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Indigenously Developed Testing Kits for COVID-19

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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

Source:TH