Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2020-01 **Version: 30/01/2020**	**Serious Quality Management System issues reported on the manufacturing site of Access Bio Inc located 65 Clyde Rd. Suite A, Somerset, NJ 08873 (USA)**

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 is issuing this QA Information Notice to provide recommendations and advice regarding the Notice of Concern (NoC) issued by the WHO Prequalification Team regarding products supplied by Access Bio Inc (ABI) at the manufacturing site located at 65 Clyde Rd. Suite A, Somerset (USA) as well as Access Bio Ethiopia (ABE) located Yeka Sub-City, Woreda 9, Kebele 16, House No-New, Addis Ababa (Ethiopia).

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer / Location Manufacturing Site	**Access Bio Inc. 65 Clyde Rd. Suite A, Somerset, NJ 08873 (USA)** **Access Bio Inc. Ethiopia, Yeka Sub-City, Woreda 9, Kebele 16, House No-New, Addis Ababa (Ethiopia)**
Product Name	CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO CareStart™ Malaria HRP2 (Pf) CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO CareStart™ Malaria HRP2/pLDH (Pf) CareStart™ Malaria pLDH (PAN) CareStart™ G6PD
Product Code	**All**
Packaging & Pack size	**All**
Batch(es)	**All**

Background

On the 17th January, the WHO Prequalification Team from the Access to Medicines and Health Products Division issued a Notice of Concern on the manufacturing site of the manufacturer Access Bio Inc (ABI), located 65 Clyde Rd. Suite A, Somerset (USA).

The notice refers to inspections by the WHO Prequalification team identifying several critical and major non-conformities with the most critical non-conformities raised against control of production (lack of traceability, lack of data integrity and lack of well-established quality management systems) and service provision. As outlined in the WHO PQ Notice of Concern, the identified non-conformities could have an impact on patient safety.

This notice applies de facto, to the manufacturing activities performed at the Ethiopian site, located Yeka Sub-City, Woreda 9, Kebele 16, House No-New, Addis Ababa (ABE) which is performing packaging and labelling of intermediate products supplied by Access Bio Inc.

This notice currently impacts the Global Fund list of eligible products based on WHO Prequalification for Diagnostics Products as well as the product temporary eligible under ERP mechanism (CareStart™ G6PD).

One potential quality issues with regards to one specific products has been reported to Global Fund from Tanzania in 2016 and are still under investigations by WHO.

In addition to the Notice of concern related to the manufacturing site, WHO issued a Notice for users to alert procurers and users.

Nature of defect(s)

Details of defect or problem.	**Critical deficiencies of the quality management system implementation**
Is there any evidence or suspicion of a risk to public health / patient safety?	**For malaria RDTs: Potential misclassification of people infected with plasmodium parasites as being uninfected and not receiving approriate malaria treatment.** **For G6PD: False negative results for G6PD deficiency will lead to unsafe primaquine administration of short administration regimen (14 days) which can lead to hemolytic anemia**
Extent of the problem (eg. how many batches).	**All products manufactured at the above-mentioned manufacturing sites**
Extent of distribution of the product / batch (es).	**Worldwide distribution to Global Fund principal recipients.** **G6PD RDT distribution is limited to the following countries based on current data available:** • **Cambodia, Cape Verde, Laos, Myanmar, Sri Lanka, Timor-Leste and Vanuatu**
Number of patients potentially impacted	**No impacted patients reported to The Global Fund at this moment in time.**

Action/Investigations taken

- Global Fund QA has been informed of the Notice of Concern by WHO and is following the ongoing WHO PQ investigations
- Revised the list of eligible products for procurement with GF Funds.

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by The Global Fund QA:

- **Do not recall** the above referenced products and maintain distribution of the products within the supply chain until the end destination;
- **Stop any new procurement** of above referenced products and replace with other eligible products. Please refer to GF list of eligible Malaria RDTs available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/
- **Assess orders in process** and avoid cancellation given the negative consequences that delays and stock outs would cause country programs
- Health workforce is requested to **check carefully** the color-indicating desiccant / silica gel sachets to ensure that the products is fit for purpose, if necessary with additional light source before usage.
- For the above mentioned products already in the field, national malaria programs are advised to disseminate this information to health care workers to **increase vigilance** of potential product deficiencies or patient level adverse events including false negative tests.
- Specific advice can be provided to Recipients by Global Fund Secretariat in case lack of availability of alternative eligible products such as for G6PD Rapid Diagnostics Tests to assess the country risk from a patient perspective;
- The PR should **liaise with National Regulatory Authority** to reinforce the importance of vigilance activities in their respective market. Further advice can be found in the WHO Notice for users available at the following WHO website: https://www.who.int/diagnostics_laboratory/procurement/accessbioinc_20012020_noticeforusers.pdf?ua=1;
- As a reminder, Recipients have the possibility **to make a complaint** about the product with the manufacturer by using for example the "Complaints and Product Alerts" form available on the following WHO website: http://www.who.int/diagnostics_laboratory/postmarket/en/. The PR shall copy The Global Fund QA on any customer complaints communicated to the manufacturer.

Contacts

This IN does not require specific written response from PR. PRs should copy The Global Fund QA Team of any correspondence regarding the matter for follow-up.

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

Organisation	**Name / Function**	**E-mail address**
Global Fund	René Becker-Burgos, QA Specialist Diagnostic Products	Rene.Becker-Burgos@theglobalfund.org
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