

Thesis Title The Evaluation of Diagnostic Properties and Cost-Effectiveness
of ELISA Test for Antinuclear Antibody (ANA)

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Date of Graduation 30 May BE 2538 (1995)

ABSTRACT

For detection of antinuclear antibody (ANA) for diagnosis of autoimmune disease, indirect immunofluorescent test for ANA (IFA) is generally accepted as gold standard method. However, IFA is laborious, time consuming and need specially trained personnel. The new ELISA commercial kit is proposed as an alternative method for ANA screening because of its simplicity and reasonable accuracy.

The enzyme-linked immunosorbent assay (ELISA), as commercial kit has been used to study the level of ANA in sera from 81 suspected autoimmune

disease patients with positive ANA for IFA, 42 suspected autoimmune disease patients with negative for IFA and 26 check-up patients in clinical pathology laboratory, Siriraj hospital. By IFA as the gold standard method and ELISA test as a new candidate method, sensitivity & specificity are 72.84 % and 77.94 % respectively at cut-off point of ANA concentration by ELISA test equal to 14 units / ml. Then cost-effectiveness analysis has been done between first choice : only IFA and second choice : screening with ELISA test and confirmation by IFA in case of ELISA positive result. At setting of Siriraj hospital, the cost of IFA is 6465.80 baht per 100 tests but ELISA and IFA is 17,366.75 baht per 100 tests with 7 cases missing. So at this setting no cost-effectiveness is detected. By sensitivity analysis : simulating number of setting at regional hospital, district hospital and new medical school, the new medical school is more appropriate for using this ELISA test as a screening test ,followed by IFA as confirmatory one.