

TITLE: EVALUATION OF LATERAL FLOW IMMUNOCHROMATOGRAPHIC ASSAY AS A SCREENING TEST FOR TUBERCULOSIS

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ABSTRACT:

In Brazil, in 2018, 72,788 new cases of Tuberculosis (TB) were registered, with a national incidence rate of 34.8 cases/100,000 inhabitants. Among the Brazilian states, Amazonas has the highest incidence rate, 72.9 cases/100,000. The tests applied for the diagnosis of TB are acid-fast smear microscopy, Rapid Molecular Test (GeneXpert MTB/RIF) and culture in solid medium, which is considered the gold standard. These tests have limitations regarding the time of release of the results, the high cost in laboratory infrastructure and/or low sensitivity. Therefore, it is necessary to overcome these limitations in order to detect the infected patients as soon as possible and initiate the treatment, thus preventing the transmission of TB. Thus, rapid lateral flow immunochromatographic assay could be used as a screening test since they dispense expensive equipment and has low cost and methodological simplicity. The purpose of this study was to evaluate the lateral flow immunochromatographic assay (*OnSite* TB IgG/IgM Combo, CTK Biotech Inc.) as a screening test for TB diagnosis in a region with a high incidence of TB. In Brazil, the test is available commercially, ANVISA register (80524900050). The individuals were divided into 3 groups: TB patients (n=47), household contacts (n=25) and healthy controls (n=11). The patients had positivity under sputum smear microscopy or Rapid Molecular Test (GeneXpert MTB/RIF) or PKO culture method or radiological evidence of TB. The household contacts were healthy relatives who lived together with patients or health professionals from a reference institution for TB. The control group was composed of health individuals with no family history of TB. The blood was collected and centrifuged for separation of the plasma. A plasma droplet and a diluent were placed into the device well and the result was read after 15 minutes. The sensitivity of immunochromatographic lateral flow test was 23.4% (only IgG). The specificity was 88.0% and 100.0% when compared to household contacts and healthy controls, respectively. It is a sensitivity lower than expected and these results suggest that is necessary further optimisation for its future use as a rapid screening test for Tuberculosis.

Keywords: Tuberculosis; immunochromatographic lateral flow assay; method diagnostic.

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