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In reply please  
refer to: DH/sh

Your reference: P17-370-9

Shanghai ZJ Bio-Tech Co., Ltd  
Attention: Mr Walter Zhang  
Assistant President  
Shanghai ZJ Bio-Tech Co., Ltd.  
Building #26, 588 Xinjunhuan Road  
Shanghai 201114  
République populaire de Chine

22 May 2020

Dear Mr Zhang,

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

**Product name:** Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit

**Application number:** EUL 0486-139-00

**Product codes:** RR-0485-02

**Regulatory version:** Rest of World

We are pleased to inform you that the above-referenced product was listed as eligible for WHO procurement on **22 May 2020**. 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 **18 May 2020**.

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 “*WHO guidance on post-market surveillance of in vitro diagnostics*” (ISBN 978 92 4 150921 3).

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 in the coming days 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