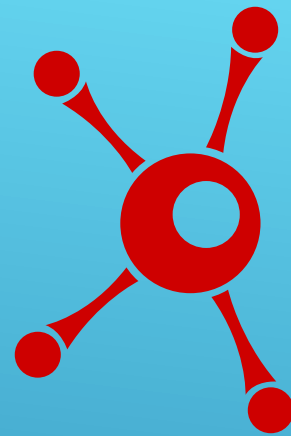




**BioMedomics**  
TESTS FOR LIFE

COVID 19 SCHNELL-TEST



# BioMedomics

TESTS FOR LIFE

Verpackungseinheit: 20 Tests in einem Paket

ab 10.000 Stück

Empf. Verkaufspreis

15.50 Euro

Staffelungen möglich

100.000 Stück

1 Million Stück

5 Millionen Stück

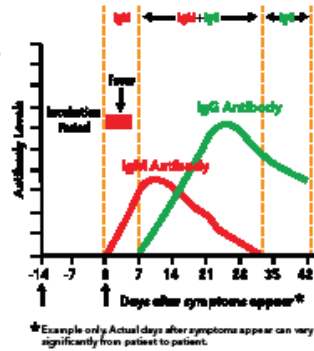
Alle Preise sind zzgl. ges. MwSt. und Frachtkosten

**COVID-19**  
IgM-IgG Rapid Test

In vitro diagnostic test  
for the rapid detection of  
IgM and IgG antibodies to  
SARS-CoV-2

## BioMedomics' new rapid test provides accurate COVID-19 antibody detection in 10-15 minutes.

There is a critical, global need for serology assays that can complement nucleic acid (PCR) tests for diagnosing COVID-19 infection. Although critically important, PCR tests are only positive during the brief window of acute infection, after which they become negative. And while serology tests are not as effective as PCR early in acute infection, they are able to detect COVID-19 antibodies for a prolonged period of time after disease resolution, which enables identification of prior infection. Knowledge of prior infection is epidemiologically important and represents a significant unmet need in the management of the COVID-19 pandemic.



### 4 Simple Steps

1



Collect blood sample

2



Add blood sample to sample well

3



Place 2-3 drops of buffer in sample well

4



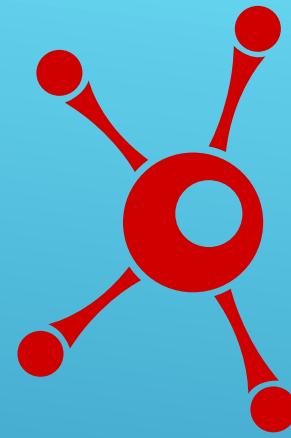
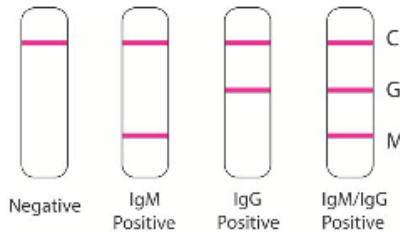
Read results after 10 minutes

### Comparison With PCR Nucleic Acid Tests

	PCR Nucleic Acid Tests	BioMedomics IgM/IgG Rapid Test
Turnaround Time	> 1 Hour	10-15 Minutes
Facility Requirement	PCR Laboratory	No special facilities needed
Operation	Requires expensive equipment	No electronic equipment needed
	Prone to False Negatives	Results are clear and easy to read
Clinical Value	Commonly used, gold standard	Helps identify prior infection

- Works with whole blood, serum, and plasma
- Tests for 2 antibodies
- 4 simple steps, results in 10 minutes
- No special equipment needed

### Results



# BioMedomics

TESTS FOR LIFE

Verpackungseinheit:  
20 Test in einem  
Paket



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bsi.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **BioMedomics, Inc**  
1100 Perimeter Park Dr  
Suite 104  
Morrisville  
North Carolina  
27560  
USA

Holds Certificate No: **FM 644662**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development and manufacture of in-vitro diagnostic medical devices used in the detection of hemoglobin disorders including laboratory and point-of-care in-vitro diagnostic medical devices.

For and on behalf of BSI: Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-10-31  
Latest Revision Date: 2019-08-27

Effective Date: 2019-10-31  
Expiry Date: 2022-10-30

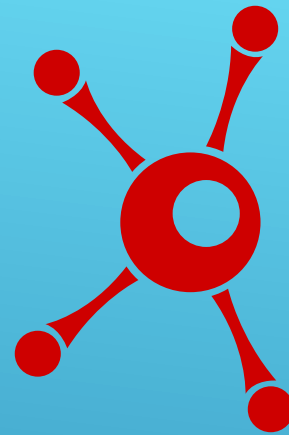
Page: 1 of 1



...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.



# BioMedomics

TESTS FOR LIFE

Bescheinigung über die Eintragung: bsi.

Qualitätsmanagementsystem – ISO 13485:2016

Zertifikat Nummer FM 644662



**MTP e. U.**

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