NEWS / HEALTH

Private labs cash in on COVID-19 antibody tests even though they have no diagnostic value

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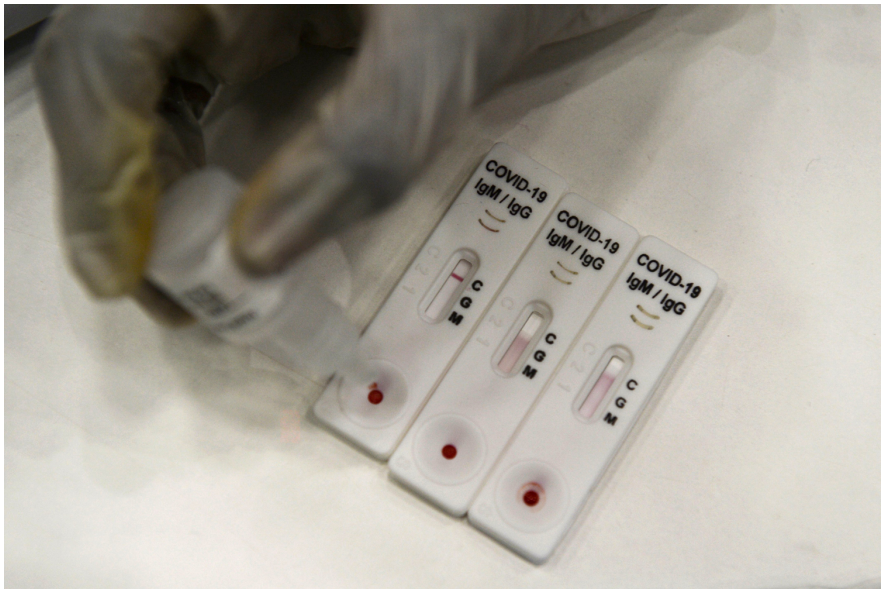

A medical technician tests a blood sample for COVID-19 antibodies at a temporary testing facility for frontline workers in Chennai as a preventative measure on 16 July 2020. ARUN SANKAR / AFP / GETTY IMAGES

COVID-19

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Private diagnostic laboratories, hospitals and online aggregators are marketing COVID-19 antibody tests as quick, cheap diagnostic tests and even as immunity certificates. But antibody tests, which are very useful tools for disease surveillance, have limited use in clinical diagnosis—a distinction that a non-specialist customer is unlikely to know. In the absence of clear directions from either the Indian Council of Medical Research or from the Ministry of Health and Family Welfare, these private healthcare players seem to be using antibody tests to cash in on public anxiety in a pandemic.

Antibody tests, also called serological tests because they measure antibodies in serum, are useful for understanding whether there has been an outbreak of disease. For instance, antibody tests are being used in serological surveys in cities like Delhi, Mumbai and Pune to gauge the spread of COVID-19. But they cannot tell us whether a person is infected at the time the test is conducted. This is because antibodies develop weeks after the onset of infection and sometimes after a person has recovered from symptoms. They have little value for people trying to decide whether they need treatment.

Yet, private laboratories are administering the tests to individuals seeking diagnosis. In early August, Aman Arya, a merchant navy officer from Bhagalpur in Bihar, took the antibody test from Thyrocare, a diagnostic laboratory chain with its headquarters in Mumbai, to check whether he was infected with COVID-19. He needed a certificate showing that he was not infected in order to join a new posting at Kandla in Gujarat. Thyrocare and other companies are offering two kinds of COVID-19 antibody tests. The first is a complete antibody test for all types of antibodies that might be produced in response to an infection and the second tests only for the IgG antibody, which develops later in the immune response but lasts longer. Testing positive on either only indicates that the person was exposed to the infection at some point in the past. Arya's results showed that he tested negative for the total antibody test and positive for the IgG test. "This test was useless, it gives me no concrete information. Now how am I supposed to interpret this?" Arya asked while speaking to me over the phone. Thyrocare advised Arya to take the test again a month later to get a definite result. When I emailed Thyrocare's corporate office about the conflicting results, Dr Prachi Sinkar, the head of laboratory for Thyrocare, replied, "Results do vary depending on what is measured, after how many days of infection and also two different brands used (though all are ICMR approved). This happens in many lab tests, not just in COVID Antibodies tests."

Most private healthcare companies started selling antibody tests in early July. A little earlier, on 23 June, the ICMR issued (https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_3 an advisory to local governments to "enable all Government and Private Hospitals, Offices, Public Sector Units etc. to perform the antibody-based testing." It maintained that the Reverse Transcriptase Polymerase Chain Reaction test, better known by its abbreviation RTPCR, remains the gold standard for diagnosing COVID-19 and "strictly advised" that antibody tests be used only for serological surveys, especially in high-risk populations. It also said that the antibody test "is not useful for detecting acute infection." But the advisory did not specifically prevent private companies from using or selling such tests.

The World Health Organisation, in an advisory (https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19) issued on 8 April, on rapid point-of-care testing tools for COVID-19, recommended against the use of antibody testing for patient care but encouraged more work to establish its usefulness in disease surveillance and epidemiologic research (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations). A systematic review (https://www.bmj.com/content/370/bmj.m2516) of the diagnostic accuracy of serological testing for COVID-19, published in the *British Medical Journal* on 1 July, concluded that serological tests for COVID-19 not only have limited utility in diagnosis of acute infection, but also have low sensitivity. Sensitivity is a measure of a test's ability to detect cases and give the true positive rate. A test with low sensitivity, like COVID-19 antibody tests, will throw up a lot of false negatives. The authors of the study said that out of those who tested for COVID-19 within one week of the onset of symptoms, between 44 and 87 percent will be falsely identified as not having infection. After three weeks of the onset of symptoms, when the sensitivity is relatively higher, the study still found many false negatives.

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Arvind Kampani, a senior assistant manager with the diagnostics company Metropolis Healthcare in Mumbai, said that getting an IgG antibody test is better as these antibodies remain in one's blood for a longer period after their exposure to COVID-19 and indicate potential immunity against the disease. HealthSpring, a corporate healthcare provider in Mumbai, says its antibody test is "a blood test to detect previous exposure and infection to COVID-19 and potential immunity." Aspira Pathlabs and Diagnostics, a diagnostic laboratory also in Mumbai, is marketing the test as "a simple blood test to detect protective antibodies" which will grant people "freedom from fear" of the pandemic. Some companies are selling antibody tests as part of immunity packages along with similar tests for dengue and malaria.

Dr Mini P Singh, a virologist at the Post Graduate Institute of Medical Education and Research in Chandigarh, who has been in charge of developing COVID-19 testing strategies and scaling up RTPCR testing across government hospitals in north India, said that there is nothing to suggest that the presence of antibodies confers complete immunity on the individual. "So any laboratory or private firm claiming that the presence of these antibodies will grant customers an immunity from the disease is falsely advertising the test and its use," she said.

At the same time, testing negative for COVID-19 antibodies does not guarantee that the person has not been exposed to the virus at all. "Often, even if the antibodies don't last for long in a patient's blood post exposure to the virus, their T cells"—lymphocytes that plays a central role in any immune response—"could still possess the memory of the viral infection," said a microbiologist from a government medical college in Chhattisgarh who asked not to be identified. "Recent research provides evidence that even without antibodies, activated T cells can begin fighting a potential re-infection three days after the onset of the disease." The microbiologist is referring to the significant study (https://www.cell.com/cell/fulltext/S0092-8674(20)31008-4) published in

mid-August by researchers from the Karolinska Institutet, which reveals that patients with mild or asymptomatic COVID-19 acquire T cell-mediated immunity even if they test negative for antibodies. So a negative antibody test does not give a definitive answer to whether a person has been infected before.

Moreover, there has been no regulation of prices of antibody tests. Currently, commercial antibody tests are offered between Rs 600 and Rs 1,500 per test. A sales executive from Metropolis Healthcare, who asked not to be named, said, "For the complete antibody test we charge Rs 950 for home sampling. If this comes positive, we suggest you take the specific IgG antibody test, which costs Rs 1,350."

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Dr Singh, the virologist from PGIMER, said, "Regardless of the technology used, they can at most cost Rs 400 to make—not more than that."

Malini Aisola, the co-convenor of the All India Drug Action Network who has been closely monitoring private laboratories and online aggregators marketing these tests, said that there has been no oversight of their prices. "Given the scope for profiteering that commercialisation of antibody testing has opened up, it is unfortunate that ICMR has not laid down guidelines for private labs to offer such tests."

Meanwhile, unverified retailers have also emerged online, marketing antibody kits that can be used by customers to test themselves at home. One such retailer in Mumbai, who has placed his advertisement on a Facebook group for COVID-19 support, is offering to sell a set of ten testing kits at a price of Rs 700 each. "If you buy from any other manufacturer or retailer, they will not sell anything less than a hundred kits to you," he said. "These kits are safe and easy to use and all your family can test themselves at home." When I asked him if he was affiliated with a firm or a testing laboratory and whether he had any

approval from the ICMR or the National Accreditation Board for Testing and Calibration Laboratories, the man stated that he works individually and does not need approval to sell these tests. “Anyone can sell these, you can too. I can hook you up with my supplier. These kits are ICMR-approved and that’s what matters,” he said.

The antibody kits marketed by the Mumbai retailer were produced by Nulife Care, a pharmaceutical manufacturer in Noida, whose kits have been approved by the ICMR. Jareer Ahmed, the head of marketing for Nulife, said that the company had been made aware of unverified retailers selling their kits online. “We even notified the CDSCO”—Central Drugs Standard Control Organization, the central government authority that regulates drugs and medical products—“in this regard earlier, and they took appropriate action to ensure that these kits are not sold by unverified retailers online,” he said. Ahmed added that NuLife Care sells its COVID-19 rapid antibody kit for Rs 400. An email sent to the Drug Control General of India, Dr VG Somani, about kits sold by unlicensed retailers, remained unanswered at the time this story was published.

This is not the first time that private laboratories in India have benefited from the lack of regulations around serological testing. Until 2012, private laboratories conducted serological tests for tuberculosis, even though the international scientific community had been pointing out that they were inaccurate and highly inconsistent. Only after the WHO published a policy against the use of commercial antibody tests for diagnosing active pulmonary and extra pulmonary tuberculosis did the Indian government ban their use in 2012.

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Dr Madhukar Pai, an epidemiologist, a global health expert and the director of the McGill International TB Centre, agreed that currently private laboratories are benefiting from serological testing for COVID-19 just as they did with tuberculosis. “Indian private labs love serologic

antibody tests in general, because they are easier than PCR, and reagents are easier to get," he said. "Also, some serological antibody tests are available as 'rapid tests' which are quite cheap and can give results within minutes. The profit margin on these types of rapid tests is quite large."

The other big question is about whether private companies can and should use antibody tests for serological surveys. On 17 July, Arokiaswamy Velumani, the founder and managing director of Thyrocare, posted on Twitter (https://twitter.com/velumania/status/1284127894764007424) that his laboratory had conducted a serological survey in India on 53,000 people and found 15 percent sero-prevalence of COVID-19. Velumani further claimed that between 16 and 20 percent of samples taken from three neighbourhoods in Haryana's Gurugram district indicated presence of antibodies for the disease. The Gurugram health department (https://www.hindustantimes.com/gurugram/pvt-lab-says-16-20-sero-prevalence-in-gurugram-health-dept-distances-itself-from-data/story-265qYKX4XhRPeMVc5HrKEO.html) immediately distanced itself from Thyrocare's data, saying that the laboratory "made a major ethical oversight in publishing data from a commercial test as a clinical study." I contacted Thyrocare via their corporate email id, asking them whether they had received permissions for a serological survey, but did not receive a reply at the time the story was published.

Since the ICMR advisory issued on 23 June, there has been no other clarification or detailed regulations issued by a government authority on commercial serological testing. Though the ICMR has a list of all laboratories approved to conduct antibody tests since they are required to register their results with the council, there is no consolidated repository of such laboratories available in the public domain, leaving consumers with no way to ascertain whether a particular laboratory has the required accreditations and approval. Furthermore, the ICMR has not clarified the conditions a laboratory needs to meet in order to offer antibody testing. I sent emails to Balram Bhargava, the director general

of the ICMR and Rajesh Bhushan, the secretary at the Ministry of Health and Family Welfare, seeking clarification on regulations for commercial antibody testing. At the time this story was published, I had not received a reply.

"Apart from the futility of taking such a test, the issue of surveillance and data safety also arise," Anant Bhan, a bioethics researcher, said. Private laboratories are required to collect data from every individual tested for the disease and send it to the ICMR. Furthermore, some companies are now demanding that employees take antibody tests before they are allowed to resume desk work at their offices. "If such surveillance data remains in the hands of private companies, we have to consider how we safeguard that data," Bhan said. "This data can be leveraged against employees in the future, so there should be some regulations in place that hold private firms accountable."

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