University Hospital Southampton NHS
NHS Foundation Trust

Participant Information Sheet

A prospective study to evaluate the real-world diagnostic accuracy and potential clinical impact of the Veros COVID-19 test in adults presenting to the Emergency Department with suspected COVID-19: ED-POC

Chief Investigator: Professor Tristan W Clark

Research study

We are sorry that you are unwell and have had to attend hospital. This must be a stressful time for you and your family. It is difficult to ask anything of you at the moment, but our team needs your help. We are investigating how well a new COVID-19 test works and need to test it out in people who have symptoms that could be COVID-19. This is where you could help us.

You are being invited to take part in this research study. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it involves. Please take time to read the following information. You may wish to discuss it with other people. Ask us if anything is unclear, or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this information sheet.

It is up to you whether you take part or not in this research. You can withdraw from the study at any time, without giving a reason, and your care and other rights will not be affected.

What is the purpose of this study?

There have been over 600 million cases of COVID-19 since the pandemic started, and there are new cases every day. Many new tests for COVID-19 are being developed to try to make diagnosis faster and simpler. A new handheld test has been designed gives results in about 15 minutes. This could make testing for COVID-19 faster and easier. However, because it is a new test, we don't yet know how accurate it is (compared to the tests we currently use in hospital). **We are doing this study to find out how accurate this new test is and how quickly it can provide results.**

Why have I been asked?

You have come to hospital with symptoms that could be caused by COVID-19. To test for COVID-19, your doctors and nurses have taken (or will plan to take) a nose and throat swab that they will test on the current analyser.

What happens if I decide to take part?

After you have finishing reading this, you will have the opportunity to discuss the study in more detail with a member of the research team. If you are happy to take part, you will be asked to read and sign a consent form. You get a photocopy of the form you sign.

Because you have symptoms that could be due to COVID-19, your medical team will take a nose and throat swab to test for COVID-19 (this involves a swab being put briefly to the back of your throat and up one nostril). This test result will be used to plan your care.

In addition to this routine swab, the research team will take two more swabs. One is from the nostrils, and we immediately test this on the new COVID-19 test. As this new test is still being investigated, the results will not be used to plan your care and you and your medical team will not be told the result. The second swab, taken from the nose and throat, may have further tests done on it, such as seeing if any virus grows from the sample. This is called a viral culture.

Once the swabs have been taken, there is nothing else that you need to do for the study. The researchers will need to look at your hospital record in the near future in order to check the results of your routine COVID-19 test and details of your admission, like how long you were in the Emergency Department and what symptoms you had when your tests were taken. Being in the study only takes a few minutes.

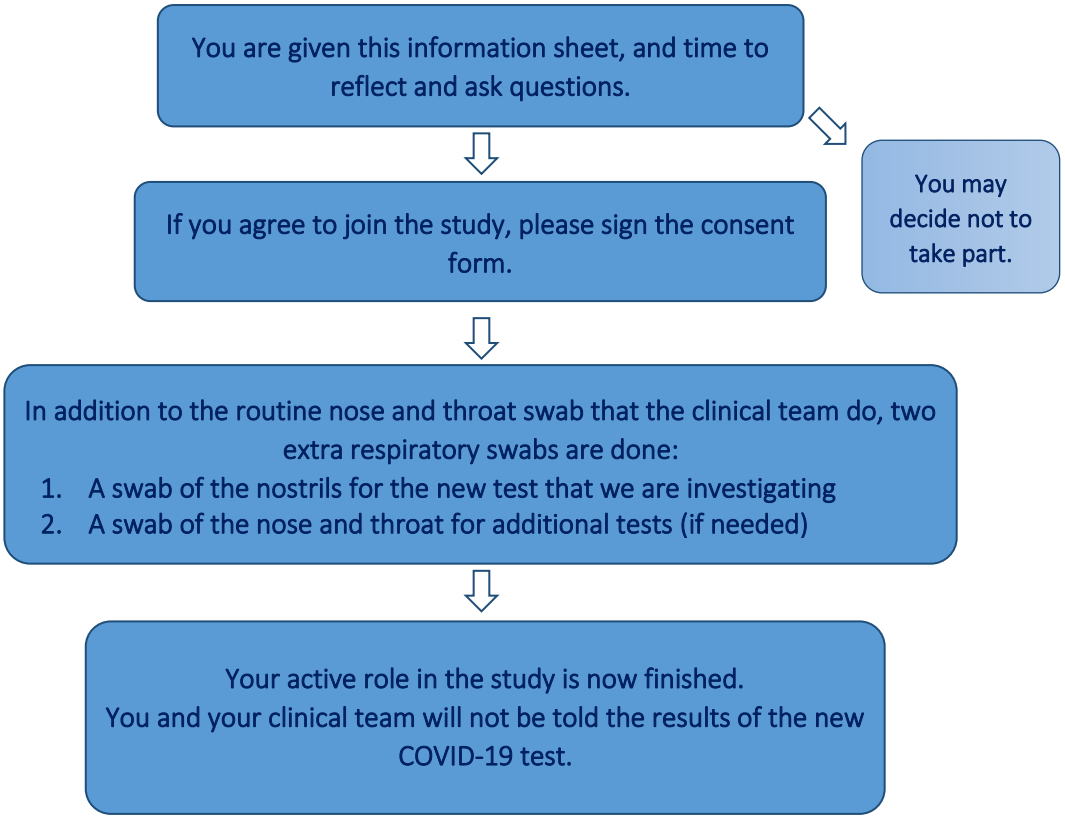
What are the risks?

The risks of having simple swabs taken from your nose and throat in this study are minimal, but it can be mildly uncomfortable for some people while the swabs are being performed.

What are the benefits?

As the results of the new test will not be used by your medical team, there are no immediate benefits to you. However, all participants may feel that they are helping sick patients in the future, and helping the NHS improve care, by being part of this research.

Summary of what happens in the study



What about confidentiality?
We take confidentiality very seriously. We only ask you for a small amount of personal identifiable information if you join the study. When we look at and publish results from the study, all information is presented anonymously. Your details and personal information are never made available outside the study.

We keep information that could identify you separately to our main research records. Our main research records, and any samples we take, refer to you as a unique number (or code) instead of your name or other personal details. This protects your anonymity and confidentiality. Only the research team, and the authorities that regulate us (including the sponsor's monitors and auditors), have access to your personally identifiable information.

What if I don't want to participate, or decide to withdraw from this study?
You can decide not to participate, or to withdraw from this study, at any time. You don't have to give a reason and your care and other rights will not be affected.

If you withdraw from the study, you have a choice as to whether we keep your samples or destroy them (although any anonymised data, already collected, will be retained). We also have to keep a small amount of your personally identifiable information to record that you were enrolled in, and then withdrawn from, the study.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data that we hold about you.

What happens when the research study stops?
Once the study finishes and all the data has been collected, results will be analysed by the research team to see how accurate the new test is. If samples are leftover, and participants have consented to their samples being retained for future research, they will be frozen and stored for up to five years. They will have been anonymised when they were first stored and will be stored on the sponsor's premises (but may subsequently be anonymously stored at other research institutes). After this study, these samples may be used for further ethically approved research, such as investigating other viral tests, or pathogen sequencing (but not involving human genetic analysis).

After five years, if a participant consented to their samples being retained for future research, samples will either be used in ethically reviewed research, stored in a licensed biobank (i.e. a location within the UK that stores human tissue samples for research), or destroyed.

What will happen to the results of the research study?
We intend to publish the results of our research in medical journals and to present them at scientific meetings. The information from these journals is available on the internet. All results are anonymous in any publications or presentations. The results may improve how medical professionals treat patients. We will make sure that no-one can work out who you are from the reports we write.

Who is organising and funding this research?
This research is funded by the company that makes these tests. The makers of the new tests have no rights or access to your data, they have had no role in the design or running of this

study and will have no role in analysing or publishing the results. This all is done by our research team.

Who has approved this study?

A Research Ethics Committee, the Heath Research Authority, the sponsor of the study, and the local NHS Research and Development department have approved this study to go ahead.

Who can I talk to further?

The research team are happy to answer further questions. If you wish, you can talk to your doctors and nurses, or family and friends, about participating. Should you have any specific concerns you are welcome to discuss them with a research team member, or those listed here:

- Professor Tristan Clark, Chief Investigator: Professor and Consultant in Infectious Diseases. Tel: 02381218410. T.W.Clark@soton.ac.uk
- Dr Mary Chapman, Co-investigator: Clinical Research Fellow. Mary.chapman@uhs.nhs.uk
- Patient Support Services, University Hospital Southampton NHS Foundation Trust. Tel: 02381206325. patientsupportservices@uhs.nhs.uk.

How will personal data that is collected be used?

University Hospital Southampton NHS Foundation Trust is the legal sponsor for this study. We will be using information from you and your medical records to undertake this study and we will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University Hospital Southampton NHS Foundation Trust will securely keep identifiable information about you for 15 years after the study has finished.

University Hospital Southampton NHS Foundation Trust will use your name, date of birth, NHS number and hospital number and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Your personal data never leaves University Hospital Southampton, or the UK. Individuals from University Hospital Southampton NHS Foundation Trust (or individuals employed by the University of Southampton with a contract for the hospital too), and regulatory organisations may look at your medical and research records to check the study's accuracy. The only people in University Hospital Southampton NHS Foundation Trust who will have access to information that identifies you will be people who need to audit the data collection process.

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws. Universities and NHS organisations may use patient data to do research to improve healthcare.

Universities and the NHS are funded from taxes, and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'. If they could do the research without using patient data, they would not be allowed to get your data.

If you want to raise a concern about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Office on 023 8120 5079 or dataprotection@uhs.nhs.uk. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).