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 **ARIA SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) (Specimen: nasal swab)** manufactured by: Beijing Lepu Medical Technology Co., Ltd– 3th Floor and 5th Floor Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has a Product Registration from Ministry of Health, Welfare and Sport of Netherlands. 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 Ramathibodi Hospital, Mahidol University in Thailand as of June 2021 as recommended by the Research Institute for Tropical Medicine (RITM) is 90% diagnostic sensitivity and 100% diagnostic specificity. The product complied with the required sensitivity $\geq 80\%$ and specificity $\geq 97\%$, based on the FDA Memorandum 2021-009.

This certification is issued upon the request of **LABX CORP**. with business address at Ground Floor, Unit-A, Clipp Center Building, 11th ave. cor 39th Street, BGC, Taguig 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 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. : 121620216136/ 72122464953
Amount : PhP 510.00
Date : December 16, 2020/ July 21, 2022
SC-2022-203
DTN: 20201215133305/ 20220719133832
/009
/REISSUANCE

FDA-0605564