The evaluation of two HIV-1 incidence assays in subjects infected with non-B subtype viruses

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Background

Two most frequently used HIV incidence assays with mean duration of recency (MDR) in subtype B are:

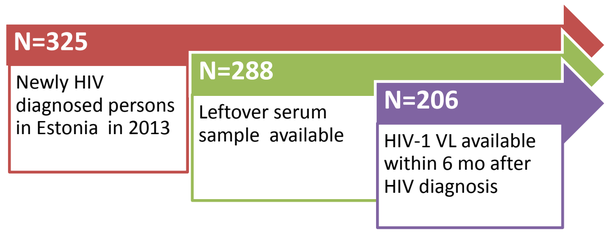
- Sedia HIV-1 LAg-Avidity EIA (LAg) with 130 days
- Bio-Rad avidity incidence assay (BRAI) with 240 days

Limited information of the performance of these assays in subjects infected with HIV recombinant forms exists.

Objective

- **To describe the performance of two incidence assays in the population infected mainly with the CRF06_cpx viruses.**
- **Hypothesis: if the discrepancy between two assays is due to differences in MDR only, then**
  (i) all recent infections determined by LAg are recent by BRAI, and
  (ii) all LT infections by BRAI are LT by Lag.

Material and Methods



Sample collection: Estonian HIV reference laboratory
Data collection: Estonian Health Board, Estonian HIV cohort study, and hospitals' laboratory databases
LAg recent: normalised optical density ≤ 1.5
BRAI recent: avidity index ≤ 30%
Clinical parameters: presenting with AIDS and HIV-1 viral load within 6 mo after HIV diagnosis

Proxy for recency: CD4+ T cell count
Final LT/recent: classified LT/recent based on the results of assay and considering clinical parameters

Results

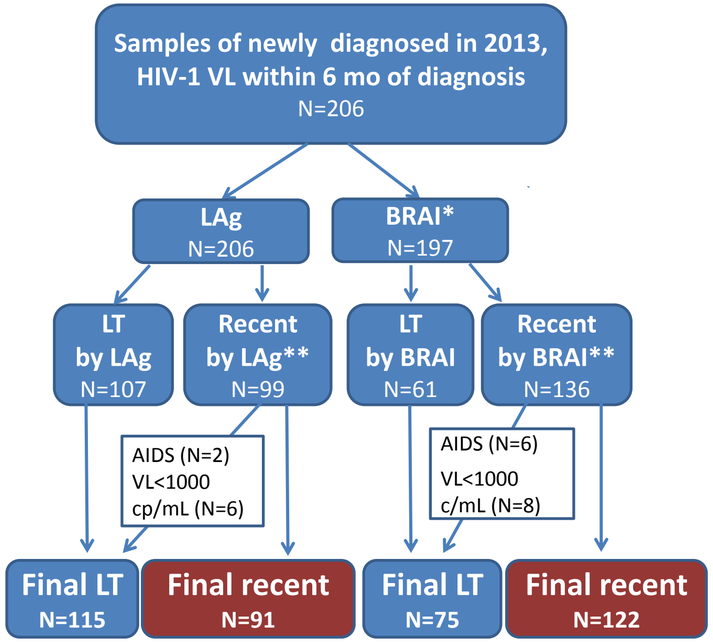


Figure 1. The work-flow of final recency classification. Note. *9 samples were unavailable for BRAI testing; **Pending results were considered as recent

The characteristics of study population:
Subtype: 87% CRF06_cpx or URFs
Median HIV-1 VL: 5 (IQR: 4.4-5.6) $\log_{10}$ cp/mL
Median CD4+ T cells: 360 (IQR: 208-526) cells/µl
Presenting with AIDS: 2% (N=6)
All 5 known recently infected persons were classified recent by both assays.

Table 1. The total recency rates of LAg and BRAI	Recency rates % (95% CI)	
	LAg	BRAI
Assay *only* (N=288)	**44** (39-50)	**70** (64-75)
Final classification (N=206)	**44** (37-51)	**61** (54-68)

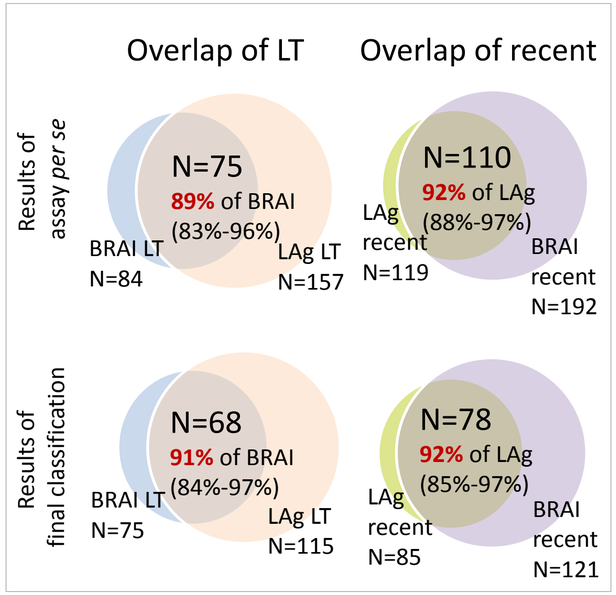


Figure 2. The overlaps between the assays according to the hypothesis. Note. Light blue – LT by BRAI; light orange – LT by LAg; light green – recent by LAg; light purple – recent by BRAI

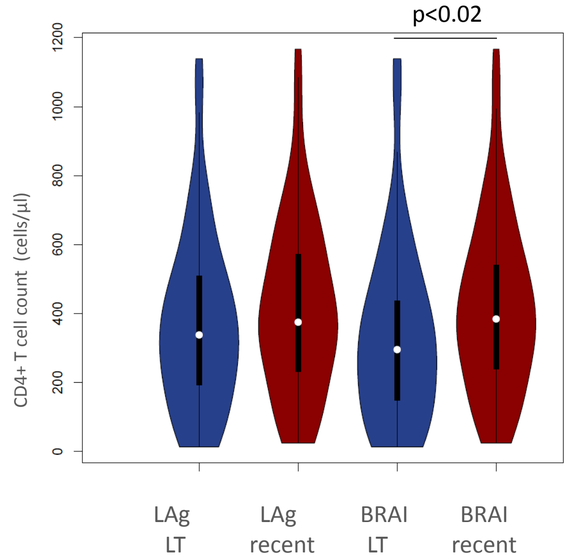


Figure 3. The distribution of CD4+ T cell counts between recent and LT infection by LAg and BRAI. Note. The violin plots include the medians (dots), 25th and 75th percentiles in the box plot format.

Conclusions

- **Despite, the high overlap of recency between LAg and BRAI, near 10% of persons classified as recent by LAg were not recent by BRAI indicating that the difference in MDR is not the only factor explaining the discrepancy in the performance of these assays.**
- **Using CD4+ T cell count as a proxy, our results indicate that BRAI with MDR of 240 days might distinguish recent and LT infection better in our population than LAg with MDR of 130 days.**

Abbreviations. BRAI – Bio-Rad avidity incidence assay; CI – confidence intervals; IDU – intravenous drug use; IQR – interquartile range; LAg – Sedia HIV-1 LAg-Avidity EIA ; MDR – mean duration of recency; VL – viral load

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