

BioPharma Services
News
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Eurofins Viracor BioPharma partners with Moderna, performing essential clinical trial testing for COVID-19 Vaccine

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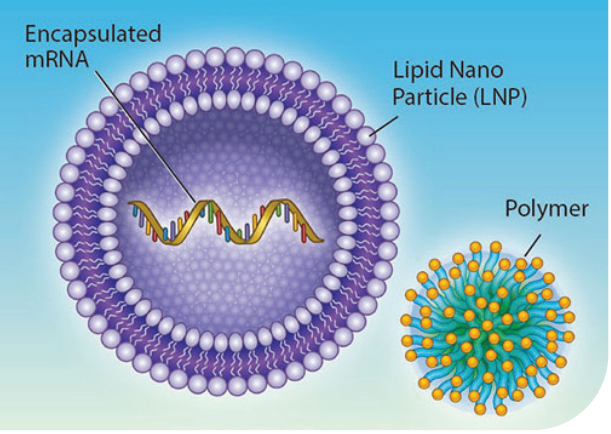
It was early 2020 when the head of Moderna's vaccine development team first met with Eurofins Viracor. Moderna scientists were working feverishly to move their COVID-19 vaccine candidate programme into the clinical phase, but their laboratory partner did not have all the validated assays ready to meet the needs of the trial. Eurofins Viracor was also gearing up to enter the fight against the COVID-19 pandemic with the launch of their new Coronavirus (COVID-19) SARS-CoV-2 RT-PCR test. A qPCR assay that the US Food and Drug Administration (FDA) would later show to have the highest sensitivity of any they evaluated.

Not having worked with Eurofins Viracor previously, Moderna was understandably skeptical about partnering with someone new for such a high-stakes project. So much so that they lined up backup providers in case Eurofins Viracor was unable to meet their clinical testing needs. But Eurofins Viracor didn't fail. After developing a sensitive and robust quantitative polymerase chain reaction (qPCR) assay for Moderna's study, that was bridged to their EUA assay, the Eurofins Viracor laboratory team performed over 2,000 Phase II tests, and more than 85,000 tests (on NP swab and saliva samples) to support their >30,000 subject Phase III trial; matching Moderna's intensity and proving that their newly chosen molecular testing partner was equal to the task.

The two organisations worked closely and collaboratively, in a joint response to the COVID-19 pandemic, performing essential laboratory testing to assess the efficacy of the Moderna vaccine candidate against novel coronavirus infection. The ultimate result was the successful completion of Moderna's clinical trial for the mRNA-1273 COVID-19 vaccine candidate, and emergency use authorisation (EUA) by the US FDA on December 18, 2020, with subsequent approvals by regulatory agencies around the globe.

Without the accurate and reliable molecular testing Eurofins Viracor provided, the Moderna trial could not have met the aggressive timeline needed for regulatory submission and approval for their COVID-19 vaccine. As the Moderna vaccine continues to be distributed around the world to thwart the spread of the deadly COVID-19 virus, the Eurofins Viracor team looks back with pride at the contribution to its success and are humbled by the impact it will have on the health and safety of millions of people across the world. For more information, visit: *www.eurofins-viracor.com/biopharma*

N°28 - February 2021



Eurofins holds a wealth of cGMP experience testing RNA based drugs

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In December 2020, the Food and Drug Administration granted emergency authorisation to the Pfizer/BioNTech and Moderna coronavirus vaccines. This historic research sprint has reduced the typical seven-year vaccine development process to an unprecedented 10 months. As the initial winners in the coronavirus vaccine development race, the Pfizer and Moderna vaccines have one thing in common, they are both mRNA based, resulting in a new focus on RNA drug development technology.

Messenger RNA (mRNA) is a type of oligonucleotide that is critical to the translation of genetic sequence information of DNA into proteins manufactured in the cell. In the case of these new vaccines, this protein is the signature spike protein of the coronavirus. These mRNA products are considered to be their own unique modality. Distinct from traditional small molecule drugs and biologics such as monoclonal antibodies, they have their own unique analytical challenges. At Eurofins BioPharma Product Testing, supporting RNA based drug development candidates is nothing new. Eurofins' laboratories in Lancaster, PA; San Diego, CA; and Dungarvan, IRE, have supported both mRNA and RNAi development candidates from leading innovators with their broad cGMP testing service portfolio for close to a decade. Some of the methods employed include:

- Characterisation of Exons (5' Cap) and Poly (A) Tails (3'End) by Orthoginal Mass Spec
- Purity/Impurity of Starting Materials by LC/MS
- Purity/Impurity by Ion Exchange RP-HPLC and CE
- Identity by Reverse Transcription (RT) Sanger Sequencing
- Total RNA by Spectroscopy
- Potency - Cell Based Bioassays
- Residual Solvents and Metals by GC and ICP
- Residual plasmid DNA by PCR

The approved vaccines are carried into the body by lipid nanoparticles with polyethylene glycol (PEG), adding to their complexity. Therefore, additional analytical methodologies are employed to characterise the lipid and drug product, including, % RNA encapsulation by Ribogreen, Lipids by HPLC-CAD, Particle Size and Dispersity by Light Scattering.

As with any biopharmaceutical product, various other characteristics are typically required to support stability and release testing as described in USP/EP, including pH, osmolality, appearance, particulate matter, sterility, bacterial endotoxin, and bioburden.

Finally, drug developers are constantly employing novel delivery systems and formulations to increase the efficacy of their products, so additional assays may be required to provide information to cover these aspects of the final product. Contact us to learn more: *www.eurofins.com/BPT-Contact-Us.*

Eurofins Bioanalytical Services develops surrogate virus neutralising antibody detection assays against SARS-CoV-2

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The world is entering a new era of the COVID-19 pandemic in which there is an increasing call for reliable antibody testing. Conventional neutralising antibody serological testing requires the use of a live virus conducted in a Biosafety Level 3 (BSL-3) laboratory, which presents challenges for COVID-19 development programmes. An alternative approach is the use of a surrogate virus test (sVNT) that removes this obstacle and is the first neutralising antibody serology test to receive emergency use authorisation (EUA) from the FDA. This innovative assay detects the presence of neutralising/blocking antibodies against the SARS-CoV-2 virus, that block the interaction between the receptor-binding domain (RBD) of the viral spike glycoprotein and the ACE2 cell surface receptor.

Current testing methods, such as PCR, determine whether someone is actively infected by confirming the presence of viral material or IgG/IgM antibodies that detect (binding and blocking) induced immune response from exposure to the virus. Being an ELISA methodology, the in-house, fully validated surrogate virus neutralisation test (sVNT) is amenable to high-throughput testing, at a lower analytical cost, and requires no extended validation timelines for Eurofins' client base. It also removes the obstacle faced by many COVID-19 development programmes, by eliminating the requirement for a Biosafety level 3 containment.

The advantage over historic antibody IgG/IgM tests is that this new gold standard assay tests for neutralising antibodies (versus binding antibodies), by confirming neutralising function without the need for a secondary antibody and is isotype and species independent.

As the world strives to combat the COVID-19 pandemic, Eurofins is committed to being part of global solution by expanding capacity to develop reagent kits and investments in non-proprietary assays to offer for industry COVID-19 analytical Nab testing. For more information, visit: *www.eurofins.com/*

Targeting pro-inflammatory cytokines for COVID-19 therapy: Qualified cell-based assays for accelerated drug discovery

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The COVID-19 pandemic has left the world racing against time for remediation. As a result, there have been hundreds of therapeutic strategies have emerged globally in the last several months. Among several noteworthy approaches is the targeting of pro-inflammatory cytokines such as IL-6, IL-1, TNFα, GM-CSF, etc. An uncontrolled and dysfunctional release of these cytokines after viral infection causes cytokine release syndrome, a condition linked to mortality in COVID-19 patients. Therefore, several new and existing drugs targeting these cytokines are in development for COVID-19 treatment. However, this requires robust cell-based bioassays that can accelerate the development and market-release of such therapeutics, but such assays have repeatedly proven to be challenging to develop. From cell line development and characterisation to assay qualification and implementation, the process of assay development can take anywhere from nine months to over a year, thus impacting the timeline of a drug's release into the market.

To address these challenges, Eurofins DiscoverX offers a comprehensive menu of ready-to-use, qualified bioassays for drugs targeting the key cytokines. Each of these bioassays reflects the drug's mechanism of action and is qualified with specific innovator drugs, e.g. tocilizumab (Actemra®), anakinra (Kineret®), and adalimumab (Humira®), among others. During qualification, each bioassay is rigorously tested to ascertain a high degree of assay accuracy, precision, linearity, and reproducibility to ensure these are fit-for-purpose for potency and stability testing. Thus, such qualified bioassays that would otherwise take over a year to develop are readily available for implementation in drug development programmes.

Through its expertise in cell-based assays, Eurofins DiscoverX strives to help companies bring effective therapeutics to the market faster than ever before with confidence. Learn more about assays for COVID-19 drug discovery at *www.discoverx.com/covid-19*.

Eurofins launches new tests and massive capacity to detect and monitor new variants of SARS-CoV-2

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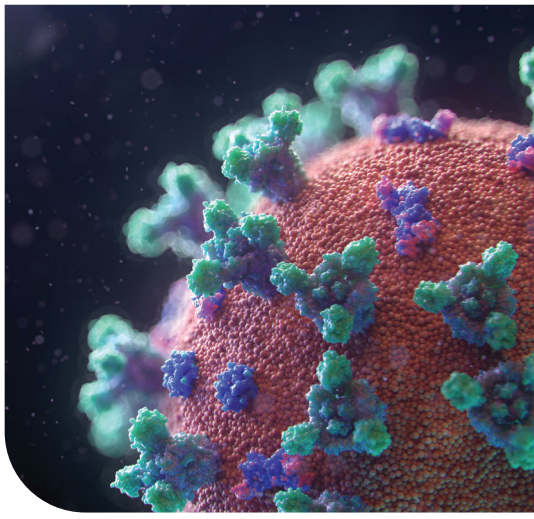

The increasing diversity of SARS-CoV-2 variants and the potential higher infectivity of some new viral strains, underline the need to identify, trace, and track mutations across the complete viral genome. Currently, strains of concern include the B.1.1.7 variant, first identified in the United Kingdom, the B.1.351 variant, first identified in South Africa, and the P.1 (B.1.1.28.1) first identified in Brazil.

Eurofins is pleased to announce the following initiatives to support health authorities' variant detection and monitoring programmes:

- Increasing, to more than 5,000 full genomes per day, the capacity for its ARTIC Next Generation Sequencing (NGS)
- The launch of NovaType, a SARS-CoV-2 RT-PCR assay, clinically validated for the identification of new variants with a short turn-around time, ideal for retesting millions of positive samples to detect if the virus is the B.1.1.7 (UK), B.1.351 (South Africa), or P.1 (B.1.1.28.1; Brazil)
- NovaType is already available as a Laboratory Developed Test (LDT) in Germany and will shortly be made available to the more than 50 Eurofins laboratories worldwide testing patients for COVID-19
- NovaType is being made available to health authorities in a number of European countries for trial and potential inclusion in their monitoring programmes in response to these new variants
- The NovaType assay was launched as a Research Use Only (RUO) kit in Europe at the end of January 2021

As previously outlined, the Eurofins-Viracor SARS-CoV-2 RT-PCR diagnostic test has been ranked as the most sensitive out of more than 115 kits evaluated by the FDA SARS-CoV-2 Reference Panel (*www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2*). Furthermore, this RT-PCR test maintains very high sensitivity in the detection of variants such as B.1.1.7 and B.1.351.

Through Eurofins' current COVID-19 testing and clinical diagnostics activities globally and its partnerships with leading biopharmaceutical and vaccine companies, Eurofins is able to closely monitor the identification of new variants of SARS-CoV-2 and intends to add new detection capabilities to NovaType as additional variants appear. Eurofins' ability to produce and distribute primers and probes, and commercial PCR kits, additionally enhances the speed of development of new assays. For more information, visit: *www.eurofinsgenomics.eu/en/next-generation-sequencing/applications/*

Testing disinfectants for virucidal efficacy, a daily job at Eurofins!

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Disinfectant products have become pervasive in our daily lives as a result of COVID-19, being used much more widely and frequently than before. Demand for such products has increased significantly in all geographies, as have testing requirements. Proving efficacy of virucidal products, through validated and internationally recognised test methods, is essential in supporting manufacturers' regulatory requirements and marketing efforts. Eurofins has supported manufacturers for more than 15 years through these processes, providing extended consultancy and testing services.

In response to increasing global demand for virucidal testing services in the wake of COVID-19, Eurofins BioPharma Product Testing Italy (Eurofins BTP Italy) has expanded its virucidal testing capacity with the opening of a dedicated laboratory, in its Milan campus. The laboratory will carry out efficacy testing and studies on disinfectant products, materials with antiviral properties, and devices for disinfection or sanitisation of air or surfaces.

Delivered in just three months, the 400 square meters BioSafety Level 2 laboratory is now fully complete and running, and all required staff and scientists were recruited and trained in parallel with construction, to allow for operations to commence at the beginning of December 2020.

The laboratory hosts ISO 17025 accredited tests and Good Laboratory Practices (GLP) studies to assess and demonstrate the general virucidal activity (against enveloped and/or non-enveloped viruses) of products and determine efficacy levels against viruses such as COVID-19 or Influenza. Tests are performed following international validated standards and guidance: CEN, ISO, ASTM and OECD.

With eight biohazard virucidal workstations and cell culture manipulation testing equipment, the laboratory increases Eurofins BPT Italy's virucidal study capacity from 40 to more than 100 studies per month. The laboratory has been designed in such a way that will allow for further expansion to double testing study capacity as and when required. It has also been designed to facilitate current COVID-19 social distancing health and safety measures. For more information, visit: *www.eurofins.com/consumer-product-testing/covid-19-product-testing/disinfectants/*

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