

Faster TB diagnosis

Tuberculosis (TB) is caused by bacteria which are becoming increasingly resistant to antibiotics. Doctors in the developing world have to frequently rely on diagnostic techniques that are insensitive or slow leading to the over prescription of antibiotics. By providing access to faster diagnostic methods, doctors will be able to target treatment effectively slowing the development of drug resistant TB bacteria.

Europe's National Measurement Institutes working together

The European Metrology Research Programme (EMRP) brings together National Measurement Institutes in 23 countries to address key measurement challenges at a European level. It supports collaborative research to ensure that measurement science meets the future needs of industry and wider society.

Challenge

Tuberculosis (TB) is a global problem made more serious by challenges associated with diagnosis and identification of drug resistance. A major challenge is quickly identifying the presence of TB causing bacteria in a patient's sample. Conventionally, for the most accurate diagnoses, samples are cultured for six weeks before being tested and while newer culture methods have reduced this, several days are still needed. Modern laboratories increasingly use an analysis technique called Polymerase Chain Reaction (PCR) which specifically detects bacterial DNA - if the pathogen is present - in a matter of hours.

Many different routine PCR techniques are used in TB diagnosis around the world, and increasingly automated instruments that do not need specialised laboratories and highly trained staff are being introduced. This makes these methods suitable for use in developing countries where TB prevalence is high. To ensure the accuracy with which labs can routinely detect disease bacteria in patient samples they participate in externally run quality assessment schemes during which all participants analyse the same material. This enables the results to be compared and a lab's disease diagnosis capability to be assessed. However, robustly relating participant results is challenging due to a lack of well characterised reference materials and appropriate highly accurate and traceable analysis methods.

Solution

The EMRP project *Metrology for monitoring infectious diseases, antimicrobial resistance, and harmful micro-organisms* developed and validated highly accurate Digital PCR (dPCR) based approaches for counting the quantity of specific bacterial DNA sequences in a sample.

The UCL Centre for Clinical Micro-biology, based at the Royal Free Hospital in the UK, an internationally recognised centre for micro-bacteriology research provided the project with TB bacterial samples to enable the generation of appropriate reference materials. These materials enabled the calibration of other clinical PCR techniques and allowed their direct comparison to the dPCR assigned values. This created a traceable measurement route for clinical PCR techniques.

The project also identified best practice for sample preparation and storage to enable delivery of the most accurate results across all techniques.

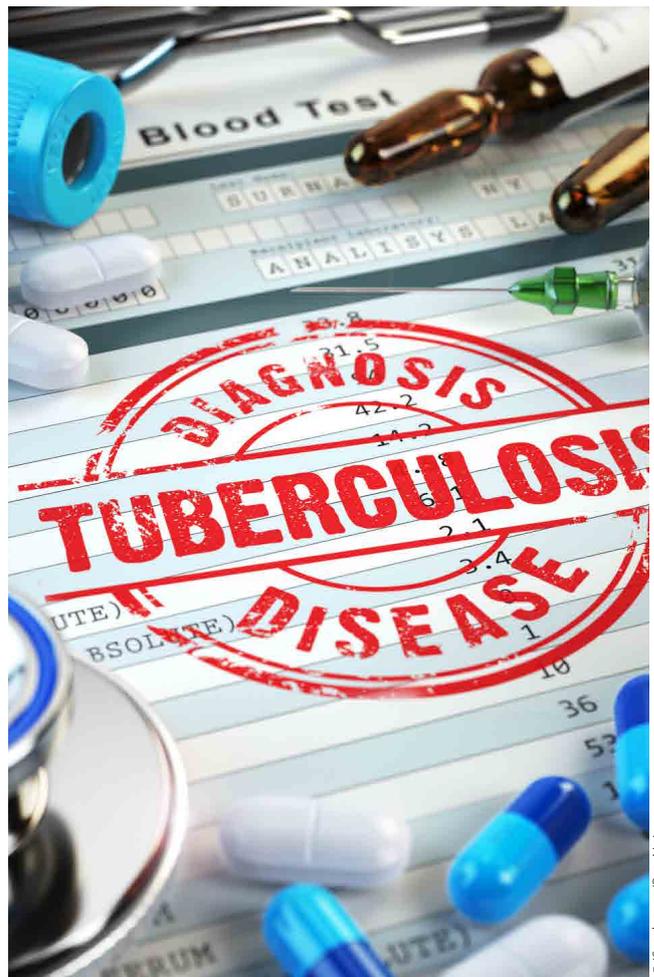
Impact

The TB reference materials assessed during the project were used in a comparison exercise to evaluate the performance of diagnostic tools by nine project partners and collaborators. Great Ormond Street Hospital, an important TB pathology laboratory in the UK, participated in this exercise and were able to confirm that PCR techniques correctly detect TB bacteria. The project's reference material established a reliable and traceable baseline, allowing organisations to demonstrate the robustness of their techniques in detecting the bacterial DNA.

The reference materials and best practice guidance developed as a result of this project are helping to assure the performance of PCR-based measurements and will increase confidence in the accuracy of TB testing. Faster rigorous TB diagnosis will help doctors prescribe and modify drug regimens to maximise effectiveness, minimise side effects, and slow the development of drug resistant bacteria.

Metrology for infection control

The EMRP project *Metrology for monitoring infectious diseases, antimicrobial resistance, and harmful micro-organisms* developed new measurement methods and materials to enable accurate quantification of infectious disease-causing pathogens in clinical samples. Infectious diseases account for over 20 % of human deaths globally and reliable diagnostic tools, such as these, are vital for public health protection. The project results provide much-needed support to emerging molecular approaches for efficient, harmonised and rapid diagnosis and monitoring of infectious diseases.



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