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New HIV peptide-based immunoassay resolves vaccine-induced seropositivity in HIV vaccine (Phase III) trial participants

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Background

HIV Vaccine trials bring the significant risk of vaccine-induced HIV seropositivity(VISP) resulting in negative personal consequences for vaccinees. The overall rate of VISP in licensed EIA tests is reported as 41.7%(JAMA 2010;304:275-283). We have developed and modified the peptide-based HIV Selectest immunoassay(J.Virol 2006;80:2092-2099), which discriminates VISP from true HIV infection, in a format suitable for routine laboratory use, and have evaluated its performance on samples from three Phase III HIV vaccine trials.

Methods

The HIV Selectest incorporated five synthetic peptides in a single well microplate ELISA. Serum panels evaluated comprised well-characterized HIV-positive sera from clades A,B and C, worldwide panels comprising all major clades, blood donor controls, and sera from vaccine and placebo recipients in RV144, Vax003 and Vax004 trials.

Results

360 serum samples from the RV144 vaccine trial, including 170 samples from vaccinated subjects at the peak immune response, 120 pre-immune samples, and 70 subjects from the placebo group were tested on the HIV Selectest. One (1) subject(0.6%) among the vaccine recipient group yielded false-positive results, while 3 placebo recipients (4.3%) and 1 pre-immune serum sample (0.8%) were also false positive in the HIV Selectest. All false-positive samples demonstrated broad non-specific cross-reactivity that was not restricted to a particular HIV-specific peptide.

Similar results were obtained with samples from the VAX003 and VAX004 vaccine trials. One subject out of 87(1.2%) tested after the final vaccination(7^{th}visit) at the peak of the immune response was detected as false positive. Two additional samples out of 96(2.1%) taken after the 4^{th}visit were likewise detected as false-positive, bringing the average false-positive rate for both groups to 1.6%.

Blood donors yielded a statistically equivalent false-positive rate of 1.2%. Detection sensitivity for HIV positive samples was 96% among 648 serum samples representing different clades.

Conclusion

The HIV Selectest ELISA has demonstrated significantly better discrimination of VISP than currently licensed HIV serologic assays.

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