

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

Product: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

EUL Number: EUL 0582-223-00

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:

- 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 Antigen Rapid Test Kit (Colloidal Gold) with product code G10313, manufactured by JOYSBIO (Tianjin) Biotechnology Co., Ltd., Tianjin International Joint Academy of Biotechnology & Medicine, 9th floor, No. 220 Dongting Road, TEDA 300457, Tianjin, China, is not eligible for WHO procurement.

Product dossier assessment

JOYSBIO (Tianjin) Biotechnology Co., Ltd submitted a product dossier for SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) 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 external product evaluating assessor appointed by WHO.

Based on the review of the submitted product dossier documentation by WHO staff and external technical experts (assessors), it was established that insufficient information was provided by JOYSBIO (Tianjin) Biotechnology 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*".