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Tarikh: 3 ~~April~~ Mei 2021

YBrs. Dr,

LAPORAN UJIAN PENILAIAN KIT NOVEL CORONAVIRUS (COVID-19): NEWGENE BIOENGINEERING COVID-19 ANTIGEN DETECTION KIT

Dengan segala hormat merujuk kepada perkara di atas.

2. Adalah dimaklumkan bahawa pihak kami telah menjalankan ujian penilaian terhadap kit novel Coronavirus (2019-nCoV) *test kit* seperti yang dimohon oleh pihak YBrs. Dr.

3. Bersama-sama ini dikemukakan laporan bertajuk *Performance of NEWGENE Bioengineering COVID-19 Antigen Detection Kit, Manufacturer:* New Gene (Hangzhou) Bioengineering Co., Ltd., China, untuk perhatian dan rujukan pihak YBrs. Dr.

Sekian, terima kasih.

"PRIHATIN RAKYAT : DARURAT MEMERANGI COVID-19"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR. HAJI TAHIR BIN ARIS)
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INSTITUTE FOR MEDICAL RESEARCH
KUALA LUMPUR

Performance of Newgene Bioengineering COVID-19 Antigen Detection Kit

Intended use
This product is suitable for the qualitative detection of novel coronavirus in nasopharyngeal swab or sputum samples. It provides an aid in the diagnosis of infection with novel coronavirus.

Manufacturer
New Gene (Hangzhou) Bioengineering Co., Ltd., China.

Test Principle
This kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid from protein from SARS-CoV-2. When the sample is added into the sample well, colloidal-gold conjugated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2 absorbed in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). Absence of T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C).

Test Kit
The evaluation was carried out using this kit with the lot number of 20210228-01, and the expiry date is Feb 27, 2022.

Instrument Used
NA

Reagent and Sample Preparation, Result Interpretation
Kindly refer to product package insert in the attachment

Sample Used
Sample type = Deep throat saliva (DTS)
Known Positive Sample= 50
Known Negative Sample= 50
Total samples used for analysis = 100

Performance Analysis

Test		Tested Kit Assay		Interpretation
		Positive	Negative	
IMR In-house Panel	SARS-CoV2 Positive (COVID-19)	48	2	Sensitivity= 96%
	SARS-CoV2 Negative (COVID-19)	0	50	Specificity = 100%

Comments
This kit was tested using DTS samples that had been tested positive using our RT-qPCR test system and the Ct values were ranged from 12 to 28. Saliva samples that had been tested negative using COVID-19 RT-qPCR test system and cultured samples of Influenza A H3, Influenza A pdm09, Adenovirus and Dengue were selected as negative panels.

Test performed by		Reviewed by	Approved by
E. Kav	Hayati		31/1/21
Pn. E. Kavithambigai A/P Ellan Evaluator 1/Officer in charge	Pn. Hariyati Md. Ali Evaluator 2 /Officer in charge	Dr. Ravindran A/L Thayan Head of Virology Unit, IDRC, IMR	Dr. Hj. Tahir bin Aris Director of IMR