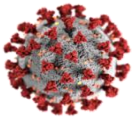


Bangladesh Finalises Antibody Test Policy as Virus Cases Keep Surging

The government has finalised the policy on rapid antibody test kits amid rampant coronavirus cases.

The Directorate General of Drug Administration will give the green light to the use of rapid test kits once the health ministry gives it a go-ahead.

The test kit cannot be used to diagnose the novel coronavirus infection, but to determine if a person has antibodies created in them to fight the virus.

"We have prepared the kit for surveillance. Through the rapid antibody test, we can determine if a patient who has recovered from COVID-19 has developed immunity against the disease. They can donate plasma if they have enough antibodies in their blood. This test can help us identify plasma donors," Md Salahuddin, deputy director of DGDA, told **bdnews24.com**.

Gonoshasthaya Pharmaceuticals made a rapid testing kit but the authorities did not 'approve' it as it 'failed to meet the standards", he said adding some other companies sought permission to import such test kits.

"It was necessary to determine the rules to follow for using rapid test kits. Therefore, a group of experts drafted the policy."

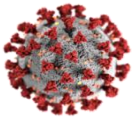
The Ministry of Health formed a 14-strong panel to evaluate medicines, investigational drugs, vaccine and medical devices needed for the treatment of COVID-19 on Jun 4. The panel includes experts from BSMMU, ICDDR,B and the National Institute of Laboratory Medicine and Referral Centre.

According to the drafted policy, the rapid antibody testing kit can be used for sero-surveillance, convulsant plasma therapy and research. The kit will be permitted to be used only by the laboratories to prevent 'misuse'.

A rapid test kit must have these words written on its package: 'this is not a diagnostic kit; the kit will be used only for detecting antibody, not in the acute stage'.

The policy disallows the kits to be used at 'points of care.' The combined sensitivity immunoglobulin M, which is developed at the beginning of the infection and immunoglobulin G, which is developed later, should be 90 percent in the kit and specificity should be 95 percent, according to the policy.
The sensitivity mentioned here describes the percentage of antibodies found in the blood after 14 days of COVID-19 symptoms subside, said Salahuddin.

Dr MA Khan, head of Haematology at Dhaka Medical College Hospital, who leads the expert committee on plasma therapy hailed the new policy as a great initiative.



"More people are being infected with the COVID-19 now, but all of them cannot go through a diagnostic test. An antibody test with rapid test kits for surveillance will give us the real number of infections. Also, it will provide the antibody level in the blood," he said.

The rapid testing kit is necessary as antibody test is needed for a convulsant plasma therapy, said Ashraful Haque, assistant professor of Sheikh Hasina National Burn and Plastic Surgery Institute.

"There is no use of plasma transfusion if the donor does not have a specific level of antibody in his or her blood. According to WHO, many patients who recovered from COVID-19 do not develop enough antibodies," he said.

The RT-PCR test cannot detect it if the sample has virus copies less than 200, meaning a swab test will turn out to be negative in such cases.

"But the lungs may have more than 200 viruses. So even if the test result turns out to be negative, the patient is coronavirus-positive. The body develops antibodies after a certain time. The rapid antibody test kit will ensure if the patient was infected with COVID-19 or not."

Safe collections of samples are important as there is a high risk of them getting mixed up for many reasons, leading to false-positive results, said Prof Ashraful. It was found that some patients were not infected at all when they went to donate plasma.

"Also, it is necessary to check if the donated plasma is working or not. An antibody test is needed for that too."

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