

Cornell University

TuBe -- A Rapid Point-of-Care Technology for Diagnosing Mycobacterium Tuberculosis and Rifampicin Resistance in Limited Resource Settings

We propose TuBe - a saliva based point-of-care diagnostic for the detection of *Mycobacterium tuberculosis* and associated Rifampicin antibiotic resistance based on a combination of our previously developed AnySource© isothermal PCR platform and CRISPR mutation detection methodology. Tuberculosis is the leading infectious disease killer globally. At our field site in India we work in a community of nearly 100,000 people and currently provide TB clinical services to over 3,000 patients annually, of whom nearly 15% show resistance to Rifampicin. The cornerstone for treatment and prevention of TB is active surveillance including community case finding and contact investigation for every active TB case detected. Current diagnostic methodologies for pulmonary TB based on sputum sample collection and subsequent analysis are difficult to implement in the community setting due to the: difficulty in collecting the sputum, the time involved in obtaining the result, or the infrastructure required to operate newer nucleic acid based methods (e.g. GeneXpert). We have recently developed two technologies that we believe can address this problem: (1) AnySource isothermal PCR system and (2) a CRISPR based diagnostic method for detecting mutations that give rise to antibiotic resistance. As we will demonstrate, our system can cut the sample-to-answer cost of nucleic acid diagnostics to below \$2/test, without loss of flexibility, for three reasons (1) It uses a single “PCR-tube” like container for sample collection, processing, amplification, and detection – reducing consumable costs, (2) It allows for flexibility in the heating source and mobile device based interpretation of results – reducing capital costs, and (3) It can be operated without reliance on external infrastructure – reducing operational costs.