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# Cov19 FluoBolt™-DAT

## Quantitative Duplex Antibody Test (DAT) for antibodies to SARS-CoV-2

**Art.Nr. FIA-1707-FC5**

**Version 210720**

**Innovation made in Austria**

The new test for simultaneous, quantitative determination of anti-$S1_{RBD}$ and anti-nucleocapsid antibodies against SARS-CoV-2.
2 in 1. One test, one measurement, two antibodies.

CE

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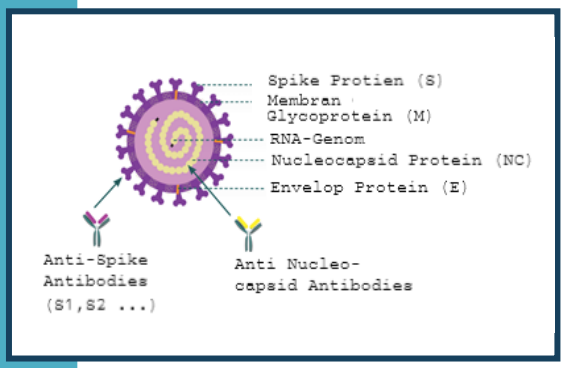
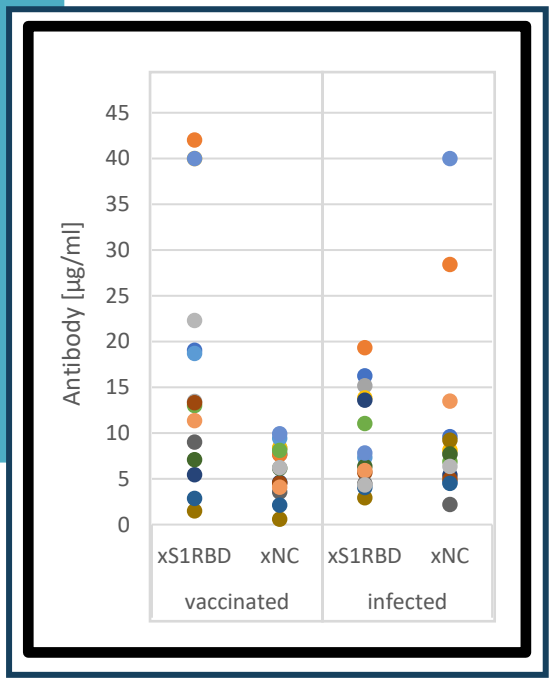
## What is known

Since the outbreak of the SARS-CoV-2 pandemic, a large number of assays have been developed to determine antibodies against SARS-CoV-2 (1,2). As the immune system can form antibodies against various components of the virus (S, M, E, NC) (see picture to the right), analytical specificity is of utmost importance. This means that which antibodies are detected against which proteins is highly relevant for the clinical interpretation of data (e.g. protection against future infection). So far, the focus has been on the determination of so-called neutralizing antibodies (3) against the receptor binding domain (RBD) of the S1 protein, which are induced by all currently approved vaccines.




## What's new

Anti-nucleocapsid (NC) antibodies also play an essential role in the humoral immune response against SARS-CoV-2. This is also manifested by high anti-NC antibody concentrations in infected persons:




Recent studies (4) suggest that anti-nucleocapsid antibodies also protect against infections. The first vaccines (5) that induce anti-NC antibodies are already being developed.

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Measurement of anti-$S1_{RBD}$ **and** anti-NC antibodies is necessary to determine the adaptive immune-response to SARS-CoV-2 vaccination or infection.

## Our Solution – Innovation made in Austria

# Cov19 FluoBolt™-DAT

Quantitative Duplex Antibody Test (DAT) for antibodies to SARS-CoV-2

### Properties

- Simultaneous duplex determination of anti-$S1_{RBD}$ and anti-nucleocapsid antibodies to SARS-CoV-2
- Real quantitative test (µg/ml IgG)
- Simultaneous detection of infection and/or vaccination
- Patented and proven FluoBolt™ microtiter plate technology
- CE-certified according to IVDD 98/79/EC, developed and produced according to ISO 13485
- Validation by NIBSC/WHO standards
- fast

### Your benefits

- The only test with duplex benefit, only one measurement for the determination of two important antibody species
- Independent verification of results possible
- 2 in 1. Only one measurement necessary
- Highest sensitivity & specificity. Can be used in any laboratory
- Checked and assured quality
- 80 patient results after only 60 min

**What makes the Cov19 FluoBolt™-DAT unique**

Simultaneous duplex determination

Real quantitative test

Patented and proven FluoBolt™ microtiter plate technology

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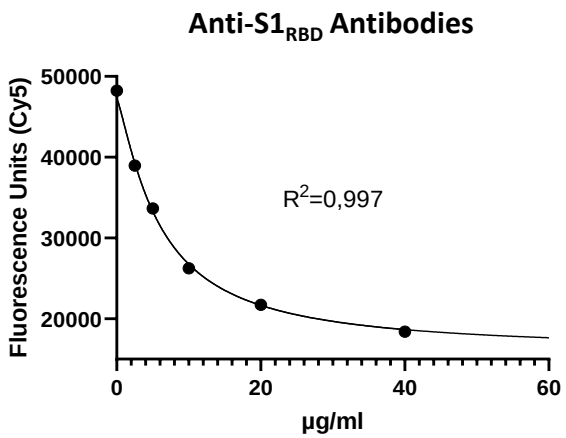
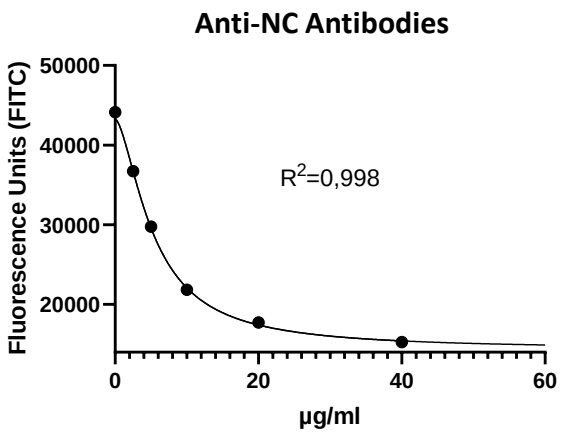
## How the Cov19 FluBolt™-DAT test works

When performing the assay, 10 µl of a patient serum or plasma sample are simultaneously mixed with 50 µl of two different fluorescence-labeled tracer antibodies against the $S1_{RBD}$ and against the NC protein and incubated in our special fluorescence-enhancing microtiter plate for 60 minutes. By measuring at 2 different wavelengths, their displacement by homologous antibodies from the patient sample is determined simultaneously. The signals at one wavelength provide information about the concentration of anti-$S1_{RBD}$ antibodies. The signals at the other wavelength indicate the concentration of anti-nucleocapsid antibodies.

By using the supplied calibrators, a calibration curve for the anti-$S1_{RBD}$ and the anti-NC antibodies is constructed, and the antibody concentration of a patient sample is read from it.
With just a single measurement, this results in a quantitative determination of these two antibody species against SARS-CoV-2, which represent the majority of the immune response and may protect against infection and illness.

For measurement, any commercially available fluorescence microtiter plate reader can be used.

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## Literature

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2) **SARS-CoV-2 serology testing: Progress and challenges** Shi AC, Ren P.J Immunol Methods. 2021 Apr 26;494:113060. doi: 10.1016/j.jim.2021.113060

3) **Serology testing demonstrates that antibodies to SARS-CoV-2 S1-RBD correlate with neutralization of virus infection of Vero E6 cells.** Freeman J. et al. J Appl Lab Med. 2021 Apr 2:jfab027. doi: 10.1093/jalm/jfab027

4) **The Nucleocapsid protein triggers the main humoral immune response in COVID-19 patients**. Smits VAJ et al., Biochem Biophys Res Commun. 2021 Mar 5;543:45-49

5) **Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers** .Lumley SF et al., N Engl J Med. 2021 Feb 11;384(6):533-540. doi: 10.1056/NEJMoa2034545.

6) **Replicating bacterium-vectored vaccine expressing SARS-CoV-2 Membrane and Nucleocapsid proteins protects against severe COVID-19-like disease in hamsters**. Jia Q et al., NPJ Vaccines. 2021 Mar 30;6(1):47. doi: 10.1038/s41541-021-00321-8.

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