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Clinical performance evaluation of a Randox Respiratory-fleX device for respiratory infections

Submission date
25/03/2026

Recruitment status
Recruiting

Registration date
02/04/2026

Overall study status
Ongoing

Last Edited
25/03/2026

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
Respiratory infections represent a significant disease burden. Individuals of all ages and health statuses are at risk of developing a bacterial or viral respiratory infection. Individuals who are elderly, immunocompromised, or are in an at-risk population such as patients suffering from cystic fibrosis are at a significantly increased risk of serious disease. Rapid and accessible diagnostics are a key part of the patient journey and are most effective when testing is both rapid and accurate. The purpose of this research is to evaluate the clinical performance of the Randox Respiratory-fleX device for in-vitro diagnostic use (PE-IVDD). The new medical device under evaluation will be compared to a device in routine use for respiratory testing (Evidence Investigator Respiratory Multiplex Array II, EV3947A/B) and assessed using established criteria.

Who can participate?
Persons aged ≥18 years suspected of having a respiratory infection, at increased risk of respiratory infection, or have a known or suspected exposure to a respiratory pathogen.

What does the study involve?
The study will use leftover/archived specimens collected from routine respiratory testing. Consented individuals will provide their sample for analysis as part of the Randox Testing Service offered to the general public via the Randox Health website. The study will last approximately 18-months, where a specimen library will be collected for the first 12-months during routine device use, followed by a testing window of ~6 months where the devices will be used simultaneously and the sample library will be retrospectively tested. Data will be compiled at the end of the study to determine the outcome of the performance evaluation.

What are the possible benefits and risks of participating?
Participants will be contributing to the wider scientific community through their consent to participate in the study. The participant will benefit in the knowledge that the data generated using the new device aims to improve clinical practice by improving diagnostic sensitivity,

diagnostic specificity, accuracy and time-to-result of testing. The use of leftover specimens and the knowledge that no clinical decisions will be made from the results of the study present no additional risks to the participant.

Where is the study run from?
The study will be run from Randox Clinical Laboratory Services (RCLS), Northern Ireland. The study will be conducted in an ISO accredited Clinical Laboratory following the predetermined Performance Study Protocol and following Standard Operating Procedures of the Laboratory.

When is the study starting and how long is it expected to run for?
The study is expected to start on the 30th March 2026. A sample library will be compiled for 12-months from the start date until April 2027. Simultaneous testing of both routine and Respiratory-flex devices will be conducted for an additional 6-months between April 2027 and the 30th September 2027.

Who is funding the study?
The study is funded by Randox Laboratories Ltd, Northern Ireland.

Who is the main contact?
Dr Helena Murray, Molecular R&D Manager, Randox Laboratories Ltd, helena.murray@randox.com

Contact information

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Integrated Research Application System (IRAS)
368528

Protocol number
16378-RD

Study information

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

Acronym
Respiratory-fleX qPCR CPS

Study objectives
To assess the Randox Respiratory-fleX device family of assays such that they perform as intended when used according to the Instructions for Use (IFU) provided for the testing of both stored nucleic acid and freshly collected samples, when compared to the existing device currently in routine use (Respiratory Multiplex Array II Evidence Investigator Assay, EV3947A/B).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/02/2026, North West - Greater Manchester South Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 26/NW/0043

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Detection and discrimination of causative pathogens of respiratory infections.

Interventions
An observational clinical performance study will be conducted to demonstrate that, under routine use conditions and following device instructions for use, the Respiratory-fleX device family will meet intended use and labelling claims. The study will retrospectively test nucleic acids from a stored library collected over a period greater than or equal to 12 months, and on freshly collected sample nucleic acids during a concurrent testing window (approximately 6

months) with the Randox Evidence Investigator Respiratory Multiplex Array II Assay (EV3947A /B) as a comparator.

Nucleic acids will be isolated from an oral-nasal swab or sputum sample for the purposes of routine respiratory testing using the predicate assay (EV3947A/B). The Respiratory-fleX device will detect and distinguish between nucleic acids from various respiratory pathogens including: Influenza (Subtypes A and B), Respiratory Syncytial Virus, Parainfluenza Virus, human Metapneumovirus, Bordetella pertussis, Rhinovirus/Enterovirus, Adenovirus, human coronaviruses (229E/NL63 and OC43/HKU1), Streptococcus pneumoniae, Moraxella catarrhalis, Haemophilus influenzae, Chlamydophila pneumoniae and Mycoplasma pneumoniae.

Results of the Respiratory-fleX device will be compared to that of the reference method (EV3947A/B). Any discrepant positive or negative results between the assays will be initially re-tested using the Respiratory-fleX device to control for nucleic acid degradation. Resolution of the discrepant result will be completed using a third commercial assay to determine concordance of the result between the Respiratory-fleX and predicate devices.

Intervention Type
Other

Primary outcome(s)
1. Correlation of results with reference method (EV3947A/B) measured using percentage difference data collected in study records at the end of the study

2. Analysis of results tested using the Respiratory-fleX device to meet minimum acceptance criteria (in brackets) measured using diagnostic sensitivity(≥90%), diagnostic specificity (≥90%), positive predictive value (>85%), negative predictive value (>90%), positive likelihood ratio (>8.5) and negative likelihood ratio (<0.167) at the end of the study

Key secondary outcome(s))

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Persons who are suspected of having a respiratory infection, at an increased risk of respiratory infection, or believed to have a previous exposure to a respiratory pathogen and require screening.
2. Individuals aged 18 or over.
3. Samples with appropriate consent for use for performance evaluation testing.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Contamination and/or deterioration of the specimen or nucleic acid isolate from a specimen that, in the investigator's professional opinion, may impact the handling of the specimen or analysis of the test result.

Date of first enrolment
30/03/2026

Date of final enrolment
29/09/2027

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Randox Clinical Laboratory Services
30 Randalstown Road
Antrim
Northern Ireland
BT41 4LP

Sponsor information

Organisation
Randox (United Kingdom)

ROR
https://ror.org/04cte7x29

Funder(s)

Funder type

Funder Name
Randox Laboratories Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available