ABSTRACT

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Title of Thesis: Comparison of subjective and instrumental evaluation of direct agglutination of anticardiolipin antibodies in the diagnosis of syphilis

Background: The thesis consisted of a theoretical summary of information about the syphilis disease and its diagnosis. Furthermore, it consisted of an experimental part, the aim of which was to compare the evaluation results of manual and instrumental performance of the nontreponemal test. The evaluation was compared in three groups of patients. The first group consisted of patients with a recent diagnosis of syphilis, the second group consisted of patients already treated for syphilis, and the third group consisted of patients with a negative test for syphilis. Another aim was to evaluate the agreement of sorting the samples into negative and positive, regardless of the antibody titer. The aim was also to evaluate the repeatability and reproducibility of the automatic RPR assessment using the AIX1000 analyzer**.**

Methods: The study was performed at the National Syphilis Reference Laboratory with samples sent for confirmation. 170 samples were included in the study, of which 50 samples were from treated patients, 20 from negative and 100 from patients with a recent diagnosis of syphilis. The VDRL method (Dialab s.r.o.) was used for manual evaluation, the AIX1000 analyzer (Gold Standard Diagnostics) was used for automatic evaluation. The repeatability test of the automatic evaluation was performed by measuring the sample in two closely consecutive runs under the same conditions. The reproducibility test was performed by measuring one sample, by different workers and on different days.

Results: A statistically significant shift ($p<0.001$) was detected in the set of all 170 samples, the titers of the instrumental evaluation showed lower values than the manual evaluation. The shift was evident in the group of treated patients ($p<0.001$) as well as patients with a

recently diagnosed syphilis ($p<0.001$). There was absolute agreement in the group of negative patients. When evaluating the negative/positive classification, regardless of the titer, a statistically significant shift was detected in the total set of samples ($p=0.006$). In the group of treated patients, the shift was noticeable, but not statistically demonstrable ($p=0.063$), in the group of negative samples there was absolute agreement, in the group of patients with a recent diagnosis, no statistically significant shift was detected ($p=0.125$). Agreement in repeatability and reproducibility assessment using AIX1000 was 100%.

Conclusions: Instrumental evaluation of non-treponemal tests showed lower titers than manual evaluation in the total sample set, in the group of treated patients and in the group of patients with recent syphilis. There was absolute agreement in the group of negative samples. The evaluation of negative/positive classification, regardless of titer, was the same in the group of negative patients and patients with a recently diagnosed syphilis. A noticeable, but not statistically significant, shift was also seen in patients already treated. The repeatability and reproducibility test of AIX1000 showed 100 % agreement. Both methods are fully usable for diagnosis, as they reflect the range of titer distribution during treatment.

Key words: syphilis, VDRL, RPR, automatic analyzer, nontreponemal tests, AIX1000