Cat: BMPN-01

# BioKits Malaria Pf-PAN Ag Rapid Test

**(Whole Blood)**

## 1. INTENDED USE

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

## 2. INTRODUCTION

Malaria is a life-threatening parasitic disease caused by *Plasmodium* species and transmitted through the bite of infected *Anopheles* mosquitoes. *Plasmodium falciparum* is associated with severe malaria, while other species such as *P. vivax*, *P. malariae*, and *P. ovale* also contribute to malaria morbidity. Rapid differentiation of Pf from non-falciparum malaria is essential for appropriate treatment and patient management. The Biokits Malaria Pf/Pan 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/Pan Rapid Test is a lateral-flow immunochromatographic assay with a three-line detection system consisting of a *Plasmodium falciparum* test line (Pf), a Pan-malaria test line (Pan), 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 Pan-specific antibodies recognizing non-falciparum *Plasmodium* species at the Pan 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/Pan 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 Pan 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.

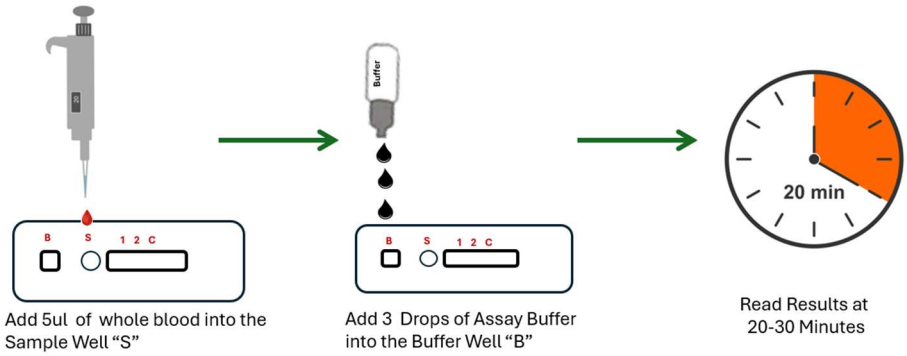
## 9. REFERENCES


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** | ✓ Test as early as possible<br>✓ Store at **2–8°C for up to 3 days**<br>✓ For longer storage, Whole Blood at **–20°C**<br>Avoid freeze–thaw cycles |

# TEST PROCEDURE



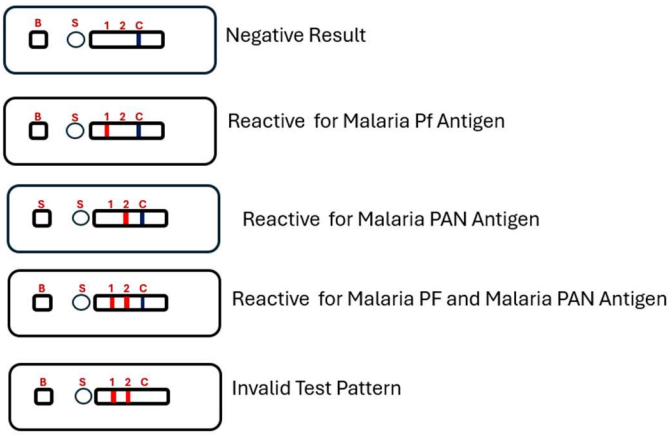

Add 5ul of whole blood into the Sample Well "S"

Add 3 Drops of Assay Buffer into the Buffer Well "B"

Read Results at 20-30 Minutes

**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/ ul for Pf and Pv

M/s: **ubio Biotechnology Systems Pvt Ltd. Plot No: 15A, Biotechnology Zone, KINFRA Hitech Park, Kalamaserry, Cochin, Kerala - 683503, INDIA.**

Symbols Used: Instructions to use | Do Not reuse | Storage temperature | Away from direct sunlight | Store dry | No of tests | IVD | For *In-Vitro* diagnostic use | REF | Product code | Manufactured site | Manufactured date | Use before | LOT | Lot number