COVID-19 antibody testing from the home (12/02/2021 v1.2)

Information sheet for participants

We would like to invite you to take part in a research project called 'COVID-19 specific antibody testing in ALSPAC (G0/G1)' This participant information sheet explains what we would like you to do and why. Please take time to read the following information carefully. It will help you decide whether you wish to take part. We would be happy to answer any questions you have about this research, so please get in touch if anything is not clear (details below).

Please be aware that the antibody test is not reliable at an individual level.

It is important that you continue to follow the current Government advice based on symptoms and possible exposures.

What is the purpose of the research?
This is an antibody research study. Antibodies are made by the immune system to fight infection. In this study, we will use the results of antibody tests from blood that you collect yourself at home and send to a laboratory for analysis. This will help us understand how many people in Children of the 90s may have already been infected with the virus which causes COVID-19.

This is part of a national initiative where other studies in the UK are also asking their participants to complete the same antibody test. Analysing the information from Children of the 90s alongside these other studies will allow a greater understanding of the impact of COVID-19 on people's health and other aspects of life.

Why have I been invited to participate?
You have been invited to participate in this study because you completed at least one of our COVID-19 questionnaires during the pandemic.

Unfortunately, participants who have an increased risk of bleeding e.g. those taking blood thinners such as Warfarin are unable to take part in this study.

What is involved?

You will be asked to take a self-collected blood sample at home by pricking your finger and squeezing drops of blood into a little tube and then send the sample to a company called Thriva. Thriva will undertake the antibody testing and send the results back to us at Children of the 90s. We will then email you with the results no later than 6 weeks after the initial invite was emailed to you.

We recommend that you watch the video (please note it is 8.54 minutes long) and read the instructions carefully before taking your blood sample. Please note that the video, which is designed for NHS patients, states that the results will be available in the next 3 to 7 days. This is not the case for this study and the results will take up to 6 weeks to be returned to you.

We will ask you to provide a blood sample (approximately 10 drops, which is about 0.5ml or one tenth of a teaspoon) for the testing of the coronavirus antibodies. If you consent to this we will also store a small volume of your sample for use in future health research.

You can find out more about what is in the kit and what it involves by watching the video here: https://www.youtube.com/watch?v=okTozcGMDlU

Do I have to take part?
No. Whether you take part in the study is entirely up to you. Even if you do decide to take part, you can change your mind at any time without giving a reason. You should be aware that data collected about you up to the time you decide to stop taking part may still be used as part of the research study results. If you decide not to participate, this decision will not in any way affect your ability to continue to participate in future Children of the 90s data collections. If you decide you do not want to take part after you have consented and received your kit please throw away the blood sampling kit as set out in the instructions.

How do I take part?
If you would like to take part, please click on the unique link in your email to access an online form to confirm your willingness to take part and give consent to provide a blood sample. The consent form asks you to confirm your contact details so that we can send you the blood sampling kit. If your address has changed you can update your details here http://www.childrenofthe90s.ac.uk/update-your-details.

Once you receive your kit, please follow the instructions in the kit. It would be best not to do the test on a Saturday as it may sit in the post for too long.

Confidentiality and data protection
Any data we collect from you will be stored with an individual ID number but with no personal information (your name, address, or date of birth) attached. Files that link this ID number to your personal details will be securely stored. Data will be used for non-genetic research i.e. research that is not about your genetic inheritance purposes only and will only be analysed by researchers who have been approved by the Children of the 90s Executive. Researchers will not have access to your personal information. Your personal details will not be shared with third parties except for specific service providers working on our behalf. Thriva is one of those who are needed for mailing out the test kits and analysing the blood samples and who have a proven relationship with the Department of Health and satisfy all data security thresholds. Data sent to Thriva will be encrypted and deleted as soon as it is no longer needed.

Under the Health Protection (Notification) (Amendment) regulations 2020, there is a legal requirement for COVID-19 results to be reported to Public Health England (PHE). These data will be provided to PHE by ALSPAC in an **anonymised** form.

Children of the 90s is compliant with GDPR (General Data Protection Regulation) and with the Data Protection Act (2018) for the collection, processing, storage and disclosure of personal information. If you would like to find out more, please see our privacy notice here: http://www.bristol.ac.uk/alspac/participants/privacy/

The results of the study (at a population level – not based on individual results) will be published in scientific journals and participants can see a summary of the results. No individual information or names will be published.

How will this research help others?
The study aims to estimate how many people in Children of the 90s have been infected with the virus that causes COVID-19 and to use the wealth of existing Children of the 90s data to help understand this disease. We don't know yet if having antibodies gives someone long-lasting protection from the virus. The results of this study may help guide public health policy and the government's plan for its antibody testing strategy.

How will I receive my results?
We will email the results of the antibody test to you up to 6 weeks after you received your first invite email. Please note that the instructional video, which is designed for NHS patients, states that the results will be available in the next 3 to 7 days. This is not the case for this study and the results will take 4 to 6 weeks to be returned to you.

What do the antibody test results mean?
Antibodies are made by the immune system to fight infection. This test looks for antibodies which are specific indicators of COVID-19 infection only. By looking for antibodies in blood, we are able to understand whether someone is likely to have been infected with the virus that causes COVID-19. This is information about infections in the past – not current infection status.

The results of this antibody test are not 100% accurate for individuals. The test is for research purposes only and allows us to analyse the study participants as a whole. This data helps track the rates of coronavirus infection and estimate the prevalence of the virus.

Please be aware that the antibody test is not reliable at an individual level.

Whatever your test result, you must continue to follow current Government advice.

It is very important that, despite what the results of this test show (whether antibodies detected, not clearly detected or an invalid test result), **you do not change your behaviour**. There is no strong evidence yet to suggest that those who have had the virus develop long-lasting immunity that would prevent them from getting the virus again.

It is important that you continue to follow the current Government advice based on symptoms and possible exposures.

How is the blood sample stored?
One of the benefits of our approach collecting antibody data from blood collected at home is that with your consent we can store a small volume of the sample left over from antibody tests. Just like the tests you have kindly given at face-to-face clinics in the past, this residual sample may be of real value to future research – for example relating to the biology of infection or even of stress and strain of lockdown in those not affected directly. Being able to collect a sample remotely is a huge benefit to Children of the 90s at the moment when we are unable to see you all in person.

The sample will be stored securely and anonymously with a unique ID number.

We are grateful to you for donating your sample as a gift the Children of the 90s. This means that you have agreed that the sample can be used for this study and other approved non-genetic research. However, you can change your mind at any time without giving a reason

What will happen to the samples I give?
Your sample will be sent to Thriva where your antibody levels will be measured. After your sample has been analysed the left-over material will be sent to the National UK Biocentre at Milton Keynes for safe storage during this project. At the end of the project your sample will be sent to the Children of the 90s biobank at the Bristol Bioresource Laboratories (University of Bristol) for long term storage if you have consented to the future use of your samples. In the future, some of your sample may be made available to researchers working in universities, hospitals or other organisations in the UK or abroad. We may ask for a fee from researchers to help cover the costs associated with sending your sample to other places. This is the same as samples taken in the past and as before, we will not sell or make any profit from the sample you donate, and it will only be used in ethically approved research that has been reviewed and approved by the Children of the 90s Executive.

What are the possible risks or side-effects of taking part?
Collecting the blood sample for the self-test requires a finger prick which can feel like a little pinch and which may cause some people a small amount of discomfort. As with any cut, there is a small risk of infection and/or bruising. However, the process and products in the kit are used routinely in a wide range of healthcare applications, including measurement of blood glucose levels in the management of diabetes. The equipment is sterile and following the instructions provided in the kit will minimise risk of infection (such as cleaning the area before and after). You should not take part if you are at increased risk of bleeding. If you continue to bleed after the finger prick, apply pressure to the puncture site until the bleeding stops

Who is organising and funding the research?
This research is organised by Children of the 90s. This data collection is funded by UK Research and Innovation (UKRI). The Department of Health and Social Care (DHSC) have provided the antibody kits for free and have not been involved in the planning of this study.

Who has reviewed this research?
This research has been reviewed and approved by:

- ALSPAC Ethics and Law Committee (ALEC)

- Children of the 90s Original Cohort Advisory Panel (OCAP) made up of study participants
- Cambridge South Research Ethics Committee (21/EE/0061)

Contacts for further information and complaints:
If you have questions or concerns about any area of this research, please contact Children of the 90s (telephone 0117 331 0010, or email info@childrenofthe90s.ac.uk). If we are unable to answer your question or concern directly, we will refer this to the Children of the 90s Chief Operating Officer, or you can do this yourself:

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Thank you for reading this document and for your ongoing support of Children of the 90s.