Estimated course of markers in SARS-CoV-2 infection

<table>
<thead>
<tr>
<th>Incubation period</th>
<th>Symptoms</th>
<th>Recovery</th>
<th>Convalescence</th>
<th>Potential long-term immunity</th>
</tr>
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- IgG antibodies
- IgM antibodies

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<tr>
<th>Days post infection</th>
<th>0 5 10 15 20 25 30 35 40 100 180</th>
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**Summary**

SARS-CoV-2, the causative agent of Coronavirus Disease 2019 (COVID-19), is an enveloped, single-stranded RNA Beta-coronavirus. Seven coronaviruses have been identified as agents of human infection, causing disease ranging from mild common cold to severe respiratory failure.

SARS-CoV-2 is transmitted primarily from person-to-person through respiratory droplets and aerosols. The incubation period from infection to detectable viral load in the host commonly ranges from two to 14 days. Detection of viral load can be associated with the onset of clinical signs and symptoms, although a considerable proportion of individuals remain asymptomatic or mildly symptomatic. The interval during which an individual with COVID-19 is infectious has not yet been clearly established; however, transmission from symptomatic, asymptomatic, and pre-symptomatic individuals has been well described.

Coronavirus genotypes encode four main structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N). The S protein is a large transmembrane protein that assembles into trimeric spikes that protrude from the viral membrane and attach to host cell receptors. Two subunits, S1 and S2, are necessary for viral entry. S1 mediates host cell binding, whereas S2 mediates membrane fusion and is cleaved upon entry to form the functional S2 (S2′) subunit.

Upon infection with SARS-CoV-2, the host usually mounts an immune response against the virus, typically including production of specific antibodies against viral antigens. IgM and IgG antibodies against SARS-CoV-2 appear to be nearly simultaneously in blood. There is significant inter-individual difference in the levels and chronological appearance of antibodies in COVID-19 patients, but median seroconversion has been observed in approximately two weeks.

Elecys® Anti-SARS-CoV-2 S

**Immunooassay for the quantitative determination of antibodies to the SARS-CoV-2 spike protein**

**Diagnostics**

- **Elecys® Anti-SARS-CoV-2 S**
  - Method Sheet 2022-03, V3.0
  - Material Numbers 09289267190 and 09289275190.

**Ordering information**

- **Product**
  - Elecsys® Anti-SARS-CoV-2 S
  - Material configuration: 300 tests
  - Material number: 09 289 275 190

- **Product**
  - PreciControl Anti-SARS-CoV-2 S
  - Material configuration: 4 x 1.0 mL
  - Material number: 09 289 313 190

**References**

6. He, X. et al. (2020).
17. 2022 Roche.
27. Respir Med. 169, 106026.
31. J Biosci. 45, 68.
32. Int J Inf Dis. 96, 577-582.
34. Int J Inf Dis. 96, 577-582.
**Test principle:** double-antigen sandwich assay (testing time: 18 minutes)

After infection or vaccination, the binding strength of antibodies
are incubated with a mix of biotinylated
Step 1 (9 minutes)
Numerous vaccines for COVID-19 are in development, many of
RBD antigen
biotin and streptavidin.

**Step 2 (measurement)**
The magnet mixture is transferred to the measuring
coated microparticles, the
**Analytical specificity:**
A total of 1,100 potentially cross-reactive samples collected before Solution 2019, including anti-MERS-CoV positive samples, samples from individuals with common cold symptoms, and samples from individuals confirmed to be infected with one of the four common cold coronaviruses were tested with the Elecsys® Anti-SARS-CoV-2 S assay. Overall specificity in this cohort of potentially cross-reactive samples was 99.98% (99.91 – 100 %).

**Clinical sensitivity**
A total of 1,166 potentially cross-reactive samples from 14 days to 1,423 of the tested samples had a sampling date of 14 days or later after diagnosis with PCR. 1,406 of these 1,423 samples were
determined with ≥0.8 U/mL in the Elecsys® Anti-SARS-CoV-2 S assay and hence considered positive, resulting in a sensitivity of 88.6% (95% CI: 99.6 – 100 %) in this sub-cohort.

**Correlation of assay results to serum neutralization capacity**
In a study investigating COVID-19 convalescent plasma for vaccine neutralization capacity plasma donors from consensued donors after anti-SARS-CoV-2 infection were analyzed for vaccine neutralizing potential using an in vitro plaque reduction neutralization test (PRNT) assay (BRAUD module, USA). Presence of ≥4 neutralization (NCl) at a dilution of ≥120 identified functional virus neutralization in sera.

**Detection of antibodies induced by active immunisation with vaccines against SARS-CoV-2**
After vaccination with the Moderna vaccine Spikevax® (mRNA-1273) and the Pfizer-BioNTech vaccine Comirnaty® (BNT162b2), applying the respective approved 2-dose vaccination scheme, the antibody response in vaccinated, infection-naïve individuals was assessed using the Elecsys® Anti-SARS-CoV-2 S assay at three time-points: pre-vaccination (time point 1), 14 days post 2nd vaccination dose (time point 2), and 14 days post 2nd vaccination dose (time point 3). For evaluation, rapidly rising antibody titers, indicating a strong humoral immune response to vaccination, were observed. All individuals that had been seronegative at baseline seroconverted after vaccination.

**Anti-RBD titers after vaccination with Spikevax®**

**Anti-RBD titers after vaccination with Comirnaty®**

**Neutralizing Titer**

**Percent Positive Agreement**

**Percent Negative Agreement**

**Positive Prediction Value**