# UK Biobank

## COVID-19 Infection Study

Version 1.0

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This documentation was prepared by UK Biobank's Health Data Group.

**UK Biobank SARS-CoV-2 coronavirus infection study overview document**

## Background and rationale

This study aimed to enable research into the impact of SARS-CoV-2 infection on subsequent health outcomes (i.e. 'long COVID').

The UK Biobank self-test antibody study used antibody lateral flow tests (LFTs) for home testing which did not distinguish between antibodies produced following infection and those produced following vaccination. In order to identify those vaccinated individuals with a 'positive' LFT result who have been previously infected with SARS-CoV-2, laboratory assay of specific (i.e. nucleocapsid) antibodies was required. Unlike spike antibodies that are produced following both infection and vaccination (and which the LFT detects), nucleocapsid antibodies are only produced in response to infection. This follow-on study therefore involved asking consented eligible participants to collect a capillary blood sample and post it to a laboratory for analysis.

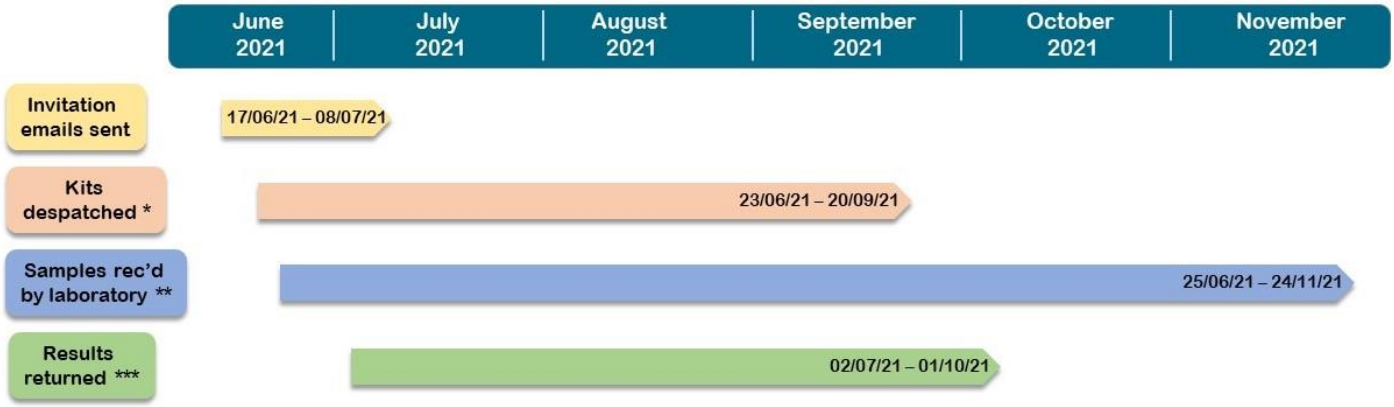
## Study design

**Design:** Cross-sectional seroprevalence study of approximately 74,000 UK Biobank participants.

**Setting:** Community – UK Biobank population**.**

**Study duration:** Recruitment and data collection took place over a period of approximately 5 months.

## Study timeline:




* Including first, second and replacement kit despatches.
The majority of first kits were despatched over a period of approximately four weeks, from 23/06/21 to 19/07/21.

** Including first, second and replacement sample returns. Samples were generally analysed within 24 hours of receipt by the laboratory.

*** Including results from first, second and replacement samples.
The majority of results from the first sample submitted were returned to participants over a period of approximately two months, from 02/07/21 to 31/08/21. For operational purposes, a cut-off date of 01/10/21 was given to participants for notification of their results. Some participants returned their samples after this cut-off date and these samples were still analysed by the laboratory. The late results (post 01/10/21) were uploaded to the UK Biobank database but were not notified to participants.

**Participant selection:** Both men and women were invited, across all ages of the UK Biobank cohort (i.e. 50-80 years; average age of 66 years).

Inclusion criteria

- UK Biobank participant had previously taken part in the UK Biobank self-test antibody study (phase 1 or phase 2);
- Participant reported a 'positive' antibody test;
- Participant reported that they had been vaccinated prior to taking the self-test antibody test (lateral flow test);
- UK Biobank participant was alive (regardless of health status);
- UK Biobank participant was willing to be contacted by UK Biobank;
- UK Biobank participant had valid email address;
- UK Biobank participant was resident in mainland UK;
- UK Biobank participant was willing and able to give informed consent for participation in the study.

Exclusion criteria

- UK Biobank participant had not previously taken part in the UK Biobank self-test antibody study;
- Participant did not provide a test result or reported a 'negative' or 'invalid' antibody test result;
- Participant reported that they had not been vaccinated prior to taking the self-test antibody test (lateral flow test);
- UK Biobank participant was dead (as identified through national death registry records or via information from a relative);
- UK Biobank participant had informed UK Biobank that they no longer wished to receive notifications;
- UK Biobank participant had an invalid email address;
- UK Biobank participant was now resident in non-mainland UK or overseas, owing to the logistics of distributing kits overseas;
- UK Biobank participant was not willing to provide consent for participation in the coronavirus infection study.

The participant materials advised people with certain conditions not to take a blood sample. These were participants with untreated clotting or bleeding disorders, or who had had a recent mastectomy and had swelling of the arm.

**Methods**

**Recruitment (see study flowchart below):** Participants meeting the eligibility criteria described above were invited to take part via email (74,388). The email invitation provided brief information about the study, web links to the study information sheet, an instructional video (https://www.youtube.com/watch?v=okTozcGMDlU&t=1s), a list of frequently asked questions (FAQs) and the online consent form. A reminder email was sent to participants who had not responded seven days after receiving the original invitation. If interested, participants were encouraged to visit the UK Biobank participant website to confirm their contact details and to consent to receive a capillary blood sampling kit at their home address then mail the sample to the laboratory. Participants who telephoned the UK Biobank Participant Resource Centre were able to consent to participate in the study via a call handler.

Consented participants received an acknowledgement email confirming their participation in the study. Up to seven days prior to kit despatch, participants received an email to let them know that their kit was being despatched. Participant addresses were securely transferred to Thriva Ltd, who despatched kits to participants using Royal Mail.

**Data collection**: Participants were mailed a capillary blood sampling kit – the Thriva coronavirus antibody test. The kit packaging contained the materials required to take a test, a copy of the instructions for use and a letter telling participants how to provide and return their blood sample.

Participants were asked to provide a sample of capillary blood (approximately 10 drops or 0.4-0.6ml) using a microsampling finger-prick device and return the sample to a laboratory. The samples were then tested for IgG antibodies to the nucleocapsid (N) protein (indicative of past infection).

A reminder email was sent to those participants who had not returned their blood sample four to six weeks after their kit had been despatched.

**Provision of test results:** Participant test results were sent from Thriva Ltd to UK Biobank, regardless of whether they were positive, negative or void. These were communicated to participants by UK Biobank by email.

**Data processing**

Following validation checks the received data underwent some minor changes before being released to researchers, due to either void or repeat tests. These changes included:

- the removal of data relating to a void antibody test result (2.5% of all returns).
- the retention of data from the earliest valid test result per participant, in cases where participants completed multiple tests.
- the removal of data from a very small number of participants who completed two tests, and where the first showed a negative result and the second showed a positive result.

**Study flowchart**