WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT
Product: SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)
Manufacturer: BGI Europe A/S
EUL Number: EUL 0630-191-00
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 Virus Antigen Detection Kit (colloidal gold method) with product code MFG030026 manufactured by BGI Europe A/S, located at Ole Maaløes Vej 3, DK-2200 Copenhagen, Denmark, is not eligible for WHO procurement.

Product dossier assessment

BGI Europe A/S submitted a product dossier for SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method) as per “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid or antigen (PQDx_0347). 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 BGI Europe A/S 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.