

## News 13 Special Report: The 'Wild West' of antibody testing brings new regulations

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HORRY COUNTY, SC (WBTW)- Some health experts said antibody testing could be the key to information to get life back to normal.

Hundreds of people have flocked to Coastal Lab in Murrells Inlet to get antibody testing for COVID-19.

"I just would really like to know if I have had it or if I haven't had it yet," said Marianne Aghbekian, who was tested for antibodies.

"If I have had this illness, I think that's probably a pretty strong indicator that up to 10 to 20 more people have had it too that have been exposed by me," said Toby Wagner, who was tested for antibodies.

The blood goes to Labtech Diagnostics based in Anderson, South Carolina.

"We need to know who's actually infected, who's not infected, and who has been infected and at this point may have some level of immunity," said Dr. Bill Hinnant, adjunct professor at Clemson University and General Counsel for Labtech Diagnostics.

Labtech decided to go above and beyond federal regulations. They said their test is in the process of emergency FDA approval, but some companies weren't doing that.

"To date, antibody testing has been wild west. We know of at least 150 companies that are coming up with different test," said Dr. David Cole, MUSC President during an Accelerate SC meeting.

The FDA loosened approval standards in March, by not forcing companies to prove their tests work. The agency reversed the policy on Monday after criticism of unproven and fraudulent tests on the market.

Now, manufacturers of all antibody tests have to ask for emergency approval and submit data showing the tests work.

In the meantime, to make sure you're getting a legitimate test look for a lab with these certifications:

Clinical laboratory improvement amendments (CLIA), College of American Pathologists (CAP) or from COLA Inc.

Antibody test are touted as the key to help determine the true extent of the pandemic by finding cases that were never formally diagnosed.

“You would not believe people that i have tested that have no symptoms at all and they came back positive. That’s the important part,” said Heather Pitts, owner of Coastal Lab.

Unlike some other tests on the market, Labtech tests for both IgG and IgM antibodies. IgM indicates a patient has an active or recent infection of COVID-19 and an IgG shows a past infection.

Dr. Hinnant said you need both test to get a more accurate depiction of where our population is in relation to the virus.

Hinnant said right now, they’re working to quantify how much immunity a person has in their body and how long immunity last. In the meantime, antibody testing isn’t going anywhere.

“This is not a test that’s gonna be obsolete in six months. This is a test that’s going to be useful and possibly even more useful in a year or 18 months when we hopefully have a vaccine,” said Dr. Hinnant.

To see which companies have been granted FDA emergency use authorization click here: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev>

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