

Development of an immunochromatographic lateral flow dipstick for the detection of *Mycobacterium tuberculosis* 16 kDa antigen (Mtb-strip)

ABSTRACT

Mycobacterium tuberculosis (Mtb) is a pathogenic bacterium that causes tuberculosis (TB). This contagious disease remains a severe health problem in the world. The disease is transmitted via inhalation of airborne droplets carrying Mtb from TB patients. Early detection of the disease is vital to prevent transmission of the infection to people in close contact with the patients. To date, there is a need of a simple, rapid, sensitive and specific diagnostic test for TB. Previous studies showed the potential of Mtb 16 kDa antigen (Ag16) in TB diagnosis. In this study, lateral flow immunoassay, also called simple strip immunoassay or immunochromatographic test (ICT) for detection of Ag16 was developed (Mtb-strip) and assessed as a potential rapid TB diagnosis method. A monoclonal antibody against Ag16 was optimized as the capturing and detection antibody on the Mtb-strip. Parameters affecting the performance of the Mtb-strip were also optimized before a complete prototype was developed. Analytical sensitivity showed that Mtb-strip was capable to detect as low as 125 ng of purified Ag16. The analytical sensitivity of Mtb-strip suggests its potential usefulness in different clinical applications.