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Evaluation of a COVID-19 antibody professional use test and a COVID-19 antibody self-test: What is the performance of the Panbio™ COVID-19 antibody self-test when performed by lay users? What is the performance of the Panbio™ COVID-19 antibody test when performed by healthcare professional users?

Submission date
24/01/2022

Registration date
26/01/2022

Last Edited
08/01/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system, and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

Antibodies detected by blood tests indicate that a person has had an immune response to SARS-CoV-2 or a COVID-19 vaccination. Antibody tests can be used to confirm prior infection, including in individuals with few or no symptoms.

The Panbio™ COVID-19 IgG Rapid Test Device (professional use test) is a rapid, lateral flow test that uses a small drop of blood (20 µL) or a small drop of serum or plasma (10 µL) for the qualitative detection of antibodies (S-IgG) to SARS-CoV-2 in human plasma, serum, venous and capillary whole blood. The Panbio™ COVID-19 Antibody Self Test is a rapid lateral flow test that

uses a small drop (20 µL) capillary whole blood for the qualitative detection of antibodies (S-IgG) to SARS-CoV-2. Both tests can be interpreted 10-20 minutes after sample application. Negative test results must be confirmed 20 minutes after sample application. The Panbio™ antibody tests (professional use and self-test) are intended to detect antibodies due to past SARS-CoV-2 infection or COVID-19 vaccination.

This study evaluates the clinical performance of the Panbio™ COVID-19 Antibody Self-Test and Panbio™ COVID-19 IgG Rapid Test Device (professional use test).

Who can participate?
Adults over 16 years (UK) or over 18 years (Spain) who are known to have been infected with SARS-CoV-2, and participants who have not been infected with SARS-CoV-2. In addition, the analyses will include participants enrolled under a separate, similar protocol in the US.

What does the study involve?
Participants will provide a fingerstick sample for testing with the Panbio™ professional use test as well as a venous sample which will be processed to plasma. The plasma will be used for testing of Panbio™ using plasma samples and for laboratory reference testing. Participants will also conduct a Panbio™ self-test (self-testers) and/or interpret a Panbio™ self-test result from someone else (test reader). Self-testers will also interpret the results of two mock devices with printed lines. All lay users will complete a usability questionnaire.

What are the possible benefits and risks of participating?
It is possible that the collection of blood through venipuncture (by a healthcare professional) and capillary finger-stick (by a healthcare professional or as a self-tester) could cause discomfort. However, as the collection of samples by a healthcare professional are routine medical procedures and the samples will be obtained by trained medical personnel, the discomfort is likely to be minimized. Other self-tests are available and approved for use in the EU and the UK. A study staff member will be present for all procedures, although will not assist the self-tester, except in a medical emergency.
COVID-19 transmission is a risk to the participants. However, convalescent patients are not expected to be transmitting the virus. There is a risk, albeit low, that asymptomatic patients in the control group will be carrying COVID-19. All operations will be conducted under strict social distancing to minimize the risk of transmission.

Where is the study run from?
Royal London Hospital (UK), Princess Alexandra Hospital (UK), Brockwood Medical Practice (UK), Bridgewater Surgeries (UK), Hampstead Group Practice (UK), Parliament Hill Practice (UK), Millway Medical Practice (UK), Medicus Health Partners (UK) and Hospital Infanta Leonor (Spain).

When is the study starting and how long is it expected to run for?
April 2020 to January 2022

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

EudraCT/CTIS number
Nil known

IRAS number
283060

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CLDG-0502, IRAS 283060, CPMS 45666

Study information

Scientific Title
Panbio™ COVID-19 antibody self-test and Panbio™ COVID-19 IgG rapid test device clinical study protocol

Study objectives
To demonstrate the sensitivity and specificity of the Panbio™ self-test (with fingerstick whole blood) and the Panbio™ professional use test (with fingerstick whole blood and venous plasma), in comparison with the CE-marked Abbott Architect SARS-CoV-2 S-IgG assay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2020, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive Newcastle upon Tyne, NE2 4NQ, UK; +44 207 104 8083; bradfordleeds.rec@hra.nhs.uk), ref: 20/YH/0155. Amendment CLDG-0502 A2) approved 25/05/2021

Study design
Multicenter observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
All participants provided a fingerstick capillary whole blood sample for testing with the Panbio™ professional use test by a study staff member. All participants also provided a venous EDTA whole blood sample. The venous whole blood sample was processed to plasma, and the plasma sample for each participant was tested using the Panbio™ professional use test and using laboratory-based SARS-CoV-2 S-IgG reference tests. In addition, lay user participants (self-testers) conducted a Panbio™ self-test. The Panbio™ self-test result was interpreted by another lay user who was enrolled as a test reader. The test reader was blinded to whether the self-tester had had a Covid-19 infection in the past, which allowed unbiased test interpretation. A lay user could be enrolled both as a self-tester and test reader. “Care-giver testing” was also permitted, where one adult lay user tested another adult lay user. Each self-tester also interpreted the results of two mock devices with printed lines. Each lay user (self-testers and test readers) completed a questionnaire to document the usability of the self-test. For each self-tester and test reader, the self-test procedures were supervised by a study staff member who documented the usability results in a questionnaire.

Intervention Type
Other

Primary outcome measure
1. The diagnostic sensitivity and specificity of the Panbio™ COVID-19 Antibody Self-Test using fingerstick capillary whole blood, when the test is performed by lay users, in comparison with the SARS-CoV-2 IgG II Quant assay, performed on the Abbott Architect® platform.

2. Diagnostic sensitivity and specificity of the Panbio™ COVID-19 IgG Rapid Test using fingerstick capillary whole blood and venous plasma, when the test is performed by professional users, in comparison with the SARS-CoV-2 IgG II Quant assay, performed on the Abbott Architect® platform.

Secondary outcome measures
1. Evaluated qualitative data from lay users on the test usability. Mock devices will also be used for the lay user usability and result interpretation evaluation at a single time point.
2. Matrix equivalence (% positive, negative and overall agreement) of fingerstick capillary whole blood compared to venous plasma for use with the Panbio™ COVID-19 IgG Rapid Test, when the Panbio™ test is performed by a professional user.
3. Diagnostic sensitivity, specificity, and overall agreement of the Panbio™ COVID-19 Antibody Self-Test as performed by lay users using fingerstick samples, in comparison with the Panbio™ COVID-19 IgG Rapid Test as performed by professional non-laboratory staff, also using fingerstick samples.

Overall study start date
08/04/2020

Completion date
05/01/2022

Eligibility

Key inclusion criteria
1. Participant is 16 years of age (UK) / 18 years of age (Spain) or older.
2. Only Self-testers and those being tested by another lay user:
Individuals with a prior suspected or confirmed COVID-19 infection with prior COVID-19 symptoms with symptom onset > 21 days prior to the study (n=at least 200) or symptom onset 14-21 days prior to the study (n=up to 30) or with a past asymptomatic infection (n= up to 30) or individuals having received COVID-19 vaccine, 30 days or more after they have received their second dose of the BNT162b2 (Pfizer) or of the mRNA-1273 (Moderna) vaccine, or a single dose of the Janssen COVID-19 Vaccine (Johnson & Johnson). (n=at least 30). These participants could be invited to the study based on a positive SARS-CoV-2 PCR result or vaccination in their medical records, and be confirmed to be study reference positive using study reference testing. The asymptomatic participants could be enrolled also through the presumed reference-negative cohort.
or
3. Evaluable individuals not suspected to have had a COVID-19 infection (n=at least 200)
4. Participant agrees to complete all aspects of the study.
5. In addition, "care-giver" testing will also be included in the self-test validation, where one lay user tests another lay user. This is intended to simulate testing in a care-giver situation; the study does not require one lay user to be the real-life care-giver for the other. No vulnerable population will be included in this study. Furthermore, lay user individuals will be enrolled to interpret the self-tester results. These individuals will be classified as “readers.” One reader may interpret up to three test results. A participant may be enrolled both as a self-tester or a “care-giver” or a person being tested and as a reader of another person’s test result. This will allow the self-test result interpretation to remain blinded.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 490 evaluable self-testers. If separate testers, “care-givers” and readers are enrolled, up to 1095 participants may be enrolled in total. The study analyses will also include participants enrolled in a similar study conducted in the US under protocol, CLDG-0511.

Total final enrolment
235

Key exclusion criteria
1. Participant has already participated in this study on a previous occasion.
2. Only self-testers or those being tested by another lay user: Participant is enrolled in a study to evaluate a new drug.
3. Participant has a visual impairment that cannot be restored using glasses or contact lenses.
4. Participant is unable or unwilling to provide informed consent.
5. Participant is a vulnerable person as deemed unfit for the study by the Principal Investigator.
6. Participant has a condition deemed unfit by the investigator to safely perform or receive the test.
7. Participant is a practicing healthcare professional or laboratory scientist/technician (self-testers, “care-givers” and readers).

Date of first enrolment
07/06/2021

Date of final enrolment
09/09/2021

Locations

Countries of recruitment
England

Spain

United Kingdom

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
Brockwood Medical Practice
The Surgery
Tanners Meadow
Brockham
Betchworth
United Kingdom
RH3 7NJ

Study participating centre
Bridgewater Surgeries
Bridgewater House
7 Printers Avenue
Watford
United Kingdom
WD18 7QR

Study participating centre
Hampstead Group Practice
75 Fleet Road
London
United Kingdom
NW3 2QU

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

Spain
28031

Study participating centre
Parliament Hill Practice
113-117 Highgate Rd
London
United Kingdom
NW5 1T

Study participating centre
Millway Medical Practice
2 Hartley Avenue
Mill Hill
London
United Kingdom
NW7 2HX

Study participating centre
Medicus Health Partners
Forest Primary Care Centre, Hertford Road
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Sponsor information

Organisation
Abbott Rapid Diagnostics (Germany)

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Abbott Rapid Diagnostics

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2023

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			28/06/2023	No	No
Results article		01/12/2023	08/01/2024	Yes	No