

**P1904 Investigation of relationship between false-positivity and test cut-off values in the fourth generation HIV screening test**

Tülin Demir\*<sup>1</sup>, Suleyman Yalcin<sup>2</sup>, Selcuk Kilic<sup>2</sup>

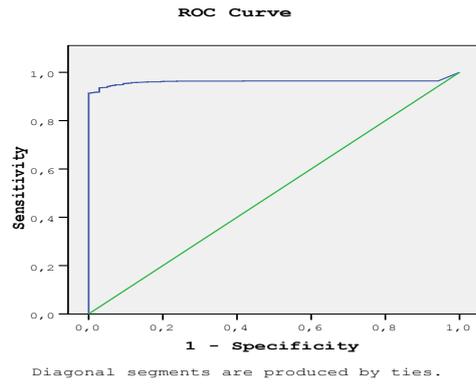
*<sup>1</sup>National Reference Center of Turkey, HIV-AIDS Confirmation Center and Viral Hepatitis Unit, ankara, Turkey, <sup>2</sup>National Reference Center of Turkey, Microbiology Department, ankara, Turkey*

**Background:** Although the 4th generation ELISA tests used for HIV diagnosis and validation have high specificity values, positive predictive value is low in populations with low HIV prevalence. In order to reduce false positivity, more specific tests should be performed in case of false positive test results. In this study, the relationship between the TV value obtained by the 4th generation ELISA test and the false positive rate was evaluated.

**Materials/Methods:** A total of 1457 serum samples with HIV screening test (VIDAS HIV Duo Ultra, bioMerieux, France) were included in the study. The values obtained by the test were recorded. The test was defined as positive by 0.24 TV. The values obtained were compared with the results of HIV confirmation tests: Geenius HIV 1/2 differentiation test, BioRad, USA. HIV RNA PCR (artus HIV-1 RNA test, Germany) and p24 antigen ELISA (VIDAS, Biomerieux) was performed to discriminate acute HIV infection. The cut-off value of the test was determined by ROC curve analysis.

**Results:** Of the 1457 samples screened with ELISA, 3.7% of the samples positive for HIV p24 antigen, 96.2% (n=1402) were positive for HIV antibody. In two samples both HIV ag and ab reactivity were detected. Serum samples with repeated reactivity was tested by the Geenius and 1259 (86.4%) were HIV1 positive and 12 (0.8%) were indeterminate. HIV RNA was positive in 58 out of 197 negative or indeterminate samples detected with Geenius and considered as acute HIV infection. When all the tests were evaluated together, 1318 (90.5%) were HIV1 positive and 139 (9.5%) samples were false negative. False negative rate decreased as TV value increased. The optimal TV cut-off value was 2.65 when the cut-off was accepted as 2.65, the sensitivity was 99.1% and specificity was 99%. No false positive test results were observed below the value.

**Conclusions:** It was determined that as the TV value increased, false positives decreased and values below 2.65 TV did not cause false positive results with 99% sensitivity and specificity values. We believe that the determination of cut-off values by similar studies with other more widely used automated ELISA devices is a requirement especially for communities with low HIV prevalence.



Area under curve:0.996 (CI 95%: 0.994-0.998; P=0.001)