SENSITIVITY AND SPECIFICITY

At present, there is no recognized standard for establishing the presence or absence of antibodies to HIV-1 and HIV-2 in human blood.

Specificity is based on testing of random blood donors and hospitalized patient populations (serum and plasma specimens).

Sensitivity for HIV-1 (including HIV-1 Group O) and HIV-2 antibodies is expressed in terms of detection rate using confirmatory assay results (e.g., Western Blot) as a basis for comparison.

All specimens in this study were tested with the AxSYM HIV 1/2 gO. The study showed that:

1. Specificity based on zero prevalence of antibodies to HIV-1 and/or HIV-2 in random blood donors (6340 tested) is estimated to be 99.94% (6336/6340) for the AxSYM HIV 1/2 gO assay (Table 2).
2. Specificity based on zero prevalence of antibodies to HIV-1 and/or HIV-2 in a hospitalized population (1670 tested) is estimated to be 99.94% (1640/1641) for the AxSYM HIV 1/2 gO assay (Table 2).
3. HIV-1 antibody detection rate in a limited population of 581 HIV-1 antibody confirmed seropositive individuals is 100% (581/581) (Table 4). This rate includes 227 clinically diagnosed patients from different disease stages of HIV-1 infections.
4. HIV-2 antibody detection rate in a limited population of 304 HIV-2 antibody confirmed seropositive individuals is 100% (304/304) (Table 4).
5. Sensitivity in seroconverting donors is equivalent to or better than the method of comparison.
6. The assay gave positive results for all HIV-1 Group O specimens tested.

NOTE: It is recognized that presently available methods for the detection of antibodies to HIV-1 and/or HIV-2 may not detect all potentially infectious units of blood or infected individuals. A negative test result does not exclude the possibility of exposure to or infection with HIV-1/HIV-2.

REACTIVITY OF RANDOM BLOOD DONOR AND HOSPITALIZED PATIENT POPULATIONS

Specificity is defined as the ability of the AxSYM HIV 1/2 gO assay to detect randomly selected specimens as negative from populations at low risk for infection. The data from 6340 random blood donors and 1670 hospitalized patients (each category from 3 geographically distinct regions) is summarized in Table 2. The specificity of the assay was calculated as follows:

$$\frac{\text{Number of specimens nonreactive}}{\text{Total number of specimens*}} = \text{Specificity}$$

* Specimens confirmed by HIV-1 and/or HIV-2 Western Blot or reactive for ABBOTT HIVAG-1 Monoclonal assay (1A01) are excluded.

Table 2
Detection of Antibodies to HIV-1 and/or HIV-2 in Human Serum or Plasma Specimens from Random Blood Donors and Hospitalized Patients

Population Group (Site)	Specimens Tested N	Initially Reactive N	Initially Reactive (%)	Repeatedly Reactive N	Repeatedly Reactive (%)
BD Serum (1 site)	2997	2	0.07	2	0.07
BD Plasma (2 sites)	3343	2	0.06	2	0.06
Blood Donors (Total)	6340	4	0.06	4[a]	0.06
Hospitalized Patients (3 sites)	1670	31	1.86	30[b]	1.80

[a] 4 specimens could not be confirmed by HIV-1 and/or HIV-2 Western Blot or by ABBOTT HIVAG-1 Monoclonal assay (1A01).

[b] 29 specimens with repeat reactive results could be confirmed by HIV-1 and/or HIV-2 Western Blot or were reactive for HIV antigen by the ABBOTT HIVAG-1 Monoclonal EIA (1A01). One specimen that was not confirmed by HIV-1 and/or HIV-2 Western Blot or by ABBOTT HIVAG-1 Monoclonal assay (1A01) with an initial result of 0.90 S/CO and repeat results of 1.09/1.03 S/CO is not included in this calculation.

The AxSYM HIV 1/2 gO was used to test specimens containing potential interfering substances and specimens from individuals presumed to have an increased risk for blood transmissible infections. Results are shown

Table 3
Detection of Antibodies to HIV-1 and/or HIV-2 in Human Serum or Plasma Specimens Containing Potentially Interfering Substances and in Individuals Having an Increased Risk for Blood Transmissible Infections

Group	Specimens Tested N	Repeatedly Reactive N	Repeatedly Reactive (%)	Confirmed Reactive
Potentially Interfering Substances[a]	390	18[b]	4.6	10[c]
High Risk[d]	169	37	21.9	36[e]

[a] This group contained specimens with antibodies which were classified as EBV IgM, Rheumatoid Factor, Toxoplasmosis IgG, Syphilis, Rubella, CMV IgM, HAV, HBV, HBsAg, HCV, HTLV-I, HTLV-II, HSV, Flu-Vaccine, Myeloma (IgG, IgM), Autoimmune antibodies (ANA), Anti-yeast, Anti-*E. coli*, HIV-1 p24 non-specifics, multiparous females and pregnant women.

[b] One specimen that was not confirmed by HIV-1 and/or HIV-2 Western Blot or by ABBOTT HIVAG-1 Monoclonal assay (1A01) with an initial result of 0.94 S/CO and repeat results of 1.07/1.08 S/CO is not included in this calculation.

[c] 10 specimens were confirmed by HIV-1 Western Blot. 8 could not be confirmed by HIV-1 and/or HIV-2 Western Blot and ABBOTT HIVAG-1 Monoclonal EIA. These belong to the following groups: EBV IgM (4), HBV (1), Anti-yeast (2), pregnant females (1).

[d] This group consisted of specimens from IVDUs, Homosexuals, STDs, Multitransfusion, Dialysis and Hemophiliacs.

[e] 36 specimens were confirmed by HIV-1 Western Blot. One specimen from IVDUs was not confirmed by HIV-1 and/or HIV-2 Westen Blot or by ABBOTT HIVAG-1 Monoclonal EIA (1A01).

DETECTABILITY AND SENSITIVITY

The ability of AxSYM HIV 1/2 gO to detect antibodies to HIV-1 and/or HIV-2 in individuals clinically diagnosed with HIV-1 infection and classified disease status or from seropositive individuals (unknown disease status) is shown in Table 4.

Table 4
Detection of Antibodies to HIV-1 (Groups M and O) and/or HIV-2 in Serum or Plasma Specimens from Patients with Classified Disease Status and from Seropositive Individuals

Group	HIV Infection	Specimens Tested N	Reactive N	Reactive (%)
Classified Disease Status	HIV-1	227[a]	227	100
Unknown Disease Status	HIV-1	354[b]	354	100
Unknown Disease Status	HIV-1 Group O	10	10	100
Unknown Disease Status	HIV-2	304	304	100
HIV-Positives	HIV-1 / HIV-2	895	895	100

[a] Specimens belonging to the following CDC classifications: CDC Stage A, Stage B and Stage C.

[b] Specimens from different geographical regions: Nigeria, Cameroon, Brazil, Uganda, Thailand, Ghana, China, India, USA, Italy.

REACTIVITY WITH SEROCONVERSION PANELS

The ability of the AxSYM HIV 1/2 gO assay to detect antibodies to HIV-1 and/or HIV-2 was evaluated in sequential specimens from 21 seroconverting donors. These specimens are commercially available from Boston Biomedica (BBI, Massachusetts, USA), North American Biologicals Inc. (NABI, USA) or Bioclinical Partners (BCP, Massachusetts, USA). These specimens are well characterized.

The AxSYM HIV 1/2 gO assay was reactive one bleed earlier for 4 out of 21 seroconversion panels than the method of comparison (AxSYM HIV-1/HIV-2, 9A44) (Table 5).

Results for Seroc

Donor	Day of Donation	AxSYM HIV 1/2 g (3D41) Result
BBI	0	0.36
PRB932	3	0.37
	13	0.39
	27	**1.47**
	34	**8.76**
	50	**5.32**
	78	**4.24**
	163	**7.50**
	194	**10.27**
NABI	1	0.39
SVO-0261	3	0.42
	10	0.47
	13	**1.24**
	17	**3.23**
	20	**11.25**
	24	**11.63**
NABI	1	0.48
SVO-0351	8	0.60
	11	**1.65**
	15	**7.50**
BCP	0	0.45
6245	45	0.47
	51	0.45
	55	0.42
	60	0.42
	66	0.38
	69	0.48
	73	**1.08**
	76	**6.42**
	84	**8.69**

[a] Data from the vendor

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