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

Product: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)
Manufacturer: Shenzhen Ultra-Diagnostics Biotec.Co.,Ltd.
EUL Number: EUL 0605-245-00
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:


Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) with product codes SC0201, SC0202, SC0203, and SC0204, manufactured by Shenzhen Ultra-Diagnostics Biotec.Co.,Ltd, located at Room 701 No.71-3, Xintian Avenue Xintian Community, Fuhai Street Baoan District, 3018103 Shenzhen China is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Shenzhen Ultra-Diagnostics Biotec.Co.,Ltd 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 Shenzhen Ultra-Diagnostics Biotec.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.”