®] Pf-Rapid Test for P.falciparum Malaria Device (Ver.3) ^a	302030025	Orchid Biomedical Systems	95.9	NA	1.3	0	4	No
ParaHIT [®] - f Ver. 1 (Device)	55IC104-50	ARKRAY Healthcare Pvt. Ltd. ^e	84.9	NA	0.0	0.0	3	Yes
ParaHIT [®] -f Ver. 1 (Dipstick)	55IC103-50	ARKRAY Healthcare Pvt. Ltd. ^e	80.8	NA	2.5	0.0	3	Yes
Rapid 1-2-3 [®] Hema [®] Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	0.0	0.2	6	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	0.5 (207)	0.2	6	No
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	0.0	0.0	6	No
SD Bioline Malaria Ag P.f (HRP2/pLDH) ^a	05FK90	Standard Diagnostics, Inc.	88 (87.0/52.0) ⁱ	NA	0.0	0.0	6	Yes
SD BIOLINE Malaria Ag Pf ^a	05FK50/05FK53	Standard Diagnostics, Inc.	95.0	NA	0.0	0.0	5	Yes
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	88.8	NA	5.2 (230)	0.7	4	No
Pf and pan								
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	0.0	0.2	5	No
BioTracer™ Malaria P.f/PAN Rapid Card ^a	17012	Bio Focus Co., Ltd.	83.0	100.0	0.0	0.0	6	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	0.0	0.2	3	No
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO ^a	RMRM(U)-XXX7X/RMRM(U)-XXX9X ^{b,f}	Access Bio, Inc.	90.0	94.3	0.4	0.0	5	Yes
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	0.5	0.0	3	No
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	2.5 (199)	0.1	3	No
DIAQUICK Malaria P.f/Pan Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	2.1	0.2	5	No
EzDx™ Malaria Pan/Pf Rapid test detection Kit ^a	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	1.4	0.0	6	No
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	1.9 (207)	0.1	6	No
Humasis Malaria P.f/Pan Antigen	AMAL-7025	Humasis, Co., Ltd.	90.0	91.4	0.9 (235)	0.7	5	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
Test ^a								
Is It... Malaria Pf/Pv Device	AL030	Medsorce Ozone Biomedicals	88.0	91.4	1.0 (206)	0.8	6	No
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	0.4 (232)	1.0	5	No
NanoSign Malaria pf/pan Ag 3.0 ^a	RMAP10	Bioland, Ltd.	92.9	97.1	0.4	0.0	4	No
OnSite Malaria Pf/Pan Ag Rapid Test ^a	R0113C	CTK Biotech, Inc.	78.0	85.7	0.0 (207)	0.2	6	No
ParaHIT - Total Ver. 1.0 (Device)	551C204-10	ARKRAY Healthcare Pvt. Ltd. ^e	84.7	82.4	0.0	0.1	4	No
Parascreen [®] - Rapid Test for Malaria Pan/Pf ^a	503030025	Zephyr Biomedicals	79.0	97.1	0.0	0.0	6	No
QuickProfile [™] Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	7.2	0.1	6	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) ^a	C30RHA25	RapiGEN Inc.	90.0	91.4	2.4 (207)	0.1	6	No
SD BIOLINE Malaria Ag P.f/Pan ^a	05FK60/05FK63	Standard Diagnostics, Inc.	94.0	91.4	0.0	0.0	5	Yes
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics, Inc.	90.8	94.1	1.3 (226)	2.8	4	No
Pf and Pv/Pvom								
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote, Inc.	92.9	97.1	4.0	0.0	3	No
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	0.0	0.1	6	No
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO ^a	RMVM(U)-XXX7X/RMVM(U)-XXX9X ^{b,g}	Access Bio, Inc.	90.8	94.1	0.0	0.0	4	Yes

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO ^a	G0171/G0171-ET	Access Bio, Inc.	89.8	91.2	0.0	0.0	4	No
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	78.0	82.9	0.0 (207)	0.5	6	No
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	3.9	0.0	6	No
FalciVax™ - Rapid Test for Malaria Pv/Pf ^a	503010025	Zephyr Biomedicals	80.0	100.0	1.4	0.0	6	No
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	0.4	0.1	4	No
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	0.0		4	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
						0.0		
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	1.3	0.0	4	No
Humasis Malaria P.f/P.v Antigen Test [†]	ANMIV-7025	Humasis Co., Ltd.	88.0	91.4	1.0 (207)	0.1	6	No
RAPID 1-2-3 [®] HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems	92.9	79.4	4.3	0.0	4	No
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	4.4 (207)	0.2	6	No
SD Bioline Malaria Ag P.f/P.v ^a	05FK80	Standard Diagnostics, Inc.	92.0	94.3	1.9	0.0	6	Yes
Pf, Pf and Pv								
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	85 (84.0/36.0) ⁱ	91.4	0.0	0.0	6	No

Product	Catalogue number*	Manufacturer	Current procurement criteria				Round	WHO Prequalified
			A	B	C	D		
			A: <i>P. falciparum</i> panel detection score \geq 75% at 200 parasites/ μ L; B: <i>P. vivax</i> panel detection score \geq 75% at 200 parasites/ μ L; C: false-positive rate against clean negatives < 10%; D: invalid rate < 5%					
Pan only								
Advantage Pan Malaria Card ^a	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	0.4	0.0	5	No
CareStart™ Malaria pLDH (PAN) ^a	RMNM(U)-XXX7X ^{b,h}	Access Bio, Inc.	84.0	88.6	0.0	0.0	5	Yes

* Some products may have different catalogue numbers for different box sizes or kit accessories or site of manufacture; contact manufacturers for detailed information.

Pan: All *Plasmodium* species; Pf: *Plasmodium falciparum*; Pv: *Plasmodium vivax*; Pvom: *Plasmodium vivax, ovale* and *malariae*

^a Product resubmission, results from most recent round of testing replace previous results. Refer to summary results of WHO product testing of malaria RDTs: rounds 1–6 (2008–2015), Table S1.

^b Please note, the first three letters in the catalogue number indicate the RDT product code, the 4th letter indicates the package type of the kit (M: multi kit, U: single kit). The XXX in the second part of the catalogue number indicates the number of RDTs in the kit, the number following this indicates the manufacturing site (e.g. 7:USA, 9: Ethiopia) and the last number indicates the CE marking (e.g. 1: CE marked, 2: Not CE marked).

^c Catalogue number was formerly G0141/G0141-ET.

^d Catalogue number was formerly G0181/G0181-ET

^e Span Diagnostics Ltd. is now ARKRAY Healthcare Pvt.Ltd.

^f Catalogue number was formerly G0131/ G0131-ET.

^g Catalogue number was formerly G0161/G0161-ET.

^h Catalogue number was formerly G0111.

ⁱ Product PDS shown along with PDS for HRP2 band and Pf-pLDH band, respectively

