

Healthineers' Covid-19 antibody test spikes an interest in vaccines



[Elizabeth Cairns](#)



The German group has come late to antibody testing, but has punchy accuracy data and a possible means of neutralising some of the competition.

Yesterday Siemens Healthineers gained US authorisation for its Covid-19 antibody test, one of the most accurate to have yet reached the market, according to the validation data submitted to the regulator. With vast production capacity and high throughput, the Total Antibody COV2T test will be a key tool in identifying people who have been exposed to the novel coronavirus.

“A serological test like ours enables you to screen populations and to establish the prevalence of disease, which is super important as public health officials determine how to safely bring people back to work,” says Deepak Nath, president of laboratory diagnostics at Healthineers. But he warns that this is still, to some degree, theoretical: no link has yet been definitively established between the presence of Covid-19 antibodies in the blood and immunity to reinfection.

Should such a link be discovered – and doing so could take months or even years – Healthineers will be in a position to capitalise in a major way. Its antibody test could help gauge the effectiveness and guide the use of a vaccine, thanks to the particular antibody it detects.

“Our antibody test detects the so-called neutralising antibodies that are related to the spike protein,” Mr Nath says. Specifically, antibodies to the S1 receptor-binding domain on the spike protein, which attaches to the Ace receptor found in the lungs and blood vessels, are believed to neutralise the virus.

Most Covid-19 vaccine candidates aim to elicit antibodies to the S1 binding site, Mr Nath says. Should one of these make it to market in mass quantities, Healthineers’ COV2T test will be able to establish immunocompetence in patients.

“We don’t know if this behaves like a flu virus, where the immunity lasts for months, or something like chicken pox where the virus that causes this triggers antibodies that live in patients’ bloodstreams for decades so effectively immunity is for life,” Mr Nath says. An accurate test for antibodies to the Covid-19 spike protein could be vital to making this discovery.

Antibody tests from some of the other diagnostics groups will not be able to do this since they detect antibodies to other parts of the coronavirus, such as the N1 protein on the capsid.

Techniques and settings

Being an automated, high-throughput laboratory-based assay is another potential advantage COV2T has over some of the other antibody tests on the market. Mr Nath says this type of test enables screening of large numbers of samples – Healthineers’ Atellica instrument can process 430 COV2T assays at once, returning results in 10 minutes – without compromising quality.

There are two other types of Covid-19 antibody test: those based on Elisa technology, an old and highly manual but very accurate technique, and lateral flow assays, which work on the same principle as pregnancy tests. Lateral flow assays are fast and convenient since they can be used at the point of care, but “typically come with a trade-off in accuracy”, Mr Nath says.

“With these serological tests, not all tests are created equal,” he adds.

There are also issues with the availability of some antibody tests, such as Abbott’s, as home kits in addition to their use in healthcare settings. When used in a hospital or doctor’s surgery, blood is taken by a nurse in the form of a venous draw. When used at home these tests rely on a much smaller volume of blood obtained by the patient pricking their finger.

“There are these fingerprick tests out there ... in general, there is a trade-off between convenience and accuracy or reliability,” Mr Nath says. “You don’t get something for free. There’s a reason why when you go into the hospital or a doctor’s office and the doctor orders some tests, that the foundation for that is a venous draw.”

Indeed the UK’s MHRA has [forced retailers to stop selling these home use kits](#) because of inaccuracy concerns.

Specificity

Sooner or later any discussion of antibody tests comes back to the question of specificity. The prevalence of Covid-19 is low – ranging from less than 5% in some regions to around 25% in places like New York, according to some studies.

Even this last figure is still considered relatively low prevalence, and this means the positive predictive value of a test – the probability that subjects with a positive test result truly have Covid-19 antibodies – can be poor unless the test’s specificity is very high ([Covid-19 antibody tests face a very specific problem](#), April 22, 2020).

“When you’re dealing with relatively low prevalence of disease it’s important to have an accurate test, especially one with high specificity, in order to be able to say in populations what the prevalence looks like and how that evolves over time,” Mr Nath says.

When it comes to how much its new product is worth to Healthineers, Mr Nath declined to discuss COV2T’s selling price. But antibody tests are reimbursed under Medicare at a rate of [\\$42 apiece](#), and Healthineers soon wants to be producing over 50 million COV2T assays per month. Not all of these will go to US customers, of course, but the test could still be a money-spinner – particularly if it can be used to determine the worth of a vaccine.