

## **Introduction**

One-third of the world's population is believed to be latently infected with *Mycobacterium tuberculosis*, the etiological agent of tuberculosis (TB), supported by the human immunodeficiency virus type I (HIV-1) pandemic and emerging multidrug resistance, underlines the need for new control measures and strategies to make a specific diagnosis and prevent transmission (*Dye et al, 1999*). Moreover, continued vigilance against active and latent TB is essential in industrialized countries because of the increased immigration from areas with endemic infection.

The compulsory screening of immigrant populations for TB has been proposed as a means of controlling this communicable disease (*Coker, 2004; Coker et al, 2004*) but, although the tuberculin skin test (TST) is the method of choice for detecting latent *M. tuberculosis* infection (LTBI), it cannot be considered a gold standard because of the number of false-positive and negative reactions, and the variability of their interpretation (*American Thoracic Society, 2000*). Another operational drawback of TST is the need for a return visit to allow a reading of the results, also the BCG vaccination of children commonly practiced in most parts of the world reduces its specificity.

New in vitro tests based on an ability to detect the gamma interferon (IFN- $\gamma$ ) released by activated T lymphocytes have

recently been proposed (*Pai et al, 2004*). These assays use antigens specific for *M. tuberculosis*, such as early secretory antigenic target 6 (ESAT-6) and culture filtrate protein 10 (CFP-10), which are two low-molecular-mass secretory proteins encoded by genes located within region of difference I (RD 1) of the *M. tuberculosis* genome (*Berthet et al, 1998; Sorensen et al, 1995*). This region is absent in all of the vaccine strains of BCG and in nontuberculous mycobacteria (NTM) with the exception of *M. kansasii*, *M. marinum*, and *M. szulgai* (*Mahairas et al, 1996*). These proteins and the synthetic overlapping peptides corresponding to the full length of each elicit a strong T-cell response in animal models of TB (*van Pinxteren et al, 2000*) and human with active TB infection (*Ravn et al, 2005; Wilkinson et al, 2005*) or LTBI (*Richeldi et al, 2004*).

The QuantiFERON-TB assay (Cellestis Limited, Carnegie, Victoria, Australia) and the T-SPOT TB assay (Oxford Immunotec, Oxford, United Kingdom) are two commercial IFN- $\gamma$  assays, and a number of in-house assays have also been assessed (*Andersen et al, 2000; Pai et al, 2004*).

**Aim of the work**

This work aims to study the degree of sensitivity and specificity of using IFN- $\gamma$  as QuantiFERON-TB Gold In-Tube (QFT-Gold IT) assay (Cellestis Limited, Carnegie, Victoria, Australia) in diagnosis of infected population with *Mycobacterium tuberculosis* instead of the tuberculin skin test (TST), as one of the new diagnostic methods so that it can be possible to create new control measures and strategies to make a specific diagnosis and prevent transmission.

The merits are that QFT-Gold IT test results are not affected by BCG vaccination or sensitization by most environmental mycobacteria. Results can be available as soon as one day after collecting a blood specimen. Doing a QFT-Gold IT test does not influence the results of future QFT-Gold IT tests.