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Medical Device Authority
Ministry of Health Malaysia

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SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)



SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

The list of Self-Test Covid-19 Test Kit that is approved for Conditional Approval based on the decision on the consensus of the Covid-19 Test Kit Expert committee is as follows.

All test submissions are scored according to: -

- the manufacturer reported clinical and analytical performance evidence.
- the evaluation test results from testing facilities are according to the committee evaluation criteria set by Clinical expert panels.
- Supporting Documents for COVID-19 IVD Test Kits Conditional Approval.

The use of COVID-19 self- test kit shall be limited for screening purpose only and all test results need further confirmation using RT-PCR.

This test kit can be supplied by registered pharmacists or private healthcare facilities.

Below is the list of all tests that have been selected to date and the status is Conditional Approval (**please note: list is updated on a routine basis**).

Notes:

***Sample type is based on testing facility evaluation report.**

NO	COMPANY NAME	PRODUCT NAME	MANUFACTURER	IDENTIFIER	DETECTION	SAMPLE TYPE
11	Dewina Consult Sdn Bhd	NEWGENE Bioengineering COVID-19 Antigen Detection Kit	New Gene (Hangzhou) Bioengineering Co., Ltd. P.R. China	COVID-19-NG08	RTK-Antigen (Self-test)	Saliva or Nasal swab

Updated 13 August 2021