

**Mandatory Requirements for submission COVID-19 Test kits/VTM for testing at NIB**

- a.** Request/Forwarding Letter from company marked to NIB for testing/evaluation purpose.
- b.** Copy of Import License/Test License (whichever applicable) issued by CDSCO.
  - i. Form MD-17 (License to Import Medical Devices for the purpose of Evaluation)
  - ii. Form MD-13 (License to Manufacture Medical Devices for the purpose of Testing)
- c.** Certificate of Analysis from Manufacturer in respect of the lot submitted for evaluation.
- d.** For imported batches, Batch Release Certificate (BRC) from Manufacturer/NCA/NCL of the Country of origin for the lot submitted for evaluation.
- e.** Pack insert and label Claim of the Product
- f.** For quantity of sample and testing fee, please refer products code K.1 to K.6 on <https://nib.gov.in/Testing%20Fees.pdf>