



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
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Ref : (53) MDA.600-1/6/35
Date : 17 April 2023

No. 4-2, Jalan Pekaka 8/3, Seksyen 8, Kota Damansara,
47810 Petaling Jaya, Selangor.

Sir/Madam,

EVALUATION RESULT OF COVID-19 TEST KIT (PROFESSIONAL USE)

According to the evaluation report received from the designated testing facility, the following test kit is **Recommended For Use** as it **meet to achieve** the minimum performance criteria for sensitivity and specificity:

Name of test kit : *BIOTEKE MULTIPLE RESPIRATORY MULTIPATHOGEN ANTIGEN TEST KIT*
Type of detection : *RTK-Antigen*
MedC@St submission ID : *MDR-20230126-66450*
Identifier : *ICA2114-8T1*
Lot number : *ICA2114-8E2022N1001*
Condition of use : *Professional Use*
Sample type : *Nasal swab*
Manufacturer's name : *BioTeke Corporation (Wuxi) Co., Ltd.*
Testing facility : *TIDREC*
Evaluation result : *Nasal swab*
Sensitivity: 100% ; Specificity: 100%

Note: Minimum performance criteria for sensitivity and specificity according to type of detection

Type of detection	Sensitivity	Specificity	Type of detection	Sensitivity	Specificity
• RT-PCR	100%	100%	• RTK antigen & antigen assay	95%	95%
• POCT molecular	90%	95%	• Breath analyzer	90%	90%
• RTK antibody & antibody assay	90%	90%	• RTK neutralizing antibody & neutralizing antibody assay	90%	90%

2. This letter does not constitute an approval or indication that the product is registered under Medical Device Act 2012 (Act 737) and shall not be used for the promoting or advertising the product.

Thank you.

MARIAMMAH A/P KRISHNASAMY
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