ISRCTN60400862 https://doi.org/10.1186/ISRCTN60400862

Evaluation of a COVID-19 antibody test: What is the performance of the Panbio™ COVID-19 IgG /IgM rapid test device in fingerstick blood, venous whole blood, serum and plasma in adult participants?

Submission date
19/06/2020

Recruitment status
No longer recruiting

Registration date
22/06/2020

Overall study status
Completed

Last Edited
28/01/2022

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.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

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 had an immune response to SARS-CoV-2. Antibody tests are important to confirm prior infection, including in individuals with few or no symptoms.
The Panbio™ COVID-19 IgG/IgM Rapid Test is a rapid test that uses a small drop of blood for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma, venous and capillary whole blood. The test is interpreted 10-20 minutes after sample application.
This study will evaluate the performance of the Panbio COVID-19 IgG/IgM test.

Who can participate?
Adults over 18 years who are known to have been infected with SARS-CoV-2, and participants who have not been infected with SARS-CoV-2.

What does the study involve?
Participants will have several different blood tests performed.

What are the possible benefits and risks of participating?
It is possible that the collection of blood through venipuncture and capillary finger-stick could cause discomfort. However, as these are routine medical procedures and the samples will be obtained by trained medical personnel, the discomfort is likely to be minimized.
COVID-19 transmission is a risk to the participants. However, convalescent patients are not expected to be transmitting virus. There is a risk, albeit low, that a symptomatic 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?
The Royal London Hospital (UK)

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

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)
Scientific

Contact name
Prof Patrick T. Kennedy

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
283040

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CLDG-0503, IRAS 283040

Study information

Scientific Title
Panbio™ COVID-19 IgG/IgM rapid test device matrix equivalence study: evaluating test performance in comparison with a laboratory reference method using venous whole blood, serum and plasma as well as capillary whole blood from adult participants

Study objectives
The performance of the Panbio COVID-19 IgG/IgM test using the matrices fingerstick whole blood, venous whole blood and serum is similar to the test performance using venous plasma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2020, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, BS1 2NT, UK; +44 (0)207 1048046; berkshire.rec@hra.nhs.uk), ref: 20/SC/0191

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

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 as well as a venous blood sample. All participants had a fingerstick capillary whole blood sample, a venous EDTA whole blood sample, a venous EDTA plasma sample and a venous serum sample tested using the Panbio COVID-19 IgG/IgM Rapid Test Device. The results are evaluated using laboratory based SARS-CoV-2 IgM and IgG reference tests.

Intervention Type
Other

Primary outcome measure
User's test result interpretation of the Panbio™ COVID-19 IgG/IgM rapid test device at 10 minutes and at 20 minutes after sample application, using fingerstick whole blood, venous whole blood and venous serum, in comparison with venous plasma

Secondary outcome measures
1. User's test result interpretation of the Panbio™ COVID-19 IgG/IgM rapid test device at 10 minutes and at 20 minutes after sample application using fingerstick whole blood, venous whole blood, venous serum and venous plasma, in comparison with laboratory reference tests
2. Prevalence of COVID-19 antibodies in all participants at the time of enrolment, as determined by a laboratory-based test

Overall study start date
06/04/2020

Completion date
03/07/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Known to have been infected with SARS-CoV-2, or who have not been infected with SARS-CoV-2
3. Agrees to complete all aspects of the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

The intended study population will include at least 103 evaluable participants who are known to have been infected with SARS-CoV-2, and at least 103 evaluable participants who have not been infected with SARS-CoV-2.

Key exclusion criteria
1. Belongs to a study group that has been filled
2. Has already participated in this study on a previous occasion
3. Is enrolled in a study to evaluate a new drug
4. Unable or unwilling to provide informed consent
5. Is a vulnerable person as deemed unfit for the study by the Principal Investigator

Date of first enrolment
15/05/2020

Date of final enrolment
10/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel Road
Whitechapel
London
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Sponsor information

Organisation
Abbott (Germany)

Sponsor details
Abbott Rapid Diagnostics Jena GmbH
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Sponsor type
Industry

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http://www.abbott.com/

ROR
https://ror.org/02x2gk324

Funder(s)

Funder type
Not defined

Funder Name
Abbott Rapid Diagnostics Jena GmbH

Results and Publications

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

Intention to publish date
28/08/2020

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?
Results article		27/04/2021	28/01/2022	Yes	No
HRA research summary			28/06/2023	No	No