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 Kit (Specimens: Nasopharyngeal swabs, anterior nasal swab)** manufactured by Triplex International Biosciences (China) Co., Ltd.– Triplex Biological Park, No.2041 Xizhou Road, Xike Town, Tongan District, Xiamen, Fujian, China has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has a Product Registration from National Institute of Pharmacy and Food Health (hereinafter: OGYEI) of Hungary. 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 Department of Pathology-Faculty of Medicine, Prince of Songkla University in Thailand as of November 26, 2021 as recommended by the Research Institute for Tropical Medicine (RITM) is 95% diagnostic sensitivity and 100% 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 [redacted] with business address [redacted] 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 July 29, 2023.

Done this 29th July 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. : 52422435644
Amount : PHP 510.00
Date : 24 May 2022
SC-2022-224
DTN: 20220524132430
/009

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

July 29, 2022

[redacted]

[redacted]

This refers to the letter of Research Institute for Tropical Medicine (RITM) regarding the performance evaluation of your product **SARS-CoV-2 Antigen Rapid Test Kit Product number: K511416D** manufactured by: Triplex International Biosciences (China) Co., Ltd endorsing and recommending the recognition of the performance evaluation conducted by Ramathibodi Hospital, Mahidol University in Thailand as of April 23, 2021. Based on performance validation result, RITM will not conduct performance evaluation of your product.

Parameter	Value
Sensitivity	88.9%
Specificity	100%

Very truly yours,

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health and Research
/009

DTN: 20220524132430