



CERTIFICATION

To Whom This May Concern:

This is to certify that the **STANDARD™ Q COVID-19 Ag TEST (Specimen: Nasal Swab)** manufactured by SD Biosensor, Inc.-C-4&5 Floor, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has Provisional Authorization from Health Sciences Authority (HSA) of Singapore. With this approval, the company is required to indicate in the product label or in the accompanying product insert the following statement:

"This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required"

The result of performance evaluation conducted by the Foundation for Innovative Diagnostics (WHO-FIND) as recommended by the Research Institute for Tropical Medicine (RITM) is 84.6% diagnostic sensitivity and 99.3 % diagnostic specificity. The product complied with the required sensitivity >80% and specificity >97%, based on the FDA Memorandum 2021-009.

This certification is issued upon the request of **TRULABORATORIES CORPORATION** with business address at 14 Detroit St., Brgy. Pinagkaisahan, Cubao, 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 August 24, 2022.

Done this 24th August 2021 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. : 42021266647

Amount : PhP 510.00

Date : 20 April 2021

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