

Quick Reference Guide

parascreen® Rapid test for the detection of Malaria Pan / Pf

Intended Use:		

parascreen® is a rapid, qualitative, two site sandwich immunoassay utilizing capillary and venous whole blood specimens of symptomatic patients for the detection of *P.falciparum* specific histidine rich protein-2 (Pf. HRP-2) and Plasmodium Lactate Dehydrogenase (pLDH) antigens produced by *P.falciparum*, *P.vivax*, *P.ovale* and *P.malariae* species. It is used in the diagnosis of malaria for differentiation of *P.falciparum* and other malaria species.

parascreen® is intended to be used by trained healthcare or laboratory professionals or other health care workers who have received appropriate training. This product can be used by trained lay providers operating at point-of-care in resource-limited settings. This product is not intended for self-testing and it is not for blood donor screening. The test is not automated; it needs to be performed and interpreted manually by the user.

parascreen® kit components:

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.	
Buffer	Ready to use buffer in a dropper bottle	
Sample Applicator	Disposable inverted cup sample applicator	
Other Accessories	Desiccant pouch, Package insert, Pictorial instructions for use, Alcohol swab and Sterile lancet	

Performance Characteristics:

nsitivity: 100% correlation with microscop	Specificity: 100% specific to <i>P.falciparum</i> HRP-2 and pan specific pLDH
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FEATURES	BENEFITS
Uses monoclonal antibodies against Pf. HRP-2 and pan specific pLDH	Sensitivity and specificity in excess of 98% for <i>P. falciparum</i> and all other malarial species
Employs Heterophile Binding Reagent (HBR)	Tests results are interference protected
Uses whole blood from finger prick or primary tube, as a sample	Well suited for field conditions, on-site diagnosis, pathological labs and reference labs, alike.
Composite kit	No additional material required for testing
Easy to use	Simple 20 minutes assay, storage at 4-40° C

Storage / Stability	Temperature	Duration
Unopened kit/pouch	4-40°C	24 Months
Opened pouch	Room Temperature	Use immediately

Available Pack Sizes		
10 Tests	25 Tests	
50 Tests	100 Tests	

