CE

parabank®

RAPID TEST FOR MALARIA

Pan

DEVICE

INTENDED USE

parabank® is a rapid, qualitative, two site sandwich immunoassay utilizing whole blood for the detection of Pan specific pLDH.

SUMMARY

Four species of the *Plasmodium* parasites are responsible for malaria infections in human viz. *P.falciparum, P.vivax, P.ovale* and *P.malariae*.

parabank® detects the presence of Pan malaria genus specific pLDH released from the parasitised blood cells, for the detection of malarial parasites such as *P.falciparum, P.vivax, P.ovale* and *P.malariae*.

The presence of the Pan malaria specific band points to the presence of any of the malarial species; viz.; *P.falciparum, P.vivax, P.ovale* or *P.malariae*. Speciation is done and results inferred in the context of prevalence rates of the malarial species prevalent in the particular region.

Since pLDH is a product of viable parasites, the Pan band may also be used to monitor success of antimalarial therapy. For speciation, more specific tests may be done.

parabank® is especially designed to exclude infected blood from the blood supply in the blood bags to prevent transfusion acquired malaria.

PRINCIPLE

parabank® utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored Agglutinating sera for Pan malaria specific pLDH-colloidal gold conjugate complexes the proteins in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the Agglutinating sera for Pan malaria specific pLDH coated on the membrane leading to formation of pink-purple colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result.

The unreacted conjugate along with the rabbit globulin-colloidal gold conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a pink-purple band. The control band formation is based on the 'Rabbit / Agglutinating sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

parabank® kit contains:

A. Individual pouches, each containing:
   1. DEVICE : Membrane assembly pre-dispensed with Agglutinating sera for Pan malaria specific pLDH - colloidal gold conjugate, rabbit globulin - colloidal gold conjugate, Agglutinating sera for Pan malaria specific pLDH and Agglutinating sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3. PIPETTE : Disposable Plastic Sample Applicator.

B. BUF : Clearing buffer in a dropper bottle.

C. Package Insert.

REF	503040010	503040025
Σ	10	25

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4°C to 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE. After first opening of the clearing buffer bottle, it can be stored between 4°C to 30°C for the remaining duration of its shelf life.

NOTES

1. Read the instructions carefully before performing the test.

2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
3. Do not use beyond expiry date.
4. Do not intermix the reagents from different lots.
5. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
6. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
7. Clearing Buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or CPDA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2°C to 8°C for up to 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **parabank**® kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device and use another device. ***Once opened, the device must be used immediately.***
3. Label the test device with patient's identity.
4. Tighten the cap of the clearing buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
5. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample applicator into the sample. Ensuring that an applicator full of blood is retrieved, blot the blood so collected in the sample port 'A'. (This delivers approximately 5µl of the whole blood specimen).

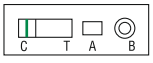
   OR

   In case finger prick blood is being used, touch the sample applicator to the blood on the finger prick. Ensuring that an applicator full of blood is retrieved, immediately blot the specimen in the sample port 'A'. (Care should be taken that the blood sample has not clotted and the transfer to the sample port is immediate).

   OR

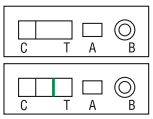
   Alternatively, 5µl of the anti coagulated or finger prick specimen may be delivered in the sample port 'A' using a micro pipette.

   NOTE : Ensure that the blood from the sample applicator has been completely taken up at the sample port 'A'.
6. Immediately dispense **two drops** of clearing buffer into buffer port 'B', by holding the plastic buffer bottle vertically.
7. Read the results at the end of **20 minutes** as follows :



NEGATIVE FOR MALARIA:
Only one pink-purple band appears in the control window 'C'.

POSITIVE FOR MALARIA:
In addition to the control band, another pink-purple band appears in the test window 'T'.



INVALID TEST:
The test should be considered invalid if no bands appear on the device. The test should also be considered invalid if only test band appears and no control band appears. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

PERFORMANCE CHARACTERISTICS

In an in-house study, a panel of 255 samples whose results were earlier confirmed with microscopy were tested with **parabank**®. The results obtained are as follows:

Sample	Total No. of samples tested	parabank®		Sensitivity (%)	Specificity (%)
		Positive	Negative		
P. falciparum positive	16	16	0	100	-
P. vivax positive	25	25	0	100	-
P. ovale positive	2	2	0	100	-
P. malariae positive	2	2	0	100	-
Malaria negative	210	0	210	-	100

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Interference due to presence of heterophile antibodies in patient's sample can lead to erroneous analyte detection in immunoassay, has been reported in various studies. **parabank**® uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of these interferences.
5. While monitoring therapy, using the 'Pan' band, if the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
6. Usually, 'Pan' band turns negative after successful anti malarial therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
7. Do not interpret the test results beyond 30 minutes.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Howard, R.J., et al., 1986: Secretion of a Malarial Histidine-rich Protein (Pf. HRP II) from *Plasmodium falciparum*-infected Erythrocytes. J. Cell Biol., 103, 1269-1277.
2. Parra, M.E., et al., 1991: Identification of *Plasmodium falciparum* Histidine-Rich Protein 2 in the Plasma of Humans with Malaria. J. Clin. Microbiol., 29, 1629-1634.
3. Rodriguez-Del Valle, M., et al., 1991: Detection of Antigens and Antibodies in the Urine of Humans with *Plasmodium falciparum* Malaria. J. Clin. Microbiol., 29, 1236-1242.
4. Piper, R. C., et al., (1999) Immuno-capture diagnostic assays for malaria utilizing *Plasmodium* Lactate Dehydrogenase (pLDH) Am. J. Trop. Med. Hyg. 60(1) 109-118.
5. Hunte-Cooke A., et al., (1999) Comparison of a Parasite Lactate Dehydrogenase-based Immunochromatographic Antigen Detection assay (OptiMAL®) with Microscopy for the Detection of Malaria Parasites in Human Blood Samples. Am J.Trop Med 60(2). 173-176.
6. Quintana M., et al.,(1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic *Plasmodium falciparum* and *Plasmodium vivax*. Am. J. Trop. Med. Hyg. 59(6) 868-871.
7. Palmer, C. J., (1998) Evaluation of OptiMal test for rapid diagnosis of *Plasmodium vivax* and *Plasmodium falciparum*. J. Clin Microbiol. 36(1) 203-206.
8. Moody A., et al., (2000) Performance of the OptiMAL® malaria antigen capture dipstick for malaria diagnosis and treatment monitoring. British Journal of Hematology, 109, 1-5.
9. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	IVD *In vitro* Diagnostic Medical Device	 This side up	BUF Clearing Buffer
 Use by	REF Catalogue Number	DEVICE Device	EC REP Authorised Representative in the European Community
 Contains sufficient for <n> tests	LOT Batch Number / Lot Number	PIPETTE Disposable Plastic Sample Applicator	

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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