



## The effectiveness of the application of serological tests and laboratory indicators as part of RITA for the detection of recent HIV infection

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### Background

Estimation of HIV incidence and detecting recent HIV infections in a population are important for monitoring, rapid initiation of treatment, plan and implement prevention activities. The accurate identification of recent HIV infection continues to be an important research area. Recent infection is defined as the period during the first 6-12 months after infection. Today there is no gold standard method to accurately define the time passed since infection, but already there are a number of kits that allow determining the approximate time of HIV infection. However, concerns about the accuracy of incidence estimates derived from using single tests have arisen and can be addressed by combining multiple assays in a recent infection testing algorithm (RITA). RITA is an approach that allows for differentiating recent and established HIV infection. Laboratory tests include detection of antibody titer, avidity index (AI), viral load (VL), and CD4-count. The aim of this study was to assess the sensitivity (correct detection of recent infection) and accuracy (correct detection of the duration of all samples in accordance with the epidemiological data) of this algorithm for the determination of HIV infection duration.

### Materials & Methods

Plasma samples (n=311) were obtained from ARV-naïve HIV patients: 185 samples from patients with infection duration up to 12 months (recent infection samples) and 126 samples from patients with duration more than 12 months (established infection samples). The duration of infection was determined on the last negative and first positive ELISA and immunoblot tests (indicators of seroconversion), by epidemiological and clinical data. Determination of antibody titers was carried out with DS-EIA-HIV-Ab-TERM kit (Diagnostic Systems, Russia) and antibody avidity was estimated by Architect HIV Ag/Ab Combo kit (Abbott, USA). Nucleotide sequences of *pol* region fragment (according to HXB2, positions 2052-3345) were obtained using AmpliSens HIV-Resist-Seq kit (CRIE, Russia). Viral subtype was determined using the HIVdb Program v. 8.9-1 (Fig.1).

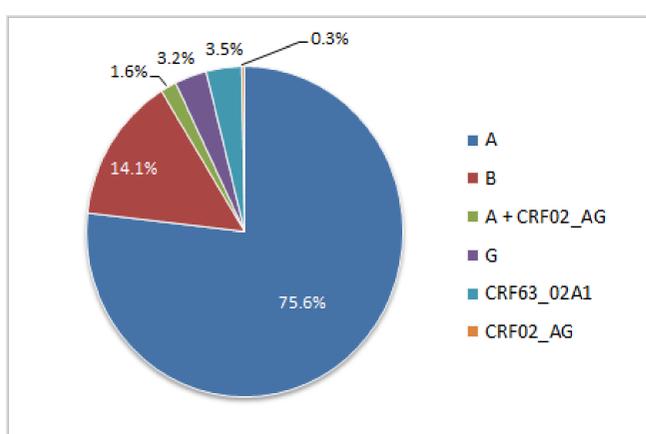


Fig.1. Distribution of samples by HIV subtype.

### Results

In the first step, all samples were analyzed by the antibody avidity and sensitive-less sensitive assays. The concordance of DS-EIA-HIV-Ab-TERM results and epidemiological data were obtained for 290/311 (93.2%) of all samples. The concurrence data for Architect HIV Ag/Ab Combo were 241/308 (78.2%) respectively (three samples had an invalid result). For using RITA in addition to serologic assays the following criteria have been defined for recent infection: viral load > 75 copies/ml; CD4-count > 200 cells/mm<sup>3</sup>; the absence AIDS-defining illness. Further, we had to establish a threshold for determining recent HIV-infection. According to WHO recommendations, this rate can range from 6 to 12 months, and it should also be calibrated and determined for each country (study or cohort) individually. In our case, the maximum values of sensitivity and accuracy of the algorithm were achieved at a threshold of 9 months: sensitivity was 67.4%, accuracy 79.7%. Moreover, these indicators were equal to 70.0% and 81.1% for subtype A, and 47.6% and 69.4% for subtype B respectively. Further analysis showed that the threshold of 6 months gives better results for detecting recent infection (Table 1).

	Threshold 9 months			Threshold 6 months		
	Total	Subtype A	Subtype B	Total	Subtype A	Subtype B
Sensitivity	67.4%	70.0%	47.6%	77.6%	78.5%	64.3%
Accuracy	79.7%	81.1%	69.4%	81.0%	79.8%	83.3%

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

### Conclusions

Study results showed that serological tests (DS and Abbott) correctly identified the duration of HIV infection in 93.2% and 78.2% respectively. If we consider RITA as a whole, then the results for subtypes A and B are extremely different, which is an important fact because subtype A predominates in the Russian Federation. Therefore, the algorithm requires further refinement and calibration and validation as recommended by WHO.

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