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Case Study

Validating a quick, safer, more productive SARS-CoV-2 testing pathway

The Francis Crick Institute's experience with Thermo Scientific™ InhibiSURE™ Viral Inactivation Medium

An innovative new viral transport medium (VTM) is making SARS-CoV-2 testing "quicker and safer", from collection to analysis.

That's according to Ruth Harvey, assistant director of the Worldwide Influenza Centre. She has been working with colleagues at London's Francis Crick Institute biomedical research centre, to validate Thermo Fisher Scientific's new Thermo Scientific™ InhibiSURE™ viral inactivation medium formula.

The world-renowned institute, a partnership between Cancer Research UK, Imperial College London, King's College London, the Medical Research Council, University College London and the Welcome Trust, works with organisations across academia, medicine, and industry to "make discoveries about how life works".

Non-hazardous, productivity boosting formulation

Unlike many viral inactivation formulations, InhibiSURE viral inactivation medium is non-hazardous and leak-proof, making it safer for front-line and laboratory staff, says Harvey. What's more, by removing the need for further inactivation steps, it streamlines workflows, boosting productivity and enabling laboratories to provide SARS-CoV-2 testing.

"Media that preserve the virus for culturing represent a biological hazard at the point of collection throughout its transport to an appropriate lab," says Harvey, explaining that any spillage or accidental opening outside of the correct level of containment represented an infection risk.

The workflow implications of this can be significant. "Before opening, every tube will need to be examined inside a microbiological safety cabinet to make sure it hasn't leaked. Depending on the sample, that might be in a containment level two or three environment, so the restrictions become quite onerous quite quickly," she admits.

Of course, InhibiSURE viral inactivation medium is not the only product to streamline this process by inactivating the virus at the point of collection. However, the fact that it does this using a non-hazardous formulation is worthy of note. Many viral inactivation formulations, for example, contain a guanidine-based chemical that, when mixed with bleach or strong acids, can release toxic cyanide gas.

"There are a number of products on the market that deliberately inactivate the virus, but they tend to do so using a formulation that can be quite toxic – they remove the biological risk but introduce a chemical risk," says Harvey.

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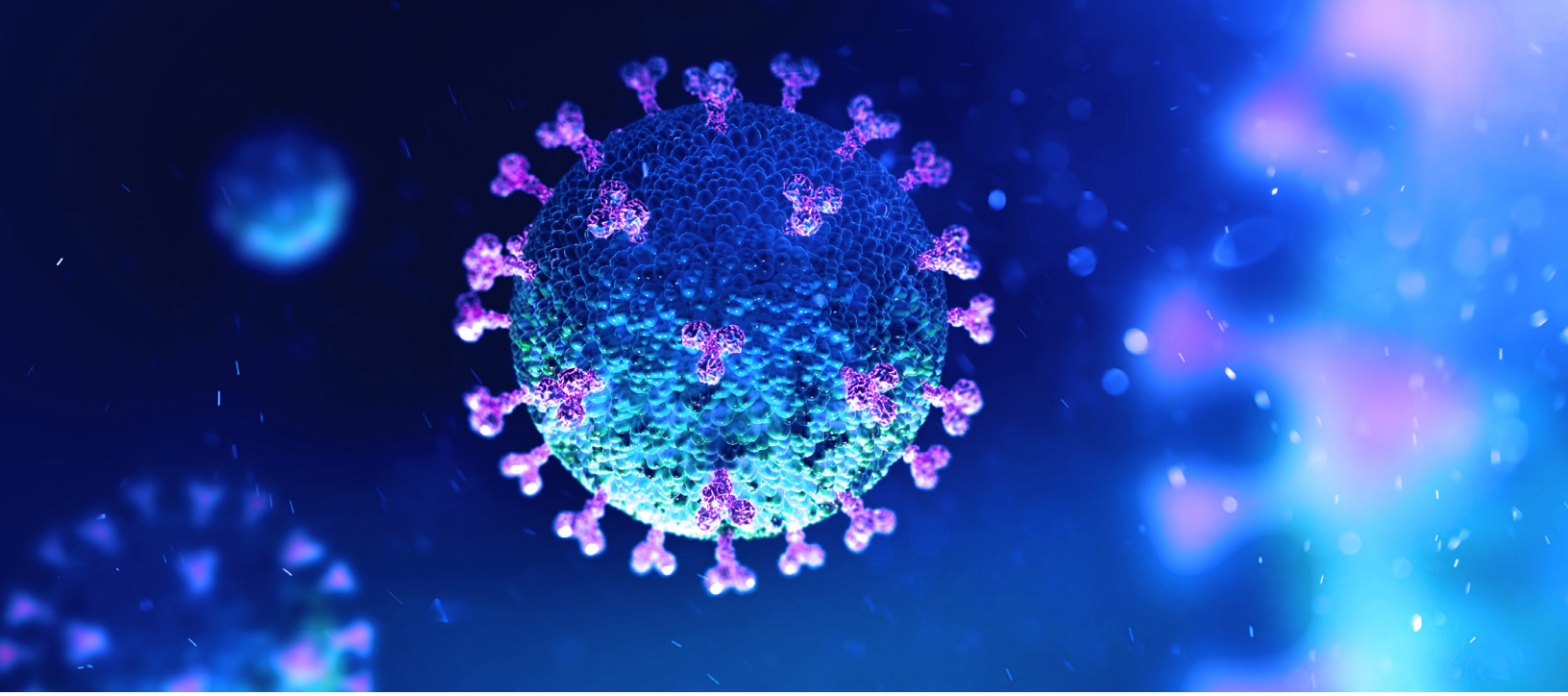

“Every lab in the world is looking for safer alternatives to some of the horrible chemicals we use because we don’t want to expose people to these risks. Removing these risks also means we don’t have to use the same level of containment.”

Of course, there is a productivity gain here, but the approach also benefits staff by reducing the amount of manual handling needed. “Speaking from personal experience,” Harvey says, “working on something on an open bench is physically a lot more comfortable than working within the confines of a safety cabinet.”

Validating the claims

While it is always a good idea for laboratories to use surrogates, Harvey says they needed to be sure the products they selected were appropriate.

“Validation is so important because people’s health and safety are on the line. We are lucky enough to have the facilities we need to work with the live virus, so we can do the testing that laboratories need to prove that this product works.”

Over the course of the last 12 months, the team set out to answer two questions: whether the InhibiSURE viral inactivation medium could effectively inactivate SARS-CoV-2 within 30 minutes, as claimed, and whether the RNA in the sample remained stable enough for detection during transportation and storage.

Inactivation

To challenge the inactivation capability of the medium, the team produced a titred virus stock of 10^7 PFU/ml. This was added to InhibiSURE-only samples, to simulated negative clinical swabs using an artificial nasal matrix, and to control samples. After 30 minutes, and various cleaning spins, the team transferred the remaining samples onto cells that were permissive for infection.

“We could obviously see that there was no live virus left in the sample because there was no infection on the cells. We then confirmed inactivation by doing three blind passages on the cells so that any virus left alive would have every chance to be amplified up,” says Harvey, adding that plaque assays demonstrated the virus had been deactivated.

The process was also carried out on a set of “difficult” samples, such as nasal swabs with excess mucus. The team used a higher PFU/ml stock to increase the volume of the sample, and still found InhibiSURE viral inactivation medium to be potent enough to deactivate the virus.

“It worked using a stock of 10^7 PFU/ml, which is much, much higher than a person would have in their nose,” notes Harvey.

RNA stability

The other main question was whether the sample would remain stable in the product for long enough to enable transportation to and storage at a testing laboratory.

Based on data from a limit of detection study, the researchers spiked samples with SARS-CoV-2 and stored them at temperatures of up to 30°C. These were then analysed at various time stamps over the course of 10 days.

Even after 10 days at 30°C, the data showed no change in the level of RNA detected and Harvey's team was able to conclude the RNA was stable.

The experiment was repeated with spiked negative clinical swabs "just in case there was anything particularly caustic or unfriendly in people's noses that may affect those results". There was still no deterioration of the signal, according to Harvey.

Next steps

Harvey's team hopes the results of their validation studies will give laboratories confidence in the InhibiSURE viral inactivation medium formulation, which can be used by healthcare professionals in clinical and population screening settings.

"We are now validating the product for the influenza virus," she says. "We will do the same set of experiments and I am confident that it will work in the same way."

As follow up from ongoing work between The Crick Institute and Thermo Fisher Scientific, InhibiSURE viral inactivation media is now available for the collection and inactivation of RNA enveloped viruses including SARS-CoV-2, RSV, influenza A, and parainfluenza virus type 3.

For more information and resources, visit
thermofisher.com/inhibisure

Product is CE marked but not 510(k)-cleared and not available for sale in the U.S. Availability of product in each country depends on local regulatory marketing authorization status.

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