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:

<table>
<thead>
<tr>
<th>Device</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer</td>
<td>Ready to use buffer in a dropper bottle</td>
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<tr>
<td>Sample Applicator</td>
<td>Disposable inverted cup sample applicator</td>
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<tr>
<td>Other Accessories</td>
<td>Desiccant pouch, Package insert, Pictorial instructions for use, Alcohol swab and Sterile lancet</td>
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</tbody>
</table>

Performance Characteristics:

| Sensitivity: 100% correlation with microscopy | Specificity: 100% specific to *P.falciparum* HRP-2 and pan specific pLDH |

FEATURES | BENEFITS
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Uses monoclonal antibodies against Pf. HRP-2 and pan specific pLDH | Sensitivity and specificity in excess of 98% for *P. falciparum* 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 | Available Pack Sizes
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Unopened kit/pouch | Room Temperature | Use immediately | 10 Tests
Opened pouch | 4-40°C | 24 Months | 25 Tests
| Room Temperature | 50 Tests
| 100 Tests