

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

**Product: Smart *Detect* SARS-CoV-2 rRT-PCR Kit**

**EUL Number: EUL 0505-145-00**

**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:

- 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.

Smart Detect SARS-CoV-2 rRT-PCR Kit, with product code COV2-E, manufactured by INBIOS INTERNATIONAL INC., 16, 562 1st Ave. South, Suite 600 Seattle, WA 98104, United States of America, is not eligible for WHO procurement.

### Product dossier assessment

INBIOS INTERNATIONAL INC., submitted a product dossier for Smart Detect SARS-CoV-2 rRT-PCR Kit as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx\_0347)*". The information (data and documentation) submitted in the product dossier was reviewed by WHO staff.

Upon review of the submitted documentation by INBIOS INTERNATIONAL INC., in support of a dossier assessment review, the information submitted did not constitute adequate evidence of compliance of the documentary evidence of safety and performance as described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx\_ 347.*"