Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATION

To Whom This May Concern

This is to certify that the **SARS-CoV-2 Antigen Rapid Test (Immunochromatography) (Self-test kit) (Specimen: Nasal Swab)** manufactured by Labnovation Technologies, Inc. – 101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518107, China has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has Special Approval fromFederal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM) of Germany.

With this approval, the company is required to provide the general public with visual aids/ graphic aids and/or video tutorial on the proper performance of the test from specimen collection to results interpretation.

The result of the performance evaluation conducted by the Biomex GmbH, Heildelberg Germany as recommended by the Research Institute for Tropical Medicine (RITM) are 97.45% diagnostic sensitivity and 100% diagnostic specificity. The product complied with the required specificity >80% and sensitivity >97%, based on the FDA Memorandum 2021-009.

This certification is issued upon the request of **CLEARBRIDGE MEDICAL PHILIPPINES INC.** with business address at #33 V. Luna Ave., Barangay Pinyahan, Quezon City for whatever legal purpose this may serve.

This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

This certificate shall be valid for one year and shall expired on January 24, 2023.

Done this 24th January 2022 at Alabang, Muntinlupa City.

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health, and Research

Not valid without FDA Seal

Seq No. : 28000
Amount : PhP 510.00
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CONFIDENTIAL
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