

## 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 Panbio™ COVID-19 Antigen Self-Test (Ref. 41 FK51 / Ref. 41 FK71 / Ref. 41FK81 / Ref. 41FK91) (Specimen: nasal swab) manufactured by Abbott Rapid Diagnostics Jena GmbH - Orlaweg 1 07743 Jena, Germany has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has confirmed CE Marking by Thuringian State Office for Consumer Protection 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 Ministry of Health, National Institute of Hygiene and Epidemiology (NIHE, Vietnam) as recommended by the Research Institute for Tropical Medicine (RITM) are 83.3% 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 SUNFU SOLUTIONS INC. with business address at Unit 615 City and Land Megaplaza, ADB Ave., Ortigas Center, Pasig 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

28000 Seg No.

PhP 510.00 Amount 10 January 2022 Date

SC-2022-010

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