WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs
PUBLIC REPORT

Product: Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
EUL Number: EUL 0593-004-00
Outcome: Not Recommended.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:


Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) with product codes W196P0003 (20 Tests) and W196P0004 (100 Tests), manufactured by Guangzhou Wondfo Biotech Co., Ltd, 8 Lizhishan Road, Science City Luogang District, Guangzhou 510663, China, is not eligible for WHO procurement.

Product dossier assessment

Guangzhou Wondfo Biotech Co., Ltd submitted a product dossier for Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid or antigen (PQDx_347)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external product evaluating assessor appointed by WHO.

Based on the review of the submitted product dossier documentation by WHO staff and an external technical expert (assessor), it was established that insufficient information was provided by Guangzhou Wondfo Biotech Co., Ltd to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid or antigen, PQDx_347.”