# Evaluation of the diagnostic performance of Anyplex MTB/NTM detection assay of Mycobacterium tuberculosis complex from patients specimens in Rajavithi hospital, Thailand

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## Abstract:

**Background:** Tuberculosis (TB) is one of the major public health problem in Thailand. Culture, conventional method, which is a gold standard for diagnosis, takes 4 to 8 weeks for confirmation. Thus, many rapid methods have been recently developed to diagnosis TB, including real-time PCR technique (molecular method). Among the new molecular platforms recently developed, the Anyplex MTB/NTM real-time detection kit warrants the detection of Mycobacterium tuberculosis complex (MTB) and non-tuberculosis (NTM) in validated specimens (sputum, bronchial washing, fresh tissue and culture). But, several types of clinical specimens, such as bronchoalveolar lavage (BAL), transbronchial needle aspiration (TBNA), Cerebrospinal fluid (CSF), vitreous, urine, bone marrow, clot marrow, pus, stool, etc. in Rajavithi hospital, were sent to Biomolecular laboratory. Thus, the aim of this study was to determine clinical sensitivity and specificity of Anyplex MTB/NTM real-time detection kit in diagnosis TB in various types of specimens.

**Objective:** To evaluate the performance of Anyplex MTB/NTM detection assay, real-time PCR technique, from patient specimens in Rajavithi hospital.

**Method:** In this study, patients samples at Rajavithi hospital from November 2017 to January 2019 were

collected and evaluated to compare the real-time PCR technique (molecular method)and culture method into 4 groups: Brochoalveolar lavage (BAL) group (N= 390), transbronchial needle aspiration (TBNA) group ( N=53), Body fluid (pleural fluid, CSF, vitreous, ascites, synovial fluid, urine, pericardial fluid (N = 126) and others ( pus, bone marrow, clot marrow, stool) group (N = 53).

**Results:** A total of 622 samples, were compared with molecular method (real-time PCR technique) and culture (gold standard method). The sensitivity, specificity and accuracy of real-time PCR were 77.5%, 96.22% and 89.5%, respectively. Positive predictive value (PPV) and negative predictive value (NPV) of this assay were 35.63% and 98.31%. We found that TBNA group and body fluid group were high sensitivity, high specificity and high accuracy (more than 80 %). For TBNA group, the sensitivity of real time PCR technique was 100%, specificity was 94.12% and accuracy was 94.34%. For body fluid group, the sensitivity, specificity and accuracy of real-time PCR technique were 80%, 95.05% and 94.44%, respectively.

**Conclusion:** These results demonstrate that real-time PCR was high specificity and high accuracy assay. Anyplex MTB/NTM detection assay is an efficient for diagnosis of tuberculosis from patient clinical specimens (TBNA and body fluid samples) in Rajavithi hospital.

## Biography

Suchada Suphanpayak has completed her B.Sc (Medical Technology) and M.Sc from Mahidol University. She is the director of Biomolecular Laboratory, Rajavithi Hospital.

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