FAQs

This summary of frequently asked questions supplements the instructions for use, in which you can find detailed information about the NADAL® COVID-19 IgG/IgM Rapid Test.

1. What are coronaviruses?

The *Coronaviridae* family (CoV) includes approximately 40 known species. Many of these viruses cause disease in mammals and birds. The known human pathogenic representatives can cause illnesses ranging from the common cold to severe acute respiratory infections.

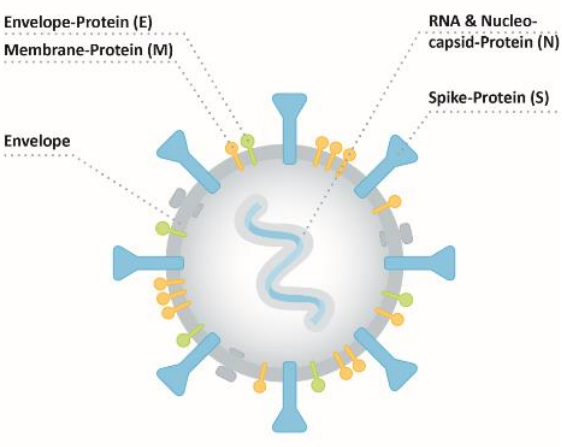

Figure 1 Coronavirus – schematic structure

A coronavirus comprises four important structural proteins – the spike (S), envelope (E), membrane (M) and nucleocapsid (N) proteins (Figure 1). Via its receptor-binding domain (RBD), the spike protein mediates the attachment to specific membrane receptors of the host cell, leading to fusion and thus viral entry into the cells. The RBD is immunogenic and, according to currently available information, possesses several highly variable and therefore specific sequence regions. It is thus the primary target for the development of detection methods, antibodies and vaccines.

2. What are SARS-CoV-2 and COVID-19?

The coronavirus officially designated SARS-CoV-2 is the seventh known human pathenogenic coronavirus and the third in the last two decades. It follows severe acute respiratory syndrome (SARS)-CoV in 2002 and Middle East respiratory syndrome (MERS)-CoV in 2012. Just like SARS-CoV, the SARS-CoV-2 receptor-binding domain (RBD) binds the ACE2 (angiotensin-converting enzyme 2) receptor, while the MERS-CoV RBD binds dipeptidyl peptidase 4 (DPP4) as its receptor (1). The clinical manifestation of an infection with SARS-CoV-2 is officially designated COVID-19.

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3. What is the course of the body's immune response?

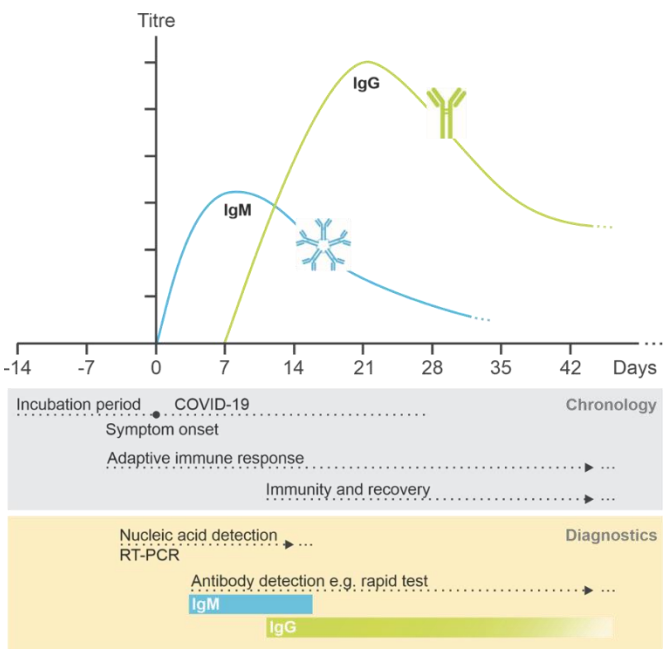

Figure 2 Chronology of the immune response and COVID-19 diagnostics

After an incubation period of 1-14 days, the body generally takes another 3-7 days after the onset of symptoms to produce specific antibodies to fight the virus (Figure 2). If the rapid test is positive for these antibodies, this means that the body's adaptive immune system has mounted a response to the virus. The subsequent presence of IgG antibodies can indicate a resolved SARS-CoV-2 infection for months – even when the virus is no longer detectable by PCR. These IgG antibodies can indicate immunity.

There are suggestions in the literature that the immune response does not always follow the 'classic' course described above. In some cases, only the IgG-class antibodies are detectable, or both classes simultaneously. (2) The immune response to a SARS-CoV-2 infection is the subject of intensive current research, so this chronology of the immune response represents the current state of knowledge.

4. What are the areas of application and the advantages of rapid tests (antibody detection) in COVID-19 diagnostics?

RT-PCR is still the gold standard. However, the accuracy of RT-PCR results is limited when the virus has long since migrated deeper into the lungs. By contrast, an IgG and IgM antibody test for COVID-19 – whether in the form of a rapid test or an ELISA – simply indicates whether the body has mounted an adaptive immune response to the virus, so that the treating physician can take appropriate action. If the result is negative, appropriate precautions must be taken and further testing or re-testing must be carried out. In addition, more potentially affected individuals can be efficiently examined, making faster and more targeted action possible and reducing the burden on laboratories. The same applies here: The more data available, the more soundly measures to contain the pandemic can be evaluated and, if necessary, modified.

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5. At what stage of the infection can NADAL® COVID-19 IgG/IgM rapid tests be used?

The NADAL® COVID-19 IgG/IgM tests are intended for the qualitative detection of anti-SARS-CoV-2 IgG and IgM in human whole blood, serum or plasma samples from symptomatic patients. It is important to note that in the early stages of the infection (3-7 days after the onset of symptoms), anti-SARS-CoV-2 IgG and IgM may be below the detection limit of the test. In some cases, antibodies can only be detected in sufficient quantities weeks after the infection. In case of a cellular immune response, the absence of antibodies is also conceivable. If the result is negative, appropriate precautions must be taken and further testing or re-testing at a later date must be carried out.

6. Can test results from the NADAL® rapid tests tell us whether an infected person is immune?

An antibody test for COVID-19 IgG and IgM indicates whether the body has mounted an adaptive immune response to the virus. This is because a primary infection is indicated by the presence of detectable IgM antibodies an average of 3-7 days after the onset of symptoms. The subsequent presence of IgG antibodies can indicate a resolved SARS-CoV-2 infection for months – even when the virus is no longer detectable by RT-PCR. These IgG antibodies can indicate immunity. However, in some cases antibodies can only be detected in sufficient quantities weeks after the infection. In case of a sufficient innate or cellular immune response to contain the virus, the absence of detectable specific antibodies is also conceivable. More precise findings about possible acquired immunity in recovered patients will only be available after future, longer-term studies.

7. Can test results from the NADAL® rapid tests tell us whether an infected person is contagious?

The NADAL® COVID-19 Rapid Test is intended for the qualitative detection of anti-SARS-CoV-2 IgG and IgM in symptomatic patients. Unfortunately, neither antibody detection via ELISA nor a rapid test can determine whether the detected antibodies have a neutralising effect on the virus. To what extent the detected antibodies allow us to draw conclusions about the contagiousness of a patient is currently the subject of scientific study.

8. Is a COVID-19 test available for home use?

As of 23/04/2020, there are no COVID-19 rapid tests on the market that are approved for home use. Because COVID-19 is a notifiable disease under §6 of the German Infection Protection Act, §3 of the Medical Product Dispensing Regulation does not permit the distribution of home tests for this disease.

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9. Does the NADAL® COVID-19 IgG/IgM Rapid Test have a CE marking?

Yes, the test has a CE marking and can be employed by professional users as an aid in the diagnosis of a SARS-CoV-2 infection.

10. Where can I get NADAL® rapid tests for COVID-19 diagnostics?

nal von minden GmbH is one of the first companies to offer a reliable, CE-marked test system for the detection of antibodies against SARS-CoV-2. If you would like a quote for our rapid tests, you can contact us through your personal sales advisor or at info@nal-vonminden.de

11. What special laboratory equipment is needed to perform the NADAL® antibody rapid test?

The test procedure is not automated and requires no special training. Special laboratory equipment is not required either.

12. How long do the test results take?

A reliable test result is available in 10-15 minutes.

13. What sample material can be used for the NADAL® rapid tests?

Serum, plasma and blood samples can be used for the NADAL® COVID-19 IgG/IgM Rapid Test.

14. Is detailed information on the performance characteristics of the NADAL® COVID-19 IgG/IgM Rapid Test available?

You can find detailed information in the accompanying instructions for use, Section 13, 'Performance characteristics of the test'. If you have any questions, you can get in touch with us at any time.

15. Are data available on the performance characteristics of the NADAL® rapid tests as they relate to the time of SARS-CoV-2 infection?

Conclusions about the time of the infection are often not possible. For this reason, all performance data refer to the time of onset of symptoms.

16. Can there be cross-reactivity with SARS-CoV?

SARS-CoV and SARS-CoV-2 are structurally very similar. With a genetic homology of over 90%, both viruses bind the same receptor type (ACE2) in the host cells. When testing for antibodies against SARS-CoV-2, cross-reactivity with SARS-CoV is thus unavoidable. Due to the locally limited spread in 2003 and the relatively small number of cases, it can be assumed that cross-reactivity with SARS-CoV antibodies has no clinical relevance – particularly since it has been shown that specific anti-SARS-CoV antibodies can no longer be detected after about 6 years (3).

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17. Where can I find more information about SARS-CoV-2 and COVID-19?

On the websites of the European Centre for Disease Prevention and Control (www.ecdc.europa.eu/en/coronavirus) and the Robert Koch Institute (www.rki.de/en). Find out more about how you can protect yourself and help others.

If you have further questions about the NADAL® rapid tests, please feel free to get in touch with our support team: *info@nal-vonminden.de*

Sources:

(1) Tai, W., He, L., Zhang, X. *et al.* Characterization of the receptor-binding domain (RBD) of 2019 novel coronavirus: implication for development of RBD protein as a viral attachment inhibitor and vaccine. *Cell Mol Immunol* (2020). doi: https://doi.org/10.1038/s41423-020-0400-4

(2) Kelvin Kai-Wang To et al. (2020) Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study, Lancet Infect Dis. https://doi.org/10.1016/S1473-3099(20)30196-1

(3) Nisreen M.A. Okba *et al.* SARS-CoV-2 specific antibody responses in COVID-19 patients. medRxiv 2020. doi: https://doi.org/10.1101/2020.03.18.20038059

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