### Malaria Rapid Diagnostic Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product code(s)</th>
<th>Manufacturer name</th>
<th>Dossier review</th>
<th>Quality Management System review</th>
<th>Product performance evaluation</th>
<th>Labelling review</th>
<th>Application number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareStart Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT</td>
<td>RMWM-02571, RMWM-02571RI, RMWM-02571CB, RMWM-02571RB, RMWM-05071, RMWM-05071RI, RMWM-05071CB, RMWM-05071RB, RMU-02571, RMU-02571RI, RMU-02571CB, RMU-02571RB, RMU-04071, RMU-04071RI, RMU-04071CB and RMU-04071RB.</td>
<td>Access Bio Inc.</td>
<td>R</td>
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<td></td>
<td>PQDx 0339-049-00</td>
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<tr>
<td>Advantage P.f Malaria Card</td>
<td>IRC16025</td>
<td>J.Mitra &amp; Co. Pvt. Ltd.</td>
<td></td>
<td></td>
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<td>R</td>
<td>PQDx 0472-062-00</td>
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<tr>
<td>BIOCREDIT Malaria Ag Pf (pLDH)</td>
<td>C14RHG25 and C14RH25</td>
<td>RapiGen Inc.</td>
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<td>PQDx 0483-160-00</td>
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<tr>
<td>BIOCREDIT Malaria Ag Pf (pLDH) HRP II</td>
<td>C13RHG25 and C13RH25</td>
<td>RapiGen Inc.</td>
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<td>PQDx 0482-160-00</td>
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<tr>
<td>BIOCREDIT Malaria Ag Pf/Pv (pLDH)</td>
<td>C61RHG25 and C61RH25</td>
<td>RapiGen Inc.</td>
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<td>PQDx 0478-160-00</td>
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<tr>
<td>ONE STEP Malaria (Pf) Test</td>
<td>ITPW11007-TC25 and ITPW11007-TC40</td>
<td>InTec Products, Inc.</td>
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<td>PQDx 0626-017-00</td>
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<tr>
<td>ONE STEP Malaria (Pf/Pv) Tri-line Test</td>
<td>ITPW11009-TC25 and ITPW11009-TC40</td>
<td>InTec Products, Inc.</td>
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<td>PQDx 0627-017-00</td>
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<tr>
<td>Wondfo Malaria P.f (HRP2/pLDH) Test</td>
<td>W037P0022, W037P0025, W037P0030, W037P0024, W037P0033, W037P0035 and W037P0037.</td>
<td>Guangzhou Wondfo Biotech Co., Ltd.</td>
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<td>PQDx 0651-004-00</td>
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</tbody>
</table>

Please note: these tables are updated regularly, while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement. Information may not yet be reflected here.

*cut update: 12 November 2022
https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment

# The product was prequalified and a change request was submitted and accepted to add an intended use claim.

Last update: 17 November 2022
https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment

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