



Public Health
England

Protecting and improving the nation's health

Evaluating detection of SARS-CoV-2 antibodies

EDSAB-HOME study: details, research protocol and outputs

Background

The EDSAB-HOME study is a study aiming to evaluate the detection of SARS-CoV-2 antibodies using home testing kits detecting antibodies against the SARS-CoV-2 virus. These kits are called lateral flow immunoassays, appear similar to a pregnancy test kit, and analyse a small amount of blood obtained from a finger prick. The study is being run by Public Health England at the request of the Department of Health and Social Care.

Recruitment has now ceased, but the study is ongoing. More details, including the full study protocol, are below.

Over 3,100 people volunteered for the EDSAB-HOME study, and over 2,800 individuals attended study clinics in June 2020. We are very grateful for their contribution, following which various pieces of work are ongoing.

What we have discovered so far

Publication

Lateral flow tests detecting antibodies to SARS-CoV-2 work much better if high levels of antibodies are present.

Note: This work has been peer reviewed and published by the British Medical Journal

People with higher levels of T cell recognising SARS-CoV-2 are protected from COVID-19.

Note: This work is a pre-print, which means it has not yet been peer-reviewed

Summary

Lateral flow tests (LFTs), small pregnancy-test type kits which detect antibodies to SARS-CoV-2, have been developed by a number of manufacturers.

In many studies evaluating how well LFTs work, samples from people who have had COVID-19 (evidenced by symptoms and positive PCR tests, a group known to have high levels of antibodies against SARS-CoV-2) are compared with samples from people who haven't had disease- typically from before the pandemic.

We show this kind of evaluation overestimates how well LFTs work. This is because most people who are infected don't have the high levels of antibodies used in the LFT comparisons. Additionally, using the device we studied we were able to show that it worked much less well at lower antibody concentrations.

T cells are immune cells generated on infection which coordinate the immune system's activities; some T cells specialise in fighting viral infections.

About 1/4 of the keyworker population studied had high levels of T cells which recognised SARS-CoV-2 in their blood when they joined the study in June 2020. By 'high levels' we mean levels similar to those seen in people who have had COVID-19 disease. However, about half the people with high levels of T cells in their blood have not had COVID-19, as far as we could tell- the cells were probably there because of previous infection with coronaviruses other than SARS-CoV-2.

Importantly, in our study people with higher levels of circulating T cells appeared to be protected from COVID-19 in the four months after recruitment in June 2020. This applies both to people who have been previously infected with COVID-19, and to those who had not.

Personal belief in past COVID-19 illness is not necessarily reliable

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Laboratory based antibody tests (Roche Elecsys anti-Nucleoprotein EUROIMMUN anti-Spike S1) detected >95% of key workers who had had previous COVID-19 tests.

About one-third of keyworkers believed they had had COVID-19. However, of this third, only half had antibodies supporting their belief. The timing of illness, and the nature of the symptoms in this group suggest many had non-COVID illnesses.

Self-reported symptoms are not a reliable way of ascertaining past COVID-19 disease.

Dried blood spot testing is substantially less sensitive than testing on liquid blood samples

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One way of doing antibody testing involves dropping blood onto a filter paper, and drying it. The antibodies in the dried blood can subsequently be washed out and analysed. We showed it was feasible to do this, but the technique could not detect low levels of antibodies.

Dried blood spot based tests will not find as many people with previous COVID-19 as doing tests on liquid blood samples.

Study details

Study protocol	The protocol for the EDSAB-HOME study
Patient information sheet	The patient information sheet for the EDSAB-HOME study
Laboratory SOP	EDSAB-HOME study: details, research protocol and outputs
Research ethics approvals	NHS Research Ethics Committee 20/NE/0166 (Health Research Authority, IRAS 284980) 2 June 2020; PHE Research Ethics and Governance Group (REGG) NR0198 21/05/2020
Funding	Public Health England
Clinical trials registration	ISRCTN56609224
Study status	Recruitment completed; follow ongoing