

Evaluation of Cobas Amplicor MTB Test to detect *Mycobacterium tuberculosis* in pulmonary and extrapulmonary specimens

Aydan Ozkutuk¹, Sevin Kirdar², Sevinc Ozden³, Nuran Esen⁴

¹Assis. Prof, Dokuz Eylul University Faculty of Medicine, Department of Microbiology and Clinical Microbiology, Inciralti-Izmir, Turkey;

²Department of Microbiology and Clinical Microbiology, Adnan Menderes University, Aydin, Turkey;

³Microbiology Laboratory, Kahramanmaraş Yenisehir State Hospital, Kahramanmaraş, Turkey;

⁴Assoc. Prof., Dokuz Eylul University Faculty of Medicine, Department of Microbiology and Clinical Microbiology, Inciralti-Izmir, Turkey

SUMMARY

Tuberculosis (TB) is one of the major public health problems in the world. Effective control of TB depends on rapid and correct diagnosis and appropriate treatment. The aim of this study was to evaluate the performance of Cobas Amplicor MTB (CA-MTB) test for pulmonary and extrapulmonary specimens isolated in our laboratory. A total of 424 specimens obtained from the suspected TB patients from January 2003 to August 2004 were included in this study. All specimens (173 pulmonary and 251 extrapulmonary specimens) were processed, stained, cultured and assayed using the CA-MTB test for identification of *Mycobacterium tuberculosis*. The CA-MTB test results were compared to culture and acid-fast staining as gold standard. The sensitivity, specificity, positive and negative predictive values of CA-MTB were determined as 73%, 100%, 100%, and 97% for pulmonary specimens, and 45%, 100%, 100% and 96% for extrapulmonary specimens respectively. The sensitivity of the test for acid-fast bacilli (AFB) smear positive pulmonary and extrapulmonary specimens was 92% and 75%. These results indicate that the CA-MTB is a rapid test for detection of tuberculosis in pulmonary specimens, but does not perform well enough in extrapulmonary specimens.

KEY WORDS: Cobas Amplicor MTB, *Mycobacterium tuberculosis*, PCR

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INTRODUCTION

In recent years tuberculosis has regained importance in many countries as a result of the AIDS epidemic, increased rates of immunocompromised patients and the cases of multi-drug resist-

ant tuberculosis (TB). The WHO estimates that, if control of the disease is not further strengthened between the years 2000 and 2020, nearly 1 billion people will be infected, 200 million people will develop overt disease, and 35 million will die (Levidiotou *et al.*, 2003).

The detection of mycobacteria by conventional methods is based on microscopic examination of the specimens stained with acid-fast technique combined with culture methods. Staining is the most widely used rapid method for detection of *Mycobacterium tuberculosis*, although both the sensitivity and specificity of this method are low. This technique requires about 5×10^3 - 5×10^4 bacil-

Corresponding author

Assis. Prof. Aydan Ozkutuk M.D.
Dokuz Eylul University Faculty of Medicine,
Department of Microbiology and Clinical Microbiology,
35340, Inciralti-Izmir, Turkey.
E-mail: aydan.ozkutuk@deu.edu.tr;
aydanozkutuk@hotmail.com