Public Health England

# Participant Information Sheet

## A study to improve antibody testing for COVID-19

### Evaluating Detection of SARS-CoV-2 AntiBodies at HOME (EDSAB-HOME study)

We need volunteers to help us assess how well coronavirus antibody tests work, particularly those that can be done at home, and to make sure they are made available to the public as rapidly as possible.

**Immune reactions to infection:**
When people are infected by the coronavirus causing COVID-19, many will produce antibodies. Because of this, antibody tests for coronavirus should help us understand who has previously been exposed to coronavirus. Antibody tests are performed on blood and differ from currently available 'nose and throat' tests, which identify whether someone is currently infected with coronavirus by looking for the virus directly.

People infected with coronavirus also generate special virus-fighting cells called T cells which, like antibodies, are present in the blood. If one could count the coronavirus-fighting T cells, this might also help us understand who has been previously infected with coronavirus. Unfortunately, tests counting coronavirus-fighting T cells are still at an early stage of development.

**What is the purpose of the study?**
Home antibody tests would help large numbers of people know whether they have been previously infected. At the moment no home antibody test for coronavirus performs well enough for use by the public, so the UK Government, universities and industry are urgently trying to develop them. There are two types of home test kits: both involve people taking a small amount of their own blood from finger-prick blood sampling.

- The first type consists of filling a small tube of blood to be sent to a laboratory for testing. These tests can also be used on standard blood samples taken from a vein.
- The second kind are 'pregnancy testing' type kits, in which bands develop when finger-prick blood is added to the kit. The results are then read by the participant from the test kit.

**How taking part in this study will help:**
Taking part in this study will:

- Help understand how well new home test kits, which will become available in the future, work and how easy they are to use.
- Help speed up the deployment of the new home test kits.
- Help speed up the assessment of other kinds of antibody or immunity tests.
- Contribute to our understanding of coronavirus immunity.

Before you decide to take part, it is important that you understand what we are doing and what taking part would involve for you. Please read the following information carefully. Our contact details are at the bottom of this sheet if you would like more information.

Participation in this study is voluntary.

By giving your consent to take part in this study you are telling us that you:
✓ Understand what you have read
✓ Agree to take part in the study as outlined below
✓ Agree for us to use your personal information as described.

**Who is running this study?**
This work is being performed by Public Health England (PHE), on behalf of Department of Health and Social Care (DHSC), in collaboration with experts from University of Bristol and University of Warwick.

**What is involved for me?**
This study will do this via a two-stage approach. Both stages will take place in a workplace clinic.
Once you sign up, you will undertake stage one.
You may or may not be invited to take part in stage two.

There are three things we would ask from you as part of stage one of this study, if you agree to take part.

(a) to complete an initial online questionnaire;
(b) to visit a "stage one" clinic which we will set up in your workplace, or another convenient location. If your organisation is doing workplace based screening for COVID-19 antibodies, we will make sure we take the blood at the same time as your NHS samples, so you won't need to give blood twice. and;
(c) to complete a short weekly online questionnaire (1-2 minutes each) for up to six months. This is an optional, but highly valuable, component of your contribution to this study.
All these three "stage one" steps are explained in more detail below.

***(a) Initial online questionnaire***

The online questionnaire will ask about who you are, your job (to understand your risk of being exposed to, and having previously had, coronavirus), and any recent respiratory and other symptoms which may indicate that you have had COVID-19. It will also ask what you have been doing (e.g. if you have been self-isolating, working in a healthcare setting etc.)

***(b) Attending a "stage one" clinic***

At the study clinic, which we plan to set up in your workplace, we will ask you:

- to allow us to take up to 20ml blood sample from a vein (this is a small amount, and is less than 5% of what is usually taken when donating blood). Your samples will then be sent off to a laboratory to help us develop antibody tests for coronavirus, including home test kits. We will also count the number of coronavirus-fighting T cells in your blood, as this may help interpret antibody results.

- From a small number of volunteers (about one person in 10 volunteering), we may also ask to collect a blood sample into a small tube using a finger-prick. This will help to develop the first type of home test kit (as explained in the section above *"what is the purpose of this study").*

After being tested, the samples will be stored for up to 10 years, and will allow future home and laboratory tests to be developed.

***(c) Follow up questionnaire***

We would like to follow up all participants who take part in the study.

1. We would like to contact you by email or text, or not at all if you choose not to, on a weekly basis for up to six months, to ask you a few simple questions. These questions will ask you whether you have become unwell in anyway in the previous 7 days. This will help us understand the impact of test results on future health. This will only take 1-2 minutes a week of your time. If you do not wish for us to do this, you are able to indicate this on your consent form.
2. We would like to link your data to our records of whether you have been admitted to hospital, and whether you have had a COVID-19 test, and its result. This will require no action from you.

**Second "stage two" visit:**
We may also invite some participants back to a clinic at a later date, to try out new home test kits if they become available. Only a sub-set of the original volunteers will be called back. If you are invited to come back, and do not wish to do so, you are free to decline. Any second visit is specifically designed to assess the

second type of home test kit which can be used and read at home. If you agree to attend, the process will be similar to the first visit:

- We will invite you to a clinic
- We will ask you to fill in a short questionnaire;
- We will ask you for an additional blood sample (as your exposure to COVID-19 may have changed between your first and second visit);
- We will give you a finger-prick home testing kit to try in the clinic, with full instructions provided on the day of how to take it; we will watch you do this in the testing clinic to make sure it can be used successfully and record our observations. We will ask you for feedback on the process.
- We may also ask you to read the results of tests other than your own, to help us improve the reading process.

If you would like to receive further information about future studies to reduce the impact of coronavirus, you can indicate this on your form.

**How much of my time will the study take?**
Completion of each step will take different amounts of your time. Completing the online questionnaire will take about 10-15 minutes. For attending a "stage one" clinic, you will be allocated a slot of up to 30 minutes, however we believe that the process may take less time. The follow-up questionnaire will only take 1-2 minutes each week, for up to six months. Attending a "stage two" clinic, if you are invited back and agree to do so, will take between 30 to 60 minutes.

**Will you tell me my results?**
Yes, but only if you want us to. The Chief Medical Officer has stated that various laboratory based antibody systems are now good enough for NHS use. Your blood will be tested using some of these antibody testing systems. If you wish, we will let you know your results and will provide standard NHS advice about what they mean. It may take us 3-4 weeks to do this, and you will receive your result, if requested, by a secure email.

We will also do some tests on your samples using testing systems which are still being developed and are not being used by the NHS at the moment. These tests include experimental antibody tests and tests counting coronavirus fighting T cells. These tests are much less well understood, and we will not be sending you results obtained from these less developed tests. This is normal practice in studies such as this one.

At your second visit, if you are invited to one, you use the 'pregnancy test type' home test kit and you will be able to know your result. We will provide you with information on the day as to what the test kit result means to you, based on the data we have at the time.

**Will my employer receive my results?**
Your employer will not receive any individual results. They will receive an overall summary of the results from their site. We will provide a report stating the number and percentage of antibody positive people by age groups (e.g. 18-35, 36-50 etc), by employment group (e.g. Hospital Doctor, GP, Hospital nursing), by gender, and by whether people reported COVID-19 like symptoms. We will ensure you cannot be identifiable from this report – for example by combining categories if only a few people fall into a particular category. If you would also like to receive the summary results from the study, you are able to indicate this on your form.

**When and where will the study take place?**
Testing centres will be set up between June and August 2020, in workplace settings across England; we will aim to make these as accessible to you as possible.

**Will I benefit from taking part in the study?**
You will receive the results from the laboratory-based antibody test if you wish to do so, and from the finger-prick home test kit if you are invited to take one. However, this will not necessarily benefit you personally.
You may benefit indirectly, as you will be contributing to antibody testing programme.

**Who can volunteer for the study?**
Initially we are looking for healthcare workers and public service workers (such as police officers) who

- are aged 18 or over;
- are currently working in their place of work, not self-isolating at home;
- do not currently have symptoms suggestive of COVID-19;

- have not have COVID-19 compatible symptoms in the last seven days;
- have not been diagnosed with COVID-19 in the last seven days;
- proficient in written and spoken English;
- Can read normal sized print e.g. a newspaper (with glasses if necessary);
- Are not taking part in trials of COVID-19 vaccines.

You can contribute whether or not you have previously had a COVID-19 "nose and throat" test done, irrespective of the results.

**Is there any risk?**
We do not anticipate risk associated with taking part in the study. The risks involved with giving blood are minimal. You may feel faint when you give blood and/or bruising may appear, however these will both pass and are not harmful. If you do a finger-prick blood test, the finger may be sore afterwards.

We will maintain social distancing in the study clinic, exclude anyone with COVID-19 symptoms, and follow current infection control guidance to minimise the risk of cross infection between you, clinic staff and workplace colleagues who may also be contributing. All staff at the clinic will use Personal Protective Equipment, including masks where appropriate.

**Do I have to be in the study? Can I withdraw from the study once I've started?**
Being in this study is completely voluntary and you do not have to take part.

If you decide to take part in the study, and then change your mind, you are free to withdraw from the study at any point without explanation. Should you decide to withdraw, we will delete all of your identifiable data (such as your name, email, phone number etc). Your anonymised record will remain in our database, but if we have not already carried out the analyses, we will not include your record. It may not be possible to remove your blood samples, as these may be stored amongst hundreds of other samples.

**What will happen to the information about me that is collected during the study?**
The survey will be conducted using an online survey system hosted within PHE on a secure PHE server. The data you provide during this study will be kept confidential and any identifiable data will not leave PHE. Your names and contact details will only be available to PHE study staff who need to access it.

Statistical experts who are working on the data analysis will have access to anonymous data gathered by the study. The results may be presented to a variety of academic and professional audiences; however, it will not be possible to identify you.

We aim to maintain this volunteer bank for up to 2 years, during which time you may be called back to a "stage two" clinic to test new home antibody devices as they become available. One year following the conclusion of this bank, all personal identifiable information will be removed.

We may link your data with other routine PHE data sources (e.g. hospital admissions and laboratory results) to further understand your clinical outcomes relating to coronavirus. This is normal in research studies such as this one. The data you provide during this study will be kept confidential in accordance with General Data Protection Regulations (GDPR) and the Data Protection Act of 2018. You have this right to know what data we hold on you – more information about this provided at https://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter.

**What will happen to the blood taken from me during the study?**
We will separate the plasma (the clear part of the blood) from the cells (red cells, and immune cells) which are in your blood. We will develop antibody-based assays for COVID-19 using the plasma. We may also test for antibodies to other infectious diseases (such as glandular fever), to vaccines given in childhood, and for other antibodies which may interfere with coronavirus antibody tests. We will not test your blood for HIV or hepatitis viruses. This testing is solely to help with interpreting coronavirus antibody levels, and will not be shared outside of this study. PHE will store the plasma for up to 10 years.

The number of coronavirus-fighting T cells in your blood will be counted. This work will be done by Oxford Immunotec Ltd, a well established UK diagnostics company which specialises in counting disease fighting T cells. The blood tube we send them will have a code number on it, and no other information. They will measure the number of coronavirus-fighting T cells in your blood and return the results to PHE.

Finally, we would like to store the cells present in your blood. Recent experiments have shown your immune response can be analysed using DNA present in your white cells, because the DNA in your blood lymphocyte cells is modified during the immune response. This may be the basis of tests for coronavirus immunity in the future. This is optional, and does not alter how much blood we will take. We will ask you permission to do so, and if you agree, we will store this material in an approved Research Biobank for up to 10 years as well. If you do not give us your permission, we will dispose of the part of your blood that contains your red and white cells.

We will not sell data or samples from the study to commercial companies.

**Who has reviewed the study?**

This work has been reviewed and approved by the NHS Research Ethics Committee (REC) by North East – Newcastle & North Tyneside 2 Research Ethics Committee. Patient and public involvement groups, including lay reviewers from the general public, have also reviewed the study.

**Who should I contact if I wish to raise a complaint about the study?**

If you wish to raise a complaint about the study, please contact: *Complaints Manager, Strategy Directorate, Wellington House, 133 – 155 Waterloo Road, London, SE1 8UG. Or email: complaints@phe.gov.uk*

## Next Steps

**What do I do if I am not interested in participating?**

You do not need to take any action.

**What if I would like further information about the study before signing up?**

If you have any further questions after reading this document, please feel free to contact the study team at phe.edsab.home.participants@nhs.net.

**What do I do if I am interested?**

Please complete the online electronic questionnaire, which can be accessed at https://snapsurvey.phe.org.uk/edsab-home-nhs

On completion of your questionnaire, you will be directed to instructions on how to book online. In the email sent to you by your employer, it will have stated the dates will be running a study clinic at your site.

If this process is not working for you, or you need assistance, please let us know at phe.edsab.home.participants@nhs.net and we will reply.

Thank you.