ISRCTN57715622 https://doi.org/10.1186/ISRCTN57715622

Evaluation of digital microfluidic molecular point-of-care testing for the diagnosis of respiratory pathogens

Submission date
21/10/2025

Recruitment status
Stopped

Registration date
24/10/2025

Overall study status
Stopped

Last Edited
19/11/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
When a patient presents at the Emergency Department (ED) with clinical signs of respiratory infection, the time it takes to diagnose and initiate appropriate treatment can influence the patient's outcome and disposition. The quicker the therapeutic regime is started, the better the outcome for the patient. Furthermore, the sooner the presence of a pathogen is confirmed, the quicker the patient can be appropriately isolated to stem the spread of infection. This is a prospective, single-centre, single-visit, diagnostic performance evaluation study. The study aims to compare the performance of the current gold standard testing diagnostic device (called Cepheid) to the novel testing device (called Logicore System) in terms of turnaround time to receipt of diagnosis and sensitivity/accuracy of the devices.

Who can participate?
Patients presenting to the ED at Addenbrooke's Hospital with clinical symptoms of respiratory tract infection who will require standard of care diagnostic testing in line with the Trust Infection Prevention and Control policy.

What does the study involve?
Patients need to have a nasopharyngeal swab (up the nostril) taken for diagnostic testing with the Cepheid device as part of the standard care pathway outside the study. Those who are recruited into the study will simply have an additional nasopharyngeal swab taken simultaneously (one swab from each nostril). One swab will be tested by Cepheid as usual, and the second swab will be tested by the Logicore System. In this way, each participant will act as their own control. There is no treatment in the study; participants will return to the standard care pathway in the ED.

What are the possible benefits and risks of participating?
There is no particular benefit to individual participants from taking part in the study. There are no payments to participants for taking part, and the study has no bearing on the clinical care

each participant receives. However, participants may experience a sense of altruism from taking part in a study aiming to reduce diagnostic time and spread of infection for future patients with respiratory infections in the ED.

Whenever a nasopharyngeal swab is used, there is a potential risk of discomfort and/or a small possibility of a nosebleed. This will be explained to the participants during the informed consent process, and staff are trained in the swabbing procedure to minimise the likelihood of discomfort and/or nosebleeds. The ED research nurse (or designated member of the research team) will wear standard Personal Protective Equipment and follow standard measures for cleaning and disinfection to reduce the potential risk of spreading infection between staff and patients, in line with the CUH Infection Control and Prevention Guideline.

Where is the study run from?
Logilet (UK) Ltd, UK.

When is the study starting and how long is it expected to run for?
August 2025 to April 2026. The study will be open to recruitment from December 2025 to March 2026, dependent on approvals, contracts and training being in place.

Who is funding the study?
Logilet (UK) Ltd, UK.

Who is the main contact?
The Emergency Department Research Team at Addenbrooke's Hospital, cuh.
edresearchteam@nhs.net

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
363005

Protocol serial number
SMARTUK01

Study information

Scientific Title
Study for multiplex assessment and respiratory test evaluation

Acronym
SMART

Study objectives
The primary objective of the study is to demonstrate that the Logicore System multiplex 6 panel respiratory pathogens point of care testing device has increased diagnostic sensitivity when compared to the current gold standard point of care multiplex panel at Cambridge University Hospitals NHS Foundation Trust (Addenbrooke's Hospital) whilst maintaining accuracy, including Positive Predictive Value (PPV), Negative Predictive Value (NPV) and specificity.
The secondary objectives are: 1) To compare the time from sample acquisition to receipt of result (turnaround time) for Logicore System point of care testing and current point of care testing (Cepheid multiplex GeneXpert), 2) To evaluate the acceptability of the Logicore System device by study participants and staff, and 3) To produce targeted Cost Benefit analysis for the Logicore System device.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 09/10/2025, West of Scotland REC 4 (Level 2 - Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 314 0213; ggc.wosrec4@nhs.scot), ref: 25/WS/0171

Study design
Prospective single-centre diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Point-of-care testing for diagnosis of respiratory infections in the Emergency Department setting of Addenbrooke's Hospital.

Interventions
This is a prospective, single-centre, diagnostic accuracy study. There is no therapeutic agent and no randomisation. Study participants will have 2 nasopharyngeal swabs taken simultaneously (one from each nostril). One swab will be tested using the gold standard point-of-care testing device (Cepheid), and the other swab will be tested using the novel point-of-care testing device (Logicore System). Therefore, participants act as their own controls for the study. Assessments take place in a single visit to the Emergency Department at Addenbrooke's Hospital. The diagnostic results and the amount of time to receive the results will be compared.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Investigational Logicore System device, Cepheid GeneXpert device.

Primary outcome(s)
The sensitivity and accuracy of the Logicore System POC diagnostic test compared to the gold standard POC multiplex test (Cepheid GeneXpert), including Positive Predictive Value (PPV), Negative Predictive Value (NPV) and specificity measured using data collected at the time of the test during a single visit

Key secondary outcome(s))
1. Determination of turnaround time for Logicore System, measured using time recorded by the Logicore System and documented in patients' medical notes by research staff, and Cepheid tests measured using time documented in patients' medical notes by research staff, at one timepoint
2. Evaluation of the acceptability of the Logicore System POCT to study participants and staff, measured using a simple Likert scale, at a single timepoint
3. Monetised savings from avoided testing and operational savings due to the reduction in time spent in ED or in isolation within the ED measured using data collected from patient medical records at one timepoint

Completion date
30/04/2026

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Male or female
2. Any age
3. Presenting to the CUH Emergency Department

4. Symptomatic of respiratory tract infection as evidenced clinically by the presence of any of the following indicators:
4.1. Acute onset of persistent cough (with or without sputum)
4.2. Hoarseness
4.3. Nasal discharge or congestion
4.4. Shortness of breath
4.5. Sore throat
4.6. Wheezing
4.7. Sneezing
4.8. Persistent Acute respiratory distress syndrome
4.9. Influenza-like illness
4.10. Fever ≥ 37.8 degrees C
4.11. Any other symptom known to be indicative of acute respiratory episode such as palpitations, headache, anosmia (COVID) or gastrointestinal symptoms (diarrhoea) (influenza)
5. Signed consent form for participation
6. Requiring standard of care diagnostic testing as per CUH Trust IPC policy
7. Able to read and/or understand the age-appropriate participant information sheet in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unwilling or unable to comply with study nasopharyngeal swabbing procedures
2. Those who are incapacitated or deemed to be lacking capacity to provide informed consent to participate
3. Prisoners or young offenders

Date of first enrolment
01/12/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Emergency Department of Addenbrooke's Hospital
Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
Logilet (UK) Ltd

Funder(s)

Funder type
Industry

Funder Name
Logilet (UK) Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	09/10/2025	23/10/2025	No	No