

Analytical comparison of a new PSA testing method to the gold standard laboratory testing method in blood samples taken in a community setting

Submission date 25/08/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 26/08/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Prostate specific antigen (PSA) is a protein that can be measured in the blood. PSA testing is commonly used to help identify men who may need further investigation for prostate problems.

At present, PSA tests are usually carried out by sending a blood sample to a laboratory. This process can take time and requires access to healthcare services. EDX Medical Limited has developed a new rapid testing system that is designed to measure PSA and other related biomarkers closer to where people live and work. The test can be used by trained healthcare professionals in community settings such as sports clubs, social clubs and workplaces.

The aim of this study is to find out how closely the new testing system agrees with standard laboratory PSA testing. The study will also assess whether smaller blood samples collected using capillary blood collection devices provide results that are comparable to traditional blood samples taken from a vein. In addition, researchers will evaluate how easy the new system is for healthcare professionals to use in real-world community settings.

Who can participate?

Up to 2,000 men aged 40 to 79 years may take part.

Participants must be attending a community-based PSA testing event organised by charitable organisations. These events take place in local community settings such as sports clubs, social clubs and workplaces.

What does the study involve?

Participants will already be having a blood sample taken as part of routine PSA testing.

During the same visit, an additional small blood sample of approximately one teaspoon may be collected for the study. Some participants may also be asked to provide a capillary blood sample using a blood collection device placed on the upper arm.

The blood samples will be tested using both the new rapid testing system and the standard laboratory method. Researchers will compare the results from the two methods to see how closely they match.

Participants only need to attend one study visit. Information related to the study may continue to be collected for up to one month after participation.

What are the possible benefits and risks of participating?

Participants may not receive any direct medical benefit from taking part. However, the information collected could help researchers develop more accessible community-based PSA testing services in the future.

The risks of taking part are considered low. Blood sampling may cause temporary discomfort, mild pain, bruising or light-headedness. These effects are usually short-lived. People who are uncomfortable with needles may experience these effects more strongly.

For participants who provide a capillary blood sample using the upper arm collection device, there may be mild skin irritation, temporary marks or minor bruising where the device is applied.

No additional visits are required beyond the community testing event.

Where is the study run from?

The study will take place at community-based PSA testing events organised by charitable organisations. These events are held in locations such as sports clubs, social clubs and workplaces where men in the target age range regularly attend.

When is the study starting and how long is it expected to run for?
August 2026 to August 2028.

Who is funding the study?

The study is sponsored and funded by EDX Medical Limited (UK).

Who is the main contact?

EDX Medical Limited, contact@edxmedical.com

The Scottish Prostate Cancer Initiative can also be contacted for information:

info@scottishprostate.com

<https://www.scottishprostate.com/>

Contact information

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)

369530

Study information

Scientific Title

Analytical comparison of a point-of-care prostate specific antigen (PSA) assay system with laboratory-based reference methods in a community setting (EDX Prostate Point Of Care Holism)

Acronym

EPPOCH

Study objectives

Primary objectives:

1. To assess the analytical agreement between a quantitative point-of-care (qPoC) PSA assay system and established laboratory-based reference methods using blood samples collected in a community-based cohort
2. To compare the equivalence of non-venipuncture and venous blood sample collection methods for PSA measurement using both the qPoC assay system and laboratory-based reference methods

Secondary objectives:

1. To evaluate participant acceptability of non-venipuncture blood collection methods in a

community setting

2. To assess user (healthcare professional) usability of the qPoC assay system and associated sampling device in a community setting
3. To assess the precision and reproducibility of the qPoC assay system when used in a community setting
4. To enable exploratory analysis of blood-based biomarker measurements using stored samples, where consent is provided

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/05/2026, West of Scotland REC 3 (West of Scotland Research Ethics Service Admin Building, Level 2 Gartnavel Royal Hospital 1055 Great Western Rd, Glasgow, G12 XH, United Kingdom; no telephone number provided; ggc.WoSREC3@nhs.scot), ref: 26/WS/0068

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Prostate specific antigen assay

Interventions

Multi-centre, observational study involving analytical comparison and usability assessment of a quantitative point-of-care (qPoC) PSA assay system in a community setting.

Analytical comparison:

Assess the agreement between measurements obtained from a quantitative point-of-care PSA assay system and those obtained using established laboratory-based reference methods, using blood samples collected from participants in a community setting.

Sampling method comparison:

Compare PSA measurements obtained from non-venipuncture blood collection methods with those obtained via standard venous sampling, across both qPoC and laboratory-based methods.

Usability and acceptability assessments:

Evaluate the usability of the qPoC assay system and its associated sampling device when used by healthcare professionals in community settings, and to assess participant acceptability of different blood sampling methods.

Participants in this study will be men aged 40–79 years who are already attending a community-based PSA testing event. These events take place in local settings such as sports clubs, workplaces, or community venues. When booking their PSA test, individuals will be given information about the study and invited to take part. Those who agree will provide electronic consent before attending their appointment. At the testing event, participants will have a standard blood sample taken as part of routine PSA testing. If they take part in the study, an

additional small blood sample (approximately one teaspoon, around 5 mL) will be collected at the same time. Some participants may also be asked to provide a small capillary blood sample (approximately 1 mL) using a device applied to the upper arm. The additional sample will be tested using a new testing method, while the routine sample will be tested in a laboratory as normal. The results from the two methods will later be compared, but only the laboratory result will be used for any clinical follow-up as part of the community testing event. Participants will only attend one visit, and no extra appointments are required. Some participants may be asked to complete a short questionnaire about their experience. Basic study information may be collected for up to one month after the visit.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

EDX

Primary outcome(s)

1. Measures of analytical agreement between the qPoC PSA assay system and laboratory-based reference methods across the study cohort measured using PSA values (ng/ml), correlation coefficients, bland altman analysis, trueness, repeatability, reproducibility, and linearity at baseline

2. Measures of analytical agreement between the non-venipuncture and traditional venipuncture sampling methods established using both the qPoC PSA assay system and laboratory-based reference methods across the study cohort measured using PSA values (ng /ml), correlation coefficients, bland altman analysis, trueness, repeatability, reproducibility, and linearity at baseline

Key secondary outcome(s)

1. Patient acceptability and usability data on the test device and ancillary sampling device measured using quantitative and qualitative survey data at baseline

2. User acceptability and usability data on the test device, system and ancillaries measured using quantitative and qualitative survey data at baseline

3. Identification and capture of usability and acceptability issues measured using quantitative and qualitative survey data at baseline

Completion date

28/08/2028

Eligibility

Key inclusion criteria

1. Individuals who are biologically male at birth
2. Aged 40 to 79 years of age at the time of consent

3. Individuals attending community-based PSA testing programmes
4. Individuals who are able and willing to provide written informed consent prior to any study-related procedures

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

40 Years

Upper age limit

79 Years

Sex

Male

Total final enrolment

0

Key exclusion criteria

1. Individuals who are biologically female at birth
2. Individuals with a known diagnosis of prostate cancer currently undergoing active treatment
3. Individuals who have previously undergone surgical treatment of the prostate, including radical prostatectomy
4. Individuals with a known absence of the prostate, whether congenital or surgical

Date of first enrolment

28/08/2026

Date of final enrolment

30/12/2026

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Study participating centre

SPCI

18 Woodside Place

Glasgow
Scotland
G3 7QL

Study participating centre
GFCT
66b Smith Street
Warwick
England
CV34 4HU

Sponsor information

Organisation
EDX Medical

Funder(s)

Funder type

Funder Name
EDX Medical

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2	18/05/2026	26/08/2026	No	Yes