Quality Assurance (QA) for Health Products

QA Information Notice

IN No 2018-03
Version: 1/10/2018

ELIGIBILITY REINSTATED FOR PRODUCTS MANUFACTURED BY DIAGNOSTICS FOR THE REAL WORLD

SAMBA HIV-1 Semi-Q Test for use with SAMBA I instrument
SAMBA II HIV-1 Semi-Q Test for use with SAMBA II instrument

Addressees

- Any person using the products for clinical decision making in the intended use
- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The Global Fund QA team is issuing this information notice to provide notice of the reinstatement of the eligibility of the following products.

Identification of the product(s) and manufacturer

<table>
<thead>
<tr>
<th>Name of Manufacturer</th>
<th>Diagnostics for the Real World (DRW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>SAMBA HIV-1 Semi-Q Test for use with SAMBA I instrument &amp; SAMBA II HIV-1 Semi-Q Test for use with SAMBA II instrument</td>
</tr>
<tr>
<td>Product Code</td>
<td>4100-12 for SAMBA HIV-1 Semi-Q Test 4400-12 for SAMBA II HIV-1 Semi-Q Test</td>
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<tr>
<td>Packaging &amp; Pack size</td>
<td>12 tests per kits</td>
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<tr>
<td>Batch(es)</td>
<td>All batches</td>
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<tr>
<td>Expiry Date</td>
<td>n/a</td>
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Background

The manufacturer Diagnostics for the Real World (DRW) was listed on the Global Fund list of eligible products based on stringent assessment by a regulatory authority in compliance with section 8 (iii) of the Global Fund Quality Assurance Policy for Diagnostic Products.
The products were CE marked in March and June 2016. During a general manufacturer file update the manufacturer provided documentation that triggered a detailed investigation on products procured within Global Fund grants. Pending clarification of the issues raised, the Global Fund decided to temporary delist the products of the SAMBA Semi-Q product family. No incident with regards to these products has been reported to Global Fund from regulatory authorities or principal recipients.

Upon request of the GF Quality Assurance team, the manufacturer Diagnostics for Real World provided the requested evidence that the above mentioned products are compliant with the GF Quality Assurance Policy for Diagnostics Products.

**Nature of defect(s)**

Not applicable

**Action/Investigations taken**

Not applicable

**Next Steps**

Based on the evidence provided, the above mentioned products will be relisted in the next version of the Global Fund List of Diagnostics products found compliant with the Quality Assurance Policy for Diagnostics Products. The above mentioned products may thus be procured by Global Fund principal recipients with Global Fund funding.

This information will be disseminated in the same way and to the same distribution list as for the initial Information Notice.

**Contacts**

This IN does not require specific written response from PR.

Please direct the respective answers and any questions about this matter to the technical contacts listed below

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Name / Function</th>
<th>E-mail address</th>
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</thead>
<tbody>
<tr>
<td>Global Fund</td>
<td>René Becker-Burgos, QA Specialist Diagnostic Products</td>
<td><a href="mailto:Rene.Becker-Burgos@theglobalfund.org">Rene.Becker-Burgos@theglobalfund.org</a></td>
</tr>
<tr>
<td>Global Fund</td>
<td>Alain Prat, QA Team Lead</td>
<td><a href="mailto:Alain.Prat@theglobalfund.org">Alain.Prat@theglobalfund.org</a></td>
</tr>
<tr>
<td>Global Fund</td>
<td>Eileen Burke, Laboratory Specialist</td>
<td><a href="mailto:Eileen.burke@theglobalfund.org">Eileen.burke@theglobalfund.org</a></td>
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René Becker-Burgos, Quality Assurance Specialist Diagnostic Products