

# SARS-CoV-2 serology by mild symptoms of disease

Published: 24-05-2020

Last updated: 09-04-2024

Determination of the sensitivity of diverse SARS-CoV-2 antibodyassays in patients with proven SARS-CoV-2 infection but mild symptoms.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON50020

### Source

ToetsingOnline

### Brief title

SARS-CoV-2 serology

### Condition

- Viral infectious disorders

### Synonym

SARS-CoV-2 infection

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medlon b.v. Medische Diagnostiek

**Source(s) of monetary or material Support:** Medlon b.v.

### Intervention

**Keyword:** antibody testing, SARS-CoV-2, serology, validation

## Outcome measures

### Primary outcome

Sensitivity of the diverse assays in a population of patients with mild symptoms.

### Secondary outcome

not applicable

## Study description

### Background summary

The SARS-CoV-2 virus is spread all around the world. The presence of the virus can be demonstrated in nasal swabs by PCR. However antibody testing for this virus is important to prove if a patient has had the disease in the previous period. A lot of commercial assays are nowadays on the market and assay characteristics should be determined especially in patients with mild symptoms.

### Study objective

Determination of the sensitivity of diverse SARS-CoV-2 antibody assays in patients with proven SARS-CoV-2 infection but mild symptoms.

### Study design

Patients with a positive PCR in their nasal swab who are not hospitalized, are recruited. Blood is drawn by venapuncture. The samples are tested in diverse available antibody assays.

### Study burden and risks

There is no extra risk other than the risk of a venous blood sampling. The sampling will be done by experienced personnel.

## Contacts

### Public

Medlon b.v. Medische Diagnostiek

Koningsplein 1  
Enschede 7500 KA  
NL

### Scientific

Medlon b.v. Medische Diagnostiek

Koningsplein 1  
Enschede 7500 KA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

18 years or older

Ability to read and understand informed consent

Proven SARS-CoV-2 infection more than three weeks ago.

No hospitalisation for more than three months

No clinical symptoms of active infection at the time of bloodsampling

### Exclusion criteria

age of 17 years or younger

Unable to read the informed consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-06-2020

Enrollment: 50

Type: Actual

## Ethics review

Approved WMO

Date: 24-05-2020

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

**Register**

CCMO

**ID**

NL74124.100.20

## Study results

Date completed: 09-12-2020

Actual enrolment: 39