FDA Advisory
No. 2020-437

TO : All Licensed Importer/Distributors of COVID-19 Test Kits

SUBJECT : DISTRIBUTION OF FDA APPROVED COVID-19 RAPID ANTIBODY TEST KITS

The Food and Drug Administration (FDA) reiterates to all licensed importer/distributors that COVID-19 test kits are strictly for medical professional use and not intended for personal use.

The product should be strictly distributed to appropriate establishments or institutions. Subsequently, this should be acquired by the general public through a prescription from a licensed physician. The administration of the test must be performed by a doctor or a trained health professional. Furthermore, the interpretation of results must be done by a doctor.

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Director General