

**INSTITUTE FOR MEDICAL RESEARCH  
KUALA LUMPUR**

**Performance of Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test**

**Intended use**

For the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in serum, plasma (EDTA, citrate) or venipuncture whole blood specimens from patients suspected of COVID-19 infection.

**Manufacturer**

Cellex, Inc. (United States of America)

**Test Principle**

A lateral flow immunoassay

**Test Kit**

The evaluation was carried out using this kit with the lot number of ZCFX20200609WI5513C-3, and the expiry date was Dec 05, 2022.

**Instrument Used**

None

**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


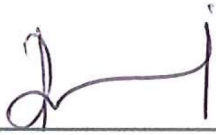
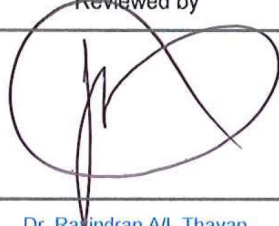
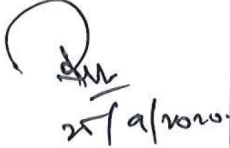
Total samples used for analysis = 100

**Performance Analysis**

Test		Tested Kit Assay		Interpretation
		Positive	Negative	
IMR In-house Panel	SARS-CoV2 Positive (COVID-19)	49	1	Sensitivity= 98%
	SARS-CoV2 Negative (COVID-19)	0	50	Specificity = 100%

**Comments**

None

Test performed by		Reviewed by	Approved by
			
Pn. Nur Izwani Shaiful Bahrin Evaluator 1 / Officer in charge	Dr. Rozainene Mohd Zain Evaluator 2 / Officer in charge	Dr. Ravindran A/L Thayan Head of Virology Unit, IDRC, IMR	Dr. Hj. Tahir bin Aris Director of IMR

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