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Using rapid testing in sexual health clinics to support targeted antibiotic treatment

Submission date
02/06/2026

Recruitment status
Not yet recruiting

Registration date
03/06/2026

Overall study status
Ongoing

Last Edited
03/07/2026

Condition category
Infections and Infestations

[X] 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 such as chlamydia, gonorrhoea and Mycoplasma genitalium are common and increasing in the UK. Many people with these infections do not have symptoms, but untreated infections can lead to serious health problems. Current testing usually involves sending samples to a laboratory, meaning results can take several days. Because of this delay, people are often given antibiotics before their results are known. This can lead to unnecessary antibiotic use and may contribute to antibiotic resistance.

This study aims to evaluate whether a rapid test that provides results during the same clinic visit can help healthcare staff give more targeted antibiotic treatment. The study will also assess whether the test improves patient experience and reduces the number of clinic visits needed.

Who can participate?
Adults aged 16 years and over attending the Morley Street Sexual Health Clinic in Brighton may be able to take part if they:

Have symptoms that may be caused by chlamydia, gonorrhoea or Mycoplasma genitalium, or
Have had sexual contact with someone diagnosed with one of these infections

Participants must be willing to provide a urine sample or vaginal swab and take part in the consent process.

What does the study involve?
The study has three phases. First, researchers will review routine clinic data collected before the rapid test is introduced. Second, clinic staff will be trained to use the rapid test and new clinic pathways will be developed. Third, the rapid test will be introduced into routine care at the clinic.

Participants in the intervention phase will attend the clinic as normal. They will receive information about the study and be asked to give written consent. A urine sample or vaginal swab will be collected as part of routine sexually transmitted infection testing. Samples will also be tested on-site using the rapid test, which provides results in around 20 minutes.

Participants may be asked to complete a short questionnaire about their experience of the rapid test. Healthcare staff using the test will also complete questionnaires about how the test works in routine clinic care.

What are the possible benefits and risks of participating?
Participants may benefit from receiving test results during the same clinic visit, which could allow faster and more targeted treatment. The study may also help improve future sexual health services and reduce unnecessary antibiotic use.

The risks are low. Sample collection may cause mild discomfort. As with any diagnostic test, there is a small possibility of incorrect or delayed results. However, all routine laboratory testing will still be carried out to confirm results, and any unexpected findings will be managed according to standard clinic procedures.

Where is the study run from?
The study is being run at the Morley Street Walk-In Sexual Health Clinic in Brighton, United Kingdom.

When is the study starting and how long is it expected to run for?
The study is expected to start in May 2026 and finish in June 2027.

Who is funding the study?
The study is funded by Roche Diagnostics.

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
368875

Central Portfolio Management System (CPMS)
74211

Study information

Scientific Title
The clinical utility of the Roche Cobas Liat point of care test to inform targeted antibiotic use for chlamydia, gonorrhoea and mycoplasma genitalium in sexual health services

Study objectives
Primary objective:
To evaluate whether use of the Roche cobas® Liat® CT/NG/MG assay reduces antibiotic use among attendees presenting to the sexual health clinics with symptoms consistent with non-gonococcal urethritis (NGU) or proctitis, or as a sexual contact of an STI

Secondary objectives:
1. To determine whether use of the assay reduces the number of clinic visits required per

attendee
2. To assess patient experience and satisfaction with point-of-care testing
3. To evaluate the impact of different clinical pathways incorporating the assay on patient flow and service efficiency

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/06/2026, East Midlands - Leicester South Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 2071048093; leicestersouth.rec@hra.nhs.uk), ref: 26/EM/0113

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Historical

Assignment
Single

Purpose
Diagnostic, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chlamydia, Gonorrhoea and Mycoplasma genitalium

Interventions
Intervention: introducing the Roche cobas Liat CT/NG/MG point-of-care assay into routine workflows at a sexual health clinic.

The Roche cobas Liat CT/NG/MG assay will be implemented in a walk in sexual health clinic (Morley Street). Data collection will continue prospectively, using the same outcomes as in baseline for before–after comparison. Participants will also be asked to complete a brief questionnaire to explore patient experience and acceptability of receiving same visit CT/NG results. Healthcare professionals involved in using the Roche cobas Liat CT/NG/MG assay in clinic will also be asked to complete a brief questionnaire to explore acceptability, usability, and workflow impact of the cobas Liat device and the new pathway. The questionnaires used will be the PSDT-Q and CSDT-Q which are both validated for measuring satisfaction with a diagnostic test among patients and clinicians. Patient questionnaires will be available in English, Spanish, Portuguese, French, Arabic, and Mandarin, reflecting the most commonly spoken languages among attendees at the clinic.

Intervention Type
Drug/Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Roche cobas® /MGLiat® CT/NG point-of-care test

Primary outcome(s)
1. Proportion of attendees with non-gonococcal urethritis (NGU), proctitis, or reporting as sexual contacts of a sexually transmitted infection (STI) who receive empiric antibiotic treatment at the index visit measured using Review of routinely collected clinical records / electronic patient records to identify presenting diagnosis or indication (NGU, proctitis, or STI contact) and antibiotic prescribing at the index visit; comparison between standard care and use of the Roche cobas® Liat® CT/NG/MG assay at Index visit, during: Baseline phase (12-week standard care period); Intervention phase (12-week period following implementation of Roche cobas® Liat® CT/NG/MG assay)Intervention phase (12-week period following implementation of Roche cobas® Liat® CT/NG/MG assay)Intervention phase (12-week period following implementation of Roche cobas® Liat® CT/NG/MG assay)

Key secondary outcome(s)
1. Number of clinic visits per attendee from index presentation to completion of management, and proportion of attendees achieving same-day clinical closure measured using review of routinely collected clinical records / electronic patient records to determine total number of attendances and whether clinical management was completed on the same day as the index visit at index visit until completion of management

2. Patient-reported experience and satisfaction with point-of-care testing measured using Study-specific structured patient questionnaire administered at the index visit assessing experience and satisfaction with point-of-care testing at Index visit (during the intervention phase)

3. Patient flow and service efficiency, including length of stay, waiting times, clinic throughput, staff time, and operational costs measured using Analysis of routinely collected service data, including clinic operational records, time-stamped patient flow data, staffing logs, and cost data at during: Baseline phase (12-week standard care period); Intervention phase (12-week period following implementation of Roche cobas® Liat® CT/NG/MG assay)

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Capable of giving informed consent
2. Aged 16 years or older
3. Reported sexual activity within the past six months
4. Presenting either:
4.1. Symptomatic with suspected genital CT, NG or MG infection
4.2. Asymptomatic and presenting as a sexual contact of a CT- or NG- or MG-positive index case,

with last sexual contact occurring more than 2 weeks prior
5. Able and willing to provide an appropriate specimen:
5.1. 25–50 mL first-catch urine sample
5.2. Clinician- or self-collected vaginal swab

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Symptomatic with suspected rectal CT, NG or MG infection
2. Previous participation in this study
3. Current or recent antimicrobial therapy (antibiotic use within 14 days prior to clinic visit)
4. Urination within the 1 hour prior to specimen collection

Date of first enrolment
01/09/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Morley Street Walk-In Sexual Health clinic
Morley Street
Brighton
England
BN2 9RE

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type

Funder Name
Roche Diagnostics

Alternative Name(s)
Roche Diagnostics Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available