WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag
WHO reference number: PQDx 0294-074-00

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag with product code MFLRPD-02, manufactured by Meril Diagnostics Pvt. Ltd., rest-of-world regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 09 November 2018.

Summary of WHO prequalification assessment for MERISCREEN Malaria Pf/Pv Ag

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prequalification listing</td>
<td>09 November 2018</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>13 September 2018</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>20 July 2018</td>
</tr>
<tr>
<td>Product performance evaluation</td>
<td>2016</td>
</tr>
</tbody>
</table>

MR: Meets Requirements

Intended use

According to the intended use claimed by the manufacturer ‘One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag’ test kit is an in vitro diagnostic immunochromatographic assay for the qualitative detection of infections with Plasmodium falciparum and P. vivax parasites causing malaria in human whole blood specimens. It does not assess parasite densities. It assists trained users (in either laboratory or point-of-care settings):

- in detecting Plasmodium falciparum and P. vivax infections
- to differentiate infection between Plasmodium falciparum histidine-rich protein II (Pf-HRP-II) and Plasmodium vivax Plasmodium lactate dehydrogenase (Pv-pLDH)

The assay is intended for trained users and for an initial screening as well as an aid to the diagnosis of malaria infection.

Note: Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not recommended for monitoring response to anti-malarial treatment. The assay is to be used in the diagnosis of malaria in symptomatic patients as well as asymptomatic patients i.e., pregnant women and children. Testing is not intended for blood donors’.
Assay description

According to the intended use claimed by the manufacturer ‘One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag’ test utilizes the principle of immunochromatography in which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line Pf) specific to Histidine-Rich Protein II (Pf-HRP-II) of the Plasmodium falciparum and one monoclonal antibody (test line Pv) specific to lactate dehydrogenase of Plasmodium vivax (Pv-pLDH). Thus, the following Plasmodium antigens are detected in this test:

- Histidine Rich Protein II specific for P. falciparum (Pf-HRP-II)
- Plasmodium lactate dehydrogenase to Plasmodium vivax (Pv-pLDH)

The cassette contains a test strip pre-coated with capture antibodies.

The sequence of events is as follows:

1. Whole blood is applied to the specimen well (labelled well “S”).
2. Next, buffer is applied to the buffer well (labelled well “B”).
3. Migration of the blood/buffer mixture starts towards the opposite end of the cassette.
4. The blood-buffer mixture passes the conjugate pad, which contains detection antibodies targeting Pf-HRP-II and Pv-pLDH. These detection antibodies are conjugated to colloidal gold. If present in the specimen, Plasmodium target antigens bind to this detection antibody-conjugate.
5. The antigen-antibody-conjugate complex migrates further and binds to the capture Plasmodium specific antibodies present on the test line. These capture antibodies bind to another site (epitope) of the Plasmodium target antigens.
6. The capture antibodies are applied on a narrow section of the test strip: as a result, the antibody conjugate with the colloidal gold will be concentrated and become visible as a pinkish-purple colored line.
7. The excess of the detection antibody-conjugate that was not bound by the Plasmodium target antigens and the capture antibodies moves further to absorbent pad.
8. At control zone Goat anti-chicken IgY (as blue coloured line) is immobilized and it binds to IgY colloidal gold conjugate to give a pinkish-purple colored control line. The visualization of the control line indicates that the migration was successful. It does not confirm the presence of specimen’.
Test kit contents

<table>
<thead>
<tr>
<th>Component</th>
<th>30 tests/kit (product code MFLRPD-02)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cassette packaging, each containing 1 device and 1 desiccant</td>
<td>30</td>
</tr>
<tr>
<td>Assay buffer bottles (protein stabilizer, detergent and preservatives)</td>
<td>2 × 3.0 mL</td>
</tr>
<tr>
<td>Specimen transfer device</td>
<td>30 × 5 µL</td>
</tr>
<tr>
<td>Lancet</td>
<td>30</td>
</tr>
<tr>
<td>Alcohol swab</td>
<td>30</td>
</tr>
<tr>
<td>Pack insert</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided
- Disposable gloves
- Pen
- Timer
- Sharp box
- Non-sharp disposal container
- Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

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

Shelf-life upon manufacture
24 months.

Warnings/limitations
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 7, MERISCREEN Malaria Pf/Pv Ag was given priority for WHO prequalification.

Dossier assessment
Meril Diagnostics Pvt. Ltd submitted a product dossier for One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag 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 13 September 2018.

Commitments for prequalification
1. The manufacturer agreed to submit a complementary study regarding the sensitivity of the kit with specimens sourced from pregnant women and children by **26 August 2019**
2. The manufacturer agreed to submit evidences of validation of the usability of the product by **20 January 2019**.
3. The manufacturer agreed to submit the results of Phase II of Shipping Stability Study by **20 January 2019**.
4. The manufacturer agreed to submit a new clinical performance study by **26 August 2019**.

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 One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag meets WHO prequalification requirements.

Manufacturing site inspection
A comprehensive inspection was performed at the site of manufacture (second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India) of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag between 27 -29 September 2017 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 25 July 2018.

Based on the site inspection and corrective action plan review, the quality management system for One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag meets WHO prequalification requirements.

**Product performance evaluation**

The seventh round of WHO product testing of RDTs for malaria antigen detection was completed in 2016. The product was evaluated against a Plasmodium *falciparum* cultured line panel, *P. falciparum* wild type parasite panel, *P. vivax* wild type parasite panel and a Plasmodium *spp.* negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded.

Based on the demonstrated *P. falciparum* panel detection score (78.0% at 200 parasites/µl), *P. vivax* panel detection score (85.7% at 200 parasites/µl), false-positive rates (0.0% for clean negatives, 0.5% for *P. falciparum* at 200 parasites/µl, 0.7% for *P. vivax* at 200 parasites/µl, 0.0% for *P. falciparum* at 2000 to 5000 parasites/µl, 1.4% for *P. vivax* at 2000 to 5000 parasites/µl) and invalid rate (0.0%), One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag meets the current laboratory evaluation requirements for prequalification.

<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>Clean negatives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200 parasites/µl</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pf</td>
<td>Pf</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pv</td>
<td>Pv</td>
<td></td>
</tr>
<tr>
<td>One Step test for Malaria Pf/Pv Ag</td>
<td>78</td>
<td>85.7</td>
<td>0.5</td>
</tr>
<tr>
<td>MERISCREEN Malaria Pf/Pv Ag</td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.0</td>
</tr>
</tbody>
</table>
Labelling

1. Labels
2. Instructions for use
1. Labels

Product Box Label - Side:1

Product Box Label - Side:2

One Step Rapid test for the detection of Malaria infection in human whole blood specimen, indicating differential detection between *Plasmodium falciparum* histidine-rich protein-II (Pf-HRP-II) and *Plasmodium vivax* Plasmodium lactate dehydrogenase (Pv-pLDH).
2. Instructions for use
One Step test for Malaria Pf/Pv Ag

**MERISCREEN Malaria Pf/Pv Ag**

**Intended use:**
One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is an *in vitro* diagnostic immunochromatographic assay for the qualitative detection of infections with *Plasmodium falciparum* and *P. vivax* parasites causing malaria in human whole blood specimens. It does not assess parasite densities. It assists trained users (in either laboratory or point-of-care settings)
- in detecting *Plasmodium falciparum* and *P. vivax* infections
- to differentiate infection between *Plasmodium falciparum* histidine-rich protein II (Pf-HRP-II) and *Plasmodium vivax* Plasmodium lactate dehydrogenase (Pv-pLDH)

The assay is intended for trained users and for an initial screening as well as an aid to the diagnosis of malaria infection.

Note: Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not recommended for monitoring response to anti-malarial treatment.

The assay is to be used in the diagnosis of malaria in symptomatic patients as well as asymptomatic patients i.e., pregnant women and children. Testing is not intended for blood donors.

**Principle:**
One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test utilizes the principle of immunochromatography in which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line Pf) specific to Histidine-Rich Protein II (Pf-HRP-II) of the *Plasmodium falciparum* and one monoclonal antibody (test line Pv) specific to lactate dehydrogenase of *Plasmodium vivax* (Pv-pLDH). Thus, the following Plasmodium antigens are detected in this test:
- Histidine Rich Protein II specific for *P. falciparum* (Pf-HRP-II)
- Plasmodium lactate dehydrogenase to *Plasmodium vivax* (Pv-pLDH)

The cassette contains a test strip pre-coated with capture antibodies.

The sequence of events is as follows:
1. Whole blood is applied to the specimen well (labelled well “S”).
2. Next, buffer is applied to the buffer well (labelled well “B”).
3. Migration of the blood/buffer mixture starts towards the opposite end of the cassette.
4. The blood-buffer mixture passes the conjugate pad, which contains detection antibodies targeting Pf-HRP-II and Pv-pLDH. These detection antibodies are conjugated to colloidal gold. If present in the specimen, Plasmodium target antigens bind to this detection antibody-conjugate.
5. The antigen-antibody-conjugate complex migrates further and binds to the capture Plasmodium specific antibodies present on the test line. These capture antibodies bind to another site (epitope) of the Plasmodium target antigens.
6. The capture antibodies are applied on a narrow section of the test strip; as a result, the antibody conjugate with the colloidal gold will be concentrated and become visible as a pinkish-purple colored line.
7. The excess of the detection antibody-conjugate that was not bound by the Plasmodium target antigens and the capture antibodies moves further to absorbent pad.
8. At control zone Goat anti-chicken IgY (as blue coloured line) is immobilized and it binds to IgY colloidal gold conjugate to give a pinkish-purple colored control line. The visualization of the control line indicates that the migration was successful. It does not confirm the presence of specimen.

The main ingredients of the kit are:
- Test strip
  - Detection antibodies conjugated to colloidal gold:
    - Mouse monoclonal antibodies specific to Pf-HRP-II-gold Colloid
    - Mouse monoclonal antibodies specific to Pv-pLDH-gold Colloid
    - Chicken IgY – gold Colloid
  - Capture antibodies:
    - Test lines
      - *P. falciparum* (Pf) line: Mouse monoclonal antibodies specific to Pf-HRP-II
      - *P. vivax* (Pv) line: Mouse monoclonal antibodies specific to pan-pLDH
    - Control line: Goat anti-Chicken IgY polyclonal antibodies (as blue coloured line)
- Assay buffer
  - Protein stabilizers, detergent and preservatives

**Intended User**
- The test must be performed by a trained user (in either laboratory or point-of-care settings).

**Specimen required:**
- Capillary blood or venous blood with the following anticoagulants: EDTA, Heparin, Citrate
- Time between collection and analysis:
  - Capillary: immediately
  - Venous: immediately. If immediate testing is not possible, store the whole blood specimen at 2-8°C for maximum 72 hours (3 days).

**Warnings and precautions**
- For *in vitro* diagnostic use only.
- Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
- Apply standard biosafety precautions for handling and disposal of potentially infective material.
  - Handle all specimens as potentially infectious.
  - Wear gloves while handling specimens and performing the test.
  - Avoid splashing and aerosol formation.
  - Clean up spills thoroughly using an appropriate disinfectant.
- The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use any other buffer than the buffer supplied within this kit.
- Do not use the RDT kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use any other specimen than whole blood.
- Do not use if the product has been exposed to excessive heat or humidity.
- Perform the test immediately after opening of the cassette packaging.
- Do not re-use the test.
- Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
- Do not use the lancet if the seal is broken.
- Do not touch the tip of buffer bottle, it might contaminate buffer.
- Allow all reagents and specimen(s) to attain room temperature (18°C to 30°C) before use.
- Do not smoke, eat or drink while handling specimens and performing a test.
Procedure

Before testing:

• Contamination of specimen transfer devices and/or reagents can lead to inaccurate results.

Materials

Materials provided:

• 30 cassette packaging, each containing:
  o 1 device
  o 1 desiccant
• 2 Assay buffer bottles - each of 3.0 ml
• 30 Specimen transfer devices - 5 μL
• 30 Lancets
• 30 Alcohol swabs
• 1 Pack Insert

Materials required but not provided:

• New pair of disposable gloves
• Pen
• Timer
• Sharp box
• Non-sharps disposal container
• Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

Test Kit Storage and Stability

• Store the kit between 1-40 °C
• Do not store the kit in the freezer.
• Protect the kit from excessive heat and humidity.
• The kit including assay buffer has a shelf life of 24 months from the date of manufacture. The test kit is stable until the expiration date marked on the kit box and/or the packaging of individual components when stored as specified.
• Once opened the Test Device, it gives accurate results within 24 hours, but it should be used immediately.

Test procedure

Capillary whole blood from finger prick

1. Wear gloves.
2. Choose a finger for the finger prick:
   • Do not choose a finger that is swollen, bruised or scarred.
3. Preferably choose the 3rd or 4th finger of the hand which the patient does not use to write.
4. Open the packaging of the alcohol swab. Take out the alcohol swab.
   Do not throw away the empty packaging (wrapper) but keep it aside.
5. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
6. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the patient’s blood).
7. Take the safety-seal lancet.
8. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the fingerprint.
   Dispose the lancet immediately into the sharps box.
9. Make sure a well-formed drop of blood is present on the tip of the finger.
10. If there is no well-formed drop of blood, repeat the finger prick. Use a new lancet and choose a different puncture site.
11. Take the specimen transfer devices and collect 5 μl of blood by dipping the circular end of the specimen transfer devices into the whole blood drop.
12. Place the circular end of the specimen transfer devices in the circle well/specimen well (marked “S”) so that it touches the strip (pad at the bottom of the well). Press down lightly to transfer the whole blood to the strip. Put the used specimen transfer devices into the non-sharps disposal container.
13. Take the alcohol swab you put aside (step 5). Ask the patient to press it to the finger prick to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container.
14. Take the buffer bottle. Hold the open buffer bottle vertically above the square well/buffer well (marked “B”). Squeeze the bottle gently and apply exactly four drops into the square well/buffer well (marked “B”).

Venous whole blood from venipuncture

1. Wear gloves.
2. Collect blood by standard venipuncture procedure into a tube containing the correct anticoagulant (EDTA, heparin or Citrate).
3. Mix the tube gently.
4. Transfer 5 μl of whole blood using specimen transfer devices in the circle well (marked “S”) of the cassette using a precision pipette.
5. Perform steps 12 - 16 of the previous section (“Capillary whole blood from finger prick”)

Interpretation of the test result:
1. After 20 but no later than 30 minutes: compare the test lines with the presentation in the table below.
2. Where possible, have the results confirmed by a second reader within this time frame.
3. Line intensities may vary from faint to strong intensity. Consider also faint test line as a positive result.
4. Record the test results as noted in the table below. Consult the national guidelines for malaria case management to complement the table below.

Note: The faint blue line at “Control” position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation.

<table>
<thead>
<tr>
<th>Lines that you see</th>
<th>Picture/ Drawing</th>
<th>Record, the following result, take the following action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faint Blue line at Control position even after addition of samples and assay buffer</td>
<td><img src="Image_187x200" alt="Image" /></td>
<td>Invalid. Take a new cassette packaging and repeat the test.</td>
</tr>
<tr>
<td>NO Pink Purple line at ‘C’ (=control)</td>
<td><img src="Image_200x220" alt="Image" /></td>
<td>Invalid. Take a new cassette packaging and repeat the test.</td>
</tr>
</tbody>
</table>

Limitations of the product, causes of false-negative and false-positive results
- The test procedure, precautions and interpretation of result for this test must be followed when testing.
- The test kit is intended for an initial screening as well as an aid to the diagnosis of infection. Other clinically tests are required only if questionable results are obtained. As with all diagnostic tests, the test result must always be co-related with clinical findings.
- The performance of product may be degraded at an ambient temperature of 45°C.
- One Step test for Malaria P.fPv Ag MERISCREEN Malaria P.fPv Ag test kit was tested with interfering substances such as, bilirubin (conjugated & unconjugated), triglyceride, acetaminophen, total protein, vitamin B12, sodium azide, thimerosal, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting samples such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematosus (SLE), Anti-Nuclear Antibodies (ANA) and the performance of One Step test for Malaria P.fPv Ag MERISCREEN Malaria P.fPv Ag test kit was not affected by these interfering and cross-reacting factors. Interfering substances, cross reacting factors other than these may affect the performance of the kit.
- False positive result can occur – amongst others in the following conditions:
  - Some viral infection other than hepatitis B or hepatitis C, HIV or dengue
  - Parasitic infection (e.g. Schistosomiasis and Trypanosomiasis)
  - Presence of heterophile antibodies in patient’s sample other than Rheumatic diseases and autoimmune disorder may lead to false results.
- False negative result can occur in the following conditions:
  - Hook effect due to very high parasite densities i.e., ≥ 26,000 parasites/μl for P. falciparum and ≥ 22,000 parasites/μl for P. vivax. Repeat the test by using different dilutions of same sample.
  - If antigen concentration/parasite densities present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
  - Deletion in the HRP-II gene resulting in no production of HRP-II antigen
- A positive test should be carefully interpreted to distinguish between new infections and effectively treated old infections. This is due to the persistence of HRP II antigen in the blood for 1-3 weeks after effective treatment. Therefore, malaria RDTs are not recommended for monitoring treatment of malaria.
• This assay cannot be used for the diagnosis of infection by other type of malarial parasites (P. malariae, P. ovale or P. knowlesi).

• A negative result at any time does not preclude the possibility of exposure or infection.

• Repeat the test in case of very faint band or if have any doubt for test band.

• This kit is intended for initial screening of malaria infection as well as an aid to the diagnosis of infection. This test kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative results caused by various factors.

• Although the test is accurate in detecting HRP-II specific to P. falciparum or pLDH specific to P. vivax in blood specimens, low incidence of false results may occur. Other clinically available tests should be used if questionable results are obtained.

• “Pv” band may turn negative after successful anti-malarial therapy.

• In few cases, HRP-II band appears in certain post treatment malaria, however, such observations are also observed in certain untreated malaria. In such cases, re-testing after 2 days is recommended.

• In P. falciparum malaria infection, HRP-II is not secreted in gametogony stage. Hence, in “Carriers”, the HRP-II band may be absent.

Note: The presence of the pink-purple control line only means that migration of the test occurred. It does not guarantee that:
- The correct specimen has been used
- The specimen has been applied correctly
- The specimen and test have been correctly stored
- The test procedure was followed correctly

Performance specifications:

A. Sensitivity and Specificity

88 P. falciparum positive specimens, 89 P. vivax positive specimens including P. falciparum & P. vivax mixed infection positive specimens, P. falciparum and P. vivax positive specimens of pregnant women and children were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit. 1000 Plasmodium negative specimens, 107 Plasmodium negative blood donor specimens, 54 Plasmodium negative pregnant women specimens and 66 Plasmodium negative children specimens were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit. 1000 Plasmodium negative specimens, 107 Plasmodium negative blood donor specimens, 54 Plasmodium negative pregnant women specimens and 66 Plasmodium negative children specimens were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag to evaluate the diagnostic sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit.

C. Analytical Specificity (Cross reactivity)

To evaluate the interference of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit with known relevant interfering specimens, the haemolytic specimens, rheumatoid factors-contained specimens and lipaemic specimens were investigated. In this study, the performance of the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not affected by interfering substances such as, bilirubin (conjugated & unconjugated), triglycercide, acetaminophen, total protein, vitamin B12, sodium azide, thimerosol, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting factors such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematosus (SLE), Anti-Nuclear Antibodies (ANA).

D. Precision (Repeatability & Reproducibility)

One P. falciparum positive of high parasite density i.e., 5634 parasites/µl, one P. vivax positive of high parasites density i.e., 6745 parasites/ µl and three Plasmodium negative specimens were utilized for this study. These specimens are further diluted to make moderate and low positive samples. Testing was done by using these samples (high, moderate & low) in replicates of three by three different operators by using three different lots over five (05) days. Total of 1215 tests were generated and 1215 results were obtained. Out 1215, 405 results were generated for Pf, 405 results for Pv and 405 results for Plasmodium negative samples. The results have shown 100% agreement with the sample status when tested with Pf positive, Pv positive and Plasmodium negative samples by three operators, in replicates of three by using three lots over five days. The results & data analysis showed 100% sensitivity for Pf positive and Pv positive samples and 100% specificity for Plasmodium negative samples. The test results have met the acceptance criteria of the study.

<table>
<thead>
<tr>
<th>Types of specimens</th>
<th>% Sensitivity</th>
<th>% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity of P. falciparum</td>
<td>98.86%</td>
<td>95% CI value 93.83% to 99.97%</td>
</tr>
<tr>
<td>Sensitivity of P. vivax</td>
<td>96.63%</td>
<td>95% CI value 90.46% to 99.30%</td>
</tr>
<tr>
<td>Total Sensitivity</td>
<td>97.74%</td>
<td>95% CI value 94.32% to 99.38%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Types of specimens</th>
<th>% Specificity</th>
<th>% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity of Plasmodium spp. Negative samples</td>
<td>98.53%</td>
<td>95% CI value 97.69% to 99.13%</td>
</tr>
</tbody>
</table>

B. Analytical Sensitivity (Limit of Detection)

The sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag for P. falciparum (“Pf” Band) is ≥50 parasites/µl and for P. vivax (“Pv” Band) is ≥200 parasites/µl.

Bibliography:

Product Disclaimer:
Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:
The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.