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The new reality of Covid-19 testing

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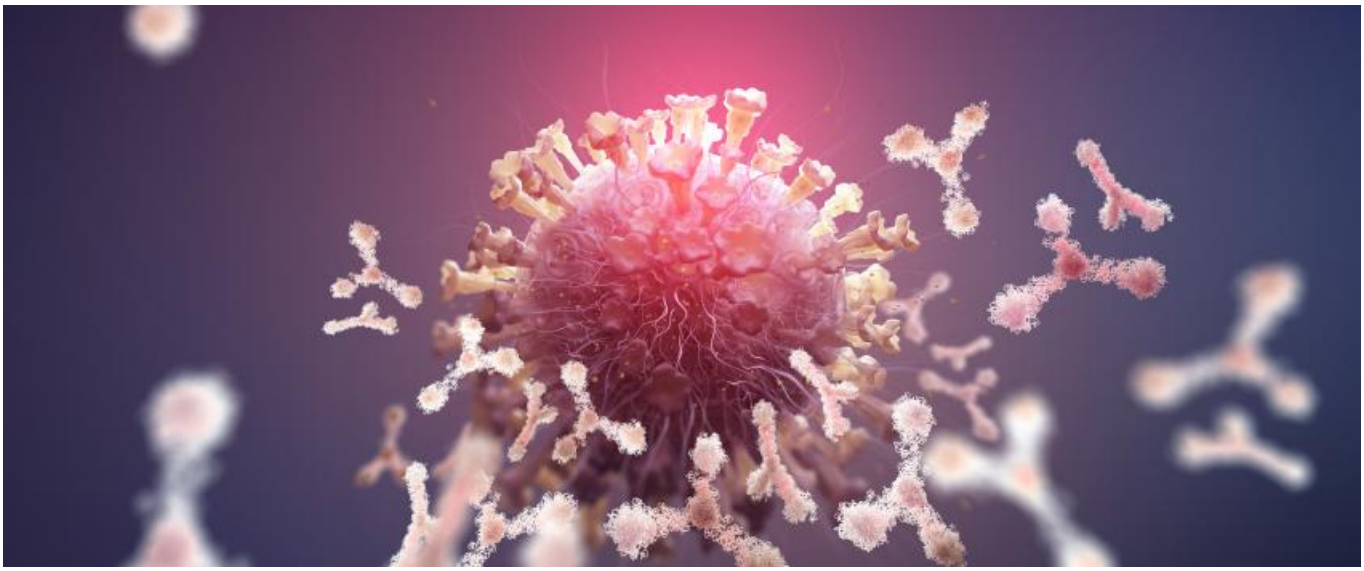

An evolving virus demands innovative diagnostic technologies.

In the spring diagnostics companies were warning that their Covid-19 test revenues had peaked, vaccination programmes having done much to halt the spread of the coronavirus. Since then the Delta variant, coupled with stubborn vaccine hesitance, has prompted another wave of infections, and demand for tests is once again on the up.

But the ways in which testing is employed have changed over the course of the pandemic. One of the crucial niches now is surveillance for yet more new variants – identifying potentially dangerous new strains as they emerge. And much work is going into technologies to predict how ill patients might become, and how long immunity might last.

One of the problems with which diagnostics groups must reckon is that the coronavirus is changing as inoculation levels increase.

“Vaccination adds a lot more evolutionary pressure,” Manoj Gandhi, senior medical director at diagnostics company Thermo Fisher Scientific, tells *Evaluate Vantage*. “What the vaccine will do is select for a strain that is more resistant.”

There is thus a pressing need for assays that can distinguish new forms of the coronavirus carrying novel mutations. Last month Thermo Fisher launched a test capable of picking out both the Delta and Lambda variants.

But Delta and Lambda are old news. Crucially, the panel can also be modified quickly and easily to detect the spread of newer variants – as soon as mutations in emerging strains are published, Thermo Fisher’s test can be tweaked to match, enabling the tracking of any new variant of concern.

“At some point, the virus will find a way to evade the vaccines. And that’s what we need to really worry about, because the vaccines need to be modified to the prevalent strains.”

Boosters

Keeping an eye out for new variants is only one of the ways in which the Covid-19 testing landscape has changed from this time last year. Another technology that is being pursued determinedly by diagnostics groups is quantitative antibody tests, with the goal of determining how long immunity might last in convalescent patients or people who have been vaccinated, and therefore when booster shots might be needed.

“The question is, after vaccination, people are producing high antibody titres – but how much of a titre is needed so people are protected?” says Christoph Pedain, head of point of care diagnostics at Siemens Healthineers, which is at the forefront of this research.

While Healthineers has developed a test that can accurately determine an individual’s antibody levels, this is only part of the puzzle. Both Mr Pedain and Mr Gandhi stress that no link has been proven between the presence of Covid-19 antibodies and immunity from infection, even 18 months into the pandemic.

Levels of antibodies are highly variable person to person, and a level that confers immunity on one person might not be high enough for another, Mr Gandhi explains. “It all depends on a person’s age and underlying disease. It’s a complicated field rather than just a cut off per se,” he says. Another wrinkle is ensuring the test detects neutralising antibodies in particular.

Healthineers, however, has been working towards squaring this circle. A year ago it began a collaboration with the CDC and the European Commission to identify the minimum antibody levels necessary for a person to be considered immune. The initiative also aims to produce a standardised test, capable of working on everyone, that can certify immunity post-vaccine or post-infection – and tell when it has worn off.

This effort is still ongoing, Mr Pedain says, though he is unable to say when it might yield results.

From diagnostic to prognostic

More imminent is testing that can assess patients presenting at hospital to determine how severe their symptoms might become. In July the small private group Memed obtained European approval for such a test, and Healthineers has released an algorithm for its diagnostic instruments that works similarly, though it assesses different biomarkers to Memed’s test.

This kind of testing is going to become more widespread, Mr Pedain says. But he says that severity prediction is most necessary in unvaccinated or partially vaccinated people – as vaccination levels rise, it might gradually become less useful.

Diagnostics companies are clearly still innovating even as the coronavirus outbreak starts to shift from the pandemic to the endemic phase. Perhaps this is a hedge against falling demand for the simple, bread-and-butter PCR, antigen and antibody tests that did so well throughout 2020.

If so, it might be an unnecessary one. In the past few weeks companies including Becton Dickinson and Quidel have reported a sudden increase in demand for their basic tests as case numbers rise again. A combination of relatively simple diagnostics and newer, more sophisticated technologies will be necessary for some time yet.