

1. INTENDED USE

The Biokits Malaria Pf/Pv Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection and differentiation of *Plasmodium falciparum* (Pf) and *Plasmodium vivax* (Pv) antigens in human whole blood. This test is intended for professional use only.

2. INTRODUCTION

Malaria is a life-threatening parasitic disease transmitted by the bite of infected *Anopheles* mosquitoes and is caused primarily by *Plasmodium falciparum* and *Plasmodium vivax*. Rapid and accurate differentiation between Pf and Pv infections is critical for appropriate treatment and patient management. Detection of specific malaria antigens in whole blood provides a reliable method for early diagnosis. The Biokits Malaria Pf/Pv Rapid Test provides a rapid qualitative result to assist in the diagnosis and differentiation of malaria infections.

3. PRINCIPLE OF THE TEST

The Biokits Malaria Pf/Pv Rapid Test is a lateral-flow immunochromatographic assay with a three-line detection system consisting of a *P. falciparum* test line (Pf), a *P. vivax* test line (Pv), and a control line (C). Malaria antigens present in the specimen bind to colloidal gold-conjugated anti-malaria antibodies and migrate along the nitrocellulose membrane by capillary action. The immune complexes are captured by immobilized Pf-specific antibodies at the Pf line and Pv-specific antibodies at the Pv line, producing visible colored lines corresponding to the species present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of malaria antigens, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Malaria Pf/Pv Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide parasite density.
2. A negative result does not exclude malaria infection, particularly in cases of low parasitemia.
3. Persistent antigens may result in positive results after recent treatment, especially for *P. falciparum*.
4. Mixed infections may produce both Pf and Pv test lines.
5. The test is validated only for human whole blood.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

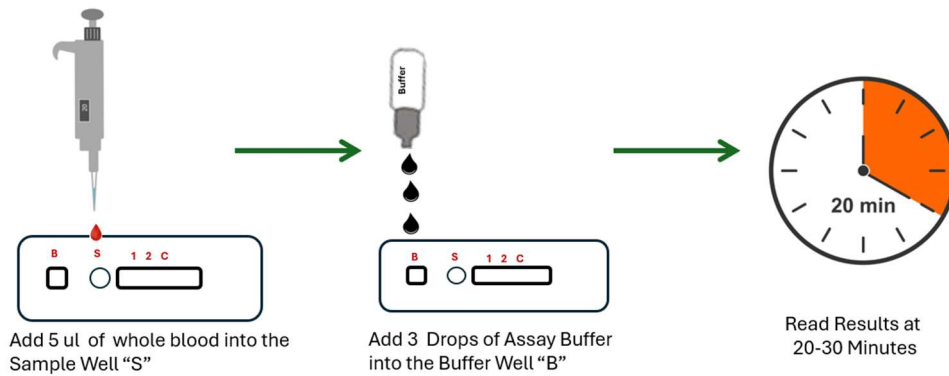
9. REFERENCES

1. World Health Organization. *Guidelines for the treatment of malaria*. WHO Press, Geneva.

SPECIMEN COLLECTION AND STORAGE

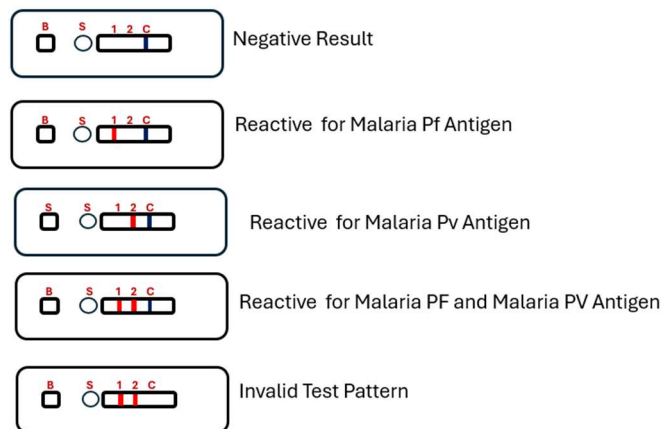
Category	Details
Accepted Specimens	✓ Whole blood (finger prick or venous) (EDTA, citrate, heparin)
Collection	✓ Finger prick or venous blood using standard procedure
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, Whole Blood at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Note: Do not read results after 30 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 99.3%
- ✓ Clinical Specificity: 98.7
- ✓ Analytical sensitivity : 50 Parasites/ μ l for Pf and Pv

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