Participant Information Sheet and Informed Consent Form

Participants in Part One

Sheffield Teaching Hospitals
NHS Foundation Trust

Study title: **A Clinical Performance Study using an Optical Fluorescence Test to Detect SARS-CoV-2 Virions**

Short title: **Performance Study of a Rapid COVID-19 IVD Test**

1. Invitation

We'd like to invite you to take part in a voluntary research study into the clinical performance of a new experimental test (known as an in vitro diagnostic or IVD test). This test will check for the SARS-CoV-2 virus particles (virions) that cause COVID-19. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether you would like to take part and answer any questions you may have. Please ask us if there is anything that is not clear or if you would like more information and feel free to talk to family or friends about the study if you wish.

This clinical performance study is looking into a new way of testing for the virus that causes COVID-19 using fresh nasal, throat and saliva swab samples. People who do and don't have COVID-19 will be able to join the study. The samples will be collected from staff, their household contacts and patients at Sheffield Teaching Hospitals NHS Foundation Trust (STH). 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. We hope 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 does this by finding "virions" (whole virus particles) in samples rather than finding leftover bits of virus.

If you would like to find out more about the research supporting this study, please contact one of the research team using the details provided at the end of this form.

Thank you for taking the time to read this.

2. What is involved?

We have developed a new test that can be used to find SARS-CoV-2 virus (the virus that causes COVID-19). So far, we have tested stored samples leftover from clinical testing at STH. We now need to collect information about how well the test can find the virus in fresh samples from people with and without the virus. Samples will be collected by nasal and throat swabs, using the same method as for a PCR (polymerase chain reaction) COVID test. We would also like you to provide a saliva swab sample.

The results of the new test will be compared to your result from the standard NHS PCR test done at

STH. These results will then be compared to an extra PCR test run at the University of Sheffield and possibly to a virus culture test where we try to grow virus from your swab samples. We 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.

Your participation today will only involve sample collection and answering a few questions, so should last no more than 15 minutes.

3. Why have I been invited?

You have been invited because either you have already tested positive for COVID-19 with a previous test in the last 24 hours, or you came here to be tested as you might have COVID-19. We plan to invite 100 people to give samples in this part of the study.

4. Do I have to give a sample?

It is up to you to decide if you wish to donate samples to this research study. Take time before you make your decision. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Your decision will not affect the standard of medical care that you receive or your employment if you work at STH. You will still receive the results of the NHS COVID-19 PCR test and you may do more lateral flow tests if you wish.

5. What would taking part involve?

You will be given a kit with instructions and asked to provide three swab samples. This is just like the other COVID-19 tests that you are used to, where you will need to swab these areas (using three different swabs):

1) both nostrils,
2) the tonsils at the back of the throat (or the area where there they would have been if they have been removed) followed by one nostril with the same swab,
3) the saliva in your mouth by rubbing a swab against the inside of your cheeks, roof of your mouth, gums and above and below your tongue.

You will then insert each swab into separate tubes containing a small amount of liquid. The total number of samples that you will provide is three.
Once you have taken the samples, you will securely pack them in the packaging provided and return to the research team member. The package will be anonymised by labelling with the study number and a sequential number, and there will be no information that could identify you with your sample. The samples will then be sent to the University of Sheffield and analysed using the new test, PCR testing and possibly another test to grow virus from the samples.

After testing at the lab, your samples will be stored securely at the University of Sheffield for up to two years from the end of the study and may be tested again on future versions of the new test or related studies. They may also be further tested using different tests to give us more information about your samples, namely microscopy, mass spectrometry and ELISA (antibody) tests.

6. What information do I have to give?

The research team member will make a note of your age, gender, ethnicity, the number of days that you have had symptoms (if you have symptoms) and the type of any symptoms. They will also ask when the last time was that you took a test, what the result was, and the type of test used (lateral flow or PCR). Finally, you will be asked for your vaccination status, date of last jab and whether you are taking specific medicines. Once consented, the whole process including the swab should take no more than about 15 minutes.

The hospital will also share your NHS PCR test result with the researchers at the University of Sheffield and the company, Paraytec Ltd. No identifiable details for you will be shared.

7. What are the possible benefits of taking part?

Although there are no direct benefits in the short-term for you, apart from contributing to research, if the test works well in enough people, it could help society find people infected with COVID-19 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.

8. What are the possible disadvantages and risks of taking part?

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 your eyes to water 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. As you will have also done a PCR test for analysis at the hospital, you will have your NHS test result. You will not receive any results from the study testing, so there is no risk of getting a false result. However, as with everything in life, there is always a small chance that unanticipated risks may occur.

There should be no risk of loss of confidentiality. Your personal information will not be shared outside the research team at STH and your data will be identified by a number rather than anything that identifies you. The information that you give will be recorded on a form and there will be no option for entering personal data. It is possible but unlikely that regulators and auditors who check the accuracy of the study may see your personal information during their usual checks.

9. Are there any alternative procedures available?

There are no other alternatives as part of the study. You are offered a PCR test through STH if you suspect that you have COVID-19 and lateral flow tests are widely available from local pharmacies and online.

10. What happens to the results of the research?

We hope to publish the results in a research journal within one year and we will put the results on the company website www.paraytec.com/covid-19-test. We will also try to add the results to the news section of the hospital and University of Sheffield websites. The data may be shared with

other researchers with whom we work. If the new test is successful, the results may be part of the submission to regulatory authorities in the UK and elsewhere to get permission to market the test. All shared and published research will use anonymised data only.

11. What if I change my mind?

Taking part in this study is completely your choice and you can change your mind at any point until your samples are sent to the University of Sheffield. If you choose not to take part or wish to withdraw from the study, it will not affect the care that you receive, your employment (if you work at STH) or your access to COVID-19 tests.

12. Who is organising and funding the research?

Paraytec Ltd is organising the research and the study is funded by Paraytec's parent company, Braveheart Investment Group plc. Braveheart Group will pay STH for the hospital's expenses to include you in this study.

13. Will my taking part in this study be kept confidential?

All the information that you provide will be kept confidential; only the research team at STH will be able to access your data, and no individual will be identifiable from their stored data, or in the analysis and publications of our findings. We will collect information (age, gender and ethnicity) from you, but it will not be reasonably possible to identify you from this information. Once the study is complete, your personal data will be deleted by the courier company and the research team within 3 months; however, the informed consent forms will be kept for three years beyond the end of the study. Your anonymised data may be used in future research or in publications of these findings, or as part of a regulatory submission to market the test. In this last case, the anonymised results from your samples may be kept for up to 10 years from the end of the study or 10 years after the last product is available for market.

Paraytec Ltd is the overall Data Controller for this study and is responsible for looking after your information and making sure it is used properly (Data Protection Officer (DPO) – Vivian Hallam). Both the University of Sheffield and STH will also act as Data Controllers. Neither your name nor identifying data will be recorded outside the hospital or its secure record system (DPO – Michael Maginnis). Regulatory authorities, ethics committee representatives and the Paraytec's representative for this study may have direct access to records only if needed for the purposes of checking the accuracy of the study. Within three years of the end of the study, the link between your data and your personal information will be destroyed. The study results will be held at the University of Sheffield (DPO – Luke Thompson) and at Paraytec Ltd. All data are managed in line with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, and data protection legislation.

14. What if something goes wrong?

This study is insured in the unlikely event of any injury or adverse event as a direct result of participation in this study.

If you have a concern about any aspect of this study, you should ask to speak to the researchers

who will do their best to answer your questions (0114 2715779). If you remain unhappy and wish to complain formally, you can do this by contacting Patient Services at STH who are independent from the study team on 0114 271 2400 or email them at sth.pals@nhs.net. You can also contact the company representative Sue Hagan at Paraytec Ltd, sahagan@paraytec.com.

15. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by London Central Research Ethics Committee. The study design and documents have also been reviewed by clinicians involved in COVID-19 testing at STH.

16. Contact for Further Information

More information on the new test can be found on Paraytec's website:
www.paraytec.com/covid-19-test

If you have any questions or worries about the study or your rights, then please contact the research team for advice. If you have any injury as a result of the study, please contact the research team:

Chief Investigator: Dr Cariad Evans

Telephone Number: 0114 2266477

Research Nurse: .....

Telephone Number: .....

You will be given a copy of this Patient Information Sheet and of the signed Consent Form to keep.

Thank you for your co-operation and for considering taking part in this study.

APPENDIX: Consent Form for Part One

Hospital/Institution headed paper

Title of Study: **A Clinical Performance Study using an Optical Fluorescence Test to Detect SARS CoV-2 Virions**

Subgroup: **Part One**

Paraytec Ltd Study Number: **PA-000201-CP**

STH Project No. **STH21689**

IRAS Number: **309237**

Participant sequential number: ……..

		Please initial box
1.	I have read and understood the information sheet dated 6th May 2022 (Issue 2) for the above study.	☐
2.	I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
3.	I understand that my participation is voluntary. I am free to withdraw at any time until my samples are sent to the University of Sheffield, without giving any reason, and without my medical care or legal rights being affected.	☐
4.	I understand that this study will involve me providing three swabs (one nasal swab, one nose/throat swab and one saliva swab) as well as providing some information about myself.	☐
5.	I understand and agree that my anonymised samples will be sent to the University of Sheffield for analysis and that the samples will have **no** identifiable information.	☐
6.	I understand and agree that my anonymised NHS PCR result will be shared with the researchers and Paraytec Ltd for the purposes of this study.	☐
7.	I understand that identifiable data collected during the study may be looked at by an individual from Paraytec Ltd, regulatory authorities or STH, but only where it is relevant to my taking part in this research. I give permission for these individuals to access these records.	☐
8.	I understand that my personal details will not be revealed to any other people outside the research team at STH.	☐

9.	I understand that the information collected about me will be used anonymously to support other research in the future, may be shared anonymously with other researchers and used in publications and reports.	☐
10.	I agree to take part in the above study and follow the study instructions provided with the kits.	☐
11.	I understand that my samples will be stored securely at the University of Sheffield and I agree that they may be used for future research	☐

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Name of Participant	Date	Signature

.....	.....	.....
Name of Researcher receiving consent	Date and Time	Signature

One copy for participant; one to be kept with hospital study site file.