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

Product: COVID-19 IgM/IgG test kit (Rare earth nano fluorescence immunochromatography)
EUL Number: EUL 0574-231-00
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:


COVID-19 IgM/IgG test kit (Rare earth nano fluorescence immunochromatography) with product code RF01Ab-25, manufactured by Xiamen AmonMed Biotechnology Co., Ltd., 120 Xinyuan Road, Haicang District, Xiamen, China, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Xiamen AmonMed Biotechnology 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 Xiamen AmonMed Biotechnology Co., Ltd. to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics detecting antibodies to SARS-CoV2 virus, PQDx_ 357.”