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

Product: QuantuMDx SARS-CoV-2 RT-PCR Detection Assay
EUL Number: EUL 0570-229-00
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:


QuantuMDx SARS-CoV-2 RT-PCR Detection Assay with product code Q22003, manufactured by QuantuMDx Group Ltd, Lugano Building, 57 Melbourne Street, Newcastle upon Tyne, NE1 2JQ, United Kingdom, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, QuantuMDx Group 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 QuantuMDx Group Ltd to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347.”