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Clinical performance evaluation of a quantitative Randox STI-fleX qPCR device for sexually transmitted infections

Submission date
17/06/2025

Recruitment status
Recruiting

Registration date
30/07/2025

Overall study status
Ongoing

Last Edited
03/09/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and Study Aims
Sexually transmitted infections (STIs) are a considerable threat to public health worldwide. They can cause acute urogenital conditions such as cervicitis, urethritis, vaginitis and genital ulceration, with some of the etiological agents also infecting the rectum and pharynx. Many STIs are generally asymptomatic in the early stages of infection, which increases the potential for undetected transmission. If left undiagnosed and untreated, common STIs may cause complications and long-term health problems. Randox has developed a sensitive, multitarget approach for detecting nine common STIs with the STI-fleX qPCR device family, which comprises four diagnostic assays. The study aims to assess the performance of the Randox STI-fleX qPCR device family for potential use in routine STI testing.

Who can participate?
Persons aged ≥18 years who are suspected of having an STI infection, at increased risk of STI, have a known exposure to any STI, or contact tracing.

What does the study involve?
The study is confined to de-identified leftover/archived residual samples received at Randox Clinical Laboratory Services (RCLS) during routine diagnostic testing of STI samples. All samples have informed consent for research use. Results obtained using the STI-fleX qPCR device will be compared to results obtained using a reference method. Results will be used to demonstrate the clinical performance of the STI-fleX qPCR device.

What are the possible benefits and risks of participating?
Although no clinical decisions will be made from the results of this study, participants will be contributing to the wider scientific community through their participation in the assessment of a new diagnostic test that aims to improve sensitivity, accuracy, and time-to-result of STI testing, thereby improving clinical practice. As the study involves testing of pre-characterised leftover clinical samples, there are no risks to participating.

Where is the study run from?
Randox Clinical Laboratory Services (RCLS), Northern Ireland.

When is the study starting and how long is it expected to run for?
The study started on 14th May 2025. Testing is expected to commence on 14th July 2025 and should be complete within 60 working days.

Who is funding the study?
Randox Laboratories Ltd, Northern Ireland

Who is the main contact?
Dr Helena Murray, Molecular R&D Manager, Randox Laboratories Ltd
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
359709

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
169RDIM Clinical Performance Study

Study information

Scientific Title
Clinical performance evaluation of the Randox STI-fleX qPCR

Acronym
STI-fleX qPCR CPS

Study objectives
The Randox STI-fleX qPCR device family is designed for the qualitative detection and differentiation of DNA from nine common STIs in urine or swab samples. Quantitative polymerase chain reaction (qPCR) is a sensitive and specific technology that allows for the selective amplification and detection of target nucleic acid from a sample using fluorescent dyes. The fluorescent signal generated during PCR amplification increases exponentially with each PCR cycle and can be measured, enabling simultaneous detection of all targets. The study aims to assess the performance of the Randox STI-fleX qPCR device family for potential use in routine STI testing.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/07/2025, North East - York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048052; york.rec@hra.nhs.uk), ref: 25/NE/0125

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Laboratory

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Detection of sexually transmitted infections

Interventions
A retrospective clinical performance study will be conducted to demonstrate that, under the anticipated conditions of use, the STI-fleX qPCR device family will meet the intended use and labelling claims. The study will be observational in design. The STI-fleX qPCR device family assays are designed for the qualitative detection and differentiation of DNA from CT, NG, HSV1, HSV2, TP, TV, MG, MH and UU in urine or swab samples using real-time PCR technology.

Specimens used for this clinical performance study will be remnants of specimens taken for purposes of routine STI diagnostic testing (leftover or archived) through a swab or urine from male and female subjects. Specimens may come from persons suspected of having an STI infection, but also from those who need a diagnostic test due to other reasons, such as persons at increased risk of STI, have a known exposure to any STI, or contact tracing.

Study endpoints will include the correlation of results with a reference method (Randox Sexually Transmitted Infection Multiplex Array II) presented as a percentage difference, diagnostic sensitivity, diagnostic specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Likelihood Ratios (positive and negative).

Intervention Type
Other

Primary outcome measure
The following primary outcome variables will be used to correlate STI-fleX qPCR device results with the reference method measured using the Randox STI Multiplex Array II at one timepoint:
1. Percentage difference
2. Diagnostic sensitivity
3. Diagnostic specificity
4. Positive Predictive Value (PPV)
5. Negative Predictive Value (NPV)
6. Positive Likelihood Ratio
7. Negative Likelihood Ratio

Clinical Performance Study acceptance criteria will be as follows:
Sensitivity ≥90%
Specificity ≥95%

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
14/05/2025

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Persons aged ≥18 years
2. Persons who are suspected of having an STI infection, at increased risk of STI, have a known exposure to any STI, contact tracing.

Participant type(s)
Service user

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
640

Key exclusion criteria
1. Subjects under the age of 18
2. Contamination and/or deterioration of the specimen that, in the investigator’s opinion, may impact its handling and/or analysis.

Date of first enrolment
29/07/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Randox Clinical Laboratory Services
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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Randox Laboratories Limited

Results and Publications

Publication and dissemination plan
Study results will be submitted to regulatory authorities for market authorisation of the STI-fleX qPCR device family.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to sexually transmitted infection test results having already been generated and provided to these patients; the current clinical study aims to show that the STI-fleX qPCR device family will generate equivalent results to the reference method in routine use by the testing laboratory.

IPD sharing plan summary

Not expected to be made available