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Evaluation of a COVID-19 lateral flow self-test: What is the performance of the Panbio™ COVID-19 self-test device when performed by lay users?

Submission date
27/01/2022

Registration date
27/01/2022

Last Edited
01/02/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Coronavirus disease (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus can infect the respiratory (breathing) system. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. Some people do not have symptoms but can carry the virus and pass it on to others. SARS-CoV-2 is spread by human-to-human transmission via droplets or direct contact. If someone gets infected with SARS-CoV-2, antigens to SARS-CoV-2 are presented in his /her tissue fluids. Any substance that induces the immune system to produce antibodies against it is called an antigen. Any foreign invaders, such as pathogens (bacteria and viruses), chemicals, toxins, and pollens, can be antigens. Nasal or nasopharyngeal (nose and throat) swab tests can be used to indicate if someone is infected with SARS-CoV-2. COVID-19 rapid antigen tests based on nasal or nasopharyngeal swabs can help to identify infected patients early and to limit the spread of the virus.

A lateral flow test is a simple device intended to detect the presence of a target substance in a liquid sample without the need for specialized and costly equipment.
The aim of this study is to compare the Panbio™ COVID-19 Antigen Self Test (performed by the lay user) results with the Panbio™ COVID-19 Antigen professional use test (performed by a professional.

Who can participate?
Adults aged 16 years or older (UK) or 18 years or older (Spain and Sweden) from the general population; in particular those who are believed to be infected with SARS-CoV-2.

What does the study involve?
Each participant (lay user) was provided with a Panbio™ COVID-19 Antigen Self-Test single-use test kit. The participant self-collected one nasal swab from both nostrils, and performed and interpreted the Panbio™ COVID-19 Antigen Self-Test, following the product Instructions for Use.

A study staff member then collected a nasopharyngeal swab from the participant and conducted a Panbio™ COVID-19 Antigen Professional Use test (study reference test). Basic medical history and demographic information was collected, and each participant completed a usability questionnaire to investigate lay user acceptability and feasibility in performing the test and self collecting their own nasal sample.

What are the possible benefits and risks of participating?
Benefits: None
Risks: There is no risk to the participant associated with performing the Panbio™ COVID-19 Antigen Self-Test.
There is a risk of transmission of COVID-19 to the healthcare professionals from COVID-19-infected participants. Facility SOPs should be followed when testing subjects potentially infectious for COVID-19. Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, that can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infectious materials.

Where is the study run from?
Royal London Hospital (UK), Princess Alexandra Hospital (UK), East Surrey Hospital (UK), Darlington Memorial Hospital (UK), Queen's Medical Centre (UK), Fritchie Research Center (UK), Hospital Infanta Leonor (Spain), and CTC Clinical Trial Consultants AB (Sweden).

When is the study starting and how long is it expected to run for?
February 2021 to August 2021

Who is funding the study?
Abbott Rapid Diagnostics (Germany)

Who is the main contact?
Prof. Patrick T. Kennedy, p.kennedy@qmul.ac.uk

Contact information

Type(s)
Principal investigator

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Prof Patrick Kennedy

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
296441

Protocol serial number
CLDG-1001, IRAS 296441, CPMS 48588

Study information

Scientific Title
Clinical Evaluation of the Panbio™ COVID-19 antigen self-test device as an over-the-counter (OTC) self-test

Study objectives
To demonstrate the sensitivity and specificity of the Panbio™ COVID-19 Antigen Self-Test, as performed by self-testers (lay users) using nasal self-collected samples, compared with the Panbio™ COVID-19 Antigen Professional Use test, as performed by health care professionals using nasopharyngeal samples, collected from the same study participant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2021, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 1048310; solihull.rec@hra.nhs.uk), ref: 21/WM/0081

Study design
Multicenter observational case-control study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
The study methodology was similar for every participant in the trial. Each participant (lay user) was provided with a Panbio™ COVID-19 Antigen Self-Test single-use test kit. The participant self-collected one nasal swab from both nostrils performed and interpreted the Panbio™ COVID-19

Antigen Self-Test, following the product instructions for use. A study staff member observed the procedures and recorded their observations related to the test procedures, without communicating with or helping the study participant. A study staff member who was blinded to the participant's COVID-19 status then collected a nasopharyngeal swab from the participant and conducted a Panbio™ COVID-19 Antigen nasopharyngeal Professional Use test (study reference test). The lay user and the study staff member then completed a usability questionnaire.

Intervention Type
Other

Primary outcome(s)
The clinical performance (diagnostic sensitivity and specificity) of the Panbio™ COVID-19 Antigen Self-Test device, as performed by self-testers (lay users) using self-collected nasal samples. The lay user result will be compared with the Panbio™ COVID-19 Antigen Professional Use test (study reference result), as performed by health care professionals using nasopharyngeal samples, collected from the same subject at a single time point

Key secondary outcome(s))
The assessment, through lay user and study staff observer questionnaires, of the usability of the Panbio™ COVID-19 Antigen Self-Test, as performed by lay users with no laboratory or clinical experience at a single time point

Completion date
13/08/2021

Eligibility

Key inclusion criteria
1. Male or female participants ≥16 years old (UK) or ≥18 years old (Sweden and Spain);
2. Participant belongs to a general population (all-comers), in particular:
2.1 Participant has tested positive for COVID-19 by PCR with a sample obtained within the past 4-120 hours and is symptomatic within 0-7 days of onset, OR
2.2 Participant is symptomatic within 0-7 days of onset but has not been tested and has no specific known exposure, OR
2.3 Participant has tested positive for COVID-19 with a sample obtained within the past 4-48 hours and is asymptomatic for the last 14 days, OR
2.4 Participant is suspected, by study staff or by themselves, to have been exposed to COVID-19 within the last 10 days (period of self-isolation) and is symptomatic or asymptomatic

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
312

Key exclusion criteria
1. If symptomatic, participant is ≥8 days post first symptom onset.
2. Participant has had a nasal or a nasopharyngeal swab taken within the last 4 hours.
3. Participant has prior medical or laboratory training.
4. Participant currently works within a laboratory and/or point of care environment in a non-administrative role.
5. Participant is a trained laboratory professional or health care professional.
6. Participant has active nose bleeds or acute facial injuries/trauma.
7. Participant is currently enrolled in a study to evaluate an investigational drug.
8. Participant has already participated in this study.
9. Participant is unable or unwilling to provide informed consent.
10. Participant belongs to a vulnerable population and is deemed inappropriate for study participation by site Principal Investigator.

Date of first enrolment
09/04/2021

Date of final enrolment
13/08/2021

Locations

Countries of recruitment
United Kingdom

England

Spain

Sweden

Study participating centre
Royal London Hospital
Barts Health NHS Trust
Whitechapel
London
United Kingdom
E1 1FR

Study participating centre
Princess Alexandra Hospital
The Princess Alexandra Hospital NHS Trust
Parndon Hall
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
East Surrey Hospital
Surrey and Sussex Healthcare NHS Trust
1st Floor, Trust Headquarters
Redhill
United Kingdom
RH1 5RH

Study participating centre
Darlington Memorial Hospital
County Durham and Darlington NHS Foundation Trust
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Queen's Medical Centre
Research and Innovation Department
Nottingham University Hospitals NHS Trust
South Block C Floor
QMC Campus
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Fritchie Research Center
Gloucestershire Health and Care NHS Foundation Trust
Charlton Lane Hospital Site
Charlton Lane

Cheltenham
United Kingdom
GL53 9DZ

Study participating centre
CTC Clinical Trial Consultants AB
Dag Hammarskjöldsväg 10B
Uppsala
Sweden
75237

Study participating centre
Hospital Infanta Leonor
Gran Vía del Este, 80
Madrid
Spain
28031

Sponsor information

Organisation
Abbott Rapid Diagnostics

Funder(s)

Funder type
Industry

Funder Name
Abbott Rapid Diagnostics

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as consent has not been obtained for making de-identified participant data available under GDPR. The data will be clearly explained in a peer-reviewed publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No