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ICMR invites licensees for commercializing TB diagnostics

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The Indian Council of Medical Research (ICMR), New Delhi is seeking companies interested in commercializing a technology on novel primers for PCR-RFLP assay for the identification of pathogenic mycobacteria. An Indian patent (No. 242073) has been granted on this technology. Interested parties may apply for license by January 31, 2013.

Accurate identification of mycobacteria at species level is very important for patient management. The present technology relates to the rapid identification of the pathogenic mycobacteria. More particularly, it relates to the development of new primers and a rapid method to identify the mycobacterial isolates at species level by gene amplification restriction analysis using primers encoding 16S-23S rDNA spacer region and flanking parts of the 16S as well as 23S rDNA.

Differentiation of mycobacteria at species level is usually done by time consuming evaluation of phenotypic and biochemical characteristics. The development of DNA probes for identification of mycobacteria has provided rapid and specific approach, but it suffer as they are expensive and have cost limitations, and limited probes are available for a few species or groups of mycobacteria. PCR sequencing of variable stretches of 16S rRNA is considered as gold standard and has been found to be very useful for identification of mycobacteria.

Salient features of the technology

- This system accurately identifies pathogenic mycobacteria by gene amplification analysis
- The assay has been validated on reference strains as well as on Indian clinical and environmental isolates from different places of country deposited in the national repository for mycobacteria
- It is used to differentiate pathogenic mycobacteria from non-pathogenic strains
- This assay allows better and easier differentiation on gels since the fragments generated from amplicons by this assay are bigger, which can be easily separated and analyzed
- Both slow growing and rapid growing mycobacteria could be well differentiated by using this technology
- Results indicated that this system is a simple, rapid and reproducible method to identify clinically relevant disease causing mycobacteria
- It is cost-effective and rapid method and found to be robust
- The technology has been developed at laboratory scale
- It can differentiate *M. tuberculosis from M. avium, M. intracellulare, M. fortuitum, M. chelonae complex, M. terrae, M. vaccae, M. kansasi, M. flavescense, and M. mrinum*

Tuberculosis (TB), is one of the most common human infectious diseases, and according to WHO, caused 1.8 million deaths in 2011. About one-third of the world's population have latent TB. Moreover, the HIV-TB co-infection is another serious problem. India, which has the highest burden of TB, accounts for more than 25% of the world's incident cases. Such cases are of particular concern because they perpetuate the continued disease transmission in the community; pose a serious risk of drug-resistant TB that leads to difficulty in its treatment, and to high TB mortality.