INSTITUT KESIHATAN NEGARA
NATIONAL INSTITUTES OF HEALTH (NIH)
KEMENTERIAN KESIHATAN MALAYSIA
INSTITUT PENYELIDIKAN PERUBATAN (IMR)
Aras 6, Blok C6
No.1, Jalan Setia Murni U13/52
Seksyen U13 Setia Alam
40170 SHAH ALAM, SELANGOR

Telefoni : 603-3362 7900
Faksimili : 603-3362 7901

Ruj.kami: IMR/IDRC/VIRO(SA)/2301/23/01 (73)

Tarikh: 20 Januari 2021

En. Chia Kum Luan,
Malaysian Diagnostics Corporation Sdn. Bhd. (457619-T),
No. 1, Jalan Serindit 2,
Bandar Puchong Jaya,
47100 Puchong,
Selangor Darul Ehsan.

Tuan,

LAPORAN UJIAN PENILAIAN KIT NOVEL CORONAVIRUS (COVID-19): HUMASIS COVID-19 AG TEST

Dengan segala hormat merujuk kepada perkara di atas.

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

3. Bersama-sama ini dikemukakan laporan bertajuk *Performance of Humasis COVID-19 Ag Test, Manufacturer: Humasis Co., Ltd., Gyeonggi-do, Korea* untuk perhatian dan rujukan pihak tuan.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR. HAJI TAHIR BIN ARIS)
MPM: 28418 NSR: 127511
Pengarah
Institut Penyelidikan Perubatan (IMR)
☏ 03 – 3362 8906
✉ tahir.a@moh.gov.my

S.k.:

En. Ahmad Shariff Bin Hambali
Ketua Eksekutif
Pihak Berkuasa Peranti Perubatan (*Medical Device Authority*)
Aras 5 & 6, Prima 9, Prima Avenue II, Blok 3547, Persiaran Apec, 63000 Cyberjaya, Selangor

INSTITUTE FOR MEDICAL RESEARCH
KUALA LUMPUR

Performance of Humasis COVID-19 Ag Test

Intended use
This kit is one step in vitro diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimen of suspected patients.

Manufacturer
Humasis Co., Ltd., Gyeonggi-do, Korea

Test Principle
This kit uses monoclonal antibodies specific to COVID-19 antigens to detect COVID-19 specific antigens in human nasopharyngeal swab specimens. When the extracted swab specimen is added to the sample well, it will migrate to the conjugate pad, which contains conjugated antibodies conjugated with colloidal gold directed against the SARS-CoV-2 antigen. If the sample contains SARS-CoV-2 antigens, antigen-antibody-conjugate complex will be formed and binds to immobilized antibodies to form a visible coloured band in the test line. The sample will continue to move until it reaches the control line where excess conjugate binds and produces a second visible line. This control line indicates that the samples has migrated across the membrane as intended and the test was performed properly.

Test Kit
The evaluation was carried out using this kit with the lot number of COVGNP0001, and the expiry date was May 31, 2022.

Instrument Used
NA

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

Sample Used
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)	45	5	Sensitivity= 90%
	SARS-CoV2 Negative (COVID-19)	0	50	Specificity = 100%

Comments
The positive panels were selected among the samples that had been tested positive using our COVID-19 RT-qPCR test system and the Ct values were ranged from 15 to 25. As the negative panels the cultured samples of Influenza A H3, Influenza A pdm09, Influenza B, Adenovirus and Dengue were tested.

Test performed by		Reviewed by	Approved by
E. Kavi			30/11/21
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