

## False positive results in a fourth-generation human immune deficiency virus (HIV) 1-2 screening test among blood donors with low intake levels of biotin and associated mycotic infections

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Although 4<sup>th</sup> generation Combitests for detection of antibodies and viral antigens have surely shortened the window period in the serodiagnosis of HIV infection, an increasing percentage of false positive samples have been reported especially in subjects with high doses of biotin intake (i.e. > 5 mg/day) or ongoing mycotic or viral infection. Aim of this study was to evaluate prevalence of such interference within a group of blood donors and compare specificity of Combi test with HIV 1-2 Vitros chemiluminescence test (CIA) (Ortho Clinical Diagnostics).

5,923 blood donors (4,675 males and 1,248 females, median age: 41.5), collected from January 2010 to November 2012, were tested for the presence of anti-HIV 1/2 using HIV Ag/Ab Combi test (Roche Diagnostics). Repeatedly reactive samples were then tested using a secondary screening test, Vitros HIV-1-2 assay (Ortho Clinical Diagnostic) and a confirmatory test as RIBA HIV 1/2 (Ortho Clinical Diagnostics). Reactive samples were also tested with CobasAmpliPrep/TaqMan HIV-1 assay (Roche Diagnostics).

Of 5923 blood donors, only 22 (0,4 %) were repeatedly HIV 1/2 positive, with a S/Co ratio between 1 and 6.5. Of them, 21 (95.4%) showed no reactivity if tested with VitrosECi HIV 1-2 test and RIBA HIV1/HIV 2 and were also HIV 1-RNA negative. By the analysis of donation forms, we noticed in 12/19 (63.1%) presence of chronic fungal infections and in 17/19 (89.5%) daily intake of biotin at lower levels than 2.0 mg.

These data clearly show biotin intake at concentrations below those indicated by the test (5 mg) or concomitant mycotic infections may be interfering factor in the Elecsys HIV 1/2 Combi test.

### Biography

Arnolfo Petruzzello has completed his Ph.D. in Cellular and Molecular Biology at the age of 25 years at University of Naples "Federico II" where also obtained, 4 years later, his postdoctoral degree in Microbiology and Virology. He is actually head of Laboratory of Diagnostic Virology and Molecular Biology "V. Tridente" at National Cancer Institute - Fondazione G. Pascale- IRCCS Italia, Naples and Professor in Clinical Microbiology. He obtained bachelor's degree in Biomedical Laboratory Techniques, University of Naples. He has published several papers in reputed journals and was speaker in numerous conferences, seminars, and refresher courses. He is also keynote speaker of several thesis in Molecular Diagnosis and Biology at Faculty of Mathematical, Physical and Natural Sciences, University of Naples "Federico II".

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