

Information Sheet for Patients

Rapid Community Testing for COVID-19 (RAPTOR-C19)

We would like to invite you to take part in our research study. Taking part is voluntary. Before you decide whether or not to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you want to. Please ask us if there is anything that is not clear or if you would like any more information.

Study overview and key points

- We are doing a research study to compare how accurate different tests are at detecting past or current coronavirus (COVID-19) infection.
- We will be comparing the results of new rapid tests with standard laboratory tests for COVID-19.
- If this study identifies a good rapid test for COVID-19 it might be useful in the future for helping doctors and nurses give instant advice about self-isolation which might help block the spread of the virus.
- You or your child have been invited to take part in this study because you are having, or have had, symptoms that might mean you have COVID-19 now or in the past and are having lab test as part of your care.
- If you or your child take part in the study you will have at least two tests for COVID-19. You will get the standard swab test from the nose or mouth. These samples will be sent to a laboratory and your GP will receive the results a few days later. You will also have at least one rapid test, but you will not find out the results of these as they may not be accurate, these are what we are testing.
- Adults (≥ 16) taking part in the study will also give blood samples so we can look for past infection.
- We would ask to follow up with you daily for 28 days to ask about symptoms.
- You do not have to take part in this study if you do not want to, and this will not affect the care that you receive from your GP.

Please ask your GP or the study team if you have any questions about the study, or you do not understand the additional information we have provided over the next few pages.

What is the full study title?

The full title of the study is 'Expanding national RAPid community Test evaluation capacity fOR COVID-19. We usually refer to the study as RAPTOR-C19.

Who is doing the study?

The study is being done by the University of Oxford, in collaboration with the Royal College of General Practitioners Research and Surveillance Centre (RCGP-RSC). Results of this study will be shared across a national network of researchers evaluating COVID-19 tests. This is the called COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR).

What is rapid testing for COVID-19?

Rapid testing is a way of identifying people with COVID-19 quickly (in a few minutes/hours) in the GP surgery or at home rather than waiting for several days for tests to be completed in specialist laboratories.

Why would rapid testing for COVID-19 be helpful?

Rapid tests for COVID-19 could potentially be useful in giving people instant advice about self-isolation and blocking spread of the virus, but only if these tests are accurate.

Who has made the rapid tests for COVID-19?

Many different companies have developed rapid tests for COVID-19. These tests commonly use swabs from the mouth or nose, a sample of saliva or a drop of blood taken from a finger prick. Companies check their tests work in laboratories but often these tests do not work so well in real life. In our study we will do the rapid tests in lots of people who have had a range of symptoms that might be caused by COVID-19 and compare them with the standard laboratory tests. This will probably be 500-1000 people per test.

Who will be asked to take part in the study?

Your GP or nurse will ask you if you would like to take part in the study if you have told them that you or your child have COVID-19 related symptoms. Most people will have had a fever, a new continuous cough or a loss or change in their sense of taste or smell. However, there is a range of other symptoms that might make them suspect COVID-19 and prompt them to invite you to join the study including shortness of breath, chest pain, wheezing, sneezing and nasal congestion.

Alternatively, you or your child may be asked to join the study if a search of your GP records suggests that you might have had COVID-19 in the past, or if a letter from hospital or A&E suggests that you might have the infection. You may already have had one test for COVID-19 but if you are willing to be tested again, you can take part in the study.

What will happen if I agree to take part in the study?

The first thing that will happen is that you will be asked to give your consent for you or your child to take part in the study. This is to check that you understand what is involved and that you are happy to continue. You will be asked to answer a series of yes/no questions on an electronic device that the GP, nurse or researcher will hand to you. Alternatively, a GP, nurse or researcher will ask you the questions and will record the

answers you give. Your completed electronic consent form will be stored securely and confidentially, and you will be provided with a copy.

We will then ask you for some more information about you/your child's symptoms, possible COVID-19 cases in your household, where you are receiving your care, any clinical measurements, whether you have had a vaccine and any past COVID-19 tests and their results. This will either be completed by you on the electronic device or asked by the researcher and recorded electronically. We will also want to know about your or your child's general health and may look at information in your health records. All of this information will be stored securely and confidentially.

You or your child will normally receive at least two tests for COVID-19.

Adults (≥ 16) and children will get the standard test which is used in the UK to see whether you have current COVID-19. This is a nose and/or mouth swab. Your doctor or nurse may do these tests in the GP practice, or you may be given the kit to do it yourself or for your child in the GP practice or at home. These standard tests are sent to a Public Health England (PHE) national laboratory (lab) for analysis. You will have this test as part of your care whether or not you take part in the study. We would ask that we can be informed of the results, to compare to the other tests.

Adults will also have standard blood tests to look for antibodies, which tells us if you have had COVID-19 in the past. We would take 6ml, just over 1 teaspoon. After around four weeks we will also ask adult participants to visit their GP surgery to give another blood sample to repeat the test. This will also be sent to a PHE lab for analysis. You will be able to discuss the result of this test with your GP.

Children under 16 will not be asked to give blood samples to check for past COVID-19 infection. You and your child will give samples for a least one new rapid test. This may involve taking another sample from your nose or mouth with a swab, taking a sample of saliva or taking a small drop of blood from your finger. Children under 10 years old will not be asked for blood.

We would also like to know more about how your illness may be affecting you after the first appointment. A representative from your GP practice will check in daily for 28 days to ask about your or your child's symptoms. We would also like to be able to follow up through NHS records for a year. This information will be held confidentially and securely.

Will I get the results of the tests?

The results of the standard tests that get sent to the lab will be sent back to your GP by PHE. It usually takes two to three days for the swab test results to be made available, and a while longer for the antibody test. Your GP can tell you the results of these tests, and with your consent will inform us.

We will not give you the result of the rapid tests that we are evaluating. This is because we do not know how accurate they are and we may cause you or others harm if we gave you the wrong result.

How will infection control be managed?

Everyone involved in sample collection for the study will be required to follow the current PHE infection prevention and control guidance at all times including wearing appropriate personal and protective equipment (PPE) – which may involve masks, gloves and aprons. We will minimise contact time with you as much as possible and you may be asked to do some of the tests yourself at home or in the GP surgery.

Do I or my child have to take part?

No taking part is completely voluntary. Your decision whether or not to take part will not affect the care you or your child receive from your GP now or in the future.

Can other members of my household take part?

Yes, they can. Anybody who has been in close contact with somebody who has a suspected or confirmed COVID-19 infection can take part. They need to be able to consent to the study themselves, or if they are aged under 16 years and have a parent or guardian who can do this for them. They should get in touch with their GP surgery or the study team using the contact details below.

Will I receive any payment if I take part?

No, you will not receive any payment. Your GP surgery will be reimbursed for your involvement.

What are the advantages for me of taking part?

The main benefits of the study are for healthcare professionals and public health officials to know which rapid tests are the most accurate and might be useful in the future.

It may be useful for you to know if you have had a COVID-19 infection in the past. It may not change your treatment, especially if you only have mild symptoms. However, it might change whether you and your household need to self-isolate.

What are the possible disadvantages of taking part?

Taking part in the study will require some of your time collecting information about you or your child and performing the tests.

Nose and mouth swabs can be uncomfortable but they only last a few seconds. They are safe to use, and to do yourself, even if you have not done one before. Finger-prick blood tests may cause a small amount of pain and occasionally a bruise. Taking a sample of blood from your arm can cause mild pain, bruising and very rarely infection. These side-effects are normally very short-lived. You should seek advice from your doctor or nurse if are concerned about any problems after the tests.

There is a small chance that result returned from the standard test sent to PHE is wrong. You or your child could be told that you have COVID-19 when you do not or vice-versa. This is the same for all people who are tested for COVID-19 across the UK. Your doctor or nurse will help interpret the test results with you and advise you what to do. It is important that if you or your child became seriously unwell you seek help from a medical provider or telephone 111, even if you or your child have had a negative test.

Should I still self-isolate once I/my child has had the test?

If you or your child you have current symptoms of COVID-19 infection you must self-isolate according to PHE and government guidelines.

You can find the latest guidance here: <https://www.gov.uk/coronavirus>.

Once you have received a test result from PHE, you will be told what to do. Your doctor or nurse can discuss this further with you. If you live in a household with other people you should follow the current household isolating guidance on the government website above.

What will happen to the samples that I provide?

The samples taken for the rapid tests will be thrown away by the study team as soon as they have been used. If you agree, the blood samples taken for the antibody tests may be kept for use in future research. They would be made available to other ethically approved research in a form that does not identify you.

What will happen if I no longer want to take part in the study?

You can leave the study at any time without giving a reason. This will not affect your or your child's care in any way.

Will anyone know that I have taken part in the study?

Only your GP will know that you have participated in the study.

Will my information be stored confidentially?

Yes it will. We will follow all ethical and legal practices to ensure information about you is handled confidentially. You will only be identified by a participant ID number on all study documents and any electronic database. Responsible members of the University of Oxford and the relevant GP Practice may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your/ your child's medical records, NHS Digital and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible. These registries include the Royal College of General Practitioners and Public Health England. The Universities of Oxford and Surrey process data on their behalf.

We will keep identifiable information about you for less than 3 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 20 years after the end of the study.

Your GP practice will use your name and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with their policy for retention of medical records.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information by contacting RAPTOR@phc.ox.ac.uk.

What will happen to the results of this study?

We may publish the study findings through journal articles, press reports, presentations and conference papers. Neither you, your child, nor your GP practice will be able to be identified in any written or verbal reports from the study.

Future research

If you are willing to be contacted about research we do in the future, we would hold your contact details securely at the University of Oxford's Nuffield Department of Primary Care Health Sciences. These will be held separately from the research data. We will keep a copy of your consent form as evidence of this permission. Agreeing to be approached does not oblige you to take part in any further research, and you can ask to be removed from this list at any time.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact RAPTOR@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrugr@admin.ox.ac.uk.

Who is organising and funding the study?

This study is organised by researchers at the University of Oxford's Nuffield Department of Primary Care Health Sciences, working with the Royal College of General Practitioners Research and Surveillance Centre. It is being funded by the National Institute for Health Research (NIHR).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by North West – Liverpool Central Research Ethics Committee.

Where can I get further information?

Please ask your GP or the study team if you have any questions or you do not understand the information we have provided.

You can contact the research team at RAPTOR@phc.ox.ac.uk

Thank you for considering taking part in this study.