



bioMérieux announces the CE marking of the new generation semi-quantitative VIDAS® SARS-COV-2 IgG II serology test.

Marcy l'Étoile, France – May 10, 2021 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces CE marking of the new generation of IgG serology test with VIDAS® SARS-COV-2 IgG II to semi-quantitatively detect antibodies in people who have been exposed to the SARS-CoV-2 that causes the COVID-19 disease.

In 2021, on top of the importance of detecting COVID-19 virus, the emergence of variant strains and expansion of vaccination have generated new public health challenges. In particular, obtaining quantitative serological information by measuring antibody levels might provide important insights to help evaluate a person's immune response following either natural infection or vaccination.

VIDAS® SARS-COV-2 IgG II offers a semi-quantitative interpretation of the level of IgG antibodies directed against the Receptor-Binding Domain (RBD) of the Spike (S) viral protein. Indeed numerous vaccines for COVID-19 are available, mostly focusing on eliciting an immune response to the RBD / S viral protein. Following an internal evaluation with two of the more common vaccines (Pfizer–BioNTech Comirnaty and Moderna mRNA-1273), it was demonstrated that this new VIDAS® assay will detect anti-SARS-Cov-2 IgG antibodies post-vaccination. Additionally, we have documented correlation of the IgG level results with the WHO international standard.

“Building on three decades of experience in immunoassays, the VIDAS® SARS-COV-2 IgG II will support labs with a solution adapted to new medical needs linked to the evolution of the COVID-19 pandemic.” declared François Lacoste, Executive Vice President, R&D, bioMérieux.

Hospitals and private laboratories can run this new test on bioMérieux's VIDAS® analyzers (MINI VIDAS®, VIDAS® and VIDAS® 3) which are widely available with more than 30,000 systems installed around the world.

“bioMérieux is committed to fight against the spread of COVID-19 with both molecular biology and immunoassay solutions. Our large VIDAS® installed base and easy-to-use platform will provide a wide access to this new antibody test.” said Pierre Boulud, Chief Operating Officer, Clinical Operations, bioMérieux.

ABOUT BIOMÉRIEUX'S GLOBAL RESPONSE TO COVID-19

bioMérieux provides several SARS-CoV-2 diagnostic solutions*:

1. Molecular biology :
 - **BIOFIRE® Respiratory Panel 2.1 (RP2.1)**: this panel includes SARS-CoV-2 in addition to 21 other common respiratory pathogens and delivers results in approximately 45 minutes. **BIOFIRE® Respiratory Panel 2.1 plus**, available in international markets, includes the 21

common respiratory pathogens plus detection of MERS-Coronavirus in addition to the SARS-CoV-2 virus.

- **BIOFIRE® Respiratory 2.1-EZ Panel:** this panel identifies 19 pathogens associated with respiratory infections, including SARS-CoV-2 in approximately 45 minutes, and is used in point of care and near patient (e.g. CLIA-waived) settings. Available in the US only.
- **ARGENE® SARS-COV-2 R-GENE®** and **SARS-COV-2 RESPI R-GENE®:** these tests are available in certain international markets outside of the US and rely on real-time PCR technology and can be used with most commercially available amplification PCR-platforms. The SARS-COV-2 RESPI R-GENE® allows the simultaneous (multiplex) detection of SARS-COV-2, influenza viruses A and B and two other respiratory pathogens (RSV and hMPV).
- **EMAG®** and **easyMAG®:** equipment and associated reagents are pivotal for the extraction of nucleic acids prior to the amplification and detection of specific gene sequences. These systems are in high demand as a means of preparing nucleic acids from clinical specimens.

2. Immunoassays :

- **VIDAS® SARS-COV-2 IgM and SARS-COV-2 IgG:** these two qualitative serology tests detect antibodies as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection
- **VIDAS® SARS-COV-2 IgG II:** this semi-quantitative serology test detects antibodies as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection or vaccination with certain vaccines and the level of anti-SARS-CoV2 IgG antibodies.

** Some references may vary according to the country and regulatory clearance in some countries may not have been obtained yet.*

ABOUT VIDAS®

Launched 30 years ago, VIDAS® has transformed the field of immunoassays offering laboratories universal access to a simple, automated and robust technology providing fast and reliable results. Today, VIDAS® is still the most widely used immunoassay system in clinical laboratories worldwide.


The VIDAS® menu covers a wide range of pathologies, including infectious and chronic diseases and a range of tests dedicated to emergency and critical care. A number of these parameters are part of the bioMérieux full solution to address the global challenges of antimicrobial resistance (AMR) and sepsis. As it enters into its fourth decade, VIDAS® remains a major focus of the bioMérieux immunoassay strategy with ongoing research into new parameters and frequent launches that create value for labs and clinicians, for the benefits of the patients.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2020, revenues reached €3.1 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

 bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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