WHO Prequalification of In Vitro Diagnostics Programme
PUBLIC REPORT

Product: *CareStart*™ Malaria PAN (pLDH) Ag RDT
Number: PQDx 0234-049-00

Abstract

CareStart™ Malaria pLDH (PAN) to be labelled as *CareStart*™ Malaria PAN (pLDH) Ag RDT from October 2015 with product codes RMNM-02571 and RMNM-05071 (old product code G0111),[1] manufactured by Access Bio, Inc., rest-of-world regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 28 May 2015.

This public report was amended on 28 June 2018 to reflect the addition of a new product configuration, updates of product codes and inclusion of labelling. The product now has two configurations: **multi kit** (product codes: **RMNM-02571, RMNM-02571CB, RMNM-02571RB, RMNM-02571RI, RMNM-05071, RMNM-05071CB, RMNM-05071RB and RMNM-05071RI**) and **single kit** (product codes: **RMNU-02571, RMNU-02571CB, RMNU-02571RB, RMNU-02571RI, RMNU-05071, RMNU-05071CB, RMNU-05071RB and RMNU-05071RI**). Each multi kit and single kit has 8 different packaging configurations. For further details, please refer to the test kit content table.

Summary of prequalification status for *CareStart*™ Malaria PAN (pLDH) Ag RDT

	Date	Outcome
PQ public report amended	28 June 2018 Inclusion of a new configuration (addition of single-use buffer vials and an 'Instruction Card'), updates of product codes and inclusion of labelling.	listed
Status on PQ list	28 May 2015	listed
Dossier assessment	15 April 2015	MR
Inspection status	8-10 February 2017	MR
Laboratory evaluation	2014	MR

MR: Meets Requirements

CareStart™ Malaria PAN (pLDH) Ag RDT was accepted for the WHO list of prequalified in vitro diagnostics on the basis of data submitted and publicly available information.

[1] The old product codes RMNM-02571 and RMNM-05071, and G0111 are obsolete

For the rapid qualitative detection of malaria pLDH (plasmodium lactate dehydrogenase) in human whole blood as an aid in the diagnosis of malaria *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae* infection.

CareStart™ Malaria PAN (pLDH) Ag RDT contains a membrane strip, which is pre-coated with a monoclonal antibody as single line across the test strip. The monoclonal antibody is specific to pLDH of the Plasmodium species (*P. falciparum, P.vivax, P.malariae* and/or *P.ovale*). The conjugate pad is dispensed with antibodies absorbed on gold particles, which are specific to pLDH of PAN.

CareStart™ Malaria PAN (pLDH) Ag RDT is designed for the diagnosis of *P. falciparum*, *P.vivax*, *P.malariae* and/or *P.ovale* infection.

Other clinically available tests are required if the obtained results are questionable. A definitive clinical diagnosis should not be made based on the result of this test, but should only be made by a qualified physician after all clinical and laboratory findings have been evaluated.

Storage:
The test kit should be stored at 1 to 40 °C.

Shelf-life:
30 months.

Reading time:
20 minutes.

Consumables:

Configuration	Packaging	Item(s)
Multi kit	25 tests/kit	1 × Assay buffer bottle (4 mL)
		25 × Specimen transfer device
		25 × Lancet
		25 × Alcohol swab
		1 × Instructions for Use
	50 tests/kit	1 × Assay buffer bottle (6mL)
		50 × Specimen transfer device
		50 × Lancet
		50 × Alcohol swab
		1 × Instructions for Use
Single kit	25 single kit bags/kit	Each single kit bag contains one of each of the following items:
		- Single use buffer vial
		- Specimen transfer device

		- Lancet
		- Alcohol swab
		- Instruction card
		1 × Instructions for Use
	40 single kit bags /kit	Each single kit bag contains one of each of the following items:
		- Single use buffer vial
		- Specimen transfer device
		- Lancet
		- Alcohol swab
		- Instruction card
		1 × Instructions for use

Materials needed but not provided:

1. Pair of disposable gloves
2. Timer
3. Sharp box
4. Pencil or pen
5. Sterile gauze or cotton

The test kit contents:

	Packaging	Product code	Item	Instructions for use	Instruction card	RDT Box	Single kit bag (Lab in a pack)	Cassette packaging
Multi kit	25 tests/ kit	RMNM-02571	• Lancets (Capped) • Specimen transfer devices (Inverted cup)	IFU-RMLM71-EFSP	n/a	LB-KML2571CIA	n/a	PROL6140
		RMNM-02571CB	• Lancets (Capped) • Specimen transfer devices (Bulb)	IFU-RMLM71CB-EFSP		LB-KML2571CBA		
		RMNM-02571RB	• Lancets (Retractable) • Specimen transfer devices (Bulb)	IFU-RMLM71RB-EFSP		LB-KML2571RBA		
		RMNM-02571RI	• Lancets (Retractable) • Specimen transfer devices (Inverted cup)	IFU-RMLM71RI-EFSP		LB-KML2571RIA		
	50 tests/ kit	RMNM-05071	• Lancets (Capped) • Specimen transfer devices (Inverted cup)	IFU-RMLM71-EFSP		LB-KML5071CIA		
		RMNM-05071CB	• Lancets (Capped) • Specimen transfer devices (Bulb)	IFU-RMLM71CB-EFSP		LB-KML5071CBA		
		RMNM-05071RB	• Lancets (Retractable) • Specimen transfer devices (Bulb)	IFU-RMLM71RB-EFSP		LB-KML5071RBA		
		RMNM-05071RI	• Lancets (Retractable) • Specimen transfer devices (Inverted cup)	IFU-RMLM71RI-EFSP		LB-KML5071RIA		
Single kit	25 tests/ kit	RMNU-02571	• Lancets (Capped) • Specimen transfer devices (Inverted cup)	IFU-RMLU71-EFSP	IFU-RMLU71-E	LB-KUL2571CIA	PABO140	
		RMNU-02571CB	• Lancets (Capped) • Specimen transfer devices (Bulb)	IFU-RMLU71CB-EFSP	IFU-RMLU71CB-E	LB-KUL2571CBA		
		RMNU-02571RB	• Lancets (Retractable) • Specimen transfer devices (Bulb)	IFU-RMLU71RB-EFSP	IFU-RMLU71RB-E	LB-KUL2571RBA		
		RMNU-02571RI	• Lancets (Retractable) • Specimen transfer devices (Inverted cup)	IFU-RMLU71RI-EFSP	IFU-RMLU71RI-E	LB-KUL2571RIA		
	40 tests/ kit	RMNU-04071	• Lancets (Capped) • Specimen transfer devices (Inverted cup)	IFU-RMLU71-EFSP	IFU-RMLU71-E	LB-KUL4071CIA		
		RMNU-04071CB	• Lancets (Capped) • Specimen transfer devices (Bulb)	IFU-RMLU71CB-EFSP	IFU-RMLU71CB-E	LB-KUL4071CBA		
		RMNU-04071RB	• Lancets (Retractable) • Specimen transfer devices (Bulb)	IFU-RMLU71RB-EFSP	IFU-RMLU71RB-E	LB-KUR4071RBA		
		RMNU-04071RI	• Lancets (Retractable) • specimen transfer devices (Inverted cup)	IFU-RMRU71RI-EFSP	IFU-RMRU71RI-E	LB-KUR4071RIA		

Background information

Access Bio, Inc. submitted an application for prequalification of *CareStart*™ Malaria PAN (pLDH) Ag RDT. Based on the results of the WHO product testing of malaria RDTs Round 5, *CareStart*™ Malaria PAN (pLDH) Ag RDT was given priority for prequalification.

Product dossier assessment

Access Bio, Inc. submitted a product dossier *CareStart*™ Malaria PAN (pLDH) Ag RDT as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal report on the screening and assessment of a product dossier (PQDx_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for *CareStart*™ Malaria PAN (pLDH) Ag RDT for prequalification.

Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (65 Clyde Road Suite A, Somerset NJ, USA) of *CareStart*™ Malaria PAN (pLDH) Ag RDT in February 2017 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v3). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 23 April 2018.

Laboratory evaluation

The fifth round of WHO product testing of RDTs for malaria antigen detection was completed in 2014. The product was evaluated against a *P. falciparum* and *P. vivax* parasites cultured line panel, P. falciparum and P. vivax parasites wild type parasite panel and a *P. falciparum* and *P. vivax* parasites negative panel.

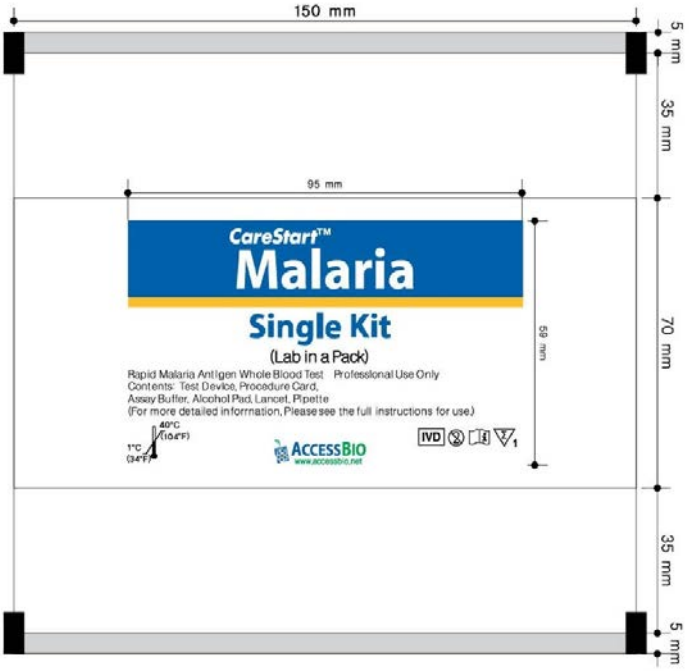
Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded.

Based on the demonstrated *P. falciparum* panel detection score (84.0% at 200 parasites/µl) and *P. vivax* panel detection score (88.6% at 200 parasites/µl), false-positive rates (0% for clean negatives), *CareStart*™ Malaria pLDH (PAN) meets the current laboratory evaluation requirements for prequalification.

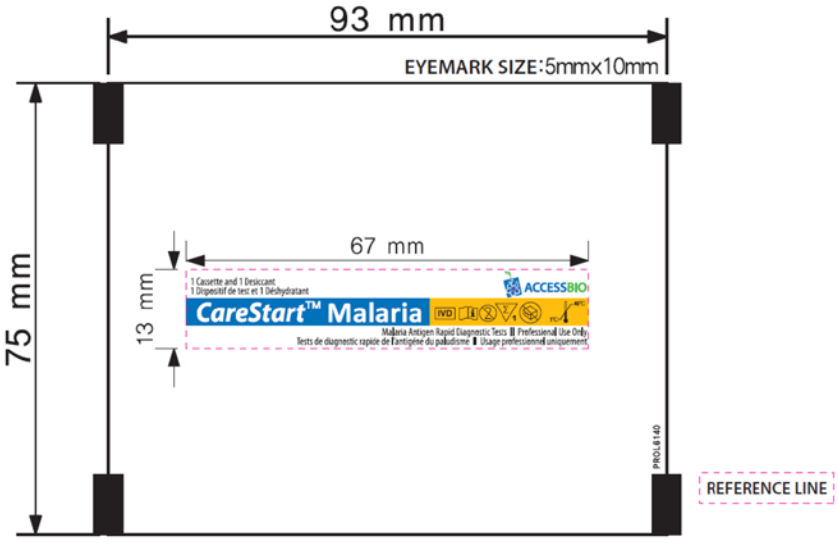
Labelling

1. **Labels**
2. **Instructions for use**
3. **Instruction Cards**
4. **RDT box designs**

Single kit bag (lab in a pack)



Cassette packaging



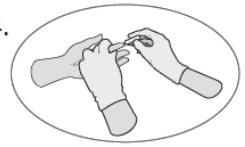
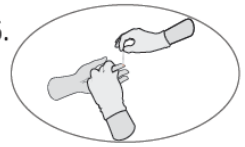
Instructions for use

Instruction cards

CareStart™ Malaria PAN (pLDH) Ag RDT

REF RMNU-02561CB / RMNU-04061CB / RMNU-02571CB / RMNU-04071CB

TEST PROCEDURE

1. Put on a new pair of gloves.
2. Write the patient's name on the cassette.
3. Clean the area to be pierced using an alcohol swab. Let the alcohol dry completely before proceeding to the next step.
4.  Squeeze the end of a fingertip and pierce the cleaned area of the fingertip using a lancet provided. Discard the lancet in the sharps box.
5. Wipe out the first drop of blood with sterile gauze or cotton.
6.  Collect the blood sample (5µl) using a provided specimen transfer device or a micopipette.

7.  Add 5µl of whole blood into "S" well.
8.  Add 3 drops (60µl) of buffer solution into "A" Well. Start a timer.
9. Read result at 20 minutes.

INTERPRETATION OF THE TEST RESULT

Negative

The presence of a line next to "C" indicates a negative result.

PAN Positive

The presence of two lines (one line in the result window next to "C" and another in the result window next to "T") indicates a positive result for *P. falciparum, P. vivax, P. ovale* and/or *P. malariae*.

Invalid

The test is invalid when a line does not appear next to "C". If this occurs, the test should be repeated using a new cassette.

For detailed information about the product and procedure, refer to the full version of instructions for use (Doc. No. IFU-RMNU71CB-EFSP) included in the RDT box.

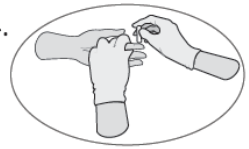
ACCESSBIO

IFU-RMNU71CB-E / Rev. B May 21, 2018

CareStart™ Malaria PAN (pLDH) Ag RDT

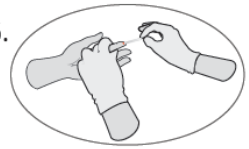
TEST PROCEDURE

1. Put on a new pair of gloves.
2. Write the patient's name on the cassette.
3. Clean the area to be pierced using an alcohol swab. Let the alcohol dry completely before proceeding to the next step.

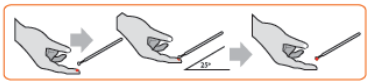
4. 

Squeeze the end of a fingertip and pierce the cleaned area of the fingertip using a lancet provided. Discard the lancet in the sharps box.

5. Wipe out the first drop of blood with sterile gauze or cotton.

6. 

Collect the blood sample (5µl) using a provided specimen transfer device or a micopipette.



7. 

Add 5µl of whole blood into "S" well.

8. 

Add 3 drops (60µl) of buffer solution into "A" Well. Start a timer.

9. Read result at 20 minutes.

REF RMNU-02561RI / RMNU-04061RI / RMNU-02571RI / RMNU-04071RI

INTERPRETATION OF THE TEST RESULT

Negative

The presence of a line next to "C" indicates a negative result.

PAN Positive

The presence of two lines (one line in the result window next to "C" and another in the result window next to "T") indicates a positive result for *P. falciparum, P. vivax, P. ovale* and/or *P. malariae*.

Invalid

The test is invalid when a line does not appear next to "C". If this occurs, the test should be repeated using a new cassette.

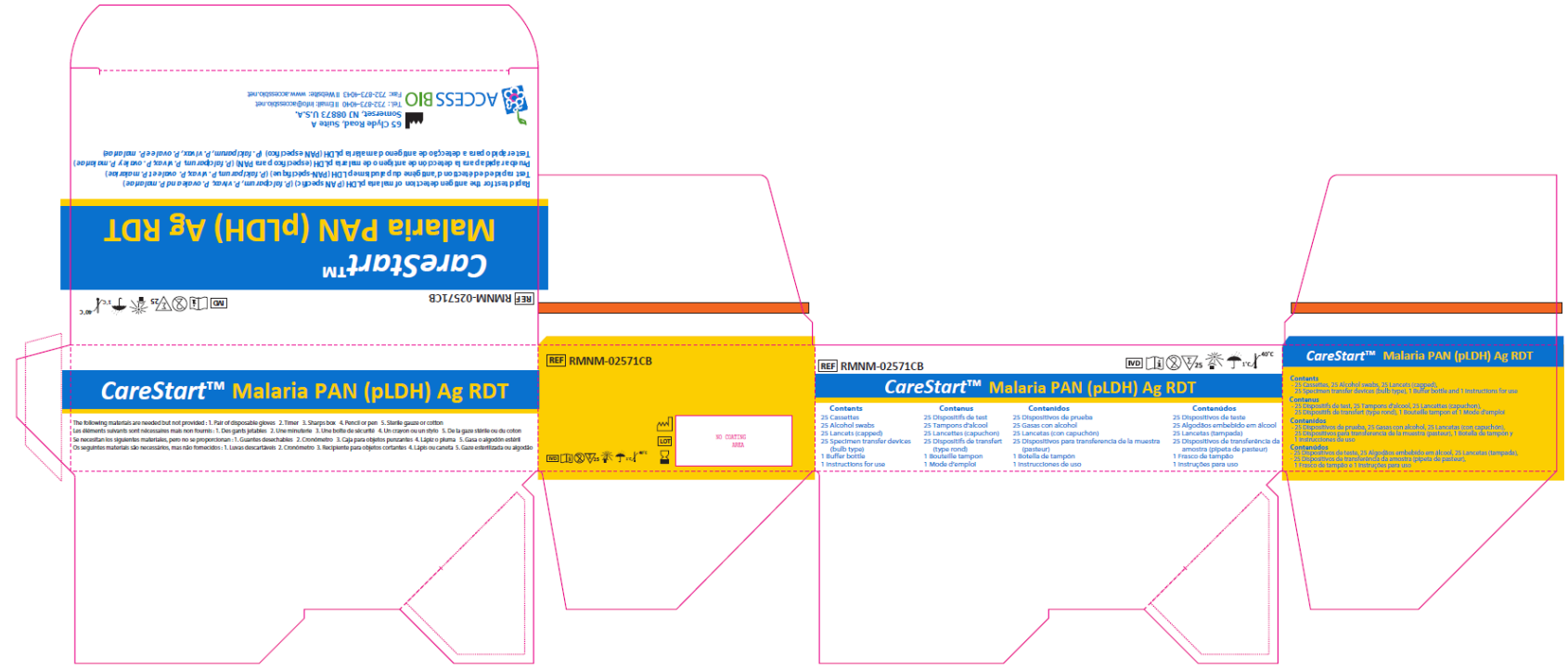
For detailed information about the product and procedure, refer to the full version of instructions for use (Doc. No. IFU-RMNU71RI-EFSP) included in the RDT box.

ACCESSBIO

IFU-RMNU71RI-E / Rev. B May 21, 2018

RDT box designs

ACCESSBIO	RDT Box Design for Malaria PAN (pLDH) Ag RDT (RMNM-02571RB)			
	Doc No: LB-KMN2571RBA, Annex 01	Revision: A	Effective Date: May 18, 2018	Page No. 1 / 1



- Access Bio, Inc.-