BIOMÉRIEUX

VIDAS® SARS-COV-2

Two immunoassay tests to detect IgM & IgG antibodies

PIONEERING DIAGNOSTICS

VIDAS® SARS-COV-2

TWO IMMUNOASSAY TESTS TO DETECT IGM & IGG ANTIBODIES

"In the face of the urgency of the COVID-19 pandemic, bioMérieux is committed to providing a comprehensive diagnostic approach that help physicians mount an effective response to the outbreak.

For serological tests, we owe it to patients to provide reliable information on their possible prior infection with SARS-COV-2. The duty of responsible diagnostic companies is to develop highly reliable and accurate diagnostic tests, with performances as close to 100% as possible."

Dr. Mark Miller, Executive Vice President and Chief Medical Officer of bioMérieux

When faced with a novel virus, how can you ensure the most rapid, accurate serological testing?

VIDAS® offers flexibility and easy, uniform protocols to rapidly detect IgM & IgG antibodies to identify patients previously exposed to SARS-COV-2.

Always count on VIDAS®

- Available 24/7 on all VIDAS® platforms
- Limited maintenance, calibration & controls
- Reliable results in less than 30 minutes

Optimize workflow to impact patient management

- Single dose automated tests for greater flexibility
- Same protocol for both IgM & IgG tests
- All-inclusive, small-size kits with long shelf life

Build knowledge of infection patterns

- Qualitative diagnostic results you can trust to contribute to better patient management
- 2 different assays to better follow the antibody responses

PERFORMANCE

SENSITIVITY

Positive Percent Agreement with RT-PCR	Days after PCR positive	
	8-15 days	≥ 16 days
IgM	90.6%	100.0%
IgG	88.6%	96.6%
IgM + IgG	96.4%	100.0%

SPECIFICITY

IgM	99.4%
IgG	99.9%

	VIDAS® SARS-COV-2 IgM	VIDAS® SARS-COV-2 IgG
Reference number (EUA*)	423833-01	423834-01
Tests / kit	60	
Time to result	27 minutes	
Sample types	Serum, plasma (lithium heparin)	
Sample volume	100 µL	
Result interpretation (i=index)	i <1 negative (no detection of IgM/IgG anti SARS-CoV-2) i ≥1 positive (detection of IgM/IgG anti SARS-CoV-2)	
Calibrators and controls frequency	28 days	
Shelf life	12 months	

* Emergency Use Authorization

- This test has not been reviewed by the FDA.
- Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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