## iFAST Diagnostics – Synopsis & request for insights – February 2023

Executive Summary

iFAST is a new spinout from the University of Southampton and UKHSA (formerly Public Health England.) It has developed an antimicrobial susceptibility test for bacterial infections which takes 4-5 hours vs. 48 hours for current methods, and which we expect to be cheaper and have higher throughput. Our mission is to build a diagnostic system that will enable every patient in hospital to receive the correct antibiotic on Day 1, and to contribute towards saving some of the 1 million lives lost every year because of antimicrobial resistance, of which over 100,000 are in Europe. We are seeking insights from professionals and clinicians in the field as we develop this system.

How does it work?

iFAST works by growing the bacteria, initially from a urine sample (we are about to start tests with blood) for a couple of hours, before exposing the bacteria to each antibiotic of interest and then incubating for a further 2 hours. Each of these samples is pumped through a microfluidic cell that measures the electrical properties of one bacterium at a time and can determine whether it has been affected by the antibiotic, by comparing with a control sample that has not been exposed. About 5,000 bacteria are measured in each sample, over 30 seconds. The images below show how it might look, plus actual results for the control, and for two antibiotics, one resistant and one susceptible.
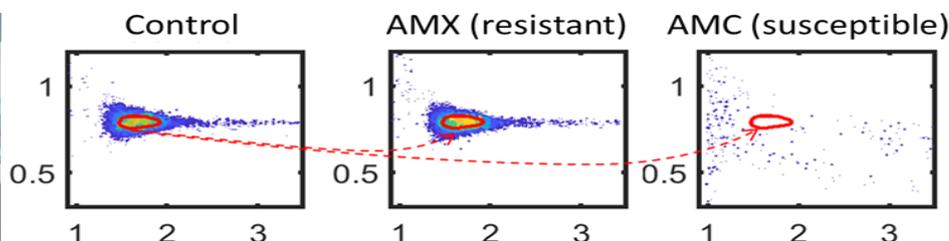
Technology and Workflow

We are designing the system to fit into the current clinical workflow but hope to demonstrate a significant time saving. We would like to explore how best to achieve this in a range of NHS microbiology labs around the country, so we don't design a system that works well in only a small number of settings, depending on workflow, availability of MALDI-TOF, for example. We are also seeking feedback on how best to display the results.

Competitive Position

As far as we understand, the current 'gold standard' tests used in almost all hospital labs are broth microdilution and disk diffusion. Both are manual, labour-intensive tests, relatively inexpensive (< £10 a test) and reasonable throughput, but both take 48-72 hours to provide a definitive 'susceptible/resistant' result for a suite of antibiotics.

We expect iFAST to be cheaper than these methods (as it is more automated and uses less consumables), and to produce a result from a fresh urine sample in only 4-5 hours. We expect to be able to deliver a result from a positive blood bottle in less than 2 hours. We hope this may enable the clinician to wait for the test result before prescribing a drug, contributing significantly to antimicrobial stewardship. There are a number of competitors, but from what we have heard, all have limitations in terms of time, cost and/or throughput.

Development Stage

The system has recently been validated by UKHSA in over 1,000 tests using their database of 50 different bacterial strains, each tested against 8 different frontline antibiotics. Clinically, it has been validated with patient samples for UTIs (99% agreement with the gold standard, n=80) and MRSA/MSSA (100% agreement, n=60). This work has been funded by an NIHR i4i product development award grant. The next development steps are to automate the system and complete the disposable cartridge design, followed by a formal clinical verification study, with a current aim to make available to hospital labs from late 2024.

Purpose of this Research

In order to develop the most effective product, that best meets the requirements and workflow of NHS hospital labs, we would like to ask Laboratory Managers and clinical specialists a few questions to understand the key parameters that will enable this to happen. We are requesting a short meeting to understand these parameters and also your views on what would make the system as clinically useful to your lab as possible.

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