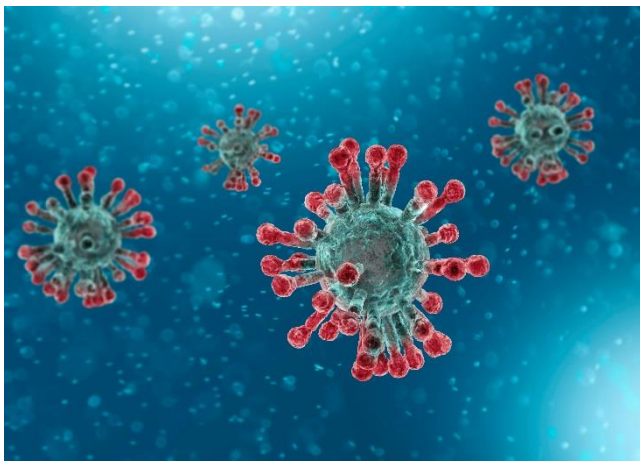
Now available at ArminLabs:

!SARS-CoV-2 Antibody Testing !

- ELISA IgG & IgA
- German IgG & IgM Quick Test
- RT-PCR (available from April 14th)



The emerging Coronavirus (SARS-CoV-2 – Severe Acute Respiratory Syndrome Coronavirus 2) led to an outbreak of the respiratory disease "COVID-19" (coronavirus disease 19) in Wuhan, China, in December 2019. Similar to previous outbreaks of human coronavirus infection, SARS-CoV in 2003[1,2] and MERS-CoV in 2012[3], the new SARS-CoV-2 infection causes clinical symptoms such as **fever, dry cough, myalgia** and/or **fatigue**. Some patients may suffer from pain or symptoms like a stuffy or runny nose, sore throat, loss of smell (anosmia)/taste (ageusia) or diarrhoea. COVID-19 developed into a **pandemic** that spread rapidly in China and later worldwide.

The outbreak of this disease has forced state authorities to take drastic steps to contain the situation, including the quarantine of many millions of people across the world. However, these efforts are limited by a serious problem - the **differentiation** of those who are/have been infected with **COVID-19** from **those who do not have the infection**. The clinical symptoms present in confirmed COVID-19 cases are **not unique** to COVID-19 since they are similar to those of other infectious viral diseases such as influenza[4]. The viral nucleic acid real-time polymerase chain reaction test is currently the standard tool for supporting clinical diagnosis of the infection[5] despite long turnaround times, the expensive equipment required and reports of false negative results for the COVID-19 RT-PCR[6]. It seems important to use various tests to ensure a **substantiated, comprehensive diagnosis**:

- **Screening tests** (these can cover a wide population and are **highly sensitive**, though at the expense of lower specificity as the need to detect positive cases supersedes the risk of false-negative cases): **RT-PCR direct detection of the pathogen**
- **Quick diagnostic tests** (a **swift diagnosis** should be ensured based on clinical symptoms; this may impair sensitivity) – **SARS-CoV-2 IgG & IgM Quick Test**
- **Confirmation tests** (used to confirm previous screening or diagnostic tests such as the RT-PCR; confirmation tests are recommended to gain additional information to support the clinical diagnosis; they have **high sensitivity** and **specificity**): **SARS-CoV-2 ELISA IgG & IgA**

To support efforts to contain the further spread there is an urgent need to use different test methods to swiftly **identify** and **classify patients infected with SARS-CoV-2**. This will help **prevent further transmission** of the virus and **ensure early treatment** of patients.

ArminLabs GmbH · CEO: Dr. med. Armin Schwarzbach
Zirbelstraße 58 · 86154 Augsburg · Germany · Phone: +49 821 780 931 50 · www.arminlabs.com
Email: info@arminlabs.com · Augsburg HRB 29350 · VAT ID: DE815543871

The human organism needs some time (usually around 2 - 3 weeks) to produce antibodies against SARS-CoV-2[7]. Antibody tests are intended to **support the diagnosis** of a SARS-CoV-2 infection and **complement direct detection of the pathogen** (PCR). Serology can also be used to collect epidemiological data, which is especially important in the case of this largely unexplored new infection.

- Median seroconversion is 13 days after the onset of symptoms – half of the patients have no detectable antibodies within the first 12 days
- The seroconversion rate is almost 100% 20 days after the onset of symptoms

The SARS-CoV-2 ELISA is therefore suited both to **supporting** the **diagnosis of SARS-CoV-2 infections** as well as **distinguishing** these **from infections with other pathogens** that cause similar symptoms.

- Differentiates SARS-CoV-2 from other acute pulmonary infections such as influenza virus
- Provides diagnostic assistance in the event of a fresh infection
- Can document a current or previous infection approx. 2 - 3 weeks after the onset of symptoms
- Monitoring the immune response in patients with confirmed infections
- Documents potential immunity if an IgG antibody is detected, without the presence of IgA
- It is recommended that the IgA antibody is not used to screen asymptomatic persons, but to monitor the immune response in patients with confirmed infection (smear PCR)

SARS-CoV-2 ELISA IgG & IgA Antibody Testing

The SARS-CoV-2-ELISA used by ArminLabs is highly sensitive and specific. IgA and IgG antibodies have a **sensitivity** of **89 - 100%**. **Specificity** of the **IgA antibodies** is **87.5 - 100%**, and **83.5 - 97.5%**[8] for **IgG antibodies.** The antigen (S1 domain) used in the test is particularly appropriate for the serological detection of SARS-CoV-2 antibodies as it is more specific than the N or full-length S protein (https://www.medrxiv.org/content/10.1101/2020.03.18.20038059v1). The test has been developed by the **German company** Euroimmun, is **CE certified**, **IVD registered** and **validated**.

SARS-CoV-2 German IgG & IgM Quick Test

The Antibody Quick Test for COVID-19 used by ArminLabs is a rapid test for the qualitative detection of IgG and IgM antibodies. The test is conducted from human serum in the laboratory with laboratory validation of the results. In addition, a medical report is provided as an official document. The **IgM antibodies** have a relative **sensitivity** of **85%** and a relative **specificity** of **96%**. The **IgG antibodies** has a relative **sensitivity** of **100%** and a relative **specificity** of **98%**. The test was developed at the **German Leibniz Institute**, is **CE certified**, and **IVD registered** and validated. The quick test shows no cross reactivity with influenza antibodies. **The result will be available the same day the sample arrives in the laboratory.**

SARS-CoV-2 RT-PCR - Gold Standard Method

The SARS-CoV-2 coronavirus causes major challenges to healthcare systems and medical facilities worldwide. The rapid diagnosis is a major contribution to prevent the rapid expansion of the coronavirus in many countries, including Germany. ArminLabs is one of the leading laboratories in the diagnosis of chronic and acute infections and has implemented the gold standard of diagnosis of SARS-CoV-2.

Nucleic Acid Amplification Technique tests are **currently the most reliable COVID-19 tests** for diagnosing infections with the new coronavirus SARS-CoV-2. This includes the PCR method (Polymerase Chain Reaction, PCR), which can be used to **directly detect** the **SARS-CoV-2** virus in infected persons on the using a throat swab, nose swab, and throat lavage.

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All tests for COVID-19 should be performed in coordination with a healthcare provider. In case of clinical suspicion, samples should be collected from the healthcare provider or from special sample collection centers.

For initial diagnostic testing for COVID-19, WHO and CDC recommends **collecting** and **testing** an **upper respiratory specimen**. The **nasopharyngeal specimen** is the **preferred choice** for swab-based SARS-CoV-2 testing. However, throat swabs (posterior pharyngeal swab, avoiding the tongue), and nasopharyngeal swabs are also recommended. If the collection of a nasopharyngeal swab is not possible, ArminLabs has established an adequate **alternative**. Since a **high concentration** of viable **SARS-CoV-2** viruses can be found in the **throat** and **sputum** within the first week after the first symptoms appear, ArminLabs offers RT-PCR also as **throat lavage solution**.

Further testing recommendations

Elderly people and patients with underlying medical conditions such as hypertension, cardiac issues or diabetes, cancer, another active infection and/or those suffering from immunosuppression are more likely to experience more severe symptoms of COVID-19[8, 9, 10]. We therefore additionally recommend checking **innate (CD3+) and natural killer cell (CD56+/CD57+) immune status**, as well as other **parameters related to current immune status**:

- CD3+/CD56+/CD57+ Cell Count **(heparin & EDTA blood tubes additionally required)**
- Zonulin
- Vitamin D3

Please check the information about these parameters provided on our website www.arminlabs.com .

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