

THE SPECIFICITY AND SENSITIVITY OF A NEW DIAGNOSTIC TEST, TB-ST TEST AGAINST ACTIVE TB

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PURPOSE The discovery of a new diagnostic approach of TB is a fact. TB-ST is a method that within 15 min diagnoses whether a patient has been infected by active TB or not. It is based on the detection of antibodies in the patient's blood (immunoproteins IgG, IgA, IgM). The goal of this research was to determine the clinical sensitivity and specificity of the TB-ST.

METHOD It has been compared with known laboratory diagnostic methods: Microscopy (bacterial staining due to culture of sputum smear), bacterial culture, PCR-results, chest x-ray. Totally, 322 individuals were counted, 153 had been healthy in this case infected by other contagious diseases whereas 169 of them had been infected by TB. The TB-ST test specificity and sensitivity have been measured in three research institutes. 1. USA. 25 tests to infected individuals, 100 tests to healthy donors. 2. India: the research has been conducted in Arimitsar medical college, 70 tests to infected individuals, 30 tests to healthy individuals. 3. Germany: 74 tests to patients with clinical TB symptoms (26 cases reacted negatively in microscopy), 23 tests to non-infected patients (10 cases were infected by other contagious diseases and 13 were healthy). The following ways were used: Specificity (%) = $(TN / (TN + FP)) \times 100$ TN= True Negative Test, FP = False Positive Test, Sensitivity (%) = $(TP / (TP + FN)) \times 100$ TP True Positive Test, FN False Negative Test.

RESULTS Specificity for confirmed negative TB cases: 99,3% (152 individuals out of the microscopy 153 reacted truly negatively). Sensitivity for confirmed positive TB cases: 78,1% (132 individuals out of 169 reacted truly positively). Detailed results of the microscopy and culture are not known for every tested case. 26 tests reacted microscopically negatively. Sensitivity to microscopically negative TB patients: 69,2 % (18 out of 26).

CONCLUSION The TB-ST is a reliable, secure, specific method for the diagnosis of active TB and this rapid test can accurately diagnose 69,2% of the microscopically negative TB patients.