Product name: Various malaria rapid diagnostic tests (RDTs) manufactured by Access Bio, Inc.; Premier Medical Corporation; Standard Diagnostics, Inc. that contain single-use buffer ampulla (listed in Annex 1).

WHO-identifier: 2014/01, version 4

Type of action: Advice to users

Date: 18/12/2014 (revised 16/01/2015)

Attention: National malaria control programme managers and their implementing partners, procurement agencies, national regulatory authorities for IVDs and national reference laboratories

Details on affected IVDs:

It has been reported to WHO that the stability of individual single-use buffer ampulla for certain malaria rapid diagnostic tests (RDTs) is less than the stability stated on the test kit box label. A total of 55 lots of nine different test kits from three manufacturers (Access Bio, Inc.; Premier Medical Corporation; Standard Diagnostics, Inc.) are now known to have been affected during 2013-2014.

Description of the problem:

Following stability testing as part of the WHO-FIND Malaria RDT Lot Testing Programme, it was observed that buffer stored within single-use buffer ampulla had evaporated from a significant number of buffer ampulla after 18 months storage at 37 °C. As there was no buffer left, the test procedure was unable to be performed, and thus the test was unusable.

WHO has been working with each of the manufacturers to resolve this issue, in accordance to international best practice for post-market surveillance of in vitro diagnostics. Thus far, each of the manufacturers has been very cooperative with requests to undertake their own investigation and in respecting timelines.

However, an appropriate field safety corrective action (FSCA) has still not been agreed upon and so as an interim measure, WHO is releasing this WHO Information Notice for Users to alert users in the field to potential problems they may encounter with products including the individual/single-use buffer ampullas.

Therefore, until an acceptable FSCA is agreed and implemented, WHO suggests that procurers and implementing partners should consider alternative options to the procurement of any test kits that contain single-use buffer ampulla, e.g. purchasing of multi-use test kits where buffer is supplied in a larger volume (a buffer vial/bottle) as these larger buffer containers are less likely to be affected by this problem. This suggestion applies to any future and on-going procurement.
Advice on action to be taken by end-users:

- For any test kits containing single-use buffer ampulla that are currently in use:
  - Quarantine any test kits that contain single-use buffer ampulla;
  - Of the quarantined test kits, verify the amount of buffer left remaining;
    - If there is *sufficient buffer volume* in the buffer ampulla to perform the test *according to the manufacturer’s instructions for use*, use the test;
    - If there is *insufficient buffer volume* in the buffer ampulla to perform the test *according to the manufacturer’s instructions for use*, do not use the test;
    - If the buffer ampulla *appears to be empty*, do not use the test.
  - Do not use buffer from any other product (whether it be another malaria RDT or any other RDT) to run the test.
  - *Send a notification to the manufacturer* with details of product code, lot number and expiry date and the number of buffer ampulla affected, ideally with photographic evidence.
  - *Send a notification to WHO* via email ([diagnostics@who.int](mailto:diagnostics@who.int)) using the WHO IVD complaint form available at the following link http://www.who.int/diagnostics_laboratory/procurement/complaints/en/

Advice on action to be taken by procurers and their implementing partners:

- Discontinue pending or future procurement of any test kits containing single-use buffer ampulla, until further notice.

The above recommended action(s) are to be taken by all recipients of this Information Notice for Users.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and comply with documented evidence to assist the manufacturers in their forthcoming Field Safety Corrective Actions.

WHO reserves the right to update this information notice for users at a later date.

Contact person for further information:

Anita SANDS, Prequalification Team – Diagnostics, World Health Organization

email: sandsa@who.int
Annex 1 – Products containing buffer ampulla known to be affected based on reports from WHO-FIND Malaria RDT Lot Testing Programme.

Please note that all lots of the below listed product codes and any other products containing the buffer ampulla may also be affected.

<table>
<thead>
<tr>
<th>Manufacturer name</th>
<th>Product name</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access Bio, Inc.</td>
<td>CareStart™ Malaria HRP2 Single Kit Test</td>
<td>G0141-SK</td>
</tr>
<tr>
<td></td>
<td>CareStart™ Malaria HRP2/pLDH (Pf/pan) Combo</td>
<td>G0131-SK¹</td>
</tr>
<tr>
<td>Premier Medical Corporation</td>
<td>Malacheck Malaria Ag (pLDH/HRP2) Combo Card Test</td>
<td>I16MCC10</td>
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<td></td>
<td>First Response Malaria Ag pLDH/HRP2 Card Test</td>
<td>I16FRC30</td>
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<td>First Response Malaria Ag P. falciparum</td>
<td>I13FRC25S</td>
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<td>HRP2 Card Test</td>
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<tr>
<td>Standard Diagnostics, Inc.</td>
<td>SD Bioline Malaria Pf/Pan POCT</td>
<td>05FK63</td>
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<tr>
<td></td>
<td>SD Bioline Malaria Pf/Pan POCT</td>
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<tr>
<td></td>
<td>SD Bioline Malaria Pf/Pv POCT Rapid Test</td>
<td>05FK80 POCT</td>
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</tbody>
</table>

¹ *A customer requested ad-hoc test kit configuration of 25 test devices and 25 single-use buffer ampulla. These two particular lots were affected by this complaint under the product code G0131. However, G0131 does not usually contain single-use buffer ampulla.

Date of issue of this notice, 16 January 2015