



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 5 & 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.mdb.gov.my
Email: mdb@mdb.gov.my



Ref. No. : (17) dlm. MDA.600-3/1/12 Jilid 67
Date : 11 May 2021

Dear Sir,

NOTIFICATION ON IMPORTATION/SUPPLY OF MEDICAL DEVICES FOR SPECIAL ACCESS UNDER THE MEDICAL DEVICE (EXEMPTION) ORDER 2016 :

- **Medical Device Name : New Gene Bioengineering COVID-19 Antigen Detection Kit**
- **Manufacturer : New Gene (Hangzhou) Bioengineering Co., Ltd.**

With regards to your notification dated 26th January 2021, I wish to inform you on the decision made by the Expert IVD Evaluation Committee Meeting held on 10th May 2021 to your notification is as follows:

Recommended for Use.

2. Therefore, for the purpose of issuance of Special Access Letter, you are kindly requested to provide us with the required information as follows:

- i. Completed Special Access Route B Form (with the information on Section B, Medical Practitioner Details);
- ii. Customer Order Form (signed and stamped by the Public or Private Pathology Laboratory/Hospital) who is requesting the supply of COVID-19 Detection Kits during COVID-19 outbreak.

Thank you.

Yours Sincerely,


(AHMAD SHARIFF BIN HAMBALI)
Ketua Eksekutif,
Pihak Berkuasa Peranti Perubatan,
Kementerian Kesihatan Malaysia.