WHO Emergency Use Assessment SARS-CoV-2  IVDs
PUBLIC REPORT

Product: SARS-CoV-2 Nucleic acids detection kit based on  Real Time PCR platform
Manufacturer: Tellgen Corporation, Shanghai
EUL Number: EUL 0517-204-00
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:


SARS-CoV-2 Nucleic acids detection kit based on Real Time PCR platform with product codes PGA4102P1 (liquid) and PGA4102P2 (lyophilized) manufactured by located at Building 1, No. 115, Lane 572, Bibo Road Pilot Free Trade Zone, Shanghai, China, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement extension, Tellgen Corporation, Shanghai was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that insufficient information was provided by Tellgen Corporation, Shanghai 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.”