# Anti-SARS-CoV-2 ELISA

## ELISA for the qualitative determination of Anti-SARS-CoV-2 specific IgG / IgA in human serum or plasma

SARS-CoV-2 is the name of a Virus, identified at the end of 2019, causing the disease COVID-19 (Coronavirus disease 2019), a disease named Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). Due to high human-to-human transmissibility, the WHO declared COVID-19 as a pandemic in March 2020.

Antibody testing for COVID-19, comprising detection of IgG, IgA and IgM antibodies to SARS-CoV-2–specific epitopes, may represent an interesting tool to document past SARS-CoV-2 infections, both in individual patients with suspected COVID-19 symptoms or late-stage complications who had no (conclusive) PCR test. In addition, measuring SARS-CoV-2 antibodies may offer a prognostic value and convey information on protective immunity in vaccination trials.
Specific IgM and IgA are the early antibody response that starts and peaks within 3 - 5 days. Specific IgG antibodies become elevated after about 10 to 18 days and are assumed as protective antibodies.
The antigen used for the detection of the antibodies in patient serum is the complete SARS-CoV-2 Spike Protein.

The Anti-SARS-CoV-2 ELISA IgG / IgA is an IVD intended for the qualitative determination of Anti-SARS-CoV-2 specific IgG or IgA in human serum or plasma. The test aids to provide an evidence for a previous infection with SARS-CoV-2.

| | |
|---|---|
| Anti-SARS-CoV 2 ELISA IgG | REF 15010-G |
| Anti-SARS-CoV 2 ELISA IgA | REF 15020-A |

The Anti-SARS-CoV-2 ELISA IgG / IgA can be performed manually or fully automated and is determined for the application by qualified and trained professionals only.
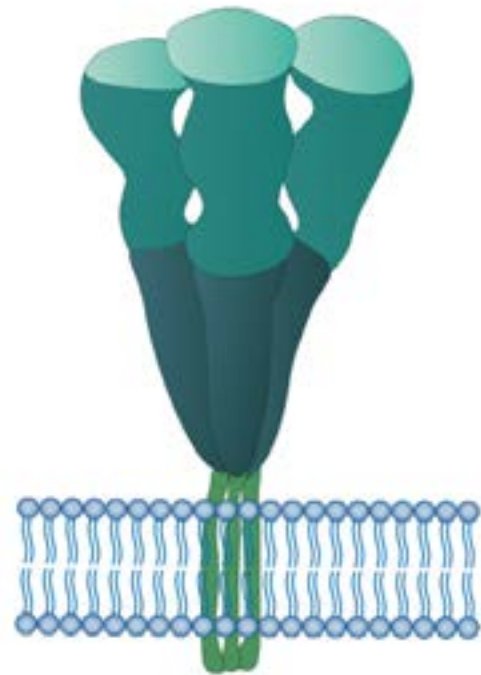


**Figure 1:**
SARS-CoV-2 Spike protein

### Anti-SARS-CoV2 ELISA Specifications

- The whole SARS-CoV-2 Spike Protein is used
- Results can be positive or negative
- Test duration ≈ 2h (30min/ 30min/ 20min)
- 10µL Serum or Plasma per determination
- Detection: HRP/TMB

## Performance Data

The intra-assay, inter-assay and lot-to-lot variations of the tests were found within the following specifications:

|  | IgG | IgA |
|---|---|---|
| Intra-Assay Variation | < 10% | < 10% |
| Inter-Assay Variation | < 15% | < 10% |
| Inter-Batch Variation | < 20% | < 15% |

The comparison of different lots of the same antibody classes to the same specificity is assisted by using the WHO International Standard for anti-SARS-CoV-2 immunoglobulins (Spike protein).

In an evaluation, the overall sensitivity and specificity (compared to a commercial available Anti-SARS-CoV-2-IgG ELISA) were determined as 91% and 93%, respectively.

For Anti-SARS-CoV-2-IgA the overall sensitivity and specificity (compared to a commercial available Anti-SARS-CoV-2-IgA ELISA) were determined as 92% and 93%, respectively.
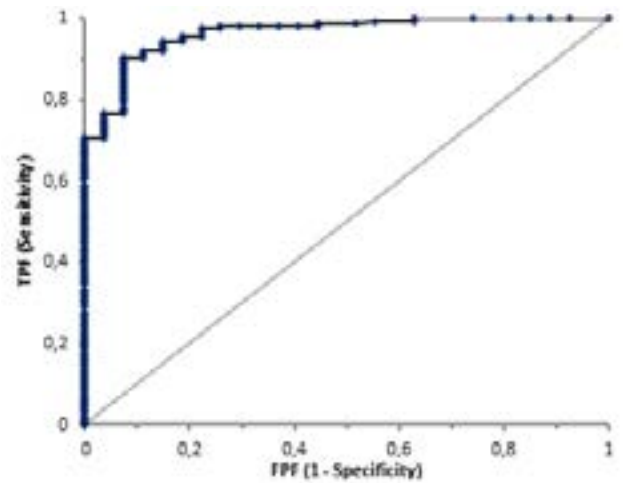


**Figure 2:** ROC analysis for Anti-SARS-CoV-2 ELISA IgG (Dr. Fooke Laboratorien GmbH) vs. a commercial available Anti-SARS-CoV-2-IgG ELISA with n=186 results.
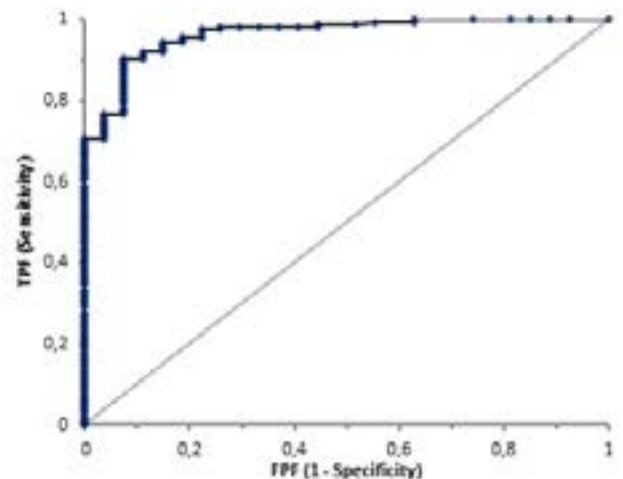


**Figure 3:** ROC analysis for Anti-SARS-CoV-2 ELISA IgA (Dr. Fooke Laboratorien GmbH) vs. a commercial available Anti-SARS-CoV-2-IgA ELISA with n=186 results.

## Literature

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# DR FOOKE