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

Product: SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method)
EUL Number: EUL 0490-186-00
Outcome: Not Accepted.

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:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method), with product code 1.10.11.09.NC.02, manufactured by ZYBIO INC., Floor 3, Building J, No. 70-1, 70-2 of Keyuan 4th Street, Jiulongpo District, Chongqing Municipality, 400039, China, is not eligible for WHO procurement.

Product dossier assessment

ZYBIO INC., submitted a product dossier for SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method) as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff.

Upon review of the submitted documentation by ZYBIO INC., in support of a dossier assessment review, the information submitted did not constitute adequate evidence of compliance of the documentary evidence of safety and performance as described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347*."