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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VERSION II

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.
- ICMR had advised that real time RTPCR, RAT, home based testing solutions, antigen/antibody ELISA/CLIA and rapid antibody tests approved by European CE/IVD, Ministry of Food and Drug Safety, Korea, PMDA, Japan, TGA, Australia, Brazil ANVISA and WHO Emergency Use Listing (EUL) procedure may be exempted from validation in India and accorded marketing permission by DCGI on the basis of existing approvals (Advisory dated 27/04/2021).

- **The advisory dated 27/04/2021 is now being modified in consultation with the Drug Controller General of India (DCGI). Earlier a sizeable number of different test kits, approved by certain external agencies listed above, could not meet the validation criteria laid down in India. However, such kits became eligible to enter the Indian market without any improvisation/ revalidation.**

In view of this, only SARS-CoV-2 RTPCR, RAT, Antigen/Antibody ELISA/CLIA and Rapid Antibody tests approved only by the following agencies will not require separate validation in India:

1. United States Food and Drug Administration (USFDA), USA
2. Pharmaceuticals and Medical Devices Agency (PMDA), Japan
3. Therapeutic Goods Administration (TGA), Australia
4. WHO Emergency Use Listing (EUL) procedure

All test kits approved by any other global agency (besides those listed at 1-4) will be subject to validation in India.

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

- All home testing kits will be validated in India.
- 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 phone based softwares.
- 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:
  - Dr Neetu Vijay: Email: drneetu.vijay@icmr.gov.in
  - Mr Ajay Singh Dhama: Email: ajaysinghdhama@gmail.com
- 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.