

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

Product: SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescent RT-RAA)

EUL Number: EUL 0512-199-00

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 (Fluorescent RT-RAA) with product code F02R13A-48, manufactured by Jiangsu Qitian Gene Biotechnology Co., Ltd., Room 501 of Zone B, Room 208 of Zone A, Xingye Building, Sensing Network, University Science Park, Taihu International Science Park, Linghu Avenue 97-1, Xinwu District, Wuxi, Jiangsu, China, is not eligible for WHO procurement.

Product dossier assessment

Qitian Gene Biotechnology Co., Ltd. submitted a product dossier for SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescent RT-RAA) 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 Jiangsu Qitian Gene Biotechnology Co., Ltd 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.*"

Quality Management Systems Review

To establish the eligibility for WHO procurement, Jiangsu Qitian Gene Biotechnology Co., Ltd was asked to provide up-to-date information about the status of their quality management system.

Upon review of the submitted documentation by Jiangsu Qitian Gene Biotechnology Co., Ltd in support of a desk assessment on the Quality Management System of the manufacturer, the information submitted did not constitute adequate evidence of compliance with ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes and the requirements described in the *“Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347”*.