Driving Innovation

Results of competition: Rapid diagnostics for human and bovine tuberculosis

Total available funding for this competition was £5.5m from the Technology Strategy Board.

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
CompanDX Limited (lead) Public Health England (Health Protection Agency) CPI Innovation Services Limited Sapient Sensors Limited	Translation of bovine tuberculosis biomarkers to the point of care setting.	£1,121,076	£873,252

Project description (provided by applicants)

Bovine tuberculosis (M. bovis) remains a major disease of cattle in the United Kingdom. The diagnosis and management of infected herds represents a significant burden to the UK taxpayer as bovine tuberculosis is a notifiable disease. Current testing regimens are laborious and time consuming, with blood samples needing to be transported to centralised testing facilities, where analysis and the reporting of findings can take a number of days. This makes rapid responses to infection difficult and costly.

Within this project we propose the development and validation of a number of blood-based biological markers which will subsequently be incorporated into a point-of-care device that can be used to rapidly obtain test results in the field. Such a device would have mobile phone/internet and global positioning system capabilities allowing results of tests conducted at a remote location to be uploaded rapidly to websites that communicate with regulatory authorities and facilitate herd management.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Enigma Diagnostics Limited (lead) Health Sciences Research Limited Queen Mary University of London	Single tube point-of-care multi-drug resistant tuberculosis test	£1,950,209	£1,310,862

Project description (provided by applicants)

Enigma Diagnostics Ltd and its partners will develop a point-of-care test for multi-drug resistant tuberculosis (TB) that will run on the Enigma® Mini-Lab instrument and will be suitable for use outside traditional laboratories. For example, it could be used in clinics and surgeries, in both high and low per capita income countries.

The test will use novel methods to process samples from patients with a newly invented system for detecting the bacteria that causes TB and detecting resistance to the drugs that are used to treat TB. It will be faster and more sensitive than tests used today and can distinguish the TB that affects people from those infecting other mammals (e.g. bovine TB). It will be safer than other methods as all the special chemistry takes place in a single closed tube.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Epigem Limited (lead) MV Diagnostics Limited University of Glasgow University of Southampton University of Edinburgh University College London SAW DX Limited	"MIMIC" - Multifunctional Integrated Microsystem for rapid point-of-care TB IdentifiCation	£1,659,808	£1,305,968

Project description (provided by applicants)

One third of the world's population is infected with TB and there are nine million new cases of active TB every year. While delays in diagnosing the disease result in a potential infection spreading, the diagnosis of TB on clinical grounds alone is difficult as patients often have only non-specific symptoms. Current diagnostic tests are facing major limitations, as they require samples to be sent to medical testing facilities and may take a further two days to perform, extending the time during which a patient is unsure and potentially infectious. This project aims at developing a 'point-of-care' system to diagnose TB, based on a blood sample from a finger-prick in a matter of minutes. It assembles a business-led consortium with a wide range of expertise, from clinical TB experts, closely involved with patients in three different universities across the UK, to engineering and biology.

The system comprises a low-cost disposable cartridge containing the sample and all the reagents required, interfaced with a reader that provides power, actuation and sensing. The manipulation of the drop of blood on the disposable cartridge is based on a patented innovation from the University of Glasgow, using the mechanical energy carried by sound waves to actuate liquids. The test is centered on a diagnostic chip using biomarkers, designed by MV diagnostics and created by Epigem Ltd that specifically detects the response of the human body to the tuberculosis pathogen. The large number of different (and proprietary) biomarkers has the potential to provide unprecedented sensitivity and specificity, within minutes, where current tests require hours or even days.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ProteinLogic Limited (lead) Microtest Matrices Limited University of Sheffield London School of Hygiene and Tropical Medicine	Research to create point-of-care TB diagnostic prototype from ProteinLogic unique TB biomarker signature and Microtest novel rapid diagnostic platform [MicroLogic].	£1,763,320	£1,181,403

Project description (provided by applicants)

Tuberculosis (TB) is responsible for over four million deaths each year. Globally there were an estimated 8.9 million new cases during 2011 and it is also a concern in the UK where there are approximately nine thousand new cases each year. Early detection and treatment is important to prevent the disease from spreading. Current diagnostic tests either lack accuracy or are not affordable or accessible to most TB patients. Delayed diagnosis is associated with reduced rates of cure. Of particular concern is our inability to diagnosis extra-pulmonary disease and TB in children or to differentiate latent infection from active TB disease.

The aim of this project is to develop an in vitro diagnostic device that would for the first time offer rapid diagnosis of all forms of active TB disease from a single, easy to collect sample (blood). Previous research by the applicants has revealed characteristic soluble proteins present in the blood of TB patients and we will combine a panel of these markers on a single detection device.

A small consortium has been created where scientists with expertise on TB biomarkers shall work with technologists who have designed and built a platform for detection of multiple markers in blood. Additional 'known' markers reported in the scientific literature may also be used to maximise sensitivity and specificity. The device will be optimised and evaluated using samples from South Africa and India. A prospective study will be undertaken in Cape Town to validate the device in situ. The primary output will be the final research prototype of the MicroLogic point-of-care test for active tuberculosis disease. We will formulate full technical and commercial plans to exploit the results of the project.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
QuantuMDx Group Ltd (lead) St George's University of London	Q-TB: Rapid, cheap POC diagnostic and drug susceptibility testing for human tuberculosis	£1,992,176	£923,223

Project description (provided by applicants)

The Q-TB project addresses some fundamental issues in the fight against tuberculosis. Firstly (SPEED and QUALITY) the project will deliver a technology that will enable patients to receive referral standard molecular diagnostic results within minutes, as they wait with their treating physician.

Secondly (PORTABLE), if the patient is in a rural location, such as a township in South Africa, or in a mountain location in Peru, or in a remote part of Asia with no electricity, laboratory, clinic, or hospital nearby, the size of the device (approximately the size of a 80's 'brick' mobile phone) and battery operation will enable even a technician or health worker (EASE OF USE) to perform a complex diagnosis.

Thirdly (DRUG RESISTANCE), the device can test for many different things at once and this project will develop tests for both diagnosis of tuberculosis and test which drugs will work best to treat the disease. This complex testing system benefits from QuantuMDx's novel and hi-tech nanotechnologies that can perform complex tests in 10-15 minutes, when normally they take hours to days, the expertise of Microsens in processing complex samples such as sputum, and the in-depth tuberculosis knowledge and testing experience of St Georges' Hospital, London, WHO TB group at Stellenbosch University, South Africa and several charities and NGOs throughout the world.

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