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

Product: VivaDiag SARS-CoV-2 Ag Rapid Test
Manufacturer: VivaChek Biotech (Hangzhou) Co., Ltd
EUL Number: EUL 0592-222-00
Outcome: Not Accepted.

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:


VivaDiag SARS-CoV-2 Ag Rapid Test with product code VCD05-01-011, manufactured by VivaChek Biotech (Hangzhou) Co., Ltd, located at Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, 311100, Zhejiang, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, VivaChek Biotech (Hangzhou) 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 VivaChek Biotech (Hangzhou) 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.”