

## SMARTube as a Test for Recent Infection

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**Objective:** Tests for recent HIV infection have traditionally been based on antibody avidity, proportion or titre. High false recent rates ( $\epsilon$ ) or low recency durations ( $\omega$ ) tend to hinder incidence estimation. In vitro stimulation of HIV-antibody production by SMARTube™ technology, which declines with time after seroconversion, suggests a novel biomarker for recent infection: namely a stimulation index (SI) defined as the ratio of stimulated to unstimulated ODn obtained by a conventional titre assay. We investigate the performance of a test for recent infection based on an SI threshold.

**Methods:** Using maximum likelihood analysis, we tested  $H_0: \epsilon = 5\%$  vs  $H_1: \epsilon > 5\%$  and  $H_0: \omega = 155$  days vs  $H_1: \omega < 155$  days (assuming infection events are uniformly distributed over an interval of at least two years preceding the survey). Rejecting either Null Hypothesis would imply little performance gain, relative to available recent infection tests such as those based on the BED assay. Data collected by the CDC in China were used, in populations infected for over a year for testing  $\epsilon$  ( $n = 70$  and  $n = 101$  using Wantai and Abbott kits respectively), and in a survey of a high-incidence population ( $n = 57$  using Wantai) for testing  $\omega$ .

**Results:** At an SI threshold of 1.2, we fail to reject  $H_0: \epsilon = 5\%$  with p-values of 0.51 and 0.97 for Wantai and Abbott respectively. Increasing the threshold has the advantage of decreasing  $\epsilon$  and the disadvantage of decreasing  $\omega$ . Even at a higher threshold of 1.4, conservatively assuming  $\epsilon = 5\%$ , we fail to reject  $H_0: \omega = 155$  days with a p-value of at least 0.44.

**Conclusion:** A recency test based on SMARTube™ technology may attain a low false recent rate and adequate recency duration. These encouraging results support further investigation, and suggest a fundamentally new type of biomarker for constructing recent infection tests.