

Abstract title: MyLabReady® for rapid and accurate point of care (POC) diagnosis of symptomatic infections and AMR guidance

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Abstract Body: (Word Count = 348)

Antimicrobial resistance (AMR) is a growing global public health threat due in part to the overuse and misuse of antibiotics. AMR contributed to 4.95 million deaths in 2019 and substantial increases in healthcare costs. Drug development pipelines cannot match the pace of rising trends in AMR.

This threat creates an urgent need by patients and healthcare workers for rapid and accurate diagnostic tests that identify pathogens causing infections and their appropriate antimicrobial treatment. Multiplex PCR assays at POC or in a patient's home can accelerate the specific and rapid detection of multiple pathogens, thereby guiding specific early, effective treatments. Currently, PCR is locked up in ~2500 locations in the EU, UK, and US. LabReady is addressing this pressing need to counter AMR threats by developing the diagnostic testing device MyLabReady. A novel innovative platform that provides rapid, accurate, qPCR-based multiplex testing similar to high-complexity hospital-based labs, but at POC (or millions of locations in the EU, UK, and US). Patient samples are processed using a simple and patented swab collection system. This device can rapidly identify viral or bacterial pathogens within a compact and closed cartridge system. MyLabReady tests can also indicate which antibiotic is needed first. It is low cost, easy to use, and a fully integrated diagnostic system suitable for use in low-resource settings without advanced training.

Results from a healthcare economic analysis by York Health Economics Consortium (YHEC) found that introduction of this device into current clinical pathways for diagnosing respiratory infections in high-risk patients alone yields significant (£400 million) annual cost savings to the NHS. Importantly, this technology platform can be easily modified to detect specific molecular targets for pathogens causing other symptom complexes, including respiratory, throat, wound, and other infections, and antibiotic resistance markers for those pathogens.

The MyLabReady device is unique and novel compared to all available tests in that it is miniature (6 oz) and AI-assisted so that a trained technical operator is not required. This is a multiplex PCR test that can detect multiple pathogens at once, down to single genetic copies, with a <30-minute turnaround time, displaying results immediately.



OUR TECHNOLOGY

The first qPCR-AI system that fully automates syndromic testing within an intuitively designed collection system



Less than 30-minute multi-pathogen identification
Diagnoses up to 5 infections per cartridge

One-step easy to use cartridge, **no fridge, tools, or mixing**

+

Reusable edge-AI analyzer **replaces PhD lab technicians**

+

Accurate results in **less than 30-minutes**

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*CE marking for illustrative purposes

Figure 1. A picture of the MyLabReady testing device showing the disposable cartridge containing the swab sample system, and the reusable analyzer base with operating electronics, and thermal-cycling components.