



भारतीय आयुर्विज्ञान अनुसंधान परिषद  
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार  
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research  
Department of Health Research, Ministry of Health  
and Family Welfare, Government of India

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## Guidance to enhance availability of COVID-19 testing kits and newer innovative testing solutions in India:

- Real time RTPCR and Rapid Antigen Tests (RAT) are the mainstay of diagnosis of SARS-CoV-2 in India.
- Currently, kits approved by US Food & Drug Administration (USFDA) under regular or emergency use are exempted from validation in India and qualify for direct marketing permission from the Drug Controller General of India (DCGI).
- **On similar lines, it is now proposed that real time RTPCR, RAT, home based testing solutions, antigen/antibody ELISA/CLIA and rapid antibody tests approved by the following reputed global agencies may also be exempted from validation in India and accorded marketing permission by DCGI on the basis of existing approvals:**
  1. European CE/IVD
  2. Ministry of Food and Drug Safety, Korea (formerly known as Korea Food & Drug Administration or KFDA)
  3. Pharmaceuticals and Medical Devices Agency (PMDA), Japan
  4. Therapeutic Goods Administration (TGA), Australia
  5. Brazil ANVISA
  6. WHO Emergency Use Listing (EUL) procedure

### Points to be noted prior to approval of home based testing solutions:

- All manufacturers intending to market such tests in India must ensure the following:
  - i. All material for sample collection, testing and disposal should be part of the kit per se.
  - ii. The kit insert should include detailed instructions for usage, interpretation and disposal of the test kit.
- All such tests must have an inbuilt system of data capture through mobile softwares or any other suitable technology.
- All manufacturers are advised to liaise with the data entry team of ICMR to ensure compatibility of data flow into the ICMR COVID-19 testing portal. Once the compatibility is ensured, DCGI may be approached for approval. The contact points at ICMR are:

Mr Ajay Singh Dhama: Email: [ajaysinghdhama@gmail.com](mailto:ajaysinghdhama@gmail.com)  
Dr Neetu Vijay: Email: [drneetu.vijay@icmr.gov.in](mailto:drneetu.vijay@icmr.gov.in)
- Manufacturers who do not have a system or are unable to synchronize data flow with ICMR, may not be considered for marketing permission under the category of home-based testing solutions and considered for approval under another appropriate category.

**This guidance is applicable for tests using nasopharyngeal, oropharyngeal, throat, nasal, oral, saliva, mouth rinse, gargle, blood and serum samples.**