# Study to evaluate the analytical performance of the Virax immune COVID-19 flow cytometry kit

Published: 28-04-2022
Last updated: 19-08-2024

Investigation of the performance of the Virax Immune COVID-19 kit when tested using blood donations from healthy participants.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON51279

**Source**
ToetsingOnline

**Brief title**
Blood Sampling for Virax Immune COVID*19 Testing

### Condition

- Other condition

**Synonym**
COVID-19 coronavirus

**Health condition**

COVID-19 testkit

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Virax Biolabs Limited
**Source(s) of monetary or material Support:** biotechnologische industrie

## Intervention

**Keyword:** assay kit, blood draw

## Outcome measures

### Primary outcome

Safety assessments during the study will consist of AEs and SAEs. Clinical

laboratory and vital signs measurements will be used to determine eligibility

of the subjects. Assessments will be performed in accordance with the schedule

of assessments.

Subject safety will be monitored from the time each subject signs the ICF until

discharge

### Secondary outcome

not applicable

# Study description

### Background summary

The Virax Immune COVID-19 kit is a new test that could potentially be used to measure the immune response to the virus that causes coronavirus disease 2019 (COVID-19). This is measured in blood samples. This immune response involves immune cells that produce specific proteins in response. For the lab test, these immune cells are stimulated in the blood with parts of the virus protein to see if and how much of the specific proteins are produced. The amount of those specific proteins is a measure of the strength of the immune response and is a measure of protection against COVID-19. Because immune cells also contain memory cells, this test can also be used to determine the longer-term protection against COVID-19, for example after vaccination

### Study objective

Investigation of the performance of the Virax Immune COVID-19 kit when tested using blood donations from healthy participants.

### Study design

For the research it is necessary that the volunteer makes 1 visit to the research center on Day 1.
For the test, 4 tubes of blood of 9 ml are taken. (total 36ml)

During the examination, the following examinations and measurements are made:
• Blood test. Blood is taken for this.
• The volunteer is asked how he/she is feeling and if there are any other details that have to do with his/her health

### Study burden and risks

blood draw and coronavirus test

## Contacts

**Public**
Virax Biolabs Limited

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GB
**Scientific**
Virax Biolabs Limited

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

1. Sex: male or female; females may be of childbearing potential, of nonchildbearing potential, or postmenopausal.
2. Age: 18 to 65 years, inclusive, on the day of consent.
3. Status: healthy subject. Good physical and mental health on the basis of medical history and vital signs, as judged by the Investigator.
4. Females must be nonpregnant; nonpregnancy will be confirmed for all females by a urine pregnancy test.
5. Nonsteroid anti-inflammatory drugs (ie, ibuprofen, diclofenac, etc.) must have been stopped at least 48 hours prior to admission to the clinical research center (evaluation through questionnaire).
6. Fluent in the language of the clinical site (Dutch) and able to read in this language.
7. Willing and able to sign the ICF and comply with study procedures.
8. Positive SARS-CoV-2 test (preferably by nasopharyngeal PCR) within 4 months prior to, but not on the day of consent.

## Exclusion criteria

1. Previous participation in the current study.
2. Employee of ICON or the Sponsor.
3. Having an underlying blood disorder, like leukemia (evaluation through questionnaire).
4. Known to have human anti mouse antibodies (ie, HAMA response; evaluation through questionnaire).
5. Taking immune suppressive medication, or receiving chemotherapy, cytokine or anti-cytokine therapy, or antithrombotic medication (evaluation through questionnaire).

more conditions apply

# Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-12-2022 |
| Enrollment: | 96 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 28-04-2022 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 18-11-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

## 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 | ID |
| --- | --- |
| CCMO | NL80952.056.22 |