



# Indigenously Developed Testing Kits for COVID-19

## Why in News

Recently, the **test kits for COVID-19** developed by the Pune-based **MyLab Discovery Solutions** and **Germany's Altona Diagnostics** have been approved by the [Indian Council of Medical Research \(ICMR\)](#).

- The two companies have also received **approval to mass manufacture the kits** after they received commercial **approval from the** [Central Drugs Standard Control Organisation \(CDSCO\)](#).
- Currently, the diagnostic kits to test people for COVID-19 are **imported from the USA**.

## Key Points

- **Approval Conditions:**
  - Earlier, the kits approved by the **United States Food and Drugs Administration** or certified by the **European Union** were allowed to offer commercial tests for detecting SARS CoV-2.
  - However, ICMR stated that it is no longer a requirement and even those **approved by the National Institute of Virology (NIV) would be eligible for testing**.
- **Feature of the Developed Testing Kit:**
  - **Quick Detection:** The developed kit **detects the infection within two and half hours** compared to over seven hours taken by current protocol.
  - **Accuracy:** The **ability to detect the early stage of detection and highest accuracy** has been observed with the indigenously developed testing kit for COVID-19.
  - **Affordable:** For the government labs, these testing kits would cost nearly **Rs 1,200 per test kit, which is about one-fourth of the current testing kit** used by India.
- **Indigenously Developed:**
  - The indigenously developed testing kits for COVID-19 by MyLabs have been manufactured **as per** [World Health Organisation \(WHO\)](#) /**Centre for Disease Control (CDC) guidelines**.
  - **MyLabs discovery Solutions is the first indigenous manufacturer** to be approved for deploying its **kits for COVID-19 testing**.
  - The approval from National Institute of Virology (NIV) to MyLabs is expected to provide major support to the ['Make in India' programme](#) in the future.

## Indian Council of Medical Research (ICMR)

- Indian Council of Medical Research (ICMR) is the apex body in India for the formulation, coordination and promotion of biomedical research.
- It was founded in **1911** with the name of Indian Research Fund Association (IRFA) and **renamed as ICMR in 1949**.
- It is **funded** by the Government of India through the Department of Health Research, **Ministry of Health & Family Welfare**.

## National Institute of Virology

- The National Institute of Virology is one of the major Institutes of the **Indian Council of Medical Research (ICMR)**.
- It was established at **Pune, Maharashtra in 1952 as Virus Research Centre (VRC)** under the auspices of the **ICMR** and the **Rockefeller Foundation (RF), USA**.

## Central Drugs Standard Control Organisation (CDSCO)

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the **Drugs and Cosmetics Act, 1940**.
- Major Functions:
  - **Regulatory control** over the import of drugs, approval of new drugs and clinical trials.
  - Approval of **certain licences** as Central Licence Approving Authority

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