

Further supporting information

Data protection

In this research study we will use relevant information provided by you and from your medical records. We will only use information that we need for the research study. Only clinicians responsible for your care will know your name or contact details, and only if they really need it for this study. Researchers at the University of Bath will only have access to anonymised data. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this. All samples will be destroyed once analysis is complete.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your initials/NHS number/name/contact details. Clinicians will use this information to collect the research data or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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 we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information from the following:

www.hra.nhs.uk/information-about-patients

From a leaflet which is available at www.hra.nhs.uk/patientdataandresearch

By asking one of the research team

By sending an email to: Mr David Jolly, djj20@bath.ac.uk, Data Protection Officer

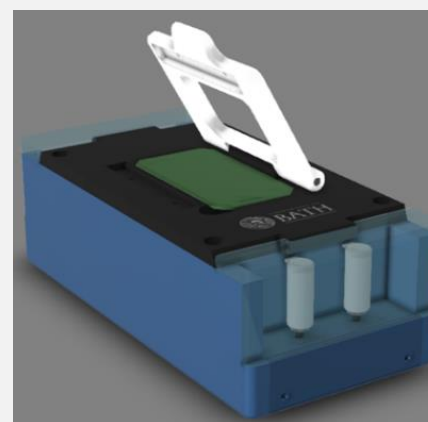
By ringing us on 01225 821345

Study title: A study to test a diagnostic system for the accurate detection of SARS-CoV-2 outside a laboratory setting

Invitation and brief summary

A team of clinicians, scientists and engineers from the Royal United Hospital in Bath and the University of Bath are developing a diagnostic testing system designed to give accurate diagnosis of SARS-CoV-2 in swabs within 10 minutes of analysis, at clinical standard accuracy but outside the diagnostic lab setting.

The system is a portable, handheld device, which carries a disposable microchip performing the core biochemical analysis. The test result is displayed on the accompanying mobile app within 10 minutes of the patient swab insertion.



LoCKamp rapid SARS-CoV-2 testing system (left) and accompanying app for result visualization (right)

This leaflet gives information about how the system functions to detect the existence of the virus. If you could read this leaflet and answer some questions it will really help us in developing our test. By taking part, you are helping us to develop an exciting new technology that will be used for pandemic control in the future. We are very grateful for your time – your answers will directly affect how we further design this test and technology..

The diagnostic system

What is it for? Testing for SARS-CoV-2 viral infection, which can cause a high temperature, new continuous cough and loss or change to the sense of taste or smell. Symptoms can vary amongst patients from fully asymptomatic to severe cases requiring mechanical ventilation support or even Intensive Care Unit admission.

How will it look and feel? The system comprises of two parts: a handheld portable device and a disposable minilab microchip. The microchip is inserted in the portable instrumentation and the patient swab is also inserted in the specific entry point of the portable device. The operator then pushes the 'test' button which releases all the required reagents in the minilab and within 10 minutes the test result appears in the accompanying mobile phone app.

How will it be used? The swabs will be collected and safely stored within the hospital every week. A researcher will then insert them sequentially into the LoCKamp system, recording the results for each anonymized patient. When alerted by the system controls that the minilab chip needs to be replaced, a fresh chip will be inserted and the previous used one will be discarded.

How does it work? The minilab is equipped with an on-chip heating apparatus and hollow cavities, allowing the DNA amplification reagents to flow over the heated area and exponentially multiply any SARS-CoV-2 RNA present in the patient sample. The amplified product is then detected by optical sensors integrated in the handheld device. A signal then transmits the reading electronically via Bluetooth to the mobile phone App..



The rapid DNA amplification minilab

What's involved?

This study involves the benchmarking of this LoCKamp technology against the existing gold standard clinical SARS-CoV-2 diagnostic tests. This study will **not** involve testing the system on the spot upon your arrival at the hospital; your diagnosis and clinical decisions will be based on the clinically validated, gold standard PCR testing of the hospital process.

What would taking part involve?

This study will involve you consenting to donate an extra swab for the University of Bath researchers to benchmark how the test performs compared to the gold standard laboratory PCR diagnostic testing. The NHS Trust research team will label the bags with your date of birth, the collection date, patient initials and a unique patient identifier number. The University of Bath researchers will **not** have any access to information that can identify you – you'll be completely anonymous.

If this pilot study is successful, the clinical team might ask whether you would be interested in testing the system in a follow up project, probably in late 2022. You are under no obligation to agree to this, and you would be able to change your mind at any time.

What are the possible benefits of taking part?

You will be supporting the development the world fastest and most accurate diagnostic test for SARS-CoV-2 globally, accelerating its use in real life for pandemic control.

What are the possible disadvantages and risks of taking part?

You will need to donate an additional nasopharyngeal swab for the purposes of this study. No further risks are anticipated.

We have some questions about this study for you:

- Do you understand why we need to do this study and what it involves?
- Do you have any questions about the study?
- If you were invited to take part, would you participate?
- If you would choose not to participate, what would your reservations be?