

# Clinical study to assess a new rapid COVID-19 test

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/02/2024	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This clinical study is looking into a new way of testing for the virus that causes COVID-19 using fresh nasal, throat and saliva swab samples. The samples will be collected from NHS staff and their household contacts during usual COVID-19 testing at the hospital. If successful, the new test will be quick (less than 5 minutes) and use an instrument to detect a signal when the virus is found. It is hoped that it will be as reliable as the best tests now in use without still giving a positive reading for those who have recovered and are no longer infectious. The new test works by finding “virions” (whole virus particles) in samples rather than finding leftover bits of virus. These leftover bits are not infectious but can stay in the body for several weeks and continue to show a positive test result by other test methods. The study will collect information about how well the test can find the virus in fresh samples from people with and without the virus. The results of the new test will be compared to the results from the standard NHS polymerase chain reaction (PCR) test done as part of usual staff testing. These results will then be compared to an extra PCR test and to a virus culture test, in which the virus is grown from the swab samples. The study will also compare the sample types (nose with throat swab, nose without throat swab, saliva swab) to see if the site that a sample is taken from affects the result given by the new test. These results will show how well the new test is working and help us improve it.

### Who can participate?

People with and without COVID-19 symptoms aged 18 years old and over who have not had symptoms for more than four days

### What does the study involve?

All participants will be given a kit with instructions and asked to provide three swab samples, in the same way as with other COVID-19 tests. The participants will do three swabs on one occasion. The first swab will be in both nostrils, the second in one nostril and the back of the throat and the third will swab saliva from around the mouth, tongue and gums. The participant will mix each of the three swabs with liquid in separate tubes, package up the samples and return them to the research team.

The samples will then be sent to the University of Sheffield and analysed using the new test, PCR testing and another test to grow virus from the samples. They may also be further tested using different tests to give us more information about the samples, namely microscopy, mass

spectrometry and ELISA (antibody) tests.

The research team member will make a note of the participant's age, gender, ethnicity, the number of days that they have had symptoms (if any) and the type of symptoms. They will also ask about any COVID-19 tests done including the type of test used (lateral flow or PCR), COVID-19 vaccination status and whether certain medicines are taken.

The hospital will share the NHS PCR test result of each participant with the researchers at the University of Sheffield and the company, Paraytec Ltd.

What are the possible benefits and risks of participating?

Although there are no direct benefits in the short-term for participating, apart from contributing to research, if the test works well in enough people it could help find people infected with COVID-19 and whether they are likely to be infectious more quickly and easily. The hope is also that the technology used in the new test can be applied to other diseases and help future patients with a variety of conditions.

The risks and inconveniences are the same as for doing nasal and throat swabs for any other COVID-19 test. The nasal swabs can be uncomfortable and cause coughing, sneezing or watering eyes but this should not last long. Throat and saliva swabs can cause gagging but again this should stop once the swab is removed. The swabs are widely used, and not expected to cause any permanent issues. Participants will not receive any results from the study testing, and will still receive their NHS PCR test result, so there is no risk of getting a false result from the study.

Where is the study run from?

The study is run by Sheffield Teaching Hospitals NHS Foundation Trust (STH), with the tests being done at the University of Sheffield.

When is the study starting and how long is it expected to run for?

November 2021 to March 2023

Who is funding the study?

Paraytec Ltd is organising the research and the costs of the study are paid for by Paraytec's parent company, Braveheart Investment Group plc.

Who is the main contact?

The main contact for the study is Professor Carl Smythe, [c.g.w.smythe@sheffield.ac.uk](mailto:c.g.w.smythe@sheffield.ac.uk).

## Contact information

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Public

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
309237

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
IRAS 309237, CPMS 51304, STH 21689, PA-000201-CP

## **Study information**

**Scientific Title**

A clinical performance study using an optical fluorescence test to detect SARS-CoV-2 virions in participants with and without COVID-19 and compared to participant data from PCR and viral culture

### **Study objectives**

The primary aim of the study is to understand the relationship between the results of the new test and the viral culture and PCR results. This may help find if the new test can show how likely someone is to spread the virus if they test positive for COVID-19.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 10/05/2022, London Central REC (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8171; londoncentral.rec@hra.nhs.uk), ref: 22/HRA/1004

### **Study design**

Prospective single-centre non-blinded cross-sectional study

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Detection of SARS-CoV-2 virions in infected participants

### **Interventions**

This study is a prospective single-centre non-blinded cross-sectional study of anonymised clinical specimens from staff and their household contacts presenting for SARS-CoV-2 clinical testing.

Participants will be recruited from ongoing testing of NHS trust staff and their households at the hospital. A research nurse will find staff and contacts who are suitable as they wait to be tested and then invite them to take part. Once the participant has given informed consent, they will answer questions about their general demography and history of COVID-19 illness, along with details of symptoms and COVID-19 vaccinations.

Participants will provide three swabs on one occasion using a kit provided. The first swab will be in both nostrils, the second in one nostril and the back of the throat (oropharyngeal) and the third will swab saliva from around the mouth, tongue and gums. The participant will mix each of the three swabs with liquid in separate tubes, package up the samples and return them to the research team. This will end their participation in the study.

### **Intervention Type**

Device

### **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

COVID-19 CX300 IVD device

## **Primary outcome(s)**

1. Detection of the presence or absence of the SARS-CoV-2 virus in test specimens measured using the CX300 device compared with the results of quantitative polymerase chain reaction (qPCR) as a reference standard on the day of the test specimens being taken
2. The sensitivity and specificity to detect the presence or absence of the SARS-CoV-2 virus measured using the CX300 device and compared with the results of qPCR as a reference standard on the day of the test specimens being taken

## **Key secondary outcome(s)**

1. Repeatability and reproducibility (intermediate precision) to detect the presence or absence of the SARS-CoV-2 virus measured using the CX300 device compared with the results of quantitative polymerase chain reaction (qPCR) as a reference standard on the day of the test specimens being taken
2. The relationship between signal strength and viral titre measured using the CX300 device compared with the results of qPCR as a reference standard in nasal/oropharyngeal swab samples cultured on the day of the test specimens being taken

## **Completion date**

31/03/2023

## **Eligibility**

### **Key inclusion criteria**

Subjects will be 18 years old and over and recruited from NHS staff and their household contacts at Sheffield Teaching Hospitals NHS Foundation Trust.

Subjects that comply with any of the following criteria:

1. Asymptomatic subjects
2. Subjects who have tested positive for COVID-19 via lateral flow testing or PCR testing from a specimen collected and tested within the previous 24 hours
3. Symptomatic subjects with 4 days or less duration of one or more COVID-19-related clinical symptoms including dry cough, loss of or changes in sense of taste, loss of or changes in sense of smell, fever, stuffy or runny nose, headache, fatigue, sneezing, sore throat, hoarse voice, chills, joint pain, myalgia, night sweats, skin changes, loss of concentration, dizziness, eye soreness, shortness of breath, loss of appetite, diarrhoea, nausea and vomiting.

### **Participant type(s)**

Population

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

125

**Key exclusion criteria**

1. Without the capacity or English literacy skills to give informed consent
2. Immunocompromised and/or taking oral or injected immunosuppressant medication such as prednisolone, cyclosporin and anticancer drugs or have stopped taking these drugs in the past four weeks
3. Currently taking oral antiviral drugs
4. Tested positive by PCR for COVID-19 in the previous three months excluding tests taken in the previous 24 hours before informed consent for this study

**Date of first enrolment**

23/09/2022

**Date of final enrolment**

08/03/2023

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Northern General Hospital

Herries Road

Sheffield

United Kingdom

S5 7AU

**Sponsor information****Organisation**

Paraytec (United Kingdom)

**ROR**

<https://ror.org/00qq0vj26>

# Funder(s)

## Funder type

Industry

## Funder Name

Braveheart Investment Group

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			22/02/2024	No	Yes