

Service Evaluation of Lateral Flow Device testing for COVID-19 in asymptomatic individuals

Participant Information Sheet (PIS)

You are being invited to take part in an evaluation project by the Department of Health and Social Care (DHSC). This project is part of DHSC's ongoing evaluation of delivery of Lateral Flow Device (LFD) testing for COVID-19 in individuals who do NOT have symptoms of COVID, and is part of a wider DHSC approach to QA (Quality Assurance) and testing how good LFDs are.

Before you decide whether to take part, it is important for you to understand why the evaluation is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish.

Please ask if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this.

About the evaluation

➤ Who will conduct the evaluation?

The University of Manchester's Asymptomatic Testing service will continue to perform the tests with the addition of another test. Anyone participating in the ongoing evaluation study will provide two samples, one which will be analysed via LFD (representing the standard of care for the site and official test) and one via qRT-PCR (AKA 'PCR'), the QA test). Only DHSC will have the results of both the LFD and the PCR test.

➤ What is the purpose of the evaluation?

The study is being run as a quality assurance exercise as part of broader set of evaluation activities to ensure that the LFDs are working well. As such, the objectives of ongoing evaluation studies are to measure how well the LFDs work when compared to standards achieved in previous studies used to evaluate performance of devices.

Please note: You will only receive results from the LFD test, while the QA test will be used to determine performance of the LFD in a given setting.

➤ Will the outcomes of the evaluation be published?

We will not be publishing any results because The University of Manchester will not receive any results that can be linked to you.

➤ Who has reviewed the evaluation project?

This has been designed and implemented by DHSC as service evaluation and advice sought by the Health Research Authority.

What would my involvement be?

➤ What would I be asked to do if I took part?

Anyone who doesn't have symptoms of COVID and is eligible for LFD testing at Asymptomatic Test Centres can take part in the ongoing evaluation study. Anyone participating in the ongoing evaluation study will provide two samples, one which will be analysed via LFD and one via PCR test.

You will only receive results from the LFD test, while the QA test will be used to determine performance of the LFD in a given setting. **Please note that your LFD may not always pick up that you have COVID and so it is important to ensure that you always adhere to the national guidance, including "hands, face, space" and "stay home, save lives, protect the NHS".**

You can opt out of the ongoing evaluation study and only provide one sample for the purposes of LFD testing as per the standard protocol. As we roll out the mass testing programme we are asking people to provide two samples. This allows us to continue evaluating different testing methods to ensure we are delivering a high standard of clinical service.

➤ **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. When you register for the test at the testing site you will be asked to give your consent. If you do decide to take part, you will be given this information sheet to keep and the person at the registration desk will complete an online consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

➤ **What information will you collect about me?**

In order to participate in this evaluation project The University of Manchester will not be collecting any data. Only the data you provide for booking your test and then registering to the NHS Test and Trace system will be needed and no-one at The University of Manchester can link this to your test results.

➤ **Under what legal basis are you collecting this information?**

When booking in for your test, we are collecting and storing this personal identifiable information in accordance with UK data protection law which protects your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, your booking information will not be linked to your test result at any time.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is **not** the Data Controller for this project.

When you agree to take part in this evaluation project, and with your informed consent, the information about you will be analysed by DHSC for ongoing evaluation of the LFD. The University of Manchester will not have access to this information. The information will only be used for the purpose of evaluation, and cannot be used to contact you regarding any other matter.

Please also note that individuals from DHSC or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data that you will have provided to NHS Test and Trace. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a participant. The University of Manchester does not have access to this information.

What if I have a complaint?

Please contact UoMccovidtesting@manchester.ac.uk

➤ **Contact details for complaints**

If you have a complaint that you wish to direct to members of the team, please contact:

UoMccovidtesting@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the team or if you are not satisfied with the response you have gained from the team in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#) Tel 0303 123 1113

Contact Details

If you have any queries about the study please contact UoMccovidtesting@manchester.ac.uk

Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this evaluation project will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this study. If you choose not to take part, please just inform the registration team. If you have any additional queries about any of the information provided, please speak with a member of the testing team.

Are there any additional considerations that I need to know about before deciding whether I should take part?

You should only take part if you do not have any symptom of COVID. If you develop any symptoms, please follow the [national guidance](#) and the University of Manchester [COVID support and FAQs](#).

What additional steps will you take to keep me safe while I take part?

All of our testing sites have been designed to be COVID-secure and our operatives are highly trained and monitored for quality assurance.

Is there any additional information that I need to know?

Please note that your LFD may not always pick up that you have COVID and so it is important to ensure that you always adhere to the national guidance, including “hands, face, space” and “stay home, save lives, protect the NHS”.

What if I have additional queries?

Please contact UoM covidtesting@manchester.ac.uk