Facilitating A SARS CoV-2 TEst for Rapid triage (FASTER)

Participant Information Leaflet and Consent Form

Would you like to take part in our research? This information leaflet tells you how you could take part. A member of our team will also discuss it with you: please ask us if you have questions. You may want to talk to other people about the study: please do so. Take your time to decide if you want to be involved.

What is the purpose of the study?

We are working in partnership with industry that has developed a new rapid test to detect the presence of Coronavirus (COVID-19). Currently the NHS uses the best test available to detect the virus using a nasal swab. The current test can take up to 4 days before the results are available which can lead to an extended amount of time in quarantine or a prolonged amount of time grouped with other patients that are suspected to have Coronavirus.

The new tests that we have available need to be validated against the current best practice. We need to use the tests with real samples to check if they are as accurate as the current test. If successful, this study may change practice and allow for early detection and appropriate isolation of patients.

In addition to this, we are working with Pfizer who have an existing vaccine which works against one cause of severe pneumonia but are working on a vaccine to prevent pneumonia specifically caused by COVID-19. The work funded by Pfizer will assess the immunologic response to COVID-19 and Pneumococcus and the relationship between the two

Do I have to take part?

No. Taking part in this study is voluntary.

Why have I been asked to take part?

We are looking for patients that are admitted to hospital with symptoms of COVID-19, these include a new persistent cough and/or temperature above 37.8^{0}C and/or shortness of breath.

You will be eligible if:

- Adults aged 18 years and over
- Have symptoms of COVID-19: shortness of breath and/or temperature above 37.8^{0}C and/or new persistent cough OR Clinical/ X-ray evidence of pneumonia (chest infection)
- Fluent spoken English - to ensure a comprehensive understanding of the research project and their proposed involvement
- Capacity to give informed verbal consent

What happens if I choose to take part?

If you choose to take part in this study and the research team agrees that you are suitable, you will be asked to give verbal consent. A copy of this information sheet will be given to you to keep and a copy of your witnessed verbal consent form will be filed where possible.

The study will involve 4 visits over a minimum of 4-5 weeks. Samples and data will continue to be collected from you throughout your stay in hospital.

What samples do you take?

We collect nasal, saliva, blood and urine samples to look for the virus and the immune response to the virus in the nose, saliva and blood.

Nasosorption: We put a small piece of blotting paper inside your nostril and hold it there for up to 3 minutes. This takes some concentrated secretions from inside your nose and will be repeated on each nostril

Nasal& throat combined swabs: We ask you to open your mouth and using a wooden spatula to keep your tongue out of the way, take a cotton swab (similar to a cotton bud), insert it into your mouth and wipe it over your throat. We then use the same swab, insert it into your nose and rotate it. We may repeat this three times at each visit.

Throat swab: We take a cotton swab and insert it into your mouth and wipe it over your throat. This is repeated at each visit.

Blood samples: We take blood samples from a vein in your arm (using a needle). We will take up to 40 mL (approx. 7 teaspoons) during this visit.

Saliva: We will ask you to spit into a tube, up to 1ml.

Urine: We will take a 20ml urine sample.

Oral test: Some participants will be required to use an oral test to take some liquid and cells from their mouth, inside their cheek to test for COVID-19. These samples will be repeated at each time point.

Exhaled detection facemask: You may be asked to breathe into an exhaled detection mask if you are not on oxygen. You will wear the face mask so it covers both nose and mouth for a duration of 30-60 minutes. There are no restrictions on talking or coughing while the mask is in situ.

You may be approached to take part in other research studies relating to COVID-19. You **are able** to take part in other research studies relating to COVID-19 as you wish. You may also be approached take part in a future research study, this would be discussed with them at the day 28 visit if appropriate. You would be consented separately for this under a separate study protocol.

What will happen at each visit?

Screening Period	
If COVID-19 Negative: Study involvement completed	
Witnessed Verbal Consent Visit: Day 0 Baseline samples	A member of the research team will discuss the study involvement with you and you will have the opportunity to ask questions and discuss the study directly with the researcher. If you are happy to take part in the study, you will be asked to give verbal consent. This will be witnessed and documented by a

	member of the clinical team. We will ask you some questions about your medical history, medications, social contacts A blood sample (up to 40ml/ approx. teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit.. A selected group of participants will undergo the oral test. A selected group will undergo the Exhaled detection Facemask
Visit 2: Day 2 * +/- 1day	A blood sample (up to 40ml/ approx. seven teaspoons) along with saliva, 2 nasosorption, throat swab, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
Visit 3: Day 7 * +/- 2days	A blood sample (up to 40ml/approx. seven teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
Visit 4: Day 28 * +/- 15 days	A blood sample (up to 40ml/ approx. seven teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
End of study	

* A group of participants selected by the research team

At each visit, the research team will access your medical records including your clinical results and they will ask about your symptoms.

If your results show that you are negative for COVID-19, you may be followed up at day 28 only. If day 28 occurs after hospital discharge, you may be invited to attend this visit in a clinic This will be arranged with you directly at a time to suit you. If you are unable to attend clinic, it may be possible for a home visit by a research nurse to be arranged.

What are the benefits in taking part?

There are no direct benefits in taking part in the study and you will not receive any payment. The study may lead to the approval of a new diagnostic test for COVID-19 that is faster than the current test used in the NHS. This could lead to appropriate isolation and rapid results thereby reducing the risk to the wider community.

What are the risks of being in the study?

The risks that you should consider *before* participation in this study are the risks associated with venepuncture, nasal and urine sampling.

Blood sampling: The risks associated with blood sampling (venepuncture) are minimal, but this may cause temporary pain, bruising and/or bleeding to your arm. The blood sampling will be performed by trained medical professionals.

Nasal sampling: There are limited risks associated with these samples. The nasal swab can be a little uncomfortable (this passes very quickly) and may cause a small amount of bleeding but this is uncommon. The nasosorption can tickle your nose a little.

Saliva sampling: There is no risk involved in saliva sampling.

Nasosorption sampling: There is no risk involved in the nasosorption sampling, it may just tickle and can make you gag a little.

Throat swab: This may make you gag a little.

Urine sampling: There is no risk involved in urine sampling.

Exhaled Detection Facemask: participants may feel claustrophobic while wearing the facemask

During the study, if you have any adverse events that you feel should be notified to the research team, you must self-report using the contact below

What if there is a problem?

You can contact the research team by phone, they will answer any questions. Any medical care you need will be provided by the NHS.

What if I wish to complain?

If you wish to complain about any aspect of the study, you can contact the study doctor or nurse. You can also contact the sponsor by email on lstmgov@lstmed.ac.uk Complaining will not affect the medical care you receive now or in the future.

The study is sponsored by the Liverpool School of Tropical Medicine (LSTM) and is covered by Clinical Trial Insurance.

What if I change my mind, or want to stop?

Even if you do start in the study, you are free to stop at any time and without giving a reason. If you decide not to take part, or to withdraw from the study, this will have no effect on your future health care.

If you decide to stop or you are withdrawn from the study, we will continue to use the samples and information that we have already collected unless you tell us not to.

Will my details be kept confidential?

Yes. For safety, we collect information about your medical history and contact details before you take part. The research team use this information to check you are healthy, and to contact you when needed.

We will also collect information which allows us to understand more about the samples, for example, you age or sex. However, those outside of the clinical team are never given information that can identify you. Your samples are given a unique number, and your name is not used.

We will request information from your GP such as vaccination history, medical and medication history. We will send your GP a questionnaire for completion retrospectively. We do not expect to find anything which would affect your health care. If we do, we will let you and your GP know about it.

All data will be collected and stored at the LUHFT and the LSTM. It will be stored for a minimum period of 15 years. Your medical notes and research data are may be looked at by those who monitor the research.

What will happen to my samples?

The samples taken during this study will be processed and stored in the LSTM. These samples will be gifted for future use in ethically approved research.

At the end of the study, remaining samples will be transferred to a research tissue bank held at the LSTM. All samples will be anonymised at the point of sampling. The stored samples will be analysed as and when new technology becomes available, when new scientific questions arise relating to protection and susceptibility of respiratory disease. Samples may be sent to national and international collaborating laboratories for their expertise however all identifiable information will be removed.

Contact details

General questions and self-reported adverse events: please contact the research team on 07740 410 290 or 0151 702 9424 during normal working hours.

*The Chief Investigator for this study is **Dr Andrea Collins**. You may contact her at the LSTM, Liverpool Life Sciences Accelerator Building, 1 Daulby Street, Liverpool, L7 8XZ, UK. Telephone: 0151 702 9439. This research is sponsored by the LSTM. It is funded by LSTM and Pfizer Inc. The research has been reviewed for scientific content by an external panel. The National Research Ethics Service Committee has reviewed the study and given approval for it to take place.*

LSTM is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. LSTM will keep identifiable information about you 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting dataprotection@lstmed.ac.uk.

LSTM will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from LSTM and regulatory organisations may look at your medical and research records to check the accuracy of the research study. LSTM (research site) will pass these details to LSTM (sponsor) along with the information collected from you and your medical records. The only people in LSTM who will have

access to information that identifies you will be people who need to contact you to regarding your participation in the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

LSTM (research site) will keep identifiable information about you from this study for 10 years after the study has finished.

LSTM will collect information about you for this research study from you and/or your GP records. Your GP will not provide any identifying information about you to LSTM. We will use this information to confirm your eligibility

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care

Liverpool University Hospitals NHS Foundation Trust

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Consent Form

Participant Study number

Please read/explain the following to the participant and gain verbal consent for each statement.
Then, print and sign and date below. **Please initial box**

I have read and understand the information sheet version **3.0** for the above study. I have been able to consider the information and to ask questions. I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	☐
I understand that this study is voluntary and that I am free to withdraw without giving any reason without my medical care or legal rights being affected.	☐
I understand that the section of my medical notes relevant to my taking part in this research and data collected may be seen by the regulatory authorities or NHS Hospital. I give permission for these people to access my medical records.	☐
I agree to my GP to be contacted to provide relevant medical history	☐
I understand that the samples collected will be used and stored for the research described above, and that samples may be sent to national and international collaborating laboratories as part of the study.	☐
I will gift these samples so that they may be used for future ethically approved research in the UK and overseas.	☐
I understand that these samples will be transferred to a research tissue bank for future use in ethically approved research at the end of this study.	☐
I understand that samples will be collected throughout my stay in hospital and I may need to return for a follow up appointment	☐
I agree to take part in this study.	☐

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Name of patient	Signature (if able)	Date
……	……..	_ _/_ _ _/ _ _ _ _
Name of person taking consent	Signature	Date

I have witnessed that the above patient has been given the information and has agreed to take part in this study.

……	……..	_ _/_ _ _/ _ _ _ _
Name of witness from the clinical team	Signature	Date

Copies: 1 for participant, original for site file and one scanned or filed in hospital medical notes