World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3927
Fax direct: +41 22 791 4836
E-mail: diagnostics@who.int

In reply please refer to: AZ/df

Your reference: P17-370-9

Acon Biotech (Hangzhou) Co. Ltd
Attention: Ms Alyssa Lu
RA Manager
No. 210 Zhenzhong Road, West Lake District
Hangzhou, 310030
République Populaire de Chine

4 April 2022

Dear Ms. Lu,

Subject: WHO Emergency Use Listing (EUL): Product eligible for listing

Product name: SARS-CoV-2 Antigen Rapid Test *(Flowflex)*
Application number: EUL 0597-021-00
Product codes: L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5 and L031-129Y5 (confirmed from LoA and IFU)
Regulatory version: CE Mark Regulatory version (MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany)

We are pleased to inform you that the above-referenced product was listed as eligible for WHO procurement on **4 April 2022.** The EUL listing can be leveraged by other international, regional and national procurement agencies. The product will be eligible for procurement for 1 year, unless circumstances dictate otherwise.

Please be advised that the on-going eligibility status of the above-referenced product depends on fulfilling the commitments to EUL listing identified in the "Dossier review complete" letter sent **30 March 2022.**

The following activities are required to maintain the eligibility status:

1. Notification to WHO of any planned changes to the above-referenced product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic*" (document number PQDx_121); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

Failure to comply with any of the above-mentioned requirements may lead to remedial action by WHO, including but not limited to, de-listing from the WHO EUL procedure list of eligible in vitro diagnostics products.

The draft public report will be sent to you for review. The final public report with an outcome of the review, any commitments to EUL listing, instructions for use and labelling will be published on our website.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+4122 791 3927).

Yours sincerely,

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