ISRCTN66255490 https://doi.org/10.1186/ISRCTN66255490

Diagnostic accuracy of a novel COVID-19 test

Submission date
06/02/2023

Recruitment status
No longer recruiting

Registration date
10/02/2023

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 diagnostic techniques and testing capacity have evolved rapidly during the pandemic. Recently, single-use analyser-free COVID tests have been undergoing development. Among these, the Veros COVID-19 test is single-use, handheld, analyser free, has no reliance on a power source, requires no dedicated user training, and uses nucleic acid amplification to provide a qualitative positive or negative result on an anterior nasal swab sample in approximately 15 minutes. This could offer scope to improve time to results and both portability and accessibility of accurate COVID-19 testing. Should the Veros COVID-19 test demonstrate acceptable accuracy when compared to the current reference standard, there is potential to improve the time to results, portability and accessibility of accurate COVID-19 testing. The study's aim is to evaluate the real-world diagnostic accuracy of the Veros COVID-19 test, and its potential clinical impact in the emergency department.

Who can participate?
Adult patients that present to the Emergency Department (ED) or Acute Medical Unit at Southampton General Hospital with symptoms of an acute respiratory illness/is a suspected case of COVID-19, and who can be recruited to the study in a timely fashion on arrival to the hospital (prior to or at the approximate time of routine point-of-care testing for COVID-19)

What does the study involve?
Potential participants will be approached by the clinical team and consented by the research team for the taking of two samples in addition to those taken as part of routine clinical care (which includes a combined nose and throat viral swab which will be tested for COVID-19 on the reference standard assay by ED staff, as is currently routine care for new presentations of possible COVID-19 infection in the ED).

The two samples required by the study will be:
1. An anterior nasal swab, to be run in the department on the Veros COVID-19 test kits by research team staff
2. A combined nose and throat swab for storage, in case later required for viral culture and other testing

Patient care will not be altered from routine clinical care as clinical staff and participants will not be informed of the results of the Veros COVID-19 tests as the Veros COVID-19 test is not yet

used during routine clinical care and has not undergone local validation or verification. Patients will have received routine COVID-19 testing from the clinical team, in the form of the combined nose and throat swab run on the reference standard assay.

Questionnaires will be given to research staff using the Veros COVID-19 test to evaluate the test' s ease of use. Research team members will carry out the Veros COVID-19 tests and results will be recorded manually in ED (as the tests do not interface with NHS systems) and the reference standard test's results will be reviewed on the participant's EPR. Participant involvement in the study is considered to have ended once their last physical interaction with the research team has been completed, although some retrospectively collected outcome measures will be extracted from the EPR after this time. For all patients, it is intended that the final physical interaction with the research team be on the same day as enrolment, at the taking of samples. The time to result for the Veros COVID-19 test will be established by the research team member recording time from sampling to result, while the time to result for the reference standard will be recorded from sampling to the time that the result is released to the patient record. The combined nose and throat swab sample, taken for potential viral culture, will be frozen at -80°C until sent for culture if required (this will allow evaluation of the infectiousness of samples with a focus on, but not limited to, samples that return discordant COVID-19 test results).

What are the possible benefits and risks of participating?
There are no individual benefits for participating patients as the result of the Veros COVID-19 test will not be relayed to the patient or clinical team, as the main purpose of the study is to investigate diagnostic accuracy and the Veros COVID-19 test is not yet used during routine clinical care and has not yet undergone local validation or verification. However, all participants may feel that they are helping to improve NHS care for unwell patients in the future by being part of this research. No greater risk to patients enrolled in this study is anticipated than those present during routine clinical care. The harm associated with respiratory swabs is minimal and typically limited to mild and short-lived discomfort at the time the swabs are performed.

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2022 to March 2024

Who is funding the study?
Sense Biodetection Limited (UK)

Who is the main contact?
1. Prof Tristan W Clark (Chief Investigator), t.w.clark@soton.ac.uk
2. Dr Mary Chapman (Co-investigator), mary.chapman@uhs.nhs.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320705

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RHM MED1913, CPMS 54620, IRAS 320705

Study information

Scientific Title
A prospective study to evaluate the real-world diagnostic accuracy and potential clinical impact of the Veros COVID-19 test in adults presenting to the Emergency Department with suspected COVID-19: ED-POC

Acronym
ED-POC

Study objectives
This study aims to evaluate the real-world diagnostic accuracy of the Veros COVID-19 test and its potential clinical impact in the Emergency Department.

COVID-19 will remain a burden on healthcare services and their patients for years to come. Diagnostic techniques and COVID-19 testing capacity have evolved rapidly during the pandemic. Recently, single-use analyser-free COVID tests have been undergoing development. Among these, the Veros COVID-19 test is single-use, handheld, analyser free, has no reliance on a power source, requires no dedicated user training, and uses nucleic acid amplification to provide a qualitative positive or negative result on an anterior nasal swab sample in approximately 15 minutes. This could offer scope to improve time to results and both portability and accessibility of accurate COVID-19 testing.
Should the Veros COVID-19 test demonstrate diagnostic accuracy comparable to the current reference standard, it could offer scope to improve time to results, and both portability and accessibility of accurate COVID-19 testing.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 28/11/2022, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8282; tyneandwearsouth.rec@hra.nhs.uk) ref: 22/NE/0225

Study design
Single-centre diagnostic accuracy study

Primary study design
Observational

Secondary study design
Diagnostic accuracy 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
The real-world diagnostic accuracy of the Veros COVID-19 test

Interventions
This study will consist of a diagnostic accuracy study of the Veros COVID-19 test, in the form of a prospectively recruited study. Adult patients presenting to the ED with suspected COVID-19 and /or symptoms of acute respiratory infection will be recruited and tested at the point of care using the Veros COVID-19 test kit (a second swab will be taken and stored for potential further tests in form of viral culture if required).

They will also be receiving testing from the clinical team in the ED as part of their routine clinical care which will be run on the Cepheid GeneXpert Xpress SARS-CoV-2 assay (a component of the Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV test).

The result of the GeneXpert SARS-CoV-2 assay, as part of their routine clinical care, will be available to clinical staff to facilitate decision-making for patients. The results of the Veros COVID-19 test will not be disclosed to clinical staff or participating patients. Active patient participation in the study will end after sample collection. Due to the low risk and brief nature of patient involvement in the study, and that no deviations from routine clinical care are planned, observation and follow-up of patients post active participation are not planned.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive values (NPV) (with 95% confidence intervals) of the Veros COVID-19 test can then be calculated using the GeneXpert SARS-CoV-2 result as the reference standard. Secondary objectives will consist of evaluating the time to results of the Veros COVID-19 test compared to the reference standard,

the reliability of the Veros COVID-19 test, the ease-of-use of the Veros COVID-19 test and the relationship between viral load and Veros COVID-19 test result. Viral culture will be used to evaluate the infectiousness of samples, with a focus on samples that return discordant results from the Veros COVID-19 test and the reference standard.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Veros COVID-19 test

Primary outcome measure
Diagnostic accuracy of the Veros COVID-19 test measured using the GeneXpert SARS-CoV-2 result as the reference standard as defined by the manufacturer's instructions at comparable timepoints

Secondary outcome measures
1. Time to result for the Veros COVID-19 test compared to the reference standard assessed at comparable timepoints at the point of care
2. Proportionate failure rate of the Veros COVID-19 test (with the failure to provide a valid result after the use of a test denoting a failed test) assessed at one timepoint at the point of care
3. Ease-of-use measured using quantitative data from the 'Veros COVID-19 Test Kits – Ease of Use' Questionnaire provided to users assessed at one timepoint at the point of care
4. Proportion of positive discordant results measured using viral culture of the stored sample at one timepoint after the final physical interaction with the participant
5. The performance of the Veros COVID-19 test across high, medium and low viral loads as determined by cycle threshold (Ct) value bins (with a Ct value of <25 indicating high levels of virus, Ct>25<30 medium levels of virus and Ct>30 low levels of virus) as calculated by the GeneXpert SARS-CoV-2 test at one timepoint

Overall study start date
30/08/2022

Completion date
03/03/2024

Eligibility

Key inclusion criteria
1. Is a patient in the ED or AMU at Southampton General Hospital, UHS
2. Aged ≥18 years old
3. Can be recruited into the study on arrival to the hospital at the time of/prior to routine point-of-care testing for COVID-19, and
3.1. Has an acute respiratory illness, or

3.2. Does not have an acute respiratory illness but is a suspected case of COVID-19 according to the current PHE case definition
4. Has the capacity to consent to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Total final enrolment
400

Key exclusion criteria
1. Not fulfilling all inclusion criteria
2. Declines nasal/pharyngeal swabbing

Date of first enrolment
09/01/2023

Date of final enrolment
03/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton
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Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Sense Biodetection Limited

Results and Publications

Publication and dissemination plan
1. Planned publication in high-impact peer reviewed journals
2. Disseminated via medical conference posters and presentations

Intention to publish date
03/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Professor Tristan Clark (CI) from 03/03/2024.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	14/12/2022	09/02/2023	No	Yes
Participant information sheet	version 2.0	14/12/2022	09/02/2023	No	Yes
Protocol file	version 1.0	20/09/2022	09/02/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		05/09/2024	28/01/2025	Yes	No