

# Evaluation of the effectiveness of serological and molecular tests for determination of HIV infection duration

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**Background.** The time passed since the infection is an important epidemiological and prognostic indicator but often is undefined. Recent Infection Testing Algorithm (RITA) is an approach based on laboratory methods that allow to differentiate recent and established HIV infection. Laboratory tests include detection of antibody titer, avidity index (AI), viral load (VL), and CD4 cell count. Recent infection is defined as the period during the first 6-12 months after infection, depending on the diagnostic tests used. Today, knowledge of molecular biology of the virus gives an opportunity to estimate the time period after infection using the additional technique. The proportion of variable positions in HIV genome can be used as a marker of the duration of infection because the heterogeneity of the viral population in the human organism increases with time. Detection of the number of variable positions by virus genome sequencing can be successfully used in practice to evaluate a recent infection. The aim of this study was to develop and assess the effectiveness of serological and molecular tests for the determination of HIV infection duration.

**Materials & Methods.** Plasma samples (n=91) was obtained from ARV-naïve HIV patients: 34 samples from patients with infection duration up to 6 months (recent infection samples) and 57 samples from patients with duration more than 9 months (established infection samples). The duration of infection was determined by epidemiological and clinical data and indicators of seroconversion. Antibody avidity was estimated by DS-ELISA-HIV-Ab-Time kit (Diagnostic Systems, Russia) and Architect HIV Ag/Ab Combo kit (Abbott, USA). Nucleotide sequences of *pol* region including protease gene and fragment of reverse transcriptase gene (according to HXB2, positions 2052-3345) were obtained using AmpliSens HIV-Resist-Seq kit (CRIE, Russia).

**Results.** According to RITA on the first step, all samples were analyzed by the antibody avidity assays. The concurrence of DS-ELISA-HIV-Ab-Time results and Architect HIV Ag/Ab Combo results and epidemiological data are presented in Table 1. The concordance of two tests was 82.4% (28/34) for recent infection samples and 80.7% (46/57) for established infection samples. Next, the sequencing of *pol* region was done. The reliable differences in a quota of variable positions in sequences were found in comparing of patients with infection duration less 6 months and more than 9 months (0.26% vs 0.37%). There was no significant difference between groups in CD4 cell count, but VL in the early stages of infection (up to 6 months) was significantly higher than in the later period (mean  $1.9 \times 10^5$  vs  $3.6 \times 10^4$  copies/ml).

Group	Total number of samples	Valid results	
		DS-ELISA-HIV-Ab-Time	Architect HIV Ag/Ab Combo
Recent infection	34	23 (67.6%)	25 (73.5%)
Established infection	57	54 (94.7%)	43 (75.4%)

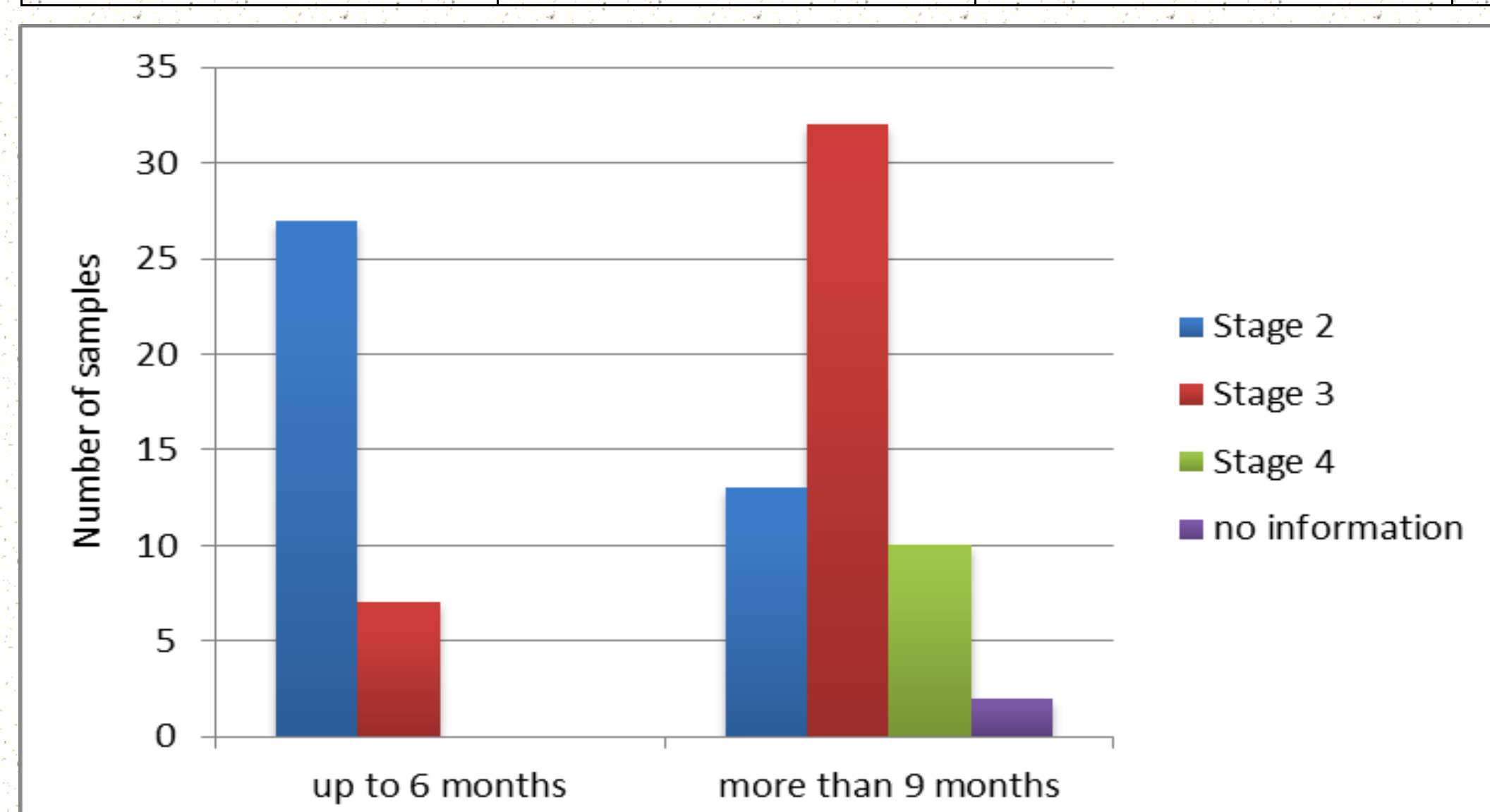


Table 1. Results of the correct identification of samples according to epidemiological data.

Fig.1. Distribution of samples by stages of infection.

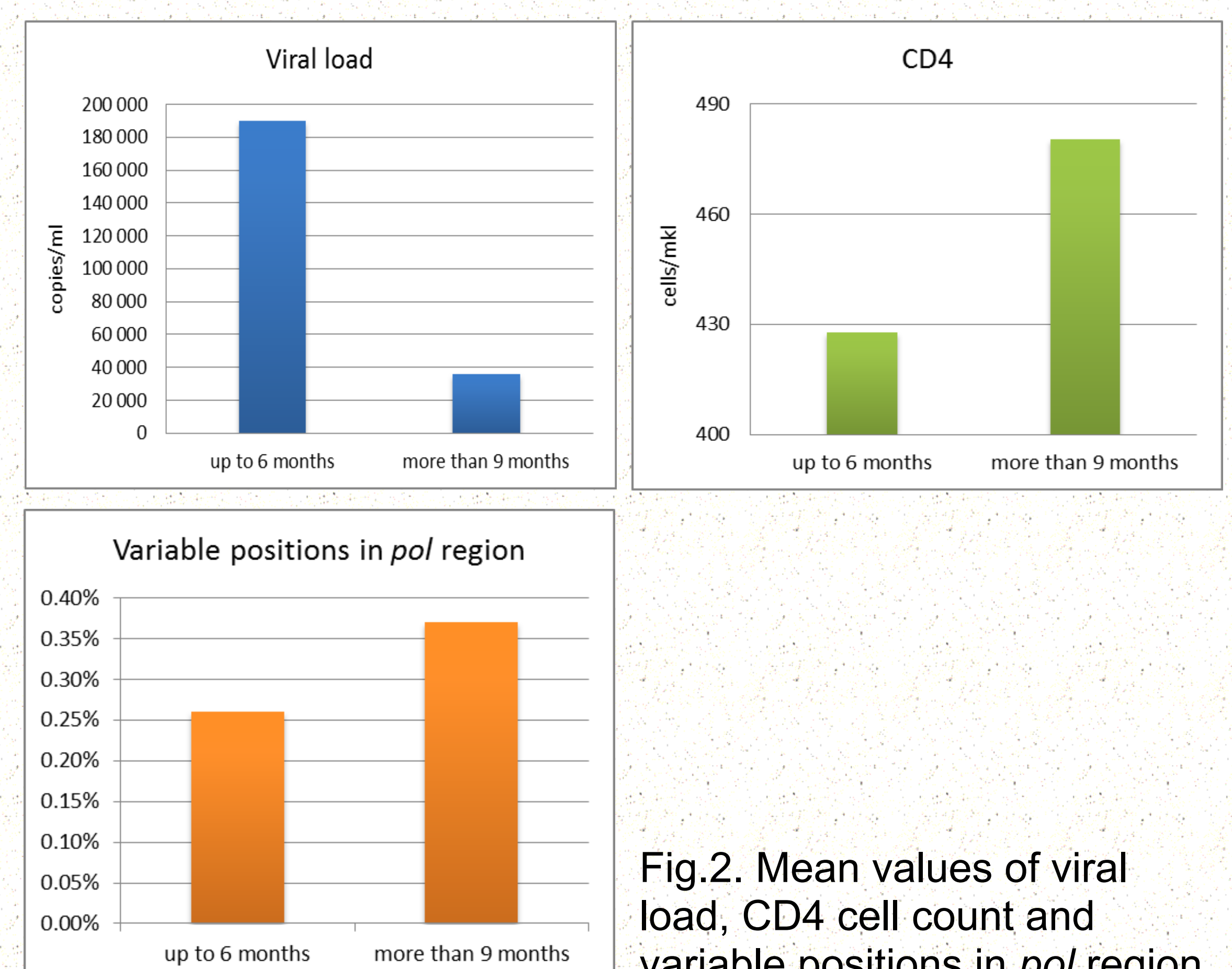


Fig.2. Mean values of viral load, CD4 cell count and variable positions in *pol* region.

**Conclusions.** Study results showed that serological tests (DS and Abbott) correctly identified the duration of HIV infection in 84.6% and 74.7% of clinical samples respectively. It was also found that cohorts of patients with recent and established HIV infection differ in viral load and degree of heterogeneity of the viral population. The inclusion of these laboratory parameters in the diagnostic algorithm will increase the accuracy of determining the recent HIV infection.