



Breakthrough infection test designed to tackle antimicrobial resistance is on target for 2025 UK NHS availability after positive trial results

TUESDAY, DECEMBER 17, 2024: UK medtech company Presymptom Health has announced positive results from its clinical trial (PRECISiON), which was designed to assess the performance of Presymptom Health's technology in the management of infection and sepsis in patients presenting to Emergency Departments with respiratory infection.

Accurate infection diagnosis, by identifying patients who don't require antibiotics, is crucial to saving lives and to tackling antimicrobial resistance, which has been labelled <u>a global emergency</u> by UK government health officials. <u>Failure to address the problem of antibiotic resistance</u> could result in an estimated 10 million deaths per year globally by 2050 and could cost the global economy £66 trillion.

As part of the PRECISiON clinical trial, which was conducted between May 2021 and April 2024 at Portsmouth Hospitals University NHS Trust and eight other NHS sites, Presymptom Health assessed the performance of its InfectiClear® diagnostic product. Early results show the InfectiClear® diagnostic product may have >95% accuracy at ruling out lower respiratory tract infection, a significant improvement over standard of care.

Once ongoing validation work is complete and the product made available in the NHS, starting in 2025, this will enable clinicians to rule out infections earlier, and avoid unnecessary prescription of antibiotics in patients presenting with non-infectious inflammatory symptoms such as fever and elevated heart rate or breathing. Such symptoms are not necessarily signs of active infection, and existing blood tests are not specific enough to diagnose infection or sepsis.

Further analysis of the trial results are ongoing and full results will be announced in 2025.

Dr lain Miller, CEO of Presymptom Health comments: "Antimicrobial resistance is a global crisis. If it's not addressed, it will kill more people than cancer does today by 2050".

"Identifying the presence, or lack of, infection at the earliest possible opportunity is crucial to tackling the crisis. Current methods to detect infection are slow and inaccurate, leading to antibiotics being prescribed when they really don't need to be. In fact, 20-70% of the UK's annual 35 million antibiotic prescriptions are unnecessary or inappropriate, depending on the clinical setting.





"This clinical trial, when combined with data from other NHS trials, was crucial to further evidencing the efficacy of the technology. It has also enabled us to collect vital data around infection from the 484 patients that took part. We are now looking to raise further funding to help us get this lifesaving technology into the NHS as a UKCA-accredited product in 2025 and to deliver further clinical trials across the NHS and overseas."

Host response analytics: a new way to detect infection

Presymptom Health was established to exploit IP developed by scientists working at the UK Defence Science & Technologies Laboratory (Dstl), initially researching how to tackle biological threat infection, such as anthrax, plague and ebola. Ploughshare – the company that finds new and inspiring uses for government inventions – identified the innovation as having potential societal impact and spun it out from the UK Ministry of Defence in 2019.

Dr Paul Schmidt, Consultant at Portsmouth Hospitals University Trust and lead researcher for the study said: "This study offered a fantastic opportunity to see how this leading-edge technology for recognising infection and sepsis, developed by UK Dstl scientists combining machine learning and molecular technologies, could benefit NHS patients. I am excited to continue to work with Presymptom Health to unlock the huge potential of this technology" Dr Schmidt led the collaborative development of the study design, working with Presymptom Health on behalf of Portsmouth Hospitals NHS Trust, the NHS Sponsor of the study.

Presymptom Health is developing a unique portfolio of blood tests powered by machine learning that accurately detect infection and sepsis up to three days before current standard of care. The technology has been trained on a dataset of blood samples collected over 15 years, encompassing thousands of cases, including patients who went on to develop infections and sepsis.

The core of the InfectiClear® technology lies in RNA-based host response analytics, which examines the body's response to an infection rather than attempting to detect the pathogen directly – a method that sets it apart from marketed tests available in the UK today. This approach provides an early, highly sensitive signal for infection or sepsis and avoids the delays and inaccuracies often seen with traditional tests, which can lead to unnecessary or incorrect treatments. These tests are platform agnostic and will over time be offered on multiple different NHS PCR platforms, which were widely deployed during the COVID pandemic and are now often under-utilised.

Earlier this year Presymptom Health was selected as one of only eight companies to be part of the Innovative Devices Access Pathway (IDAP) - a government initiative to bring new medical technologies to the National Health Service (NHS) to help with unmet medical needs.

Presymptom Health to launch a further clinical trial





Presymptom Health plans to run a follow-on 350-patient trial in 2025 to assess the accuracy and utility of InfectiClear® in patients with symptoms of respiratory and other infections. It is hoped that the results from this trial, named Precision 2, would help drive adoption at scale across the NHS. The trial is being designed with inputs under the IDAP program from the NHS, the Medicines and Healthcare products Regulatory Agency, and the National Institute for Health and Care Excellence (NICE).

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Notes to Editors

About Presymptom Health

Presymptom Health is an innovative medtech company which is developing a portfolio of diagnostic tests and decision support software to enable early diagnosis and optimal care of infection and sepsis to help save lives. Established in 2019, it was founded to exploit transformative innovation to leverage host (body) response signals to detect infection and sepsis in patients up to three days before symptoms appear.

About Ploughshare

Ploughshare is a pioneering company, owned by the Ministry of Defence, that unlocks the potential of UK government inventions, transforming them into impactful solutions that deliver real prosperity to the economy, our society, people's lives, and our environment. By establishing spin-outs and licensing technology, Ploughshare ensures that UK government's scientific breakthroughs can move from the laboratories and the frontlines, to benefit the wider world.

About Portsmouth Hospitals University NHS Trust

Portsmouth Hospitals University NHS Trust is one of the largest acute hospital trusts in the country treating over half a million patients each year. The Trust is the second largest employer in Portsmouth. It is also a major provider of training and education to a wide range of health professionals.

The Trust provides comprehensive secondary care and specialist services to a local population of 675,000 people across South East Hampshire and provide many services to a wider catchment area in excess of two million people.

Most of its services are provided at Queen Alexandra Hospital, in Cosham, but it also offers a range of outpatient and diagnostic facilities closer to patients' homes in community hospital sites and at local treatment centres throughout South East Hampshire.

The hospital also hosts the country's largest Ministry of Defence Hospital Unit, Joint Hospitals Group South, treating current and former members of the armed forces and their families and training clinicians.