



VIDAS[®] SARS-COV-2 IgG & IgM

EVOLVING SINGLE TESTS FOR ACCURATE DIAGNOSIS



PIONEERING DIAGNOSTICS

Did you know about COVID-19?⁽¹⁾

>180 Million

reported cases worldwide through June 2021

>4 Million

deaths worldwide through June 2021

With the vaccines arrival, demand in serology testing increased



**NEW
FACTS,
NEW
NEEDS**

- Need of antibody quantification
- Need of data on vaccinated populations
- Need to evaluate variants impact on serology testing

What is the purpose of SARS-CoV-2 serology testing?



- Contribute to the **diagnosis of COVID-19 in symptomatic patients**, as an indirect method



- Testing IgM & IgG separately provides better information regarding early antibody response and dynamics during acute infection or after a recent infection.



- Enable identification of infected subjects in **retrospective contact tracing** investigations.



- Facilitate identification of convalescent COVID-19 patients who have mounted high IgG responses to be used as **passive immunotherapy**.



- Measuring anti-RBD IgG levels against the Spike (S) protein may be **useful to assess the induced immune response following vaccination**.



Serology, a 1st step toward the standardization⁽²⁾

- The International Standard and International Reference Panel for anti-SARS-CoV-2 immunoglobulins were adopted by the WHO Expert Committee on Biological Standardization on Dec 10, 2020.
- The International Standard allows the accurate calibration of assays to an arbitrary unit binding antibody units (BAU) per mL.
- The conversion in BAU/mL is a first step toward the standardization creating a common language for reporting data.

VIDAS® SARS-COV-2

EVOLVING SINGLE TESTS FOR ACCURATE DIAGNOSIS



IgG II*
Semi-quantitative



IgM
Qualitative

Target the Receptor Binding Domain (RBD) of the viral Spike (S) protein

Detection of **specific immune response** and **quantification** of the level of anti-SARS-CoV-2 IgG antibodies

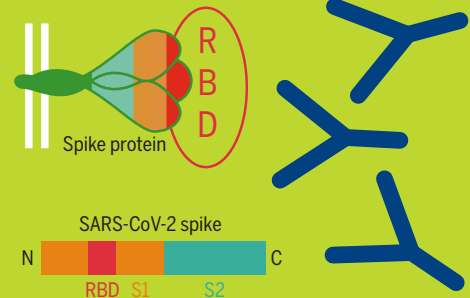
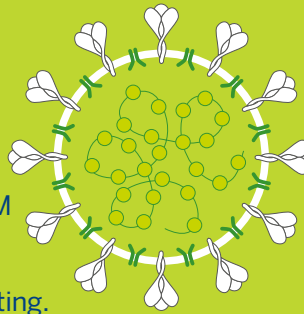
Correlation with WHO International Standard

Detection of **early immune response** following recent infection

*Launch of the first generation IgG in May 2020 – Qualitative - Detection of **specific immune response**

VIDAS® An alternative solution to virus neutralizing testing

Based on such a substantial correlation ⁽³⁾⁽⁴⁾⁽⁵⁾, VIDAS® SARS-COV-2 IgM and IgG assays may represent a RBD-specific, reliable and easy-to-use, alternative solution to virus neutralizing testing.



UNIVERSAL OFFER

- Qualitative and Semi-Quantitative tests ⁽⁶⁾
- Separated IgM and IgG to differentiate immune response from recent or past infection ⁽⁶⁾
- Detection of anti-RBD antibodies highly correlated with neutralizing antibodies ⁽³⁾⁽⁴⁾⁽⁵⁾
- Detection of antibodies in SARS-CoV-2 infected patients and in vaccinated individuals with the first available vaccines ⁽⁷⁾
- Detection of antibodies in patients infected with the B.1.1.7 UK variant ⁽⁸⁾



1 PLATFORM FOR OPTIMIZED COVID-19 PATIENT MANAGEMENT

Also available on your VIDAS® instrument:

B•R•A•H•M•S PCT™
D-Dimer Exclusion™ II

High sensitive Troponin I
NT-proBNP2

NEPHROCHECK®
Ferritin

ROBUST AND TRUSTED OFFER

FLEXIBILITY

- Results in Index value or BAU/mL
- 3 independent assays
- 24/7 availability

EASE OF USE

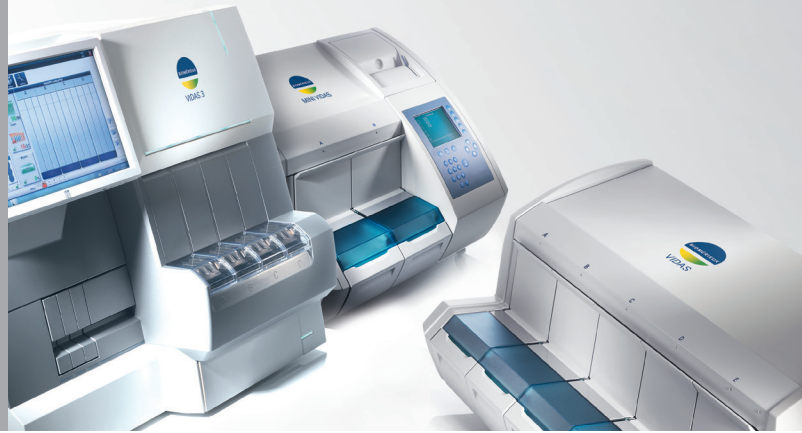
- Ready-to-use tests - Just load & go
- Automated result interpretation

COST-EFFECTIVE SOLUTION

- **New calibration** only once every **56 days** for IgG II
- Long shelf life
- Small kit size (60 tests)
- 1 patient = 1 test

ACCESSIBLE TO A WIDE RANGE OF LABORATORIES

AVAILABLE ON INSTRUMENTS OF THE VIDAS® FAMILY: VIDAS®, MINI VIDAS® AND VIDAS® 3



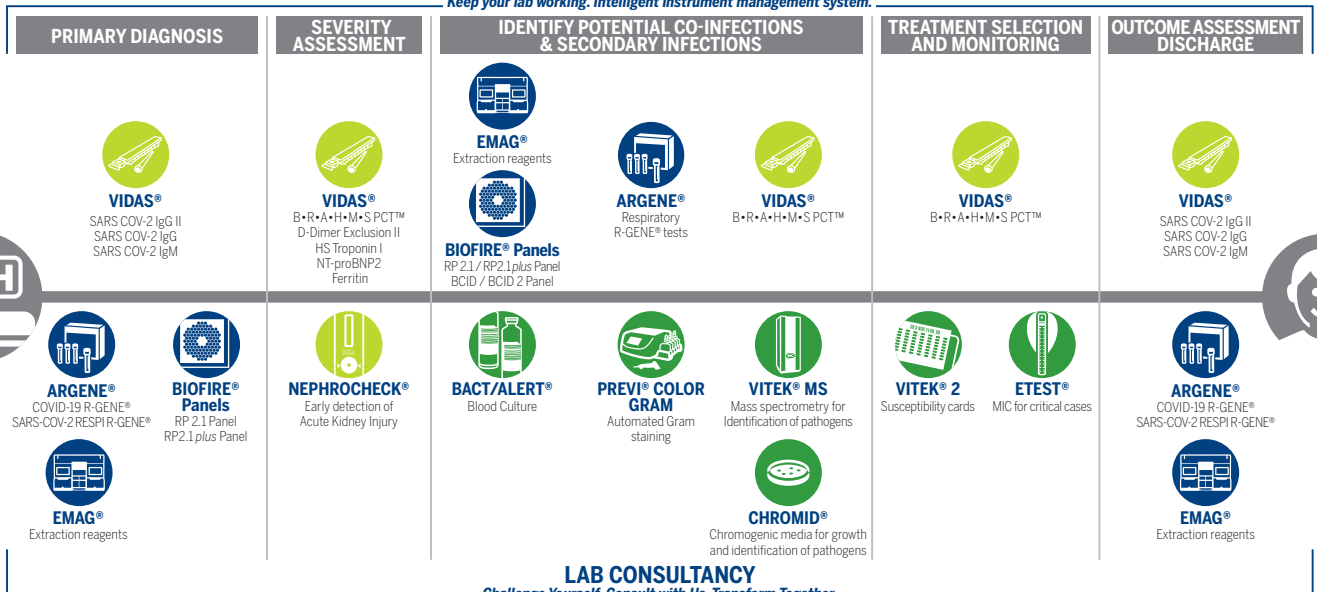
**TRUSTED
ROBUST
UNIVERSAL**

	VIDAS® SARS-COV-2 IgG II	VIDAS® SARS-COV-2 IgG	VIDAS® SARS-COV-2 IgM
Reference	424114	423834	423833
Tests / kit	60	60	60
Sample type	Serum	Serum	Serum
Calibration frequency	56 days	28 days	28 days
Shelf life	12 months	12 months	12 months

DIAGNOSTIC TOOLS FOR THE MANAGEMENT OF COVID-19 PATIENTS

VILINK®

Keep your lab working. Intelligent instrument management system.



LAB CONSULTANCY

Challenge Yourself. Consult with Us. Transform Together.

● Microbiology ● Immunoassay ● Molecular Diagnostics

Availability of these products are subject to local regulatory approvals, allocation priorities, supply chain policies, etc. Please check with the appropriate department.

REFERENCES

- <https://covid19.who.int/>
- <https://www.who.int/groups/expert-committee-on-biological-standardization>
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- VIDAS® SARS-COV-2 IgG II, IgG and IgM and Package Inserts.
- bioMérieux VIDAS® SARS-COV-2 Technical Bulletin April 2021.
- bioMérieux VIDAS® SARS-COV-2 Technical Bulletin June 2021.

PART OF THE VIDAS ASSAY RANGE FOR INFECTIOUS DISEASES

