

Figure 1
Principle of the Test: Simultaneous Detection of HIV Ag and Ab

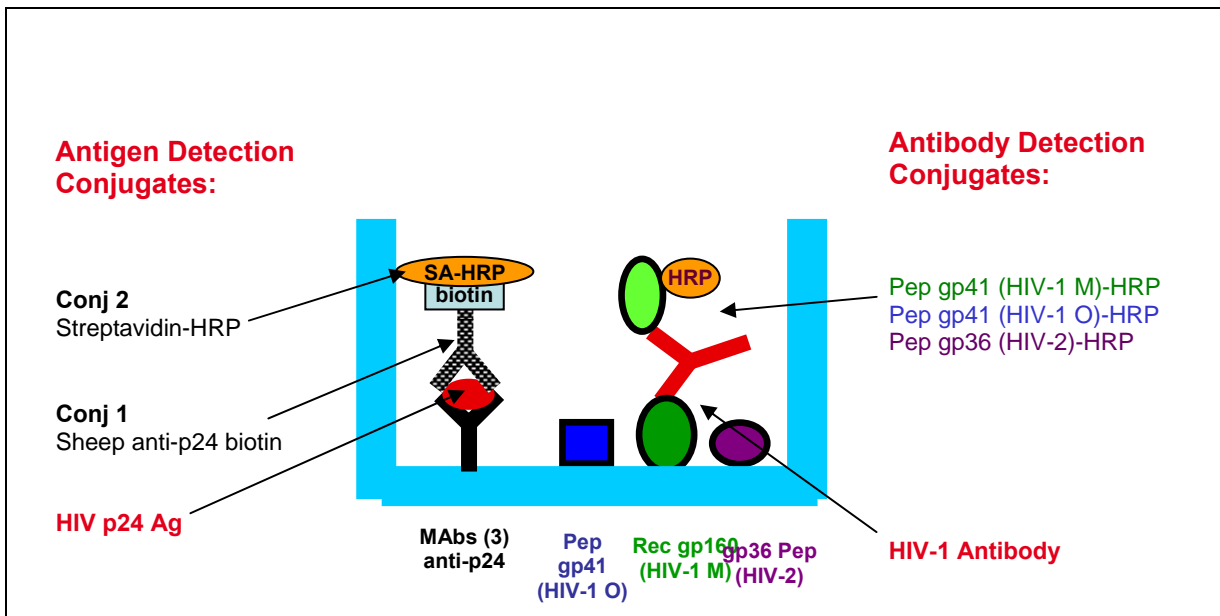
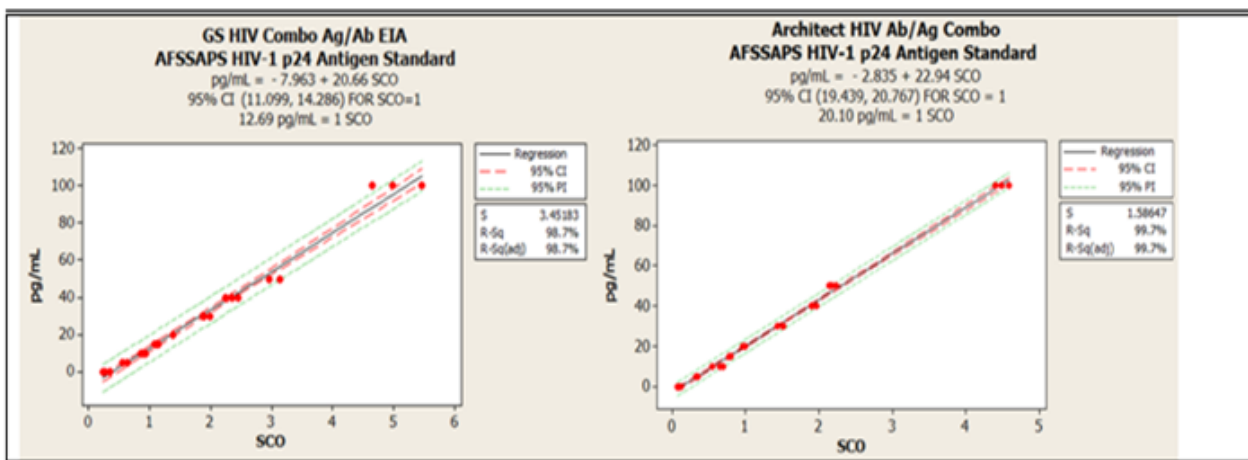
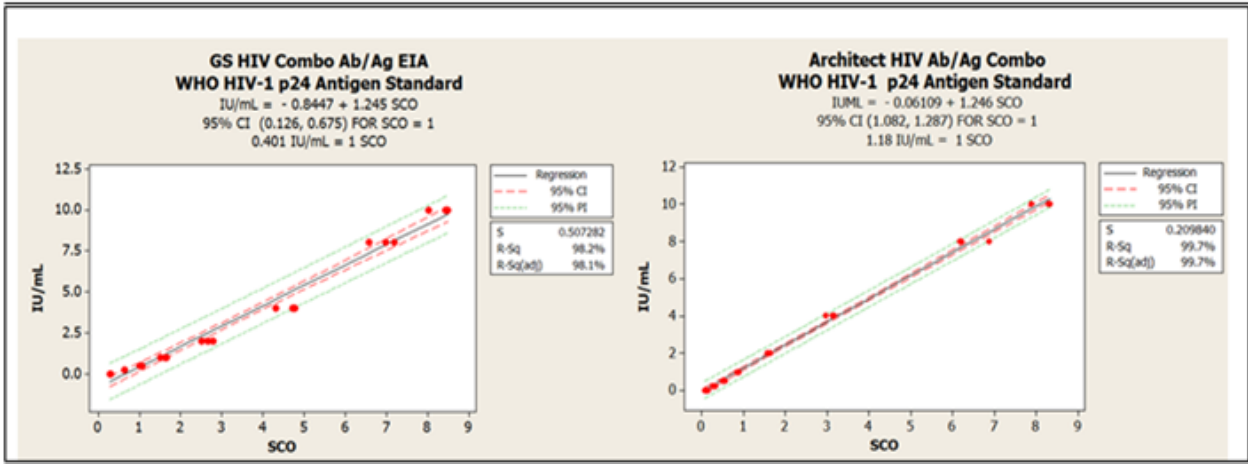


Chart 1: AFSSAPS HIV-1 p24 antigen Standard Analytical Sensitivity Required : <50pg/MI



**Chart 2: WHO HIV-1 p24 antigen International Standard
Analytical Sensitivity Required : <2 IU/mL**



**Chart 3: Closing of the Serological Window
(DAYS from Initial Bleed to WB Positive)**

Days before WB positive	Panel ID	26	25	24	23	22	21	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0	
RNA(Gene Probe C of A)	HIV9077	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
GS Combo Ag/Ab EIA	HIV9077	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	
Architect HIV Ag/Ab Combo	HIV9077	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	
Siemens HIV 1/O/2 Enhanced EIA	HIV9077	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+
Ortho Anti-HIV 1+2 EIA	HIV9077	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+
RNA(Gene Probe C of A)	HIV9079	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
GS Combo Ag/Ab EIA	HIV9079	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Architect HIV Ag/Ab Combo	HIV9079	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Siemens HIV 1/O/2 Enhanced EIA	HIV9079	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+
Ortho Anti-HIV 1+2 EIA	HIV9079	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+
RNA(Gene Probe C of A)	PRB951	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
GS Combo Ag/Ab EIA	PRB951	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Architect HIV Ag/Ab Combo	PRB951	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Siemens HIV 1/O/2 Enhanced EIA	PRB951	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+
Ortho Anti-HIV 1+2 EIA	PRB951	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+

Table 1
Summary of Analytical HIV-1 p24 sensitivity

AFSSAPS HIV-1 p24 Antigen Standard Required: <50pg/mL		WHO 90/636 HIV-1 p24 Antigen Standard Required: <2 IU/mL	
Bio-Rad GS HIV Combo Ag/Ab EIA	Abbott Architect HIV Ag/Ab Combo	Bio-Rad GS HIV Combo Ag/Ab EIA	Abbott Architect HIV Ag/Ab Combo
12.69 pg/mL	20.10pg/mL	0.41 IU/mL	1.18IU/mL
Range (11.099 -14.286)	Range (19.439 to 20.767)	Range (0.126 to 0.675)	Range (01.082 to 1.287)

Table 2
Performance in Low Risk Blood Donors

ASSAY	Number Tested	Initial Reactive	Repeat Reactive	Non Reactive	Specificity	95% CI (Wilson)
Bio-Rad GS HIV Combo Ag/Ab EIA on EVOLIS™	1000	0/1000 0 %	0/1000 0 %	1000/1000 100 %	1000/1000 100 %	99.6% to 100 %
Siemens HIV 1/O/2 Enhanced EIA on ADVIA Centaur®	1000	1/1000 0.1 %	0/1000 0 %	1000/1000 100 %	1000/1000 100 %	99.6% to 100 %
Abbott HIV Ag/Ab Combo on ARCHITECT	998	*25/998 2.5 %	3/998 0.3 %	995/998 99.7 %	995/998 99.7 %	99.1% to 99.9 %
Ortho Diagnostic, Anti-HIV 1+2 EIA on VITROS® Eci	994	4/994 0.4 %	3/994 0.3 %	991/994 99.7 %	991/994 99.7 %	99.1% to 99.9 %

Note: The initial reactive rate was higher than in the assays package insert and may due to interference from frozen samples

Table 3
Performance in Early RNA Positive Seroconversion Samples

PANEL ID	Total Panel Members Tested	HIV-1RNA Positive Samples	Bio-Rad GS HIV Combo Ag/Ab EIA on EVOLIS	Abbott HIV Ag/Ab Combo on Architect	Siemens HIV 1/O/2 Enhanced EIA Centaur	Ortho Anti-HIV 1+2 EIA on Vitros Eci
PRB951	6	4 (67%)	4 (67%)	4 (67%)	1 (17%)	1 (17%)
HIV9077	24	17 (71%)	16 (67%)	16 (67%)	14 (58%)	14 (58%)
HIV9079	25	18 (72 %)	17 (68%)	17 (68%)	15 (60%)	15 (60%)
Number	55	39/39 100 %	37/39 94.87%	37/39 94.87%	30/39 76.92%	30/39 76.92%

Table 4
HIV False Reactive Panels Zeptometrix: HIV9027 and HIV9078
Signal to Cutoff (S/CO) Values (≥ 1.00 is reactive)

Spec ID #	Dates	*Gene Probe	*Abbott HIV-1 p24 Ag	*Coulter HIV-1 p24 Ag	*GS HIV-1 /HIV-2 PLUS O	GS Combo Ag/Ab EVOLIS	Abbott HIV Ag/Ab Combo ARCHITECT	Siemens HIV 1/0/2 Enhanced CENTAUR	Ortho Anti-HIV 1+2 VITROS
HIV9027-01	Dec 2, 1997	Negative	0.41	0.381	0.084	0.276	0.100	<0.05	0.13
HIV9027-02	Dec 5, 1997	Negative	0.39	0.381	0.104	0.342	0.290	<0.05	0.13
HIV9027-03	Dec 9, 1997	Negative	0.37	0.381	0.091	0.299	0.140	<0.05	0.14
HIV9027-04	Dec12, 1997	Negative	0.46	0.381	0.096	0.316	0.120	<0.05	0.14
HIV9027-05	Dec16, 1997	Negative	0.4	0.381	0.104	0.342	2.360	<0.05	0.15
HIV9027-06	Dec19, 1997	Negative	0.49	0.476	0.094	0.309	2.360	<0.05	0.15
HIV9027-07	Dec 23, 1997	Negative	0.44	0.762	0.084	0.276	1.730	<0.05	0.14
HIV9027-08	Dec 26, 1997	Negative	0.43	0.571	0.086	0.283	1.510	<0.05	0.15
HIV9027-09	Dec 30, 1997	Negative	0.4	0.476	0.078	0.257	1.190	<0.05	0.12
HIV9078-01	May 22, 2000	Negative	0.8	0.31	0.115	0.378	0.180	<0.05	0.16
HIV9078-02	May 24, 2000	Negative	0.3	0.02	0.105	0.345	0.100	<0.05	0.15
HIV9078-03	July 9, 2000	Negative	0.3	0.26	0.106	0.349	0.080	<0.05	0.14
HIV9078-04	July 17, 2000	Negative	0.3	0.28	0.09	0.296	0.080	<0.05	0.13
HIV9078-05	July 30, 2000	Negative	0.5	0.3	0.101	0.332	0.100	<0.05	0.14

*Historical data from C of A