WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: SD BIOLINE Malaria Ag P.f/P.f/P.v
WHO reference number: PQDx 0297-012-00

SD BIOLINE Malaria Ag P.f/P.f/P.v with product codes 05FK120 and 05FK123, manufactured by Standard Diagnostics, Inc., CE-marked regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 04 December 2018. This report was amended on 29 January 2019 to reflect amendments to information about product performance.

Summary of WHO prequalification assessment for SD BIOLINE Malaria Ag P.f/P.f/P.v

<table>
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<th>Date</th>
<th>Outcome</th>
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<tr>
<td>Prequalification listing</td>
<td>04 December 2018</td>
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<td>Dossier assessment</td>
<td>15 May 2018</td>
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<td>12 October 2018</td>
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<td>Product performance evaluation</td>
<td>2018</td>
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MR: Meets Requirements

Intended use:
According to the manufacturer ‘The SD BIOLINE Malaria Ag P.f/P.f/P.v test kit is an in vitro rapid, qualitative test for the detection of histidine-rich protein II (HRP-II) antigen and plasmodium lactate dehydrogenase (pLDH) from malaria Plasmodium falciparum and pLDH from malaria Plasmodium vivax in human whole blood. SD BIOLINE Malaria Ag P.f/P.f/P.v test is intended for professional use, only for an initial screening test as an aid to diagnosis of clinical malaria disease and reactive specimens should be confirmed by a supplemental assay such as microscopic examination of blood smear’.

Assay description:
According to the manufacturer ‘The SD BIOLINE Malaria Ag P.f/P.f/P.v test utilizes the principle of immunochromatography. The SD BIOLINE Malaria Ag P.f/P.f/P.v test kit contains a membrane strip, which is pre-coated with mouse monoclonal antibodies specific to histidine-rich protein II (HRP-II) of P. falciparum in test line 1 (T1), mouse monoclonal antibodies specific to plasmodium lactate dehydrogenase (pLDH) of P. falciparum in test line 2 (T2) and mouse monoclonal antibodies specific to pLDH of P. vivax in test line 3 (T3) region. This test device has a letter of T1, T2, T3 and C as “Test Line” and “Control Line” on the surface of the device. All the Test Lines and Control Line in result window are not visible before applying any specimens. The Control Line is used for procedural control. Control Line
should always appear if the test procedure is performed properly and the test reagents of control line are working.

The principle for reactive results is as follows. As the P.f (HRP-II, pLDH) and P.v reactive specimen flow through the membrane assembly of the cassette after addition of the assay diluent, they form a complex with mouse monoclonal antibodies specific to P.f HRP-II-gold conjugates and mouse monoclonal antibodies specific to pan pLDH-gold conjugates. This complex move further on the membrane to the test line region where it is immobilized by mouse monoclonal P.f HRPII antibodies, P.f pLDH antibodies and P.v pLDH antibodies coated on the membrane leading to formation of a red-purple colored band in the respective regions which confirms a reactive test result.

Absence of a colored band in the test region indicates a non-reactive test result for the corresponding antigen.

**Test kit contents:**

<table>
<thead>
<tr>
<th>Product code</th>
<th>Tests/kit</th>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>05FK120</td>
<td>25 T/kit</td>
<td>Test device with desiccant in individual foil pouches</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Assay diluent vial</td>
<td>1 x 5 ml/vial</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Disposable inverted cup</td>
<td>25 (5 µL/cup)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Sterile lancet</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Alcohol swabs</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Instruction for Use</td>
<td>1</td>
</tr>
<tr>
<td>05FK123</td>
<td>1 test/kit (bundle kit)</td>
<td>Each kit contains all necessary accessories (Lancet, alcohol swab, disposable applicator, and assay diluent) for a single test</td>
<td>25 ea of 1 test/kit</td>
</tr>
</tbody>
</table>

**Items required but not provided:**

- Protective gloves
- Timer
- Biohazard container

**Storage:**

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

**Shelf-life upon manufacture:**

24 months.
Warnings/limitations:

- Performance of the SD BIOLINE Malaria Ag P.f/P.f/P.v test kit was evaluated during the WHO product testing of malaria RDTs: Round 8, during which it was observed that the Pf panel detection score (PDS) based only on the reactivity of the Pf – p-LDH line- was 62% at 200 parasites/μl. This is below the WHO recommended performance criterion of greater than or equal to 75% PDS for *P. falciparum* @200 parasites/μL. Therefore, false negative results can be expected in patients infected with *P. falciparum* parasites, with similar or lower parasitaemias, that do not express HRP2 due to *pfhrp2/3* gene deletions and are therefore reliant only on pf-LDH detection for *P. falciparum* detection.

- The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.

- The test procedure, precautions and interpretation of results for this test must be followed precisely.

- Refer to current version of manufacturer’s instructions for use.
Prioritization for prequalification:
Based on the results of the WHO product testing of malaria RDTs for Round 8, SD BIOLINE Malaria Ag P.f/P.f/P.v was given priority for WHO prequalification.

Dossier assessment

Standard Diagnostics, Inc. submitted a product dossier for SD BIOLINE Malaria Ag P.f/P.f/P.v as per the “Instructions for compilation of a product dossier” (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 15 May 2018.

Commitments for prequalification:

1. The manufacturer was requested in the stage following the Dossier Review to finalize the translation of the IFU. The manufacturer is requested to demonstrate implementation of the revised IFU within three months of the date of publication of this public report, 04 March 2019.
2. The manufacturer is requested to provide the final report of the evaluation of the real-time stability of the product configuration 05FK123 by September 2020.

WHO will to follow-up on implementation of these commitments at the next re-inspection.

Based on the product dossier screening and assessment findings, the product dossier for SD BIOLINE Malaria Ag P.f/P.f/P.v meets WHO prequalification requirements.

Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture Standard Diagnostics, Inc. (65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea) of SD BIOLINE Malaria Ag P.f/P.f/P.v on 26-27 April 2018 as per the “Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics” (PQDx_014 v1). 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 on 12 October 2018.
Commitments for prequalification:

1. The assessment of risks throughout product realisation to be reviewed and all necessary validation/revalidation work (including computerised systems) to be performed by the end of May 2019.

2. By June 2019, Standard Diagnostics Inc. will have evaluated whether serial dilutions of known concentrations of target antigens can be used as reference panels. Three different target antigens will be evaluated on five different malaria products.

Based on the site inspection and corrective action plan review, the quality management system for SD BIOLINE Malaria Ag P.f/P.f/P.v meets WHO prequalification requirements.

Product performance evaluation

Based on the demonstrated overall P. falciparum panel detection score against HRP2-expressing parasites (89.0% at 200 parasites/µl), P. vivax panel detection score (97.1% at 200 parasites/µl), false-positive rates (0% for clean negatives, 0% for P. falciparum at 200 parasites/µl, 0% for P. vivax at 200 parasites/µl, 0% for P. falciparum at 2000 to 5000 parasites/µl, 0% for P. vivax at 2000 to 5000 parasites/µl) and invalid rate (0%), SD BIOLINE Malaria Ag P.f/P.f/P.v meets the current laboratory evaluation requirements for prequalification. See Warning/limitations sections regarding use in areas with pfhrp2/3 gene deletions.

<table>
<thead>
<tr>
<th>Summary performance characteristics</th>
<th>Panel detection score (%)</th>
<th>False positive rate (%)</th>
<th>Invalid rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 parasites/µl</td>
<td>200 parasites/µl</td>
<td>Clean negatives</td>
</tr>
<tr>
<td></td>
<td>Pf</td>
<td>P v</td>
<td>Pf</td>
</tr>
<tr>
<td>SD BIOLINE Malaria Ag P.f/P.f/P.v</td>
<td>89 (89/62)(^1)</td>
<td>97.1</td>
<td>0</td>
</tr>
</tbody>
</table>

1. Product Panel Detection Score (PDS) of individual HRP2 test line and Pf-pLDH test line, respectively.
Labelling

1. Labels
2. Instructions for use
1. Labels
1.1 Package box for 05FK120
1.2 Foil pouch for test cassettes of 05FK120
1 test x 25/kit

Malaria Ag P.f/P.f/P.v

For in vitro diagnostic use only

Store at 1 - 40 °C (34 - 104 °F) until expiration date

CONTENTS:
1) 25 Test devices with desiccant in individual foil pouch
2) 25 Assay diluents
3) 25 Disposable specimen applicators (5 µl), 25 Sterile lancets, 25 Alcohol swabs
4) 25 Summarized instructions for use
5) 1 Instructions for use

Test qualitatif rapide pour la détection de l'antigène de la protéine II riche en histidine (HRP-II) et de la lactate déshydrogénase (pLDH) de Plasmodium falciparum et de la pLDH de Plasmodium vivax dans le sang total humain

Réservé exclusivement à un usage diagnostique in vitro

Stocker à une température comprise entre 1 et 40 °C (34 - 104 °F) jusqu'à la date d'expiration

POCT

PMS 308C
PN: 05FK123-40-1(Draft)
Date of Last Revision: 2018/11/01

SD BIOLINE
Malaria Ag P.f/P.f/P.v (POCT spec, CE)

Box, 25 Test
Size: 220 x 130 x 70mm
1.4 Outer pouch for 05FK123 [POCT]

![Outer pouch for 05FK123](image)

1.5 1-test foil pouch for test cassettes of 05FK123 [POCT]

![1-test foil pouch for test cassettes](image)
1.6 Buffer label of 05FK120

![Buffer label of 05FK120](image-url)
2. Instructions for use

2.1 IFU for 05FK120
## About the Test

SD BIOLINE Malaria Ag P.f/P.f/P.v test kit  contains a membrane strip, which  is pre-coated with mouse monoclonal antibody (mAb) specific to 

- Plasmodium falciparum HRP-II Reactive  
- Plasmodium vivax pLDH Reactive  

The test strip includes:

- Gold conjugate: Mouse monoclonal antibodies specific to
- Endogenous control: Anti-human IgG antibodies

For within-run, between-run and batch-to-batch studies. All values were identical to reference panel.

### Required Equipment

- Microscope
- Blood smear
- Specimen diluent

### Principle of the Test

The test is based on the antigen-capture principle. It involves the detection of specific antigens (HRP-II and/or pLDH) present in the patient’s blood sample on a solid phase. The test strip contains a membrane strip to which the antigens are immobilized. The antigen-antibody complexes are captured and visualized on the test line.

### Expected Results

- **Positive Result:** Presence of two colored lines ("C" and "T3") in the result window, regardless of the line color.
- **Negative Result:** Absence of any colored lines.
- **Positive Control:** Presence of two colored lines ("C" and "T1") in the result window, regardless of the line color.
- **Negative Control:** Absence of any colored lines.
- **Negative Reaction:** Absence of any colored lines.
- **Positive Reaction:** Presence of two colored lines ("C" and "T3") in the result window, regardless of the line color.

### Procedure of Test

1. **Sample Collection:** Collect a finger prick blood sample onto a filter paper.
2. **Sample Preparation:** Dilute the sample in the provided sample diluent.
3. **Test Procedure:** Immobilize the test strip and perform the test according to the manufacturer’s instructions.
4. **Reading of Results:** Observe the results after the recommended incubation period.Record the results in the test record form.

### Interpretation of Results

Consult the manufacturer’s instructions for interpretation of results.

### Limitations and Interferences

- **Limitations:** False-negative results may occur if the sample contains high levels of autoantibodies or autoagglutinins. Cross-reactions with other infectious agents or allergens may also occur.
- **Interferences:** Interfering substances may include:
  - Hemoglobin
  - Cholesterol
  - Triglycerides

### Specifications

- **Specimen:** Whole blood
- **Sensitivity:** 100% (95.5 - 99.9%)
- **Specificity:** 100% (95.5 - 99.9%)
- **Analytical Performance:** The kit is designed to detect the specific antigens HRP-II and/or pLDH in the blood sample.

### Bibliography

2. Other relevant literature and references related to malaria and diagnostic testing.

### Language Options

- **English**
- **Français**
- **Español**
- **Português**
**ONE STEP Malaria HRP-II (P.f), pLDH (P.f) and pLDH (P.v) Antigen Rapid Test**

**Preparation / Préparation / Preparación / Preparação**

1. **Open Dispensing bag and add the following:***
   - 3 test strips
   - One step test device
   - Invert cup
   - Alcohol swab

2. **Open foil pouch and look for the following:**
   - P.f/P.v test kit.

3. **Then, label the device with the patient identifier.**

4. **Dispense / Distribuir / Dispense / Distribuir:**
   - Place the test strip in the window of the result.
   - Place the circular end of the inverted cup in contact with the pad, then press gently.
   - Place 4 µl of diluent into the diluent well.
   - Place the cup of specimen in the well.

5. **Resume:**
   - Place 2 µl of specimen in the well.
   - Place 2 µl of diluent in the diluent well.
   - The result is ready in 15 minutes.

6. **Result Interpretation:**
   - **Reactive / Réactif / Reactivo / Reactivo:**
     - (Three lines) : pLDH reactive
     - (Two lines) : HRP-II reactive
     - (One line) : Does not contain pLDH and HRP-II
   - **Invalid / Non valide / No valido / Inválido:**
     - (One line) : Does not contain pLDH and HRP-II

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**Glossary of symbols / Glossaire des symboles / Glosario de símbolos / Glossário de símbolos**

- **Test strip / Bandeau de test / Bandeau / Bandeau**
- **Invert cup / Coupe inversée / Copa invertida / Copa invertida**
- **Diluent well / Trou de diluant / Faja de diluyente / Fossa de diluyente**
- **Result window / Fenêtre de résultat / Ventana de resultado / Janela de resultado**
- **Inverted cup / Coupe inversée / Copa invertida / Copa invertida**

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**Legend:**
- *C*, *T1*, *T2*, *T3* (three lines):
  - *C*, *T2* (two lines): pLDH reactive
  - *C*, *T1* (two lines): HRP-II reactive
  - *C* (one line): Does not contain pLDH and HRP-II

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**Usage unique / Usage unique / Uso único / Uso único**

- Do not reuse
- Only for diagnostic in vitro use

**Attentions:**
- Results may vary depending on local conditions. In case of doubt, refer to the instructions for use.
- In vitro and non-invasive test for diagnostic purposes only.
- Instructions for use are strictly intended for healthcare professionals and should be followed closely.
- Warning: if any of the test elements are damaged or do not conform to the specifications, do not use the test kit.
- In case of positive result, consult a healthcare professional for appropriate medical advice.

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**Validity:**
- The test is valid for 15 minutes after the test strip has been placed in the window of the result.
2.2 IFU for 05FK123 [POCT]
**Materials and reagents used in main components:**
1. **Antigen:**
   - Plasmodium falciparum (P. falciparum) Antigen
   - Plasmodium vivax (P. vivax) Antigen
   - Plasmodium ovale (P. ovale) Antigen

2. **Antibody conjugates:**
   - Goat Anti-Mouse (Murine) Conjugated to HRP
   - Goat Anti-Human Conjugated to HRP

3. **Control materials:**
   - Positive Control: Human serum
   - Negative Control: Human serum

4. **Diluent:**
   - Assay diluent
   - Assay control diluent

5. **Conjunctiveds to pLDH:**
   - Araucaria, the membrane assembly of the cassette after addition of the assay diluent, they form a complex with conjugated mouse.
   - In humans, the parasites (called sporozoites) migrate to the liver where they mature and are released and can cause an illness. This illness is called malaria. In another cell, sporozoites are released from the liver to the blood stream and enter other cells. The asexual cycle begins. The cycle finishes when malarial parasites are released from the red blood cells into the blood stream, once again releasing sporozoites into the liver. This is called the sexual cycle.

6. **Non-reactive result:**
   - If no lines appear in the test window, the sample is non-reactive. This means that the test could not detect any parasites.

7. **Techniques for blood specimen:**
   - Blood specimens must be tested within 3 days of collection to maintain integrity.

8. **Microscopic examination:**
   - Microscopic examination remains the gold standard for diagnosing malaria. However, it is time-consuming and requires specialized training.

9. **HIV-1:**
   - In some cases, HIV-1 can cause fever, chills, and anemia. It is caused by a virus that is transmitted from one person to another in blood.

10. **Plasmodium vivax:**
    - Plasmodium vivax can cause malaria and can be transmitted from one person to another through the bite of an infected mosquito. It is the most common species of malaria in the world.

11. **Tissue culture:**
    - Tissue culture is a method used to grow cells in a controlled environment. It is widely used in the study of diseases like malaria.

12. **Graphs and tables:**
    - Graphs and tables are used to present data in a clear and concise manner. They can help to visualize trends and patterns in the data.

13. **References:**
    - Reference to the original source of the data.

14. **Interpretation of results:**
    - Interpretation of results is important to ensure accurate diagnosis.

---

**Materials and reagents used in main components:**

**Components and reagents of the kit:**
- **Antigen:***
  - Plasmodium falciparum (P. falciparum) Antigen
  - Plasmodium vivax (P. vivax) Antigen
  - Plasmodium ovale (P. ovale) Antigen

- **Antibody conjugates:**
  - Goat Anti-Mouse (Murine) Conjugated to HRP
  - Goat Anti-Human Conjugated to HRP

- **Control materials:**
  - Positive Control: Human serum
  - Negative Control: Human serum

- **Diluent:**
  - Assay diluent
  - Assay control diluent

- **Conjunctiveds to pLDH:**
  - The presence of lines in the test window indicates a reactive sample.
  - The absence of lines indicates a non-reactive sample.

- **Non-reactive result:**
  - If no lines appear in the test window, the sample is non-reactive. This means that the test could not detect any parasites.

- **Techniques for blood specimen:**
  - Blood specimens must be tested within 3 days of collection to maintain integrity.

- **Microscopic examination:**
  - Microscopic examination remains the gold standard for diagnosing malaria. However, it is time-consuming and requires specialized training.

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- **Tissue culture:**
  - Tissue culture is a method used to grow cells in a controlled environment. It is widely used in the study of diseases like malaria.

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- **References:**
  - Reference to the original source of the data.

- **Interpretation of results:**
  - Interpretation of results is important to ensure accurate diagnosis.
ONE STEP Malaria HRP-II (P.f), pLDH (P.f) and pLDH (P.v) Antigen Rapid Test

Preparation / Préparation / Preparación / Preparação

1. Open the package and look for the following:
   - Pocillo para la muestra (15 min)
   - Test device with desiccant in individual foil pouch
   - Alcohol swab

2. Follow the instructions to perform the test:
   1. Clean the area to be lanced with an alcohol swab.
   2. Pique a lateral do dedo com a lanceta esterilizada fornecida. Em seguida, elimine a lanceta em álcool.
   3. Dispense 5 μl of drawn blood into round specimen well touching pad.
   4. Commencer par lire attentivement le mode d' emploi du kit de test SD BIOLINE Malaria Ag P.f/P.f/P.v.

Test procedure / Procédure de test / Procedimiento de la prueba / Procedimento do teste

1. Test device should be positioned with sample side down.
2. Remove the lateral strip from the test device.
3. Dispense 5 μl of sample into round specimen well touching pad.
4. Depending on the identification and the number of lines present:
   - Two lines: HRP-II reactive
   - Three lines: pLDH reactive
   - Four lines: pLDH and HRP-II reactive

Interpretation / Interpréter / Interpretación / Interpretação

Non-reactive/ Non réactif / No reactivo / Não-reativo

Not line "C" should be visible.

Line "C" is the control line.

Line "T" is the test line.

Reactive / Réactif / Reactivo / Reativo

- Line "C" should be visible.
- Line "T" is the test line.
- Line "C" and "T" are both visible.

Invalid / Non valide / No válido / Inválido

- No lines are visible on the test device.
- The result is invalid. The test device must be discarded.

Usage unique / Usage unique / Únicamente para uso de diagnóstico / Apenas para uso de diagnóstico

This kit is intended for use in vitro. Not for use in vivo.

Specifications:
- Sensitivity: 100% (0.22 μg/ml)
- Specificity: 99.5% (99.5%)
- Positive Predictive Value: 99.5% (99.5%)
- Negative Predictive Value: 99.5% (99.5%)
- Detection Limit: 0.05 ng/ml

Direct oral use is not recommended.

Storage:
- Room temperature: 1 °C to 40 °C
- Refrigerator: 1 °C to 40 °C
- Avoid freeze-thaw cycles.

Expiry Date:
- Date of manufacture: 05/21/2023
- Expiration date: 04/21/2024
- Batch number: N/A

Authorized Representative:
- PT: GAMA DIAGNÓSTICOS - FÁBRICA DE PRODUTOS EM SALVADOR, BA, BRASIL

Materials provided:
- Pocillo par la muestra (15 min)
- Test device with desiccant in individual foil pouch
- Alcohol swab

Usage environment:
- In vitro only. Not for use in vivo.
- Only for diagnostic purposes.
2.3 Summarized IFU for 05FK123 [POCT]
ONE STEP Malaria HRP-II (P. f.), pLDH (P. f.) and pLDH (P. v.) Antigen Rapid Test

Intended use
The SD BIOLINE Malaria Ag P. f./P. f./P. v. test kit is a rapid, qualitative test for the detection of histidine-rich protein II (HRP-II) antigen and plasmodium lactate dehydrogenase (pLDH) from Malaria Plasmodium falciparum and pLDH from Malaria Plasmodium vivax in human whole blood.

Materials provided
- Test device
- Assay diluent
- Inverted cup (5 µl)
- Alcohol Swab
- Sterile lancet
- Alcohol swab

Materials not provided

Kit storage and stability
1. The test kit should be stored at a temperature between 1 °C and 40 °C. Do not freeze the kit or its components.
2. The test device is sensitive to both heat and humidity.
3. Check the humidity indicator on the desiccant for color change and throw the pouch if the color indicates saturation (yellow: OK. Discard if green).
4. Perform the test immediately after removing the test device from the foil pouch.

Specimen collection using a lancet
1. Clean the area to be lanced with an alcohol swab.
2. Squirt the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. With a disposable inverted cup (5 µl) provided, dip the circular end of an inverted cup into the blood specimen and carefully place the circular end of the inverted cup into the round specimen well.

Test procedure
Please see the reverse side.

FRANÇAIS

Utilisation prévue
Le kit de test SD BIOLINE Malaria Ag P. f./P. f./P. v. est un test qualitatif rapide pour la détection de l’antigène de la protéine II riche en histidine (HRP-II) de la lactate déshydrogénase de plasmodium (pLDH) de Plasmodium falciparum et de la pLDH de Plasmodium vivax dans le sang total humain.

Matériels fournis
- Cassette
- Diluant
- Gobelet Inversé jetable (5 /unid) 
- Alcohol Swab
- Lancette stérile
- Tampon d’aicool

Stockage et stabilité du kit
1. Les tests doivent être conservés entre 1 °C et 40 °C. Ne pas congeler le kit ou ses composants.
2. Le dispositif de test est sensible à la fois à l’humidité et à la chaleur.
3. Vérifier que l’indicateur d’humidité sur le dessicant n’a pas changé de couleur et jeter la pochette si la couleur indique une saturation (Jaune : OK. Vert : jeter.).
4. Procéder au test immédiatement après avoir retenu le dispositif de test sur son emballage en aluminium.
5. La durée de conservation du kit est indiquée sur l’emballage externe.
6. Ne pas utiliser le kit au-delà de la date de péremption.
7. Ne pas utiliser le kit de test si l’emballage individuel est endommagé ou si la fermeture hermétique a cédé.
8. Lors du transport et de la conservation du kit, éviter toute exposition à une température élevée (supérieure à 45 °C) durant plus de 1 semaine.

Prélèvement des échantillons utilisant une lancette
1. Nettoyez la zone à piquer avec un coton imbibé d’alcool.
2. Pincez le bout du doigt et pincez avec une lancette stérile fournie.
3. Essayer la première goutte de sang avec de la gaze stérile ou du coton.
4. Prendre un goblet inversé jetable(5 µl) préparé, tremper le bout circulaire du goblet inversé dans l’échantillon de sang et placer doucement le bout circulaire du goblet inversé dans le puits rond du test.

Procédure de test
Voir le côté inverse, s’il vous plaît.

Date issued : 2018.02
05FK123-02-C-3 (Draft)

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Authorized Representative

ENGLISH

Kit storage and stability
1. The test kit should be stored at a temperature between 1 °C and 40 °C. Do not freeze the kit or its components.
2. Note: When stored at refrigerator, all kit components must be brought to room temperature (15 - 40 °C) minimum 30 mins prior to the test. Do not open the pouch whilst components come to room temperature.
3. The test device is sensitive to both heat and humidity.
4. Check the humidity indicator on the desiccant for color change and throw the pouch if the color indicates saturation (yellow: OK. Discard if green).
5. Perform the test immediately after removing the test device from the foil pouch.

Specimen collection using a lancet
1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. With a disposable inverted cup (5 µl) provided, dip the circular end of an inverted cup into the blood specimen and carefully place the circular end of the inverted cup into the round specimen well.

Test procedure
Please see the reverse side.

Materials provided
- Test device
- Sterile lancet
- Alcohol Swab
- Inverted cup (5 µl)
- Alcohol swab

Materials not provided

Materials provided
- Test device
- Assay diluent
- Inverted cup (5 µl)
- Alcohol Swab
- Sterile lancet
- Alcohol swab

Materials not provided

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ONE STEP Malaria HRP-II (P.f), pLDH (P.f) and pLDH (P.v) Antigen Rapid Test

Test procedure / Procédure de test

1. Dispense 5 μl of drawn blood into round specimen well touching pad.
2. Twist and pull tab to open assay diluent. Dispense 5 μl of drawn blood into round specimen well touching pad.
3. Repartir l’ensemble du diluant de dosage du tube de diluant dans le puits carré de dispositif du essai.
4. Wait a minimum of 15 minutes (up to 30 minutes) and read results.

Interpretation / Interprétation

Reactive / Réactif

1. “C” and “T3” (two bands) : pLDH of P.v Reactive
2. “C” and “T3” (two bands) : Reactive for pLDH

Non-reactive / Non réactif

1. One line “C” in the result window
2. One bande < C dans la fenêtre de résultat

Invalid / Invalide

1. No “C” line in the result window. It is recommended that the specimen be retested using a new test kit.
2. Pas de ligne < C dans la fenêtre de résultat. Il est recommandé de tester à nouveau l’échantillon à l’aide d’un nouveau kit.