



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR PARASCREEN (MALARIA P.f / PAN RAPID TEST)

Version number 2.0, 18.05.2026

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1. Introduction

Parascreen is a class C in-vitro diagnostic device belonging to the parasitology specialty category. It is approved in Tanzania as a kit for use in adults, children, elderly etc. by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0281
Brand Name (if relevant)	PARASCREEN
Common name	Malaria Pf / Pan Rapid Diagnostics Test
Class of the device and rule applied	Class C as per rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	52311, Multiple Plasmodium species antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Anudha Ltd, P. O. Box 5982, Morogoro road, Dar es Salaam, Tanzania.
Name and address(es) of local responsible person (LRP).	Anudha Ltd, P. O. Box 5982, Morogoro road, Dar es Salaam, Tanzania.

1.2. Assessment Procedure

The application for registration of Parascreen was submitted on 06.03.2023. The product underwent full assessment. Assessment was completed in four rounds of evaluation. Parascreen was registered on 12.12.2025.

2. Technical information

2.1. Intended use

The intended use of Parascreen as declared by the manufacturer and approved by TMDA is for detecting *P. falciparum* specific histidine rich protein-II (Pf, HRP-II) and *P. vivax*

specific pLDH in human blood. Parascreen is approved for use in healthcare settings, point of care by trained professionals only.

2.2. Device details and features

Parascreen has been registered as a kit which consists of 50 test cassettes, package insert, 50 droppers and buffer bottle.

Parascreen is used for detection of *P. falciparum* specific histidine rich protein-II (Pf, HRP-II) and *P. vivax* specific pLDH in human blood. Parascreen operates by lateral flow immunoassay. The test out-put is qualitative.

The type of specimen used is human whole blood and is collected by finger prick or venous.

The Malaria P.f Antigen Rapid Test Cassette is a lateral flow immunoassay for the qualitative detection of Histidine-Rich Protein II (HRP-II) of *Plasmodium falciparum* (P.f) in human whole blood. It provides an aid in the diagnosis of infection with Malaria.

The Immunochromatography concept is used in the Malaria Pf/Pv Ag test. It includes a membrane strip pre-coated with Monoclonal Anti-HRP II antibody (test line pf), which is specific to the Histidine Rich Protein-II of *Plasmodium falciparum*, and another membrane strip with Monoclonal Anti-pLDH *P. vivax* antibody (test line P.v), which is specific to the lactate dehydrogenase of *P. vivax* species. The colorful colloidal gold conjugates of monoclonal anti-Pf, HRP 2 antibody, and monoclonal anti-Pan specific pLDH antibody complex the lysed blood sample as the test sample passes across the membrane assembly of the device following addition of assay buffer (diluent). This compound becomes immobilized on the nitrocellulose membrane's corresponding test lines, resulting in the creation of pink-purple line(s). In *falciparum* positive samples, a line will appear under Pf at the sample location, while in *vivax* positive samples, a line will appear under P.v. A mixed infection is indicated by the presence of a line under P.f and P.v in the test region. An additional line of goat anti-mouse IgG has been immobilized on the strip as a procedural control. This will help in the formation of a pink-purple line on the control line if the test was conducted correctly.



2.3. Commercial presentation

There are one approved commercial presentations as follows: one unit in the primary pack in aluminum foil pouch. 25 units in secondary pack are placed in a box.

Additional contents include buffer bottle, droppers, package insert.

2.4. Items required but not submitted

Calibrated micropipette.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions is 1 – 40°C.

3.1.3. Shipping conditions

The recommended shipping conditions is -20°C to -35°C and 45°C + 2°C.

4. Manufacturing site audit

The manufacturer of the device is Zephyr Biomedicals, A division of Tulip Diagnostics (p) Ltd, M 46-47, Phase IIIB, Verma Industrial Estate, 403722-Verna, Goa – India.

Quality audit of the manufacturing facility was conducted through site visit on 19th – 20th October, 2023. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: Analytical sensitivity and Analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Zephyr Biomedicals. The following parameters were tested clinical sensitivity and clinical specificity.

Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Parascreen is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack



SYMBOL KEYS

	Temperature Limitation		Consult Instructions for use		Date of Manufacture		Do not reuse
	Manufacturer		In vitro Diagnostic Medical Device		This side up		Clearing Buffer
	Use by		Catalogue Number		Device		Do not use if package is damaged
	Contains sufficient for $n+1$ tests		Batch Number / Lot Number		Disposable Plastic Sample Applicator		
	Authorized Representative in the European Community				Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.		

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase II B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Website: www.tulipgroup.com Email: sales@tulipgroup.com

EC REP

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

032214/EN-03

6.3 Instructions for use/Package insert
See it on last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. Parascreeen is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
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No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date



parascreen®

RAPID TEST FOR MALARIA

Pan/Pf

DEVICE

INTENDED USE

parascreen® is a rapid, qualitative, two site sandwich immunoassay utilizing whole blood for the detection of *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) and Pan malaria specific pLDH. The test may also be used for the differentiation of *P. falciparum* and other malarial species and for the follow up of antimalarial therapy in whole blood samples. The test is intended for professional use at clinical and point of care sites in suspected cases of malaria infection.

SUMMARY

Five species of the Plasmodium parasites are responsible for malaria infections in human viz. *P. falciparum*, *P. vivax*, *P. ovale*, *P. malariae* and *P. knowlesi*. Of these, *P. falciparum* and *P. vivax* are the most prevalent. Early detection and differentiation of malaria is of utmost importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria and due to the morbidity associated with the other malarial forms.

parascreen® detects the presence of Pan malaria specific pLDH released from parasitised blood cells, for the detection of all malarial parasites. Whereas, for the detection of *P. falciparum* malaria, **parascreen®** utilises the detection of *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) which is a water soluble protein that is released from parasitised erythrocytes of infected individuals.

In the absence of *P. falciparum* specific Pf HRP-2, the presence of Pan malaria specific band points to the presence of other malarial species such as *P. vivax*, *P. ovale*, *P. malariae* or *P. knowlesi*. 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.

PRINCIPLE

parascreen® 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 colloidal gold conjugates of the Agglutinating sera for HRP-2 / 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 HRP-2 / Agglutinating sera for Pan malaria specific pLDH coated on the membrane leading to formation of pink-purple colored bands which confirms a positive test result. While both the bands will appear at the test region in falciparum positive samples, only one band will appear in non- falciparum malaria positive samples. 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

parascreen® kit contains:

A. Individual pouches, each containing:

1. **DEVICE** Test Device: Membrane assembly pre-dispensed with Agglutinating sera for HRP-2 - colloidal gold conjugate, Agglutinating sera for Pan malaria specific pLDH - colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for HRP-2, 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.

D. Pictorial representation.

Product codes	503160001	503160005	503160010	503160025	503160060	503160100
Pouch sealed tests	01	05	10	25	50	100
Clearing buffer bottles	01 x 1.25ml	01 x 2.0ml	01 x 3.0ml	01 x 4.0ml	02 x 4.0ml	04 x 4.0ml
Instructions for use	01	01	01	01	01	01

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

Size : 137 x 218 mm

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 1°C to 40°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 1°C to 40°C for the remaining duration of its shelf life.

NOTES

Read the instructions carefully before performing the test.

For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.

The test is not intended for use in screening of asymptomatic population.

Do not use beyond expiry date.

Do not intermix components of different lots.

The device & sample applicator are for single use only.

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.

Handle all specimens as potentially infectious.

Follow standard biosafety guidelines for handling and disposal of potentially infective material.

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 azides. 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 **parascreen®** 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. Place the testing device on a flat horizontal surface.
5. Tighten the cap of the clearing buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
6. 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'.

7. Immediately dispense **two drops** of clearing buffer into buffer port 'B', by holding the buffer bottle vertically.

8. 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 *P. falciparum* or mixed infection: In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pan' or only one pink-purple band appears at region 'Pf'.



POSITIVE for Other species (non falciparum): In addition to the control band, one pink-purple band appears only at region 'Pan'.



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

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

Size : 137 x 218 mm

PERFORMANCE CHARACTERISTICS

In an in-house study, a panel of 251 samples whose results were earlier confirmed with microscopy were tested with **parascreen**. The results obtained are as follows:

Sample	Total No. of samples tested	parascreen		Sensitivity (%)	Specificity (%)
		Positive	Negative		
<i>P. falciparum</i> positive	16	16	0	100	-
<i>P. vivax</i> positive	25	25	0	100	-
Malaria negative	210	0	210	-	100

parascreen has been evaluated in Malaysia with *P. knowlesi* samples. The overall sensitivity was 82.2% with low, moderate and high parasitaemia samples.

LIMITATIONS OF THE TEST

- As with all diagnostic tests, the test result must always be correlated with clinical findings.
- 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).
- Any modification to the above procedure and/or use of other reagents will invalidate the test procedure.
- 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. **parascreen** uses HETEROEPHILIC BLOCKING REAGENT (HBR) to inhibit majority of these interferences.
- In case of mixed infection (*P. falciparum*, with other malarial species), both 'Pf' and 'Pan' malaria bands will be positive. Hence, differentiation of infection due to *P. vivax*, *P. ovale* or *P. malariae* cannot be done.
- 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.
- Usually, the '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.
- In *P. falciparum* malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
- HRP-2 levels, post treatment persists upto 15 days, the 'Pan' band can be used to monitor success of therapy in *P. falciparum* malaria cases.
- In a few cases, where the HRP-2 band is positive and the 'Pan' malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Retesting after 2 days is advised, in such cases.
- Do not interpret the test results beyond 30 minutes.
- As the sensitivity of HRP-2 detection in *Pf* Malaria is higher than that of pLDH (Pan), it is possible that in *Pf* Malaria positive cases only the 'Pf' band will appear without the appearance of 'Pan' band.
- In *Pf* infection cases that has been resolved through anti-malaria treatment, the Pan (pLDH) would turn negative while residual HRP-2 would continue to circulate in the patient for a week to 10 days giving a band at 'Pf' region.

WARRANTY

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

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- 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. Hyg.* 60(2), 173-176.
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- Palmer, C. J., (1998) Evaluation of OptiMAL test for rapid diagnosis of *Plasmodium vivax* and *Plasmodium falciparum*. *J. Clin. Microbiol.* 36(1) 203-206.
- 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.
- Data on file: Zephyr Biomedicals.

Size : 137 x 218 mm

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	In vitro Diagnostic Medical Device	This side up	Clotting Buffer
Use by	Catalogue Number	Device	Do not use if package is damaged
Contains sufficient for min tests	Batch Number / Lot Number	Disposable Plastic Sample Applicator	
EC REP	Authorized Representative in the European Community		Hazardous if mishandled. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.



Manufactured by:
Zephyr Biomedicals

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