Background: Screening for HIV using fourth-generation HIV Ag/Ab Combo assays has reduced window period significantly due to high sensitivity. However, the specificity varies between 99.5% and 99.97%. Therefore false positive results are common in population with low prevalence of HIV infection. This study aims to determine the occurrence of false positive results in our Laboratory.

Materials/methods: This is a retrospective analysis of the results of HIV infection screening during 2015-2018 in Hippokratio General Hospital of Thessaloniki. Serum samples were measured using Architect HIV Ag/Ab Combo assay in Architect i2000 (Abbott Laboratories). Specimens with signal to cutoff (S/CO) values less than 1.00 were considered nonreactive. All specimens with S/CO ratio greater than or equal to 1.00, even those with intermediate results, were reanalyzed in duplicate. Repeatedly reactive specimens were confirmed at National AIDS Reference Centre of Northern Greece Medical School Aristotle University of Thessaloniki, Greece.

Results: A total of 50,450 test results were evaluated. 92 were found repeatedly reactive (0.182%). Among them 41 were positives, while 51 were false positives. The S/CO values of true positive results ranged between 31.95-1368.65 whereas S/CO values of false positives ranged between 1.01-16.48. In the majority of false positive results S/CO ranged between 1.01-2.5. Positive Predictive Value (PPV) was 44.5%. False-positive reactions in HIV immunoassays are associated with many medical conditions such as autoimmune disease, liver disease, infections, transfusions, hemodialysis, vaccinations and pregnancy. In our review 14 reactive results occurred to pregnant women, however 12 of them were false-positives.

Conclusions: Since laboratories are using fourth generation immunoassays to screen HIV, false positive results have become more of a concern, as they could cause psychological stress. HIV Ag/Ab Combo immunoassays have higher analytical sensitivity leading to lower diagnostic specificity than other immunoassays. The choice remains between eliminating all false negative results or accepting false positives. In our opinion high sensitivity is desirable for early detection and should be a priority for Hospital Laboratories. Samples with reactive results must be sent for verification to Reference Laboratories. However, each Laboratory must establish the best policy while informing patients and physicians for reactive HIV results, to prevent unnecessary distress.