Item Specification of SARS Cov-2 Rapid Ag Assay (ICT/ Lateral Flow Method).

Item Specification
Consists of; 1. Immunochromatographic assays/ lateral flow device assay to detect SARS CoV-2 specific antigen using nasopharyngeal swab. 2. Test kit should have full registration at NMRA (should provide documented evidence). 3. WHO, CE IVD, FDA or equivocal emergency usage authorization for invitro diagnosis service (need to provide traceable documented evidence of such authorization). 4. Manufacturer leaflet should be available in English language with detailed testing procedure. 5. The test kit should have sensitivity more than 80% among samples with SARS CoV-2 PCR CT value up to 30. 6. Specificity of the test kit should be more than 97% compared to SARS CoV-2 PCR assay. 7. There should be manufacturer's valid certification with documented evidence that the test kit performance is the same across all SARS CoV-2 Variants of Concerns detected to date (according to WHO classification) and regular updated performance checks against new variants should be conveyed to NMRA in writing. 8. The test kit should have its own sterile individually wrapped nasopharyngeal swab, test device, buffer/medium and needed other reagents/ consumables/ tubes/ dropper to perform the test as a point of care test or field test. 9. Results should be available within 15- 30 minutes time. 10. Kit should have appropriate biosafety features for testing procedure and ultimate discard of the used material. 11. Should have authorization letter from the manufacturer to the local agent.