The Three Millennium Development Goal Fund

A guide for the selection of Malaria Rapid Diagnostic Test kits purchased with 3MDG grants

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2. ABBREVIATIONS

3MDG Three Millennium Development Goal Fund
FIND Foundation for Innovative New Diagnostics
HRP2 Histidine-rich protein 2
LTA Long Term Agreement
Pan Plasmodium Pan
PDS Panel Detection Score
Pf Plasmodium falciparum
pLDH Parasite lactate dehydrogenase
Pm Plasmodium malariae
Po Plasmodium ovale
Pv Plasmodium vivax
RDT Rapid Diagnostic Kit
WHO World Health Organisation

3. SELECTION OF MALARIA RDTs

To assist partners of the Three Millennium Development Goal Fund (3MDG) in the selection of the appropriate Rapid Diagnostic Test kits (RDTs) to support their programmes, the Fund Manager has developed this overview of qualified RDTs based on a number of publications from WHO describing performances of RDTs from different manufacturers.

A variety of RDTs for the detection of the different malaria antigens are available on the market (over 200); quality and performance might vary substantially among the different products. Ensuring the quality of RDTs is essential to ensure accurate diagnosis. Over the past 5 years WHO and the Foundation for Innovative New Diagnostics (FIND) have conducted 4 rounds of performance evaluations of RDTs available in the market. These test results have resulted in WHO recommendations for the selection of RDTs.
To select the appropriate type of RDTs for a given area, WHO recommended selection criteria for procurement of malaria rapid diagnostic tests need to be considered:

- Target parasite species and antigens;
- Panel detection score (considering the malaria transmission intensity in the area of intended use);
- False-positive and invalid rates (false-negative);
- Ease of use;
- Thermal stability.

Based on the result of the assessment of WHO the following criteria should be used when selecting RDTs:

1. For the detection of *Plasmodium falciparum* (Pf) in all transmission settings the panel detection score (PDS) against Pf samples should be at least 75% at 200 parasites/μL;
2. For the detection of *Plasmodium vivax* (Pv) in all transmission settings the panel detection score (PDS) against Pv samples should be at least 75% at 200 parasites/μL;
3. The false positive rate should be less than 10%;
4. The invalid rate should be less than 5%;
5. Stability requirements at temperatures of intended storage, transport and use;
6. Ease of use and training requirements for the health workers.

After having considered all of the above factors, good procurement practise requires that the prices be taken into account.

Results of the four rounds of testing can be found on this[^1] page of the Find website. Furthermore WHO has published an *information note on the recommended selection criteria for procurement of malaria RDTs*, which can be found through this[^2] link, a more comprehensive document from WHO is *Good Practices for Selecting and Procuring Rapid Diagnostic Tests for Malaria*, which is available here[^3].

Lastly FIND has developed an interactive website which allows the user to select to most suitable RDT based on the following parameters:

- Targeted malaria species;
- Minimum panel detection score for Pf at 200 and 2,000 parasites/μL;
- Minimum panel detection score for Pv at 200 and 2,000 parasites/μL;
- Maximum false positive rate;
- Maximum invalid rate;
- Test format;
- Heat stability.

This website can be accessed through this link.

**Selected RDTs**

This list is developed as a tool to assist partners of 3MDG grants to identify the Malaria RDTs according to the Fund Manager Quality Assurance Policy. The list is not exhaustive; partners willing to procure product(s) not listed below there are to contact the Fund Manager and discuss the matter.

The following pages provide small descriptions of the different RDTs in the above table.

**Disclaimer:** The Three Millennium Development Goal Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Three Millennium Development Goal Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

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## 4. Plasmodium falciparum (PF) Only Tests

<table>
<thead>
<tr>
<th>No.</th>
<th>Product name</th>
<th>Manufacturer</th>
<th>Catalogue code</th>
<th>Tests per kit</th>
<th>Shelf life</th>
<th>Format</th>
<th>Storage temperature</th>
<th>Under LTA</th>
<th>Indicative price/test (in USD)</th>
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5. *Plasmodium falciparum* (PF) AND *Plasmodium Pan* (Pan) Tests

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## 6. Plasmodium falciparum (Pf) and Plasmodium vivax (Pv) Tests

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<td>Cassette</td>
<td>2-30°C</td>
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<td>46</td>
<td>Medisensor Malaria HRP2/plDH (Pf/VOM) COMBO</td>
<td>Medisensor, Inc.</td>
<td>M171</td>
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<td>47</td>
<td>OnSite Malaria Pf/Pv Ag Rapid Test</td>
<td>CTK Biotech, Inc.</td>
<td>R0112C</td>
<td>18</td>
<td>Cassette</td>
<td>1-30°C</td>
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<td>48</td>
<td>ParaCare Malaria HRP2/plDH (Pf/Pv) COMBO</td>
<td>Access Bio Ethiopia</td>
<td>G0161</td>
<td>24</td>
<td>Cassette</td>
<td>2-40°C</td>
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<td>49</td>
<td>ParaCare Malaria HRP2/plDH (Pf/VOM) COMBO</td>
<td>Access Bio Ethiopia</td>
<td>G0171</td>
<td>24</td>
<td>Cassette</td>
<td>2-40°C</td>
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<tr>
<td>50</td>
<td>RAPID 1-2-3* HEMA CASSETTE MALARIA PF/PV TEST</td>
<td>Hema Diagnostic Systems, LLC</td>
<td>MAL-PFVCAS/25(100)</td>
<td>18</td>
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<td>2-30°C</td>
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<td>SD BIOLINE Malaria Ag Pf/ Pf/ Pv</td>
<td>Standard Diagnostics Inc.</td>
<td>05FK100</td>
<td>25/kit</td>
<td>24</td>
<td>Cassette</td>
<td>1-40°C</td>
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<td>52</td>
<td>SD Bioline Malaria Ag Pf/Pv</td>
<td>Standard Diagnostics, Inc</td>
<td>05FK80</td>
<td>25/kit</td>
<td>24</td>
<td>Cassette</td>
<td>2-40°C</td>
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**Important Note:** RDT’s available under existing 3MDG Long Term Agreements, indicated in the table above as “YES”, can be ordered from 3MDG procurement section.

Those RDTs not included in existing LTA’s (indicated “NO” in the table above) are mentioned for reference proposes and should not be considered for ordering to the 3MDG procurement section.
7. DETAILS REGARDING THE DIFFERENT RDTs

7.1. ADVANTAGE P.F. MALARIA KIT/25TST

S0003541: Advantage Malaria Pf, kit/25

General Description
Advantage Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 97.5%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0.0%
Reading time: 20 minutes
Manufacturer product reference: IR016025 (J. Mitra & Co Pvt Ltd)

Supplied with
5 x Buffer, 1,5ml
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package Insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum. Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html. Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 30ºC, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.
Packaging and labelling
Primary packaging
Unit presentation: 1 (one) Advantage Plasmodium falciparum rapid diagnostic test, cassette, co-packed with blood transfer device

Secondary packaging
Kit of: 25 unit presentations, 5 x 1.5ml buffer, 25 disinfection swab, 25 lancets, 1 package insert

Weight - Volume
Estimated weight: 0.35kg
Estimated volume: 1.7cdm

7.2. BIONOTE MALARIA P.F. AG RAPID TEST KIT

S0003585: Bionote Malaria Pf, kit/25

General Description
Bionote Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood.
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 85.9%
Invalidity rate: 0.1%
False positive rate for P.spp.: 2.0%
Reading time: 20 minutes
Manufacturer product reference: RG19-11 (BIONOTE Inc.)

Supplied with
1 x Buffer, 5ml
25 x Blood transfer device
1 x Package Insert

Recommended, but not supplied
Disinfection swab (S0001425)
Lancet (S0001406)
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html. Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:
Shelf life
26 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 1 to 40ºC, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) Bionote Plasmodium falciparum rapid diagnostic test, cassette

Secondary packaging
Kit of: 25 unit presentations, 1 x 5ml buffer, 25 x blood transfer device, 1 x package insert

Weight - Volume
Estimated weight: 0.25kg
Estimated volume: 1.77cdm

7.3. CareStart Malaria HRP2(Pf)

S0003543: CareStart Malaria Pf (HRP2), kit/60

General Description
CareStart Malaria Plasmodium falciparum rapid diagnostic test, kit of 60 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 98.7%
Invalidity rate: 0.0%
False positive rate for P.spp.: 2.4%
Reading time: 20 minutes
Manufacturer product reference: G0141 (Access Bio Inc.) CareStart Malaria HRP2 (Pf)

Supplied with
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum. Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html. Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 30ºC, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) CareStart Plasmodium falciparum rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

Weight - Volume
Estimated weight: 0.56kg
Estimated volume: 2.28cdm

7.4. CARESTART MALARIA HRP2/pLDH PF Test
S0003359: CareStart Mal Pf (HRP2/pf-pLDH),kit/60

General Description
CareStart Malaria Plasmodium falciparum rapid diagnostic test, kit of 60 tests

Product Description
Qualitative indication of the presence of HRP2 and/or pf-pLDH in whole blood

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pf-pLDH
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 98%
Invalidity rate: 0%
False positive rate for P.spp.: 3.0%
Reading time: 20 minutes

Manufacturer product reference: G0181 (Access Bio Inc) CareStart Malaria HRP2/pLDH Pf test

**Supplied with**

- 1 x Buffer
- 60 x Blood transfer device
- 60 x Disinfection swab
- 60 x Lancet
- 1 x Package insert

**Recommended, but not supplied:**

- Gloves, goggles, timer, and container for bio-hazard waste

**Instructions for use**

Rapid qualitative assessment of the presence of HRP2 and/or pf-pLDH in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**

24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**

Between 4 to 30°C, protected against humidity and direct sunlight.

**Note**

Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**

**Primary packaging**

Unit presentation: 1 (one) CareStart Plasmodium falciparum rapid diagnostic test, cassette

**Secondary packaging**

Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device
7.5. CLEARVIEW MALARIA P.F.

S0003572: Clearview Malaria Pf, kit/25

General Description:
Clearview Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 83.8%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0.0%
Reading time: 15 minutes

Manufacturer product reference: VB01 (Alere Healthcare PTY Ltd.)

Supplied with
1 x Buffer
25 x Blood transfer device
1 x Package insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 40ºC, protected against humidity and direct sunlight.
Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) Clearview Plasmodium falciparum rapid diagnostic test, cassette

Secondary packaging
Kit of: 25 unit presentations, buffer, 1 package insert, 25 blood transfer device

Weight - Volume
Estimated weight: 0.30kg
Estimated volume: 1.63cdm

7.6. CORE MALARIA P.F
No information available

7.7. DIAGNOSTICKS- MALARIA (Pf)
No information available

7.8. FIRST RESPONSE MALARIA AG HRP2
S0003557: First Response Malaria Pf, kit/30

General Description:
First Response Malaria Plasmodium falciparum rapid diagnostic test, kit of 30 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 100%
Invalidity rate: 0.0%
False positive rate for P.spp.: 3.0%
Reading time: 20 minutes

Manufacturer product reference: I13FRC30 (Premier Medical Corporation Ltd.)
Supplied with
1 x Buffer, 3ml
30 x Blood transfer device
30 x Disinfection swab
30 x Lancet
1 x Package insert

**Recommended, but not supplied:**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 and pf-pLDH in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 40ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) First Response Plasmodium falciparum rapid diagnostic test, cassette, co-packed with blood transfer device

Secondary packaging
Kit of: 30 unit presentations, 3ml buffer, 30 disinfection swab, 30 lancets, 1 package insert

**Weight - Volume**
Estimated weight: 0.38kg
Estimated volume: 2.20cdm

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**7.9. ICT DIAGNOSTICS MALARIA P.F.**

S0003526: ICT Diagnostics Malaria Pf, kit/25

**General Description:**
ICT Diagnostics Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests
Product Description
Qualitative indication of the presence of HRP2 in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 86.9%
Invalidity rate: 0%
False positive rate for P.spp.: 0.0%
Reading time: 15 minutes

Manufacturer product reference: ML01 (ICT Diagnostics)

Supplied with
1 x Buffer
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package Insert

Recommended, but not supplied:
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 40°C, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.
Packaging and labelling

Primary packaging
Unit presentation: 1 (one) ICT Diagnostics Plasmodium falciparum rapid diagnostic test, cassette

Secondary packaging
Kit of: 25 unit presentations, 1 x buffer, 25 blood transfer device, 25 disinfection swab, 25 lancets, 1 package insert

Weight - Volume
Estimated weight: 0.29kg
Estimated volume: 1.34cdm

7.10. IMMUNOQUICK CONTACT FALCIPARUM

S0003570: Immunoquick Contact Malaria Pf, kit/25

General Description:
Immunoquick Contact Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

Product Description
Qualitative indication of the presence of HRP2 in whole blood

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 81.8%
Invalidity rate: 0.3%
False positive rate for P.spp.: 4.0%
Reading time: 20 minutes

Manufacturer product reference: 0519K25 (Biosynex)

Supplied with
1 x Buffer, 6ml
1 x Package Insert

Recommended, but not supplied
Disinfection swab (S0001425)
Lancet (S0001406)
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html
Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 2 to 30°C, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
- **Primary packaging**
  - Unit presentation: 1 (one) Immunoquick Contact Plasmodium falciparum rapid diagnostic test, cassette

- **Secondary packaging**
  - Kit of: 25 unit presentations, 1 x buffer, 1 package insert

**Weight - Volume**
- Estimated weight: 0.33kg
- Estimated volume: 2.7cdm

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7.11. IMMUNOQUICK MALARIA FALCIPARUM

S0003569: Immunoquick Dipstick Mal. Pf, kit/25

**General Description:**
Immunoquick Malaria Plasmodium falciparum rapid diagnostic test, dipstick, kit of 25 tests

**Product Description**
Qualitative indication of the presence of HRP2 in whole blood.
- **Technology:** Linear immuno-chromatographic assay
- **Format:** Dipstick
- **Antigen:** HRP2
- **Sample type:** Whole blood

Panel detection score (%) at low P.f. parasitemia: 91.1%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0.6%
Reading time: 10 minutes

Manufacturer product reference: 0502_K25 (Biosynex)

**Supplied with**
- 1 x Buffer, 6ml
- 25 x Test tube for dipstick
1 x Rack
1 x Package Insert

**Recommended, but not supplied:**
Disinfection swab (S0001425)
Lancet (S0001406)
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 2 to 30ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) Immunoquick Plasmodium falciparum rapid diagnostic test, dipstick

Secondary packaging
Kit of: 25 unit presentations, 1 x buffer, 25 x test tube for dipstick, 1 x rack, 1 package insert

**Weight - Volume**
Estimated weight: 0.33kg
Estimated volume: 2.7cdm

7.12. IMMUNOQUICK® MALARIA FALCIPARUM
No information available

7.13. IMMUNOQUICK® MALARIA FALCIPARUM
No information available
7.14. **MALARIA PLASMODIUM FALCIPARUM RAPID TEST DEVICE (WHOLE BLOOD)**

No information available

7.15. **MALERISCAN MALARIA PF ANTIGEN TEST**

**S0003515: Maleriscan Malaria Pf, kit/50**

**General Description**
Maleriscan Malaria Plasmodium falciparum rapid diagnostic test, kit of 50 tests

**Product Description**
Qualitative indication of the presence of HRP2 in whole blood.
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 83.7%
Invalidity rate: 0.2%
False positive rate for P.spp.: 0.4%
Reading time: 20 minutes

Manufacturer product reference: MAT-PF-50 (Bhat Bio-Tech India, PLtd.)

**Supplied with**
1 x Buffer
50 x Blood transfer device
50 x Disinfection swab
50 x Lancet
1 x Package insert

**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 2 to 40°C. Protected against humidity and direct sunlight;

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
50 Maleriscan Malaria Plasmodium falciparum rapid diagnostic tests, individually sealed together with blood transfer device, co-packed with accessories

**Weight - Volume**
Estimated weight: 0.500kg
Estimated volume: 2.62cdm

### 7.16. **NANOSign Malaria PF AG**
No information available

### 7.17. **One Step Malaria P.F Test**
No information available

### 7.18. **One Step Malaria P.F Test**
No information available

### 7.19. **Onsite PF AG Rapid Test**
No information available

### 7.20. **ParaHit - F (Device)**
S0003342: ParaHit MalariaPf, kit/50

**General Description**
ParaHit Malaria Plasmodium falciparum rapid diagnostic test, kit of 50 tests

**Product Description**
Qualitative indication of the presence of HRP2 in whole blood

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 84,9%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0%
Reading time: 15 minutes
Manufacturer product reference: 55IC102-50 (Span Diagnostics)

**Supplied with**
- 1 x Buffer
- 50 x Blood transfer device
- 50 x Disinfection swab
- 50 x Lancet
- 1 x Package insert

**Recommended but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 30°C. Protected against humidity and direct sunlight;

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) ParaHit Plasmodium falciparum rapid diagnostic test, cassette

Secondary packaging
Kit of: 50 unit presentations, buffer, 50 blood transfer device, 50 disinfection swab, 50 lancets, 1 package insert
Weight - Volume
Estimated weight: 0.63kg
Estimated volume: 4.2cdm

7.21. **ParaHit - F (Dipstick)**

**S0003341: ParaHit Malaria Pf dipstick, kit/50**

**General Description:**
ParaHit Malaria Plasmodium falciparum rapid diagnostic test, dipstick, kit of 50 tests

**Product Description**
Qualitative indication of the presence of HRP2 in whole blood

Technology: Linear immuno-chromatographic assay
Format: Dipstick
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 80.8%
Invalidity rate: 0.0%
False positive rate for P.spp.: 2.5%
Reading time: 15 minutes

Manufacturer product reference: 55IC101-50 (Span Diagnostics)

**Supplied with**
- 1 x Buffer, 12ml
- 50 x Test tube for dipstick
- 50 x Blood transfer device
- 50 x Disinfection swab
- 50 x Lancet
- 1 x Package Insert

**Recommended but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 in whole blood, indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:
Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 40°C, protected against humidity and direct sunlight

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) ParaHit Plasmodium falciparum rapid diagnostic test, dipstick

Secondary packaging
Kit of: 50 unit presentations, 1 x 12ml buffer, 50 x test tube for dipstick, 50 x disinfection swab, 50 x lancet, 1 x package Insert

Weight - Volume
Estimated weight: 0.52kg
Estimated volume: 2.81cdm

7.22. SD BIOLINE MALARIA AG PF (HRP2 / pfLDH)

S0003579: SD Bioline Mal Pf (HRP2/pf-pLDH), kit/25

General Description
SD Bioline Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

Product Description
Qualitative indication of the presence of HRP2 and/or pf-pLDH in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pf-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 87.9%
Invalidity rate: 0.0%
False positive rate for P.spp.: 2.0%
Reading time: 15 minutes

Manufacturer product reference: 05FK90 (Standard Diagnostics Inc.)

Supplied with
1 x Buffer, 5ml
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package insert
**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 and/or pf-pLDH in whole blood; indicative for the presence of Plasmodium falciparum

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 40ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**

- **Primary packaging**
  Unit presentation: 1 (one) Bioline Plasmodium falciparum rapid diagnostic test, cassette, co-packed with blood transfer device

- **Secondary packaging**
  Kit of: 25 unit presentations, 5ml buffer, 25 disinfection swab, 25 lancets, 1 package insert

**Weight - Volume**
Estimated weight: 0.33kg
Estimated volume: 1.64cdm

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### 7.23. SD BIOLINE MALARIA AG PF

**S0003581: SD Bioline Mal Pf (HRP2),kit/25**

**General Description:**
SD Bioline Malaria Plasmodium falciparum rapid diagnostic test, kit of 25 tests

**Product Description**
Qualitative indication of the presence of HRP2 in whole blood.
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 97.5%
Invalidity rate: 0.0%
False positive rate for P.spp.: 2.4%
Reading time: 15 minutes

Manufacturer product reference: 05FK50 (Standard Diagnostics Inc.)

**Supplied with**
1 x Buffer, 5ml
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package insert

**Recommended, but not supplied:**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative assessment of the presence of HRP2 and pf-pLDH in whole blood; indicative for the presence of Plasmodium falciparum.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 40ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) Bioline Plasmodium falciparum rapid diagnostic test, cassette, co-packed with blood transfer device

Secondary packaging
Kit of: 25 unit presentations, 5ml buffer, 25 disinfection swab, 25 lancets, 1 package insert
Weight - Volume
Estimated weight: 0.33kg
Estimated volume: 1.64cdm

7.24. **SD BIOLINE MALARIA AG P.F**
No information available

7.25. **TRUSTYTM MALARIA ANTIGEN P.F. TEST**
No information available

7.26. **BIONOTE MALARIA P.F.& PAN AG RAPID TEST KIT**

S0003586: Bionote Malaria Pf/pan,kit/25

**General Description:**
Bionote Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 25 tests

**Product Description**
Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood.

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 / pan-pLDH
Sample type: Whole blood

- Panel detection score (%) at low P.f. parasitemia: 93.9%
- Panel detection score (%) at low P.pan. parasitemia: 99%
- Invalidity rate: 0.1%
- False positive rate for P.spp.: 3.0%
- Reading time: 20 minutes

Manufacturer product reference: RG19-08 (BIONOTE Inc.)

**Supplied with**
- 1 x Buffer, 5ml
- 25 x Blood transfer device
- 1 x Package Insert

**Recommended, but not supplied**
- Disinfection swab (S0001425)
- Lancet (S0001406)
- Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative and differential assessment of the presence of HRP2 and pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P.vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
26 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 40ºC, protected against humidity and direct sunlight

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**

**Primary packaging**
Unit presentation: 1 (one) Bionote Plasmodium falciparum and other Plasmodium species rapid diagnostic test, cassette

**Secondary packaging**
Kit of: 25 unit presentations, 1 x 5ml buffer, 25 x blood transfer device, 1 x package insert

**Weight - Volume**
Estimated weight: 0.25kg
Estimated volume: 1.77cdm

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### 7.27. CareStart Malaria PLDH 3 Line Test

**S0003546: CareStart3line,Malaria Pf/pan,kit/60**

**General Description:**
CareStart Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 60 tests

**Product Description**
Qualitative and differential indication of the presence of pf-pLDH and pan-pLDH in whole blood

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: pf-pLDH and pan-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 88.9%
Panel detection score (%) at low P.v. parasitemia: 91.4%
Invalidity rate: 0%
False positive rate for P.spp.: 0.5%
Reading time: 20 minutes

Manufacturer product reference: G0121 (Access Bio Inc.) CareStart Malaria pLDH 3 line Test

**Supplied with**
- 1 x Buffer
- 60 x Blood transfer device
- 60 x Disinfection swab
- 60 x Lancet
- 1 x Package insert

**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Qualitative and differential indication of the presence of pf-pLDH and pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 30ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
**Primary packaging**
Unit presentation: 1 (one) CareStart Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

**Weight - Volume**
7.28. CARESTART MALARIA HRP2 / pLDH (PF/PAN) COMBO

S0003544: CareStartCombo,Malaria Pf/pan,kit/60

General Description:
CareStart Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 60 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pan-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 97.5%
Panel detection score (%) at low P.v. parasitemia: 90.0%
Invalidity rate: 0.0%
False positive rate for P.spp.: 3.0%
Reading time: 20 minutes

Manufacturer product reference: G0131 (Access Bio Inc.) CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO

Supplied with
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

Recommended, but not supplied:
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P.vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 30ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) CareStart Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

**Weight - Volume**
Estimated weight: 0.56kg
Estimated volume: 2.28cdm

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**7.29. CARESTART MALARIA SCREEN**

**S0003547: CareStartScreen,Malaria Pf/pan,kit/60**

**General Description:**
CareStart Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 60 tests

**Product Description**
Qualitative and differential indication of the presence of HRP2/pf-pLDH and pan-pLDH in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2/pf-pLDH and pan-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 86.9%
Panel detection score (%) at low P.v. parasitemia: 88.6%
Invalidity rate: 0.1%
False positive rate for P.spp.: 2.5%
Reading time: 20 minutes

Manufacturer product reference: G0231 (Access Bio Inc.) CareStart Malaria Screen, kit/60

**Supplied with**
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Qualitative and differential indication of the presence of HRP2/pf-pLDH and pan-pLDH in whole blood; indicative for the presence of *Plasmodium falciparum* and other *Plasmodium* species (*P. vivax*, *P. malariae* or *P. ovale*)

*Note:* Test does not distinguish between *P. vivax*, *P. malariae* or *P. ovale* infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 30ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) CareStart *Plasmodium falciparum* and other *Plasmodium* species (*P. vivax*, *P. malariae* or *P. ovale*) rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

**Weight - Volume**
Estimated weight: 0.56kg
Estimated volume: 2.28cdm

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**7.30. CARESTART MALARIA/PREGNANCY COMBO (PLDH / HRP2 / HCG)**

S0003548: CareStart Malaria Pf/pan/Pregn.,kit/60

**General Description:**
CareStart Malaria Plasmodium species (P. falciparum, P. vivax, P. malariae and/or P. ovale) and pregnancy rapid diagnostic test, kit of 60 tests

**Product Description**
Qualitative indication of the presence of HRP2 and/or pan-pLDH and human chorionic gonadotropin (hCG) in whole blood.
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pan-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 83.8%
Panel detection score (%) at low P.v. parasitemia: 94.3%
Invalidity rate: 0.2%
False positive rate for P.spp.: 0.0%
Reading time: 20 minutes

Manufacturer product reference: G0221 (Access Bio Inc.) CareStart Malaria/Pregnancy Combo (pLDH/HRP2/HCG)

**Supplied with**
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Qualitative indication of the presence of HRP2 and/or pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum or other Plasmodium species (P.vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. falciparum, P. vivax, P. malariae or P. ovale infections.

Qualitative indication of human chorionic gonadotropin (hCG), indicative for pregnancy.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 30ºC, protected against humidity and direct sunlight.
Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) CareStart Malaria Plasmodium species (P. falciparum, P. vivax, P. malariae and/or P. ovale) and pregnancy rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

Weight - Volume
Estimated weight: 0.56kg
Estimated volume: 2.28cdm

7.31. FIRST RESPONSE MALARIA pLDH/ HRP2 COMBO TEST

S0003549: First Response Malaria Pf/pan,kit/30

General Description:
First Response Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 30 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 / pan-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 84.0%
Panel detection score (%) at low P.pan. parasitemia: 75.0%
Invalidity rate: 0%
False positive rate for P.spp.: 0.0%
Reading time: 20 minutes

Manufacturer product reference: I16FRC30 (Premier Medical Corporation Ltd.)

Supplied with
1 x Buffer, 3ml
30 x Blood transfer device
30 x Disinfection swab
30 x Lancet
1 x Package insert

Recommended, but not supplied:
Gloves, protective glasses, timer, container for biohazard disposables
Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P.vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 40ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) First Response Plasmodium falciparum and other Plasmodium species rapid diagnostic test, cassette, co-packed with blood transfer device

Secondary packaging
Kit of: 30 unit presentations, 3ml buffer, 30 disinfection swab, 30 lancets, 1 package insert

**Weight - Volume**
Estimated weight: 0.38kg
Estimated volume: 2.29cdm

### 7.32. HiSens Malaria AG P.F./P.V. (HRP2/pLDH)
No information available

### 7.33. NanoSign Malaria Pf/Pan AG
No information available

### 7.34. ParaHIT - Total Ver. 1.0 (DEVICE)
S0003528: ParaHIT Malaria Pf/pan,kit/10

**General Description**
ParaHIT Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 10 tests

**Product Description**
Qualitative and differential indication of the presence of HRP2 and pan Aldolase in whole blood.

Technology: Linear immuno-chromatographic assay  
Format: Cassette  
Antigen: HRP2, pan Aldolase  
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 84.7%  
Panel detection score (%) at low P.pan. parasitemia: 82.4%  
Invalidity rate: 0.1%  
False positive rate for P.spp.: 0.0%  
Reading time: 25 minutes

Manufacturer product reference: 55IC204-50 (Span Diagnostics Ltd, ParaHIT-Total Ver. 1.0, Device)

**Supplied with**
1 x Buffer, 2.5ml  
10 x Blood transfer device  
10 x Disinfection swab  
10 x Lancet  
1 x Package insert

**Recommended, but not supplied**
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative and differential assessment of the presence of HRP2 and pan-Aldolase in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P.vivax, P. malariae or P. ovale).  
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)  
Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 4 to 40ºC. Protected against humidity and direct sunlight;

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

### Packaging and labelling

10 ParaHit Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) individually sealed rapid diagnostic tests, co-packed with accessories.

### Weight - Volume

- Estimated weight: 0.150kg
- Estimated volume: 0.975cdm

### 7.35. SD BIOLINE MALARIA AG PF/PAN

**S0003582: SD Bioline Malaria Pf/pan, kit/25**

#### General Description

SD Bioline Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 25 tests.

#### Product Description

- Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood
- Technology: Linear immuno-chromatographic assay
- Format: Cassette
- Antigen: HRP2 and pf-pLDH
- Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 92.9%
Panel detection score (%) at low P.pan. parasitemia: 97.1%
Invalidity rate: 0.3%
False positive rate for P.spp.: 3.5%
Reading time: 15 minutes

Manufacturer product reference: 05FK60 (Standard Diagnostics Inc.)

#### Supplied with

- 1 x Buffer, 5ml
- 25 x Blood transfer device
- 25 x Disinfection swab
- 25 x Lancet
- 1 x Package insert

#### Recommended, but not supplied

- Gloves, protective glasses, timer, container for biohazard disposables

#### Instructions for use

Qualitative and differential indication of the presence of HRP2 and pan-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 40ºC, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
Primary packaging
Unit presentation: 1 (one) SD Bioline Plasmodium falciparum and other Plasmodium species rapid diagnostic test, cassette, co-packed with blood transfer device

Secondary packaging
Kit of: 25 unit presentations, 5ml buffer, 25 disinfection swab, 25 lancets, 1 package insert

**Weight - Volume**
Estimated weight: 0.33kg
Estimated volume: 1.64cdm

### 7.36. SD BIOLINE MALARIA AG PF/PAN
No information available

### 7.37. SD BIOLINE MALARIA AG PF/PAN
No information available

### 7.38. BIONOTE MALARIAA P.F.& P.V AG RAPID TEST KIT
S0003587: Bionote Malaria Pf/Pv,kit/25

**General Description:**
Bionote Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, kit of 25 tests

**Product Description**
Qualitative and differential indication of the presence of HRP2 and pv-pLDH in whole blood
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 / pv-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 92.9%
Panel detection score (%) at low P.v. parasitemia: 97.1%
Invalidity rate: 0.0%
False positive rate for P.spp.: 4.0%
Reading time: 20 minutes

Manufacturer product reference: RG19-12 (BIONOTE Inc.)

Supplied with
1 x Buffer, 5ml
25 x Blood transfer device
1 x Package Insert

Recommended, but not supplied
Disinfection swab (S0001425)
Lancet (S0001406)
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and Plasmodium vivax

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
26 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 1 to 40°C, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) Bionote Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, cassette
Secondary packaging
Kit of: 25 unit presentations, 1 x 5ml buffer, 25 x blood transfer device, 1 x package insert

Weight - Volume
Estimated weight: 0.25kg
Estimated volume: 1.77cdm

7.39. CARESTART MALARIA HRP2/PLDH (PF/PV) COMBO

S0003365: CareStart Malaria Pf/Pv, kit/60

General Description:
CareStart Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, kit of 60 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pv-pLDH in whole blood.

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pv-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 90.8%
Panel detection score (%) at low P.v. parasitemia: 94.01%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0.5%
Reading time: 20 minutes

Manufacturer product reference: G0161 (Access Bio Inc.) CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO

Supplied with
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

Recommended, but not supplied:
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and Plasmodium vivax.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:
Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 30ºC, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) CareStart Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

Weight - Volume
Estimated weight: 0.56kg
Estimated volume: 2.28cdm

7.40. CARESTART MALARIA HRP2/PLDH (PF/VOM) COMBO

50003366: CareStart Malaria Pf/Pvom, kit/60

General Description:
CareStart Malaria Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, kit of 60 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and vom-pLDH in whole blood.

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and vom-pLDH
Sample type: Whole blood

Panel detection score (%) at low P.f. parasitemia: 89.9%
Panel detection score (%) at low P.v. parasitemia: 91.2%
Invalidity rate: 0.0%
False positive rate for P.spp.: 0.5%
Reading time: 20 minutes

Manufacturer product reference: G0171 (Access Bio Inc.) CareStart Malaria HRP2/pLDH (Pf/VOM) COMBO
Supplied with
1 x Buffer
60 x Blood transfer device
60 x Disinfection swab
60 x Lancet
1 x Package insert

Recommended, but not supplied:
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and vom-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale)
Note: Test does not distinguish between P. vivax, P. malariae or P. ovale infections.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 30ºC, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
Primary packaging
Unit presentation: 1 (one) CareStart Plasmodium falciparum and other Plasmodium species (P. vivax, P. malariae or P. ovale) rapid diagnostic test, cassette

Secondary packaging
Kit of: 60 unit presentations, buffer, 60 disinfection swab, 60 lancets, 1 package insert, blood transfer device

Weight - Volume
Estimated weight: 0.56kg
Estimated volume: 2.28cdm
7.41. FALCIVAX RAPID TEST FOR MALARIA PV/Pf (DEVICE)

S0003522: FalciVax Malaria Pf/Pv, kit/25

General Description
FalciVax Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, kit of 25 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pv-pLDH in whole blood.
Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pv-pLDH
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 98.0%
Panel detection score (%) at low P.v.. parasitemia: 88.2%
Invalidity rate: 0.0%
False positive rate for P.spp.: 7.3%
Reading time: 20 minutes
Manufacturer product reference: 50300025 (Zephyr Biomedicals)

Supplied with
1 x Buffer
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package Insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and Plasmodium vivax.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 4 to 30°C, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
25 FalciVax Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic tests, sealed together with blood transfer device, co-packed with accessories

Weight-Volume
Estimated weight: 0.275kg
Estimated volume: 1.89cdm

7.42. HiSENS MALARIA AG P.F/P.V COMBO CARD
No information available

7.43. HiSENS MALARIA AG P.F/VOM COMBO CARD
No information available

7.44. HUMASIS MALARIA P.F/P.V ANTIGEN TEST
S0003525: Humasis Malaria Pf/Pv, kit/2

General Description
Humasis Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, kit of 25 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pv-pLDH in whole blood.

Technology: Linear immuno-chromatographic assay
Format: Cassette
Antigen: HRP2 and pv-pLDH
Sample type: Whole blood
Panel detection score (%) at low P.f. parasitemia: 92.9%
Panel detection score (%) at low P.v.. parasitemia: 100%
Invalidity rate: 0.0%
False positive rate for P.spp.: 1.3%
Reading time: 15 minutes
Manufacturer product reference: AMFV-7025 (Humasis Co.Ltd)

Supplied with
1 x Buffer, 5ml
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package Insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

**Instructions for use**
Rapid qualitative and differential assessment of the presence of HRP2 and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and Plasmodium vivax.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: [http://www.unicef.org/supply/index_40962.html](http://www.unicef.org/supply/index_40962.html)

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 30°C, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed.
Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**
25 Humasis Malaria Plasmodium falciparum and Plasmodium vivax individually sealed rapid diagnostic tests, co-packed with accessories

**Weight - Volume**
Estimated weight: 0.329kg
Estimated volume: 1.80cdm

**7.45. MEDISENSOR MALARIA HRP2/pLDH Pf/Pv) COMBO**
No information available

**7.46. MEDISENSOR MALARIA HRP2/pLDH (Pf/VOM) COMBO**
No information available

**7.47. ONSITE MALARIA Pf/Pv AG RAPID TEST**
No information available

**7.48. PARA CARE MALARIA HRP2/pLDH (Pf/Pv) COMBO**
No information available
7.49. PARA CARE MALARIA HRP2/pLDH (PF/VOM) COMBO

No information available

7.50. RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST

No information available

7.51. SD BIOLINE MALARIA AG PF/ PF/ PV

S0003583: SD Bioline Malaria Pf/Pf/Pv,kit/25

General Description
SD Bioline Malaria Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, kit of 25 tests

Product Description
Qualitative and differential indication of the presence of Pf HRP2, pf-pLDH and pv-pLDH in whole blood.  
Technology: Linear immuno-chromatographic assay 
Format: Cassette 
Antigen: Pf HRP2, pf-pLDH, pv-pLDH 
Sample type: Whole blood 
Panel detection score (%) at low P.f. parasitemia: 96.9% 
Panel detection score (%) at low P.v. parasitemia: 97.1% 
Invalidity rate: 0% 
False positive rate for P.spp.: 2.2% 
Reading time: 15 minutes (up to 30 minutes) 
Manufacturer product reference: 05FK100 (Standard Diagnostics Inc.)

Supplied with
1 x Buffer, 5ml 
25 x Blood transfer device 
25 x Disinfection swab 
25 x Lancet 
1 x Package insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of Pf HRP2, pf-pLDH and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and/or Plasmodium vivax.

Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here: http://www.unicef.org/supply/index_40962.html

Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:
Shelf life
24 months from the date of manufacturing; do not use beyond its expiry date.

Storage and transportation
Between 1 to 40°C, protected against humidity and direct sunlight.

Note
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

Packaging and labelling
25 SD Bioline Malaria Plasmodium falciparum and Plasmodium vivax individually sealed rapid diagnostic test, co-packed with accessories

Weight - Volume
Estimated weight: 0.307kg
Estimated volume: 1.61cdm

7.52. SD BIOLINE MALARIA AG PF/PV
S0003368, SD Bioline Malaria Pf/Pv,kit/25

Programs and projects are advised to consider the notice-of-concern issued by WHO regarding this product (www.who.int/diagnostics_laboratory/procurement/complaints/en/index.html), and where possible consider alternative products for procurement. If this product is however selected (and not an alternative), pre-shipment lot testing is required using the WHO-FIND Lot Testing Program for Malaria RDTs.

General Description
SD Bioline Malaria Plasmodium falciparum and Plasmodium vivax diagnostic test, kit of 25 tests

Product Description
Qualitative and differential indication of the presence of HRP2 and pv-pLDH in whole blood

Supplied with:
1 x Buffer, 5ml
25 x Blood transfer device
25 x Disinfection swab
25 x Lancet
1 x Package insert

Recommended, but not supplied
Gloves, protective glasses, timer, container for biohazard disposables

Instructions for use
Rapid qualitative and differential assessment of the presence of HRP2 and pv-pLDH in whole blood; indicative for the presence of Plasmodium falciparum and Plasmodium vivax. Literature to support the selection of the most appropriate malaria RDT (mRDT) for programmes and projects is listed on UNICEF Supply Division’s web page. Documents regarding supply chain of mRDTs can also be found here:
http://www.unicef.org/supply/index_40962.html. Test should be conducted by adequately trained staff only. In order to obtain reproducible results, the following must be observed:

**Shelf life**
24 months from the date of manufacturing; do not use beyond its expiry date.

**Storage and transportation**
Between 1 to 40°C, protected against humidity and direct sunlight.

**Note**
Only initiate the testing when all components of the kits reach the temperature of the environment in which the test will be performed. Do not substitute reagents from other kits/batches. Follow strictly manufacturer instructions of the test procedure.

**Packaging and labelling**

**Primary packaging**
Unit presentation: 1 (one) SD Bioline Plasmodium falciparum and Plasmodium vivax rapid diagnostic test, cassette, co-packed with blood transfer device

**Secondary packaging**
Kit of: 25 unit presentations, 5ml buffer, 25 disinfection swab, 25 lancets, 1 package insert

**Weight - Volume**
Estimated weight: 0.33kg
Estimated volume: 1.64cdm