

# Assessment of an artificial intelligence method for determining the result of a COVID-19 lateral flow test

<b>Submission date</b> 14/05/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/07/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rapid lateral flow tests help to find cases of COVID-19 in people who may have no symptoms but are still infectious and can give the virus to others.

The test usually involves taking a sample from your tonsils (or where they would have been) and from your nose, using a swab. You can get a result in 30 minutes.

Lateral flow devices (LFD) can be used to detect COVID-19 infection. Low viral loads as well as human factors can make interpretation of these devices inconsistent between users. We aimed to develop an artificial intelligence reader to interpret lateral flow devices for COVID-19

### Who can participate?

Any health care workers invited by NHS Test and Trace can participate

### What does the study involve?

Taking a photo of a lateral flow device after testing for COVID-19 as part of the self report process from NHS Test and Trace

### What are the possible benefits and risks of participating?

Benefits: To assist improvements in the accuracy of LFD interpretation

Risks: None known

### Where is the study run from?

University of Birmingham

### When is the study starting and how long is it expected to run for?

November 2020 to March 2021

### Who is funding the study?

NHS Test and Trace (Department of Health and Social Care) (UK)

Who is the main contact  
Professor Andrew Beggs, a.beggs@bham.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Andrew Beggs

**ORCID ID**  
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**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Machine learning for determining lateral flow device results for COVID-19 in an asymptomatic population: A diagnostic accuracy study

**Study objectives**  
That use of an AI reader of lateral flow devices is at least as accurate as an expert read from an asymptomatic test site human reader

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Public Health England Ethics Committee (exempt as observational with anonymised data only)

**Study design**

Observational diagnostic accuracy study

**Primary study design**

Observational

**Secondary study design**

Diagnostic accuracy study

**Study setting(s)**

Other

**Study type(s)**

Diagnostic

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Detection of SARS-CoV-2 infection using a lateral flow device

**Interventions**

1. Participants decide to take a lateral flow test
2. They take the COVID-19 lateral flow test as per the manufacturer's instructions for use
3. They then log onto the NHS Test and Trace website to return their test result
4. They are then invited to take a photo of the lateral flow test they have used, and record their personal details (name, address, date of birth, NHS number) and whether they are reporting the test as negative or positive
5. The result is not returned to the user but is stored for comparison purposes
6. The end user then finishes the process

The whole process takes 35 minutes from end-to-end and there is no follow-up after this.

**Intervention Type**

Device

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

AI reader, lateral flow devices

**Primary outcome measure**

Accuracy of AI reader compared to human readers measured using the test result (i.e COVID lateral flow device) as reported by the user of the test and as determined by the machine learning algorithm at a single time point

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/11/2020

### **Completion date**

31/03/2021

## **Eligibility**

### **Key inclusion criteria**

1. Any health care worker invited by NHS Test and trace who is willing to participate in the study
2. Aged 18 years or above or adolescents aged 12 - 17 years (self-test and report with adult supervision) or children under 12 years (should be tested and reported by an adult)
3. Without any common COVID-19 symptoms
4. Able (in the Investigators' opinion) and willing to comply with all study requirements

### **Participant type(s)**

Health professional

### **Age group**

Mixed

### **Sex**

Both

### **Target number of participants**

100,000

### **Total final enrolment**

115436

### **Key exclusion criteria**

1. Did not agree with privacy statement
2. Any common COVID-19 symptoms
3. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

### **Date of first enrolment**

12/03/2021

### **Date of final enrolment**

31/03/2021

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### University of Birmingham

Vincent Drive

Birmingham

United Kingdom

B15 2TT

## Study participating centre

### University of Durham

Stockton Road

Durham

United Kingdom

DH1 3LE

## Study participating centre

### Sensyne Health

Schrödinger Building, Heatley Road, Oxford Science Park,

Oxford

United Kingdom

OX4 4GE

## Study participating centre

### NHS Test and Trace

c/o Department of Health and Social Care, Victoria Street

London

United Kingdom

SW1H 0EU

# Sponsor information

## Organisation

Department of Health and Social Care

**Sponsor details**

NHS Test and Trace  
Victoria Street  
London  
United Kingdom  
SW1H 0EU  
+44 (0)207 210 4850  
robert.bananathy@nhs.net

**Sponsor type**

Government

**Website**

<https://www.gov.uk/government/organisations/department-of-health>

**ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Department of Health and Social Care

**Alternative Name(s)**

Department of Health & Social Care, DH

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Preprint then publication in a high impact journal.

**Intention to publish date**

01/07/2021

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version v1.0	04/03/2021	08/07/2021	No	No
<a href="#">Preprint results</a>		21/06/2021	12/04/2022	No	No
<a href="#">Results article</a>		18/10/2022	20/07/2023	Yes	No