PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran Apec,
63000 Cyberjaya, Selangor
Malaysia.

Tel: (+603)8230 0300
Faks: (+603)8230 0200
Portal Rasmi: www.mda.gov.my
Email: mdb@mda.gov.my

Ref : (15) MDA.600.1/6/29 Jld 6
Date : 22 October 2021

SMARTTECH ENGINEERING AND RESOURCE MANAGEMENT SDN. BHD.
302C-3, JALAN DATO ISMAIL HASHIM,
11900 BAYAN LEPAS, PULAU PINANG

Dear Sir/Madam,

IVD TEST ASSAY EVALUATION (COVID-19 TEST ASSAY) WITH TESTING FACILITY

Kindly be informed that the IVD Test Assay should be evaluated by the testing facility. The following list contains information on the test kit that was designated for evaluation:

Product name	:	SARS-CoV-2Antigen Detection Kit
Identifier or Ref:	:	CovAg-NS
Detection Method & Condition of Use	:	**RTK Antigen** **Self - Testing**
Sample Type	:	NASAL SWAB or SALIVA
Product description	:	This kit uses immunochromatography for detection. Colloidal gold was used as a marker to qualitatively detect SARS-CoV-2 N protein antigen in human nasal or saliva samples. The specimen will move forward along the test card under capillary action. If the specimen contains a SARS-CoV-2 antigen, the antigen will bind to the colloidal gold-labeled new coronavirus monoclonal antibody to form an immune complex. The immune complex will be membrane fixed will be SARS-CoV-2 monoclonal antibody capture, form the fuchsia line, display will be SARS-CoV-2 antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line
Intended Use	:	This product is used for qualitative detection of SARS-CoV-2 -19 antigen in human nasal swab or saliva samples. For those with a history of exposure, but no symptoms and symptoms of coronavirus pneumonia disease, screening should be performed at the initial stage of symptoms (0 to 7 days) after infection. The SARS-CoV-2 belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the SARS-CoV-2 are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and

		diarrhea are found in a few cases. This product provides preliminary test results. A negative result does not preclude infection with a SARS-CoV-2 and is not used as the sole basis for treatment or other management decisions. For in vitro diagnostic use only
Manufacturer of the test kit	:	NINGBO LVTANG BIOTECHNOLOGY CO.,LTD
Contact person details	:	
	Name :	YEAP SHIAW HOW
	Address :	SMARTTECH ENGINEERING AND RESOURCE MANAGEMENT SDN. BHD. 302C-3, JALAN DATO ISMAIL HASHIM, 11900 BAYAN LEPAS, PULAU PINANG
	Email :	INFO@SMARTTECHENGINEERING.COM
	Tel.no :	012-5819546
Testing Facility	:	Tropical Infectious Disease Reasearch & Education Centre (TIDREC) Aras 4, Blok N & O, Fakulti Perubatan Universiti Malaya, 50603 Kuala Lumpur, Malaysia.

2. Please be advised that, in order to initiate an evaluation, you must import a total of 150-200 tests of IVD kits for testing at the appointed evaluation facility. Testing facilities will only commence testing upon the issuance of ***IVD Test Assay Evaluation*** letter from the Medical Device Authority (MDA). Please feel free to contact the MDA evaluation team for more information or inquiries: ca.covid19@mdb.gov.my.

3. The establishment is responsible for the expense of testing in testing facilities for IVD test assays.

4. Evaluation Report from the testing facilities will be provided directly to Medical Device Authority(MDA) effective from 4 August 2021.

Thank you,

(AHMAD SHARIFF BIN HAMBALI)
Chief Executive
Medical Device Authority
Ministry of Health Malaysia.