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Molecular Diagnosis of Tuberculosis

Globally, there are 8 million new *Mycobacterium tuberculosis* (TB) cases and 2 million deaths per year[1]. Once infected, most individuals enter into a state of latency with no clinical manifestations and are not contagious. This state can reactivate at a later stage, particularly if the individual becomes immunocompromised. However, the remaining individuals develop an active infectious disease. Given the infectious nature of TB, accurate and early diagnosis is a critical step in its management and control.

Overall, the accuracy of nucleic acid based tests have been shown to be far superior when applied to respiratory samples as opposed to other body fluids[1]. Studies have shown that well designed in-house assays were, for pulmonary TB, much better at ruling out TB than the commercial tests evaluated[1].

Assays designed 'in-house' for TB have statistically shown no improvement associated with a range of different nucleic acid extraction methods or different end point nucleic acid detection[2]. However, the use of a nested molecular amplification was shown to be critical to sensitivity[2]. A nested molecular amplification detection assay for TB is both fast and sensitive, but culture remains crucial for assessing viability and thus infectivity[3].

At Micropathology Ltd we use an 'in-house' nested molecular amplification assay for TB that has been continually improved over the past 15 years to take into account new sequence data as it became available. This assay has consistently given excellent results in external quality assurance schemes. As a consequence we have been included in external quality assessment pilot schemes for panels before general release.

In addition, our TB assay also detects the *Mycobacterium avium* complex. We also have separate tests that can detect TB rifampicin resistance and other members of the Mycobacterium genus.

References

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