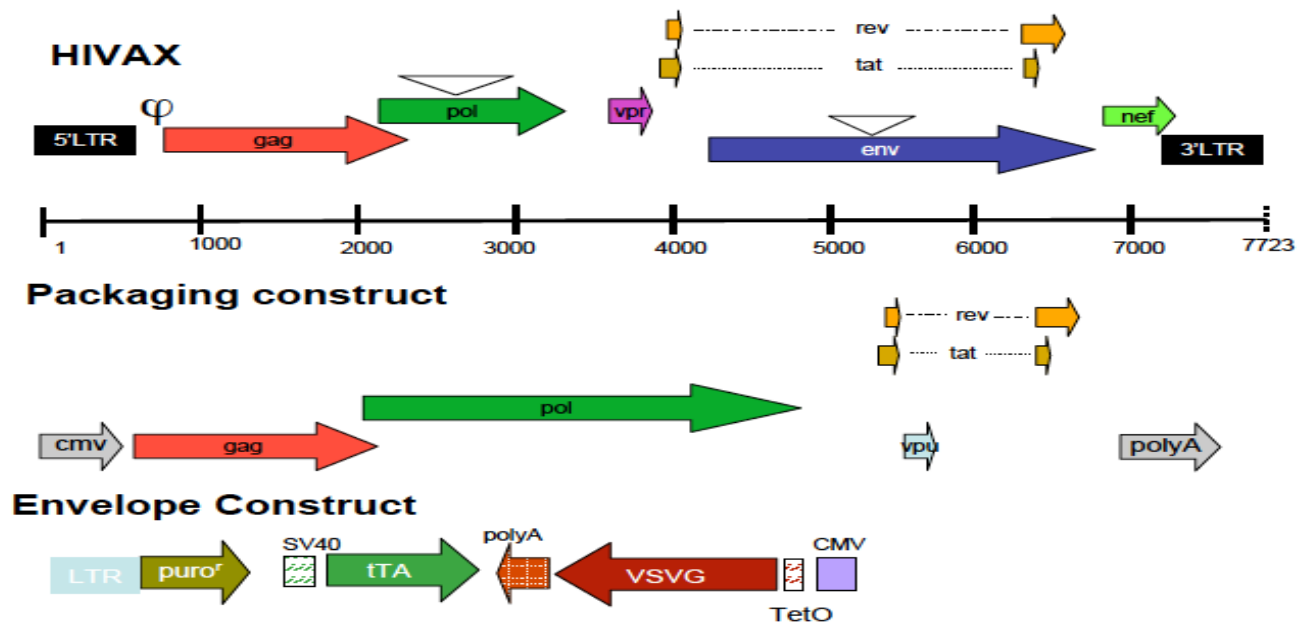


A Novel Therapeutic HIV-1 Vaccine Trial in Patients under HAART

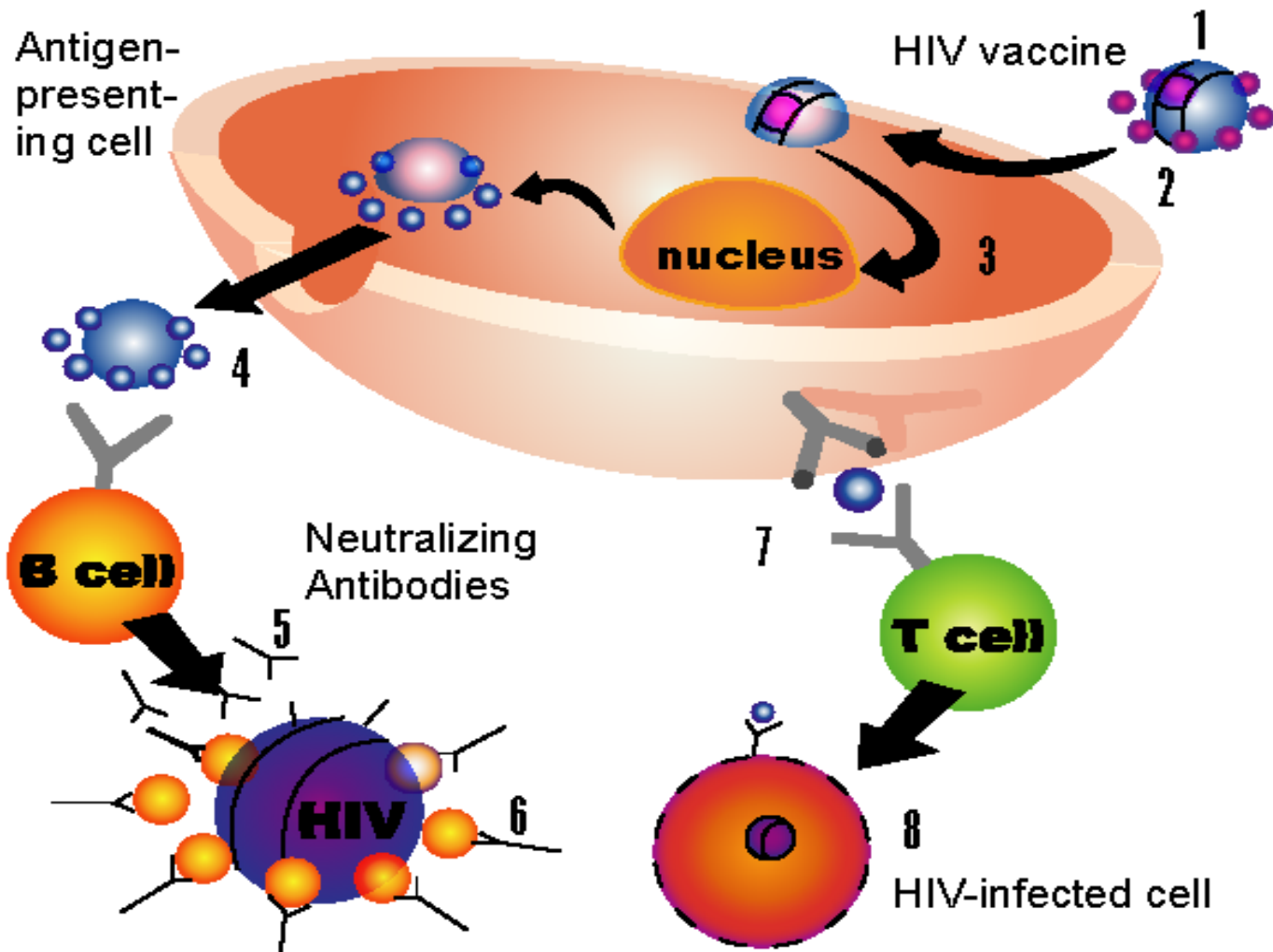


HIVAX vaccine design

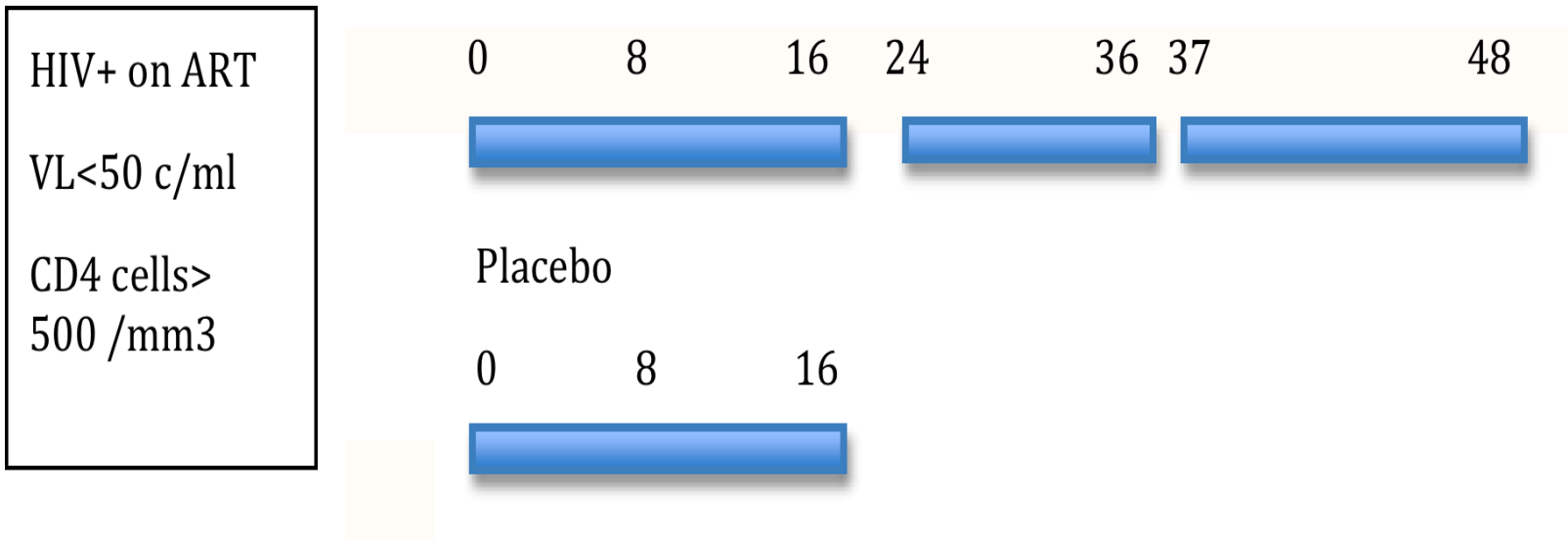
Replication Defective HIV



How HIVAX works:



Study Design



Baseline characteristics of participants at study entry

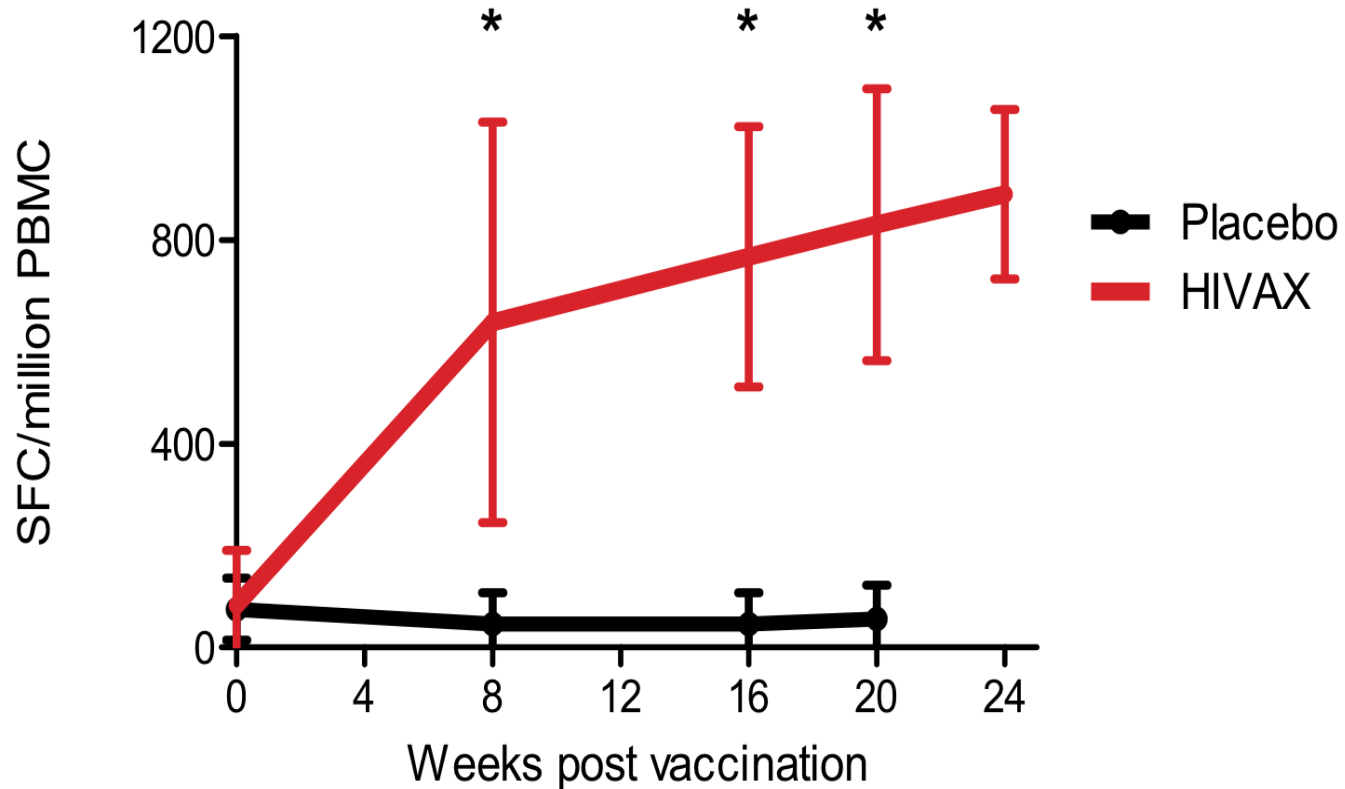
	Vaccine recipients (n=10)	Placebo recipients (n=5)
Age, median, years	46	42
Male, % of subjects	80	60
Race, % subjects		
White, non-Hispanic	0	0
Black, non-Hispanic	20	20
Hispanic	80	80
Nadir CD4 cell count, median, cell/mm ³	371	292
Pre-ART HIV-1 RNA level, median, copies/ml	23,238	38,227

Note. ART, antiretroviral therapy

HIVAX was well tolerated in vaccinated patients

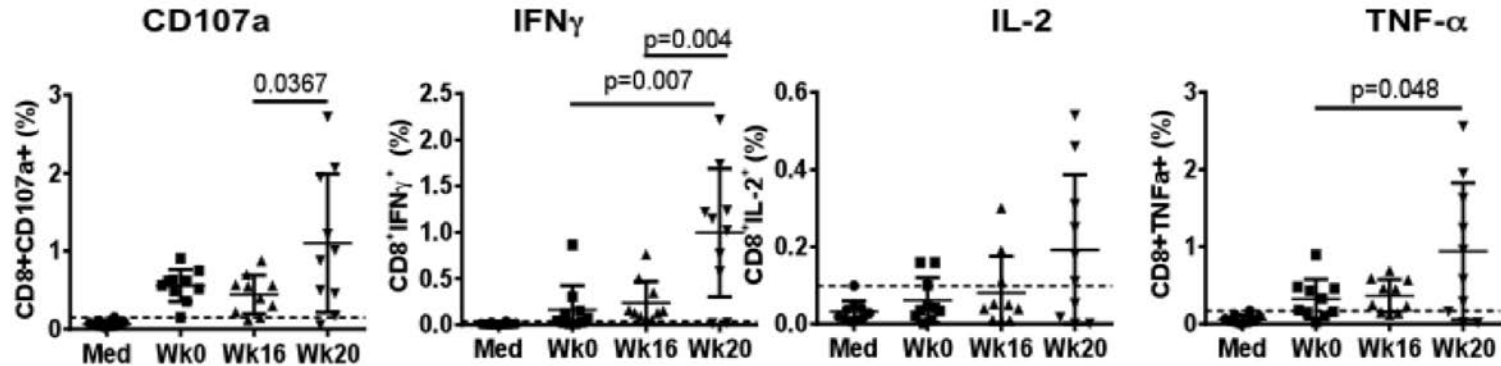
- Side Effects (grade 1 or 2): Vaccinated, 8 of 10; Placebo, 1 of 5
- Transient Injection side reactions
- Normal hematology and chemistry
- No medical treatment needed

Elispot responses increase during vaccination phase

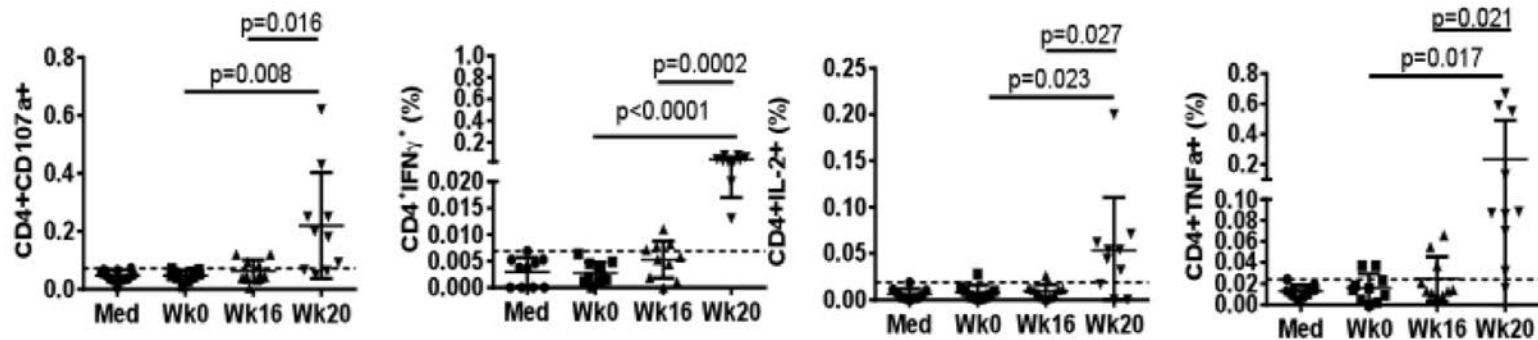


Gag specific CD4/CD8 cell function increased over vaccination phase by ICS assay

A. CD8 T cell function

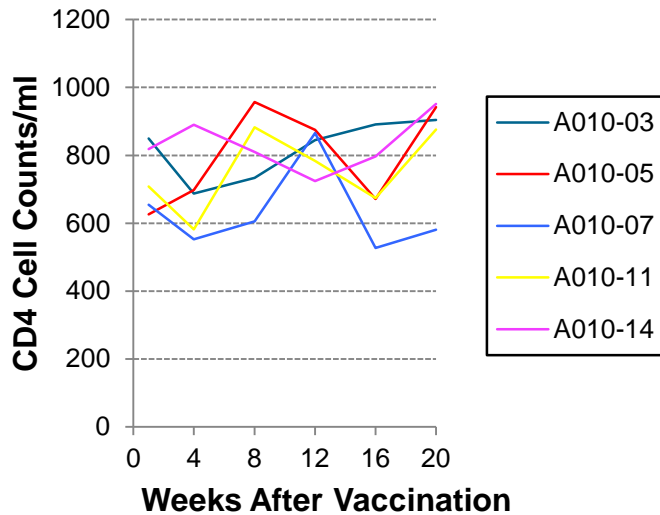


B. CD4 T cell function

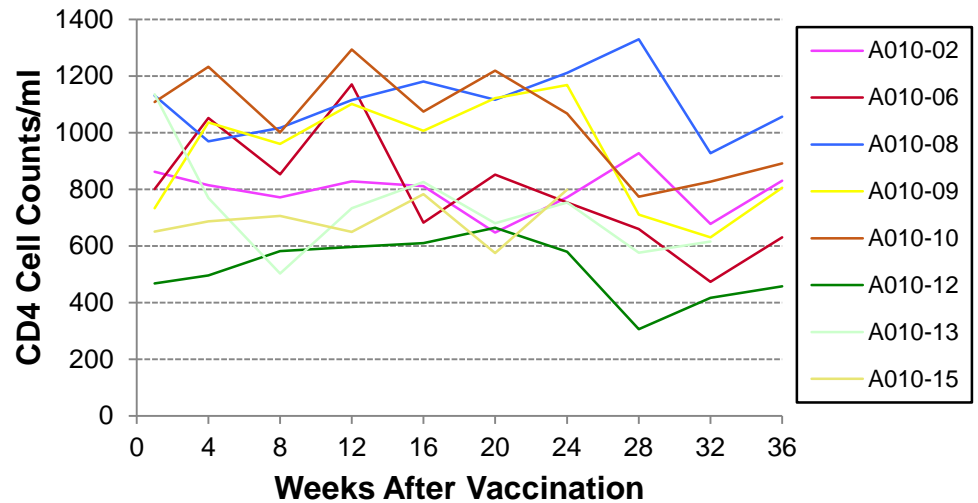


CD4 Cell Counts remain stable after vaccination

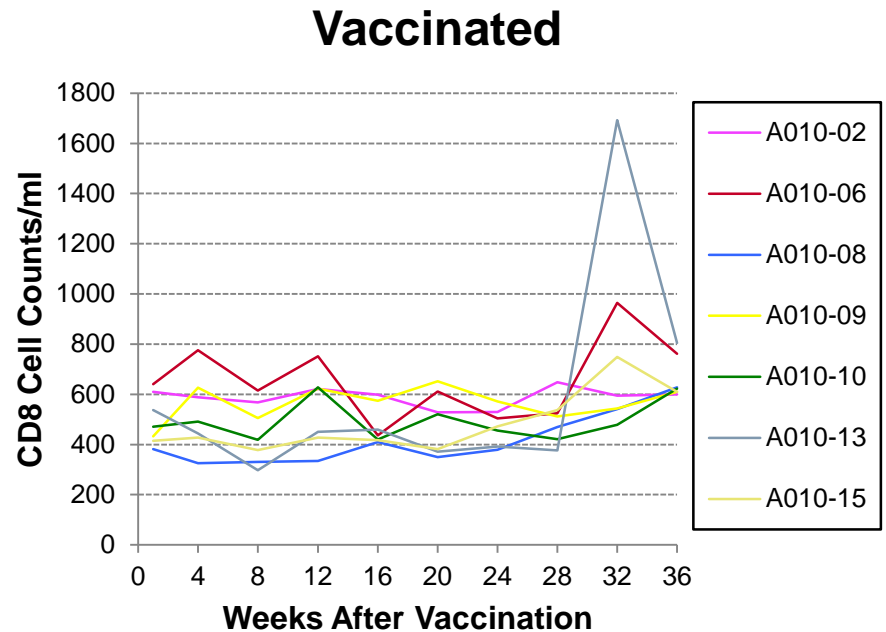
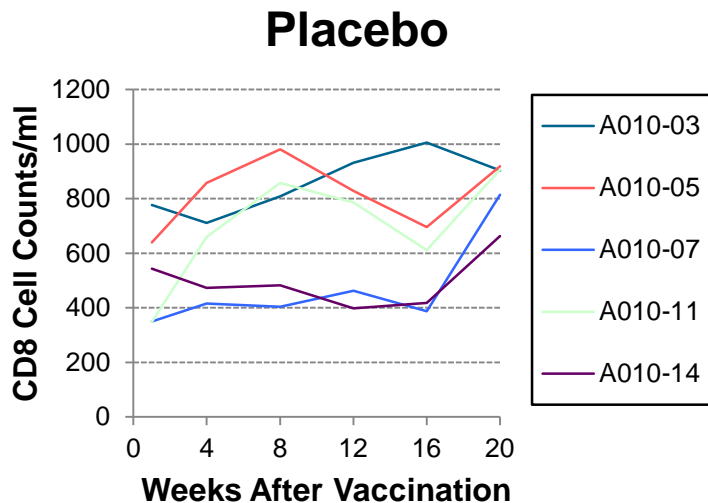
Placebo



Vaccinated

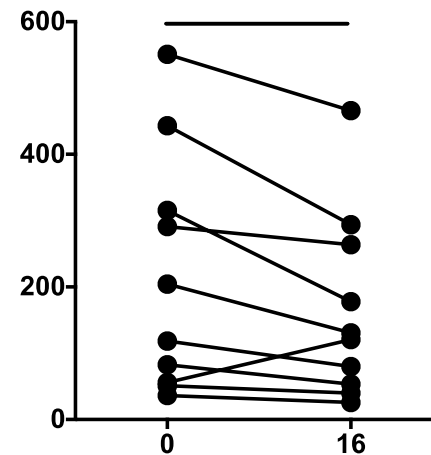
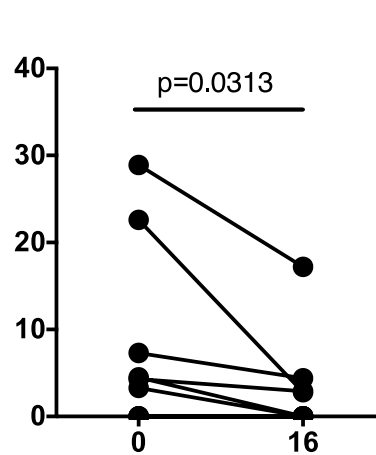


CD8 Cell Counts remain stable after vaccination

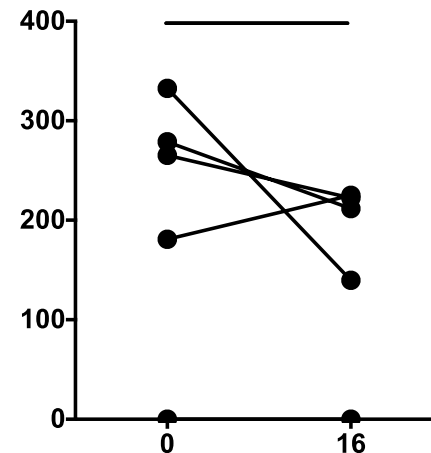
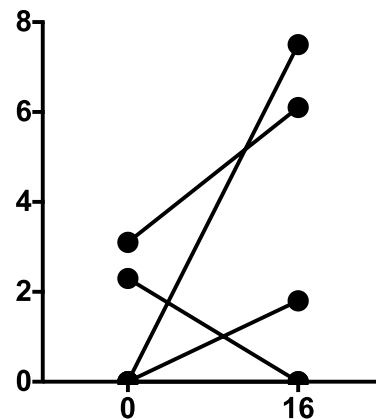


2-LTR and genomic HIV DNA decreased after vaccination

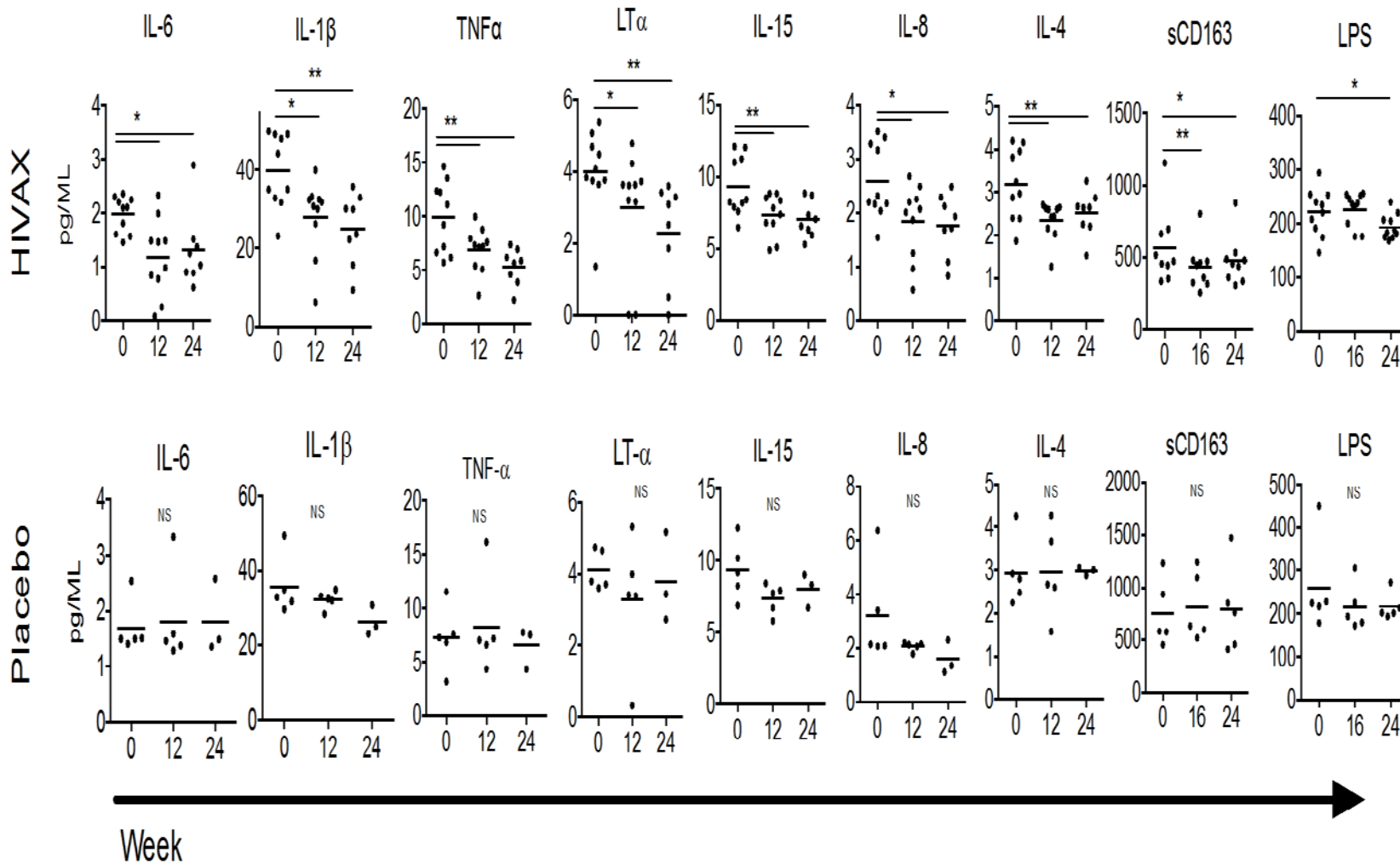
HIVAX



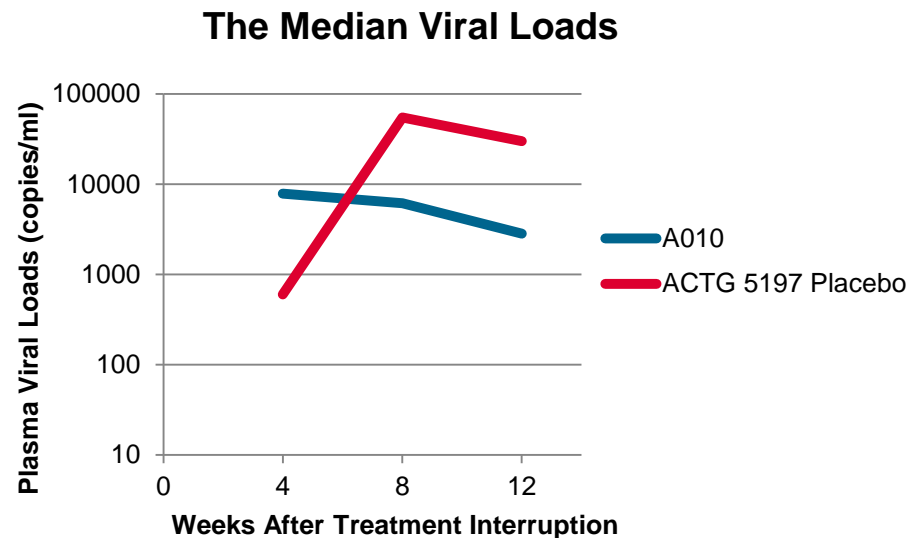
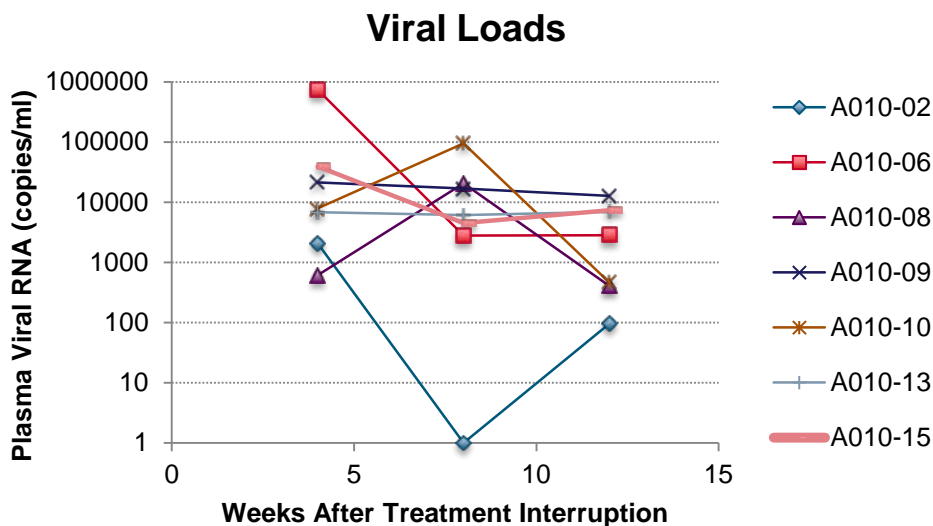
Placebo



Inflammatory cytokines reduced after vaccination




Viral load after treatment interruption is lower than historical placebo





Summary

- HIVAX is well tolerated in HIV infected subjects
 - High level of cell-mediated immune response was elicited in all vaccinees
 - Viral reservoir reduced after vaccination
 - CD4 cell count maintained as pre-vaccination
 - HIVAX is effective in control of viral load during ATI
- 



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 - Trial participants
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