World Health Organization

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In reply please refer to: P5-447-3/JG/EB/1

Your reference:

Dr Seung-Uk Yoo
Access Bio Inc
65 Clyde Road, Suite A
Somerset, NJ 08873
Etats Unis d'Amérique

17 January 2020

Dear Dr Yoo,

WHO Prequalification of In Vitro Diagnostics – Notice of Concern
Access Bio Inc, 65 Clyde Rd. Suite A, Somerset, NJ 08873, USA.

Product:	**PQDx Number:**
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	0136-049-00
CareStart™ Malaria HRP2 (Pf)	0137-049-00
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	0138-049-00
CareStart™ Malaria HRP2/pLDH (Pf)	0188-049-00
CareStart™ Malaria pLDH (PAN)	0234-049-00
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	0339-049-00
CareStart™G6PD	0368-049-00

I refer to the various communication between Access Bio Inc and the WHO Prequalification of In Vitro Diagnostics Programme. In accordance with the requirements of the said Programme, routine inspections of Access Bio Inc, the site of manufacturing of the above-mentioned products, were conducted by the WHO Prequalification Team: Inspections from 25 to 28 June 2018 and from 25 to 27 November 2019 respectively.

During the said inspections, several nonconformities were identified with the most critical non-conformities raised against control of production (lack of traceability, lack of data integrity, lack of a well-established quality management system) and service provision. It is the view of the Prequalification In Vitro Diagnostics Programme that the identified non-conformities could impact on patient safety.

The manufacturer was given an opportunity to submit proposals for corrective action plans. It is acknowledged that since the June 2018 inspection some improvements had been made, however the overall effectiveness of the quality management system at Access Bio Inc. remains inadequate.

Based on these findings, the WHO Prequalification of In Vitro Diagnostics Programme is working with procurers to perform extra risk management and quality assurance measures when they procure the current prequalified products. In addition, WHO has suspended the evaluation of products undergoing prequalification assessment. These measures will remain in effect until the nonconformities identified during the said inspections have been satisfactorily addressed and WHO has verified and confirmed the acceptability of the Access Bio Inc. corrective actions.

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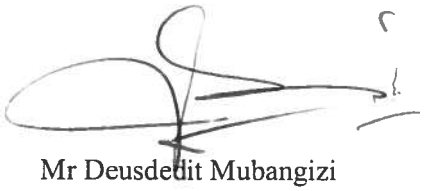
Should you wish to comment on this Notice of Concern, you are advised to email the undersigned, with details, to prequalinspection@who.int by close of business 15 January 2020. The matter will be investigated and unless advised otherwise, you can expect to receive a response within 15 working days. All feedback will be treated in confidence and without prejudice.

Publication of this Notice of Concern

In accordance with WHO procedures, WHO will publish this Notice of Concern on the WHO website. Please note that a Notice of Concern will remain active on the WHO website until WHO has confirmed the requirements for WHO Prequalification of Diagnostics have been fulfilled.

Yours sincerely,



Mr Deusdedit Mubangizi
Unit Head, Prequalification
Regulation and Prequalification Department
Access to Medicines and Health Products Division