Rapid Antigen Detection Test

Why in news?

The Indian Council of Medical Research (ICMR) approved the rapid antigen detection test for diagnosis of Covid-19.

What is the rapid antigen detection test?

- It is a **point-of-care test**, performed outside the laboratory setting.
- It is a quick diagnostic test on swabbed nasal samples. It detects antigens that are found on or within the SARS-CoV-2 virus.
- [Antigens are foreign substances that induce an immune response in the body.]
- In India, the ICMR has allowed the use of antigen detection kits developed by the South Korean company S D Biosensor.
- SD Biosensor has a manufacturing unit in Manesar.
- The kit is commercially called Standard Q COVID-19 Ag detection kit.
- It comes with an inbuilt Covid antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.

How is rapid antigen detection test different from RT-PCR test?

- RT-PCR is currently the gold standard frontline test for the diagnosis of Covid-19.
- Like RT-PCR, the rapid antigen detection test too seeks to detect the virus rather than the antibodies produced by the body.
- While the mechanism is different, the most significant difference between the two is **time**.
- As the ICMR has pointed out, the RT-PCR test takes a minimum of **2-5 hours** including the time taken for sample transportation.
- These specifications limit the widespread use of the RT-PCR test.
- It also impedes quick augmentation of testing capacity in various containment zones and hospital settings.
- In a reliable rapid antigen detection test, the maximum duration for
- interpreting a positive or negative test is **30 minutes**.

Why has been only the kit by the company SD Biosensor allowed?

- Very few reliable antigen detection kits for Covid-19 diagnosis are available

worldwide.

- The US FDA authorised the first antigen test, with US-based Quidel's antigen kit called the Sofia 2 SARS Antigen FIA.
- In India, the ICMR conducted an independent **two-site evaluation** of the SD Biosensor kit, at ICMR and AIIMS.
- The results revealed that the kit had a very high specificity, or the ability to detect true negatives, ranging between 99.3% and 100%.
- The sensitivity of the test, or its ability to detect true positives, ranged between 50.6% and 84%, depending upon the viral load of the patient.
- The higher the ability to detect true negatives, the more reliable is any positive result.
- Having allowed SD Biosensor to market its kit commercially, ICMR has also asked other manufacturers/developers who have antigen detection assays to come forward for validation.

Where will the test be used?

- As of now, the kit will be used in containment zones or hotspots and healthcare settings.
- Test will be performed onsite under strict medical supervision and maintaining the kit temperature between 2° and 30°C.
- **In containment zones** - The test can be conducted on all symptomatic influenza-like illnesses.
- Asymptomatic direct and high-risk contacts with co-morbidities of a confirmed case are to be tested once between day 5 and 10 of coming into contact.
- **In healthcare settings** - It can be used in three categories.
    1. In all persons presenting influenza-like symptoms in a healthcare setting and suspected of having Covid-19 infection;
    2. In asymptomatic patients who are hospitalised or seeking hospitalisation, in the high-risk groups and
    3. In asymptomatic patients undergoing aerosol-generating surgical procedures /non-surgical interventions.

Is the test a confirmatory one for diagnosis of Covid-19?

- According to the ICMR guidelines, if the test shows a positive result, it should be considered as true positive, and does not need reconfirmation.
- However, those who test negative in the rapid antigen test should then be tested by RT-PCR to rule out infection.

What are the limitations of an antigen test's results?

- When it gave emergency authorisation for the first antigen kit, the US FDA pointed out that antigen tests are **very specific for the virus.**
- But it also said that they are **not** as **sensitive** as molecular PCR tests.
- Also, the ICMR has said that once the sample is collected in the extraction buffer, it is **stable only for one hour**.
- Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting.
- A negative test result may occur if the level of an extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen.
- Also, children tend to shed the virus for longer periods than adults, which may result in differences in sensitivity.

Source: The Indian Express