

# Eurofins Technologies launches total antibody (IgG, IgA and IgM) detection ELISA assays to aid the rapid identification of persons who have been exposed to SARS-CoV-2 (COVID-19)

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Eurofins Technologies announces the launch of a serology-based total antibody (IgG, IgA and IgM) detection ELISA assay for indirect diagnostic of past exposure to COVID-19. The development of the assay has been led by Eurofins Ingenasa, a Eurofins Technologies company involved in the development of diagnostic tests supporting the control of infectious diseases for over 35 years in veterinary and more recently in human diagnostics.

While molecular diagnostic techniques (PCR) are a direct indicator of the COVID-19 disease, serological tests determine whether a person has been exposed to the infection and has therefore developed antibodies to SARS-CoV-2.

The CE-IVD marked INgezim COVID 19 DR is a dual recognition enzyme-linked immunosorbent assay (ELISA) capable of detecting semi-quantitatively total SARS-CoV-2 virus N-protein-specific antibodies (IgG, IgM and IgA) in a single human serum or plasma sample. The assays use the SARS-CoV-2 nucleoprotein (N protein) as antigen for the detection of antibodies to SARS-CoV-2. The N protein is one of the most abundant early-onset proteins of the virus, as well as being highly immunogenic and therefore a good candidate antigen for the diagnosis of COVID-19.

The assay is capable of detecting any type of antibody specific to the SARS-CoV-2 N protein (IgA, IgG, IgM) without differentiating between them. However, this highly sensitive test is particularly recommended for the early detection of SARS-CoV-2-specific antibodies as it favours the detection of IgM due to its ability to capture more than one conjugated N-protein molecule.

Validation of the assay with a panel of 332 well characterized sera samples confirmed an analytical sensitivity of 100% from day 17 after symptoms onset (85% between days 7 and 16) and a specificity of 99.2%. No cross-reactivity with other respiratory coronaviruses (229E, NL63, OC43 and HKU1) was detected and no interferences have been found for antibodies for respiratory viruses such as Influenza or RSV.

The ELISA assays determine total antibodies in serum samples with an incubation time of 75 minutes with no requirement for sample pre-dilution. INgezim COVID 19 DR kits are compatible with various open-platform ELISA analysers.

According to experts, there is a large range of applications for serologic testing. Serology can be used to complement the PCR swab testing that detects the virus to help diagnose acute infections status and its evolution. It can help estimate the timing of infection. As knowledge develops about the immunity to potential reinfection of patients having previously contracted COVID-19 and recovered, antibodies testing may provide information about statistically reduced contagion risks of and from these persons. It could also help identify donors of plasma from recovered patients that can be transfused into COVID-19 patients as a potential treatment.

Eurofins Technologies companies NovaTec, VIROTECH and Gold Standard Diagnostics have previously launched serological tests for the individual determination of IgG, IgM and IgA antibodies in April 2020. Today's announcement completes the Group's offering for antibody testing by ELISA.

For more information on the assay, please visit the **Eurofins Technologies webpage**.

### For more information, please visit www.eurofins.com or contact:

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#### Notes for the editor:

About Eurofins Technologies – a fast growing provider of diagnostic technologies in the field of immunoassays and molecular detection methods

Building on the experience and scientific excellence of the Eurofins Group, Eurofins Technologies is a fast growing global provider of diagnostic technologies and industry-leading ELISA-based instruments in the field of bioanalytical testing for the food, feed, environmental, animal health, and clinical diagnostics industries.

Its R&D teams located at various sites around the world share their expertise in developing a wide range of innovative methods and applications with a focus on immunoassays and molecular testing. For further information, please visit the <u>Eurofins</u> Technologies website.

About Eurofins - the global leader in bio-analysis

Eurofins Scientific, through its subsidiaries (hereinafter "Eurofins" or "the Group"), believes it is the global leader in food, environmental, pharmaceutical and cosmetics products testing and in agroscience CRO services. It is also one of the global independent market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, CDMO, advanced material sciences and in the support of clinical studies. In addition, Eurofins is one of the leading global emerging players in esoteric and molecular clinical diagnostic testing. With over **47,000 staff** across a network of more than 900 independent companies in over **50 countries** generally specialised by end client markets and operating more than **800 laboratories**, Eurofins offers a portfolio of over **200,000 analytical methods** to evaluate the safety, identity, composition, authenticity, origin, traceability and purity of a wide range of products, as well as providing innovative clinical diagnostic testing services. The Group's objective is to provide customers with high-quality and innovative services, accurate results on time and, when requested, expert advice by its highly-qualified staff.

Eurofins is committed to pursuing its dynamic growth strategy by expanding both its technology portfolio and its geographic reach. Through R&D and acquisitions, the Group draws on the latest developments in the field of biotechnology and analytical chemistry to offer its clients unique analytical solutions and a very large range of testing methods.

As one of the most innovative and quality-oriented international groups in its industry, Eurofins is ideally positioned to support its clients' increasingly stringent quality and safety standards and the increasing demands of regulatory authorities and healthcare practitioners around the world.

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