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Evaluation of the diagnostic performance of the Rapid SARS-CoV-2 Antigen Test Card for COVID-19

Submission date
20/08/2023

Recruitment status
No longer recruiting

Registration date
21/08/2023

Overall study status
Completed

Last Edited
22/08/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lateral flow tests are commonly used to detect the virus that causes COVID-19. They pick up the virus present in nasal secretions from a swab inserted gently into the nose. The aim of this study is to determine how accurate a new lateral flow test kit called the Rapid SARS-CoV-2 Antigen Test Card is compared to the PCR test normally performed in the laboratory. The researchers would also like to evaluate the lateral flow test's performance against different virus variants to ensure it can detect as many variants of the virus as possible.

Who can participate?
NHS staff and NHS patients aged 18 years and over

What does the study involve?
The hospital swabbing team will ask each participant to take two nose swabs for this study. One of these nose swabs will be taken to the laboratory for COVID-19 PCR testing, and the other one will be used to perform the lateral flow test. Healthcare professionals will perform all the tests, including the lateral flow test, so the participant does not have to perform them. The results from the nose swabs will not be reported back to the participants nor will they appear on their laboratory records. Additionally, participants will be asked to provide their age, gender, whether they have symptoms of COVID or not, and how long they have had symptoms for (if any). Statistical analysis will then be used to determine how accurate the lateral flow is compared with PCR. All of the data will be anonymized, analysed, and then submitted for publication in a medical journal.

What are the possible benefits and risks of participating?
The information we gain will help us to better understand how this lateral flow test performs for diagnosing COVID-19 disease. There may be irritation of the inside of the nose from the dry cotton swab. The researchers will advise participants not to insert the swab any deeper if they feel strong resistance or pain.

Where is the study run from?
Airedale General Hospital and Harrogate District Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2022 to December 2022

Who is funding the study?
The study is funded by Sante Group LLP.

Who is the main contact?
Dr Marco Lee, marco.lee@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Marco Lee

Contact details
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD
+44 (0)1535293489
marco.lee@nhs.net

Type(s)
Scientific

Contact name
Dr Marco Lee

Contact details
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD
+44 (0)1535293489
marco.lee@nhs.net

Type(s)
Public

Contact name
Dr Marco Lee

Contact details
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD
+44 (0)1535293489
marco.lee@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
311335

Protocol serial number
LFT122021

Study information

Scientific Title
A two-centre study for the evaluation of the diagnostic performance of the Rapid SARS-CoV-2 Antigen Test Card for COVID-19

Acronym
LFT

Study objectives
Most lateral flow tests have been historically validated for Alpha and Delta variants. With the worldwide emergence of the Omicron variant in December 2021, there is a need to validate lateral flow kits to ensure that they retain high diagnostic performance for the Omicron variant, just as they do for the Delta variant. The UKHSA has, to date, validated only a very small number of lateral flow kits to the Omicron variant (UKHSA Technical Briefing 32, 2021; Table 2, page 16). This, along with the high demand for the use of lateral flow test kits nationally, has prompted the need to do this study. The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow test kit that is manufactured by MP Biomedicals Germany GmbH and has obtained CE marking. The purpose of this evaluation is to determine the diagnostic performance of the Product Under Evaluation (Rapid SARS-CoV-2 Antigen Test Card) compared with the gold standard RT-PCR (on the Cepheid GeneXpert Xpert® Xpress SARS-CoV-2) for detection of the presence SARS-CoV-2.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/01/2022, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048096; CambridgeEast.REC@hra.nhs.uk), ref: 22/EE/0027

Study design

Two-centre observational diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Two swabs will be provided to the participant, who will perform self-swabbing:
1. An anterior nasal swab for RT-PCR (on Cepheid GeneXpert Xpert® Xpress SARS-CoV-2)
2. An anterior nasal swab for lateral flow test (the Rapid SARS-CoV-2 antigen test card, the Product under Evaluation)

The participant will be asked to perform two anterior nasal swabs, in any order.

Both anterior nasal swabs will be labelled with barcoded study numbers to achieve anonymization. The laboratory personnel performing each of the two diagnostic tests will be blinded to the results of the other test.

The following data will be collected from each participant:
1. Age
2. Gender
3. Symptomatic or asymptomatic
4. Days from symptom onset or Days from contact (if applicable)
5. CT value of RT-PCR results

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SARS-CoV-2 Antigen Test Card (MP Biomedicals™, Germany), Cepheid Xpert® Xpress® SARS-CoV-2 RT-PCR (Cepheid®, USA)

Primary outcome(s)
Diagnostic performance of the SARS-CoV-2 Antigen Test Card compared with Cepheid RT-PCR: sensitivity, specificity, accuracy, and confidence intervals calculated by comparing the results of the Rapid SARS-CoV-2 Antigen Test Card with the results of the standard reference comparator Cepheid® Xpert® Xpress SARS-CoV-2 RT-PCR. Measured at end of recruitment period.

Key secondary outcome(s))
Diagnostic performance differences (if any) in relation to:
1. Age
2. Gender
3. Symptomatic or asymptomatic

4. Days from symptom onset or Days from contact (if applicable)
5. CT value of RT-PCR results
All measured using statistical analysis (chi-squared test or Fisher exact test, as appropriate) at the end of recruitment period.

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Three groups of participants will be recruited.

Group A
This group consists of COVID-19-suspected NHS staff members who either have symptoms compatible with COVID-19 or have been in recent contact with someone who has COVID-19
1. This group consists of COVID-19-suspected NHS staff members who:
1.1. Have symptoms compatible with COVID-19 or
1.2. Have been in recent contact with someone who has COVID-19
2. Age ≥18 years
3. Within 10 days of onset of symptoms or within 10 days of contact with a confirmed COVID-19 case
4. Voluntarily presents to the Airedale swabbing centre for RT-PCR swabbing

Group B
This group consists of patients who have confirmed COVID-19 infection (with a positive PCR test result)
1. This group consists of patients in hospital who have confirmed COVID-19 infection (with a positive PCR test result) and
1.1. Admitted to hospital for >24 hours and
1.2. The medical team feels that the patient can give valid consent and
1.3. Does not require respiratory support other than supplementary nasal oxygen (i.e., participants on non-invasive ventilation such as CPAP, and intubated patients are excluded)
2. Age ≥18 years
3. Within 10 days of onset of symptoms, or if asymptomatic, within 10 days of the date of PCR test

Group C
This group consists of NHS staff members who are asymptomatic for COVID-19, have had no known COVID-19 contact in the past 10 days, and volunteering for the study
1. This group consists of NHS staff members who:
1.1. Are asymptomatic for COVID-19
1.2. Have no known COVID-19 contact in the past 10 days
2. Age ≥18 years
3. Voluntarily presents to the Airedale laboratory for swabbing

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
500

Key exclusion criteria
Exclusion criteria:
1. Demographic data not available or not provided

Sample rejection criteria:
1. Samples received without the corresponding pair
2. Anterior nasal swabs received >8 hours from the time of collection
3. Improperly stored swabs

Date of first enrolment
01/02/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Airedale NHS Trust
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
Harrogate & District NHS Foundation Trust
Strayside Wing
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Sponsor information

Organisation
Sante Group LLP

Funder(s)

Funder type
Industry

Funder Name
Sante Group LLP

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		22/08/2023	22/08/2023	No	No
Participant information sheet	Participant information sheet		21/08/2023	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file			21/08/2023	No	No
Statistical Analysis Plan			22/08/2023	No	No