

DIRECT RAPID DIAGNOSIS OF RIFAMPICIN-RESISTANT *M. TUBERCULOSIS* INFECTION IN CLINICAL SAMPLES BY LINE PROBE ASSAY (INNO LIPA RIF-TB)

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SUMMARY

M. tuberculosis is one of the leading causes of death worldwide and Multi Drug Resistant Tuberculosis (MDR-TB) is associated with a high case-fatality rate. Rapid identification of resistant strains is crucial to institute prompt appropriate therapy, and prevent the development of further resistance and spreading of MDR strains. The INNO-LiPA Rif.TB is a commercial reverse hybridisation line probe assay designed for rapid detection of *rpoB* gene mutations in clinical isolates. We applied this test directly to 44 smear-positive and 45 smear-negative clinical specimens collected from patients suspected of active TB. The capability of this technique to correctly identify local MDR-TB strains was tested on 50 MDR strains isolated in Italy. Results of the test were compared to conventional antibiogram performed on isolated strains. The concordance rate of the LiPA test results on clinical specimens with those obtained with "in vitro" sensitivity was 100%. These results show that the LiPA test can be useful in rapid detection and prompt management of tuberculosis when MDR disease is suspected.

KEY WORDS: Rifampicin resistance, *M. tuberculosis*, LiPA assay

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INTRODUCTION

Tuberculosis currently represents a global public health problem in the developing countries and in industrialized nations, and the incidence of *M. tuberculosis* strains resistant to one or more first-line drugs is also increasing (Dye *et al.*, 1999, Espinal *et al.*, 2001). Rifampicin resistance, rarely observed as monoresistance, has been proposed as a marker for MDR- *M.tuberculosis* strains (strains resistant to at least rifampicin and isoniazid) (Goble *et al.*, 1991, Mitchinson *et al.*, 1986)). Late recognition of MDR strains contributes to spreading of resistant tuberculosis and increases the mortality associated with the dis-

ease. Rifampicin resistance is due to mutation on an 86bp fragment of the *rpoB* gene encoding for the beta subunit of the RNA polymerase (Kapur *et al.*, 1994). Detection with conventional methods requires bacterial growth and results are available to the clinicians only several weeks after specimen submission to the laboratory. Different molecular techniques are now available to evaluate the presence of genomic mutations conferring resistance, but most of them require expensive equipment and technical expertise and their application is not suitable for a routine clinical micobacteriology laboratory (Soini *et al.*, 2001, Mcnerney, *et al.* 2002)) The INNOLiPA-Rif. TB is a commercial easy to