

**Centers for Disease Control and Prevention
Model Performance Evaluation Program
Human T-Lymphotropic Virus Types I and II
(HTLV-I/II) Testing**

**Figures Used for the
Analysis of the November 4, 1996
Performance Evaluation Testing Results
Reported by Participant Laboratories**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

Public Health Practice Program Office

Division of Laboratory Systems

Atlanta, Georgia 30333



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Report of the November 4, 1996 Human T-lymphotropic Virus Types I and II (HTLV-I/II) Performance Evaluation Sample Testing Results Provided by Participant Laboratories in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

The production of this report was coordinated in CDC by:

Public Health Practice Program Office Edward L. Baker, M.D., M.P.H., Director
Division of Laboratory Systems Carlyn L. Collins, M.D., M.P.H., Director
Laboratory Practice Assessment Branch Thomas L. Hearn, Ph.D., Chief

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP) William O. Schalla, M.S., Chief
MPEP Retroviral Performance Evaluation Sharon O. Blumer, M.S.
Retroviral Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-4147 or (770) 488-4366.

**Centers for Disease Control and Prevention (CDC)
 Model Performance Evaluation Program
 Human T-Lymphotropic Virus Types I and II (HTLV-I/II) Testing
 November 4, 1996 Participant Laboratory Shipment**

Table 1

Panel Letter	Vial Label	CDC Donor Number	CDC Result ²	Laboratory Interpretation ¹			
				EIA INIT. ³	FINAL ⁴	WB	IIF
I	I01, I06	09	Positive	—	—	—	—
	I02	13	Negative	—	—	—	—
	I03, I05	05	Positive	—	—	—	—
	I04	01	Positive	—	—	—	—
J	J01	13	Negative	—	—	—	—
	J02	02	Positive	—	—	—	—
	J03, J05	09	Positive	—	—	—	—
	J04, J06	06	Positive	—	—	—	—
K	K01, K02	10	Positive	—	—	—	—
	K03, K05	07	Positive	—	—	—	—
	K04	14	Negative	—	—	—	—
	K06	03	Positive	—	—	—	—
L	L01	04	Positive	—	—	—	—
	L02, L03	08	Positive	—	—	—	—
	L04	14	Negative	—	—	—	—
	L05, L06	10	Positive	—	—	—	—

¹ Laboratory Interpretation space (to be completed by participant laboratory) provided to facilitate comparison of participant laboratory result with CDC result.

² The CDC result was obtained after composite EIA, WB, and RIPA testing, and employing the interpretation criteria of the Public Health Service Working Group.

³ Initial EIA interpretation

⁴ Final EIA interpretation

**Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program for
Human T-Lymphotropic Virus Types I and II (HTLV-I/II) Antibody Testing**

**Table 2. CDC Western Blot (WB) Testing Results for the
November 4, 1996 Participant Laboratory Panel Samples**

Panel Letter	Vial Label	CDC Donor Number	CDC Western Blot Test Results Major WB Bands Detected¹	WB Test Kit Manufacturer	CDC Laboratory Interpretation²
I	I01, I06	09	r21*, 19, 24, 46 GD21*, 19, 24, 46, r46-I*	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	I02	13	NO BANDS	Both Manufacturers	Negative
	I03, I05	05	r21, 19, 24 GD21, 19, 24, r46-II*	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	I04	01	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
J	J01	13	NO BANDS	Both Manufacturers	Negative
	J02	02	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	J03, J05	09	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	J04, J06	06	r21, 19, 24 GD21, 19, 24, r46-II	Cambridge Biotech Genelabs Diagnostics	Positive Positive
K	K01, K02	10	r21, 19, 24, 46 GD21, 19, 24, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	K03, K05	07	r21, 24 GD21, 24, r46-II	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	K04	14	NO BANDS	Both Manufacturers	Negative
	K06	03	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
L	L01	04	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	L02, L03	08	r21, 19, 24, 46 GD21, 19, 24, 46, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive
	L04	14	NO BANDS	Both Manufacturers	Negative
	L05, L06	10	r21, 19, 24, 46 GD21, 19, 24, r46-I	Cambridge Biotech Genelabs Diagnostics	Positive Positive

¹ Western blot (WB) result based on band intensity of $\geq 1+$ staining.

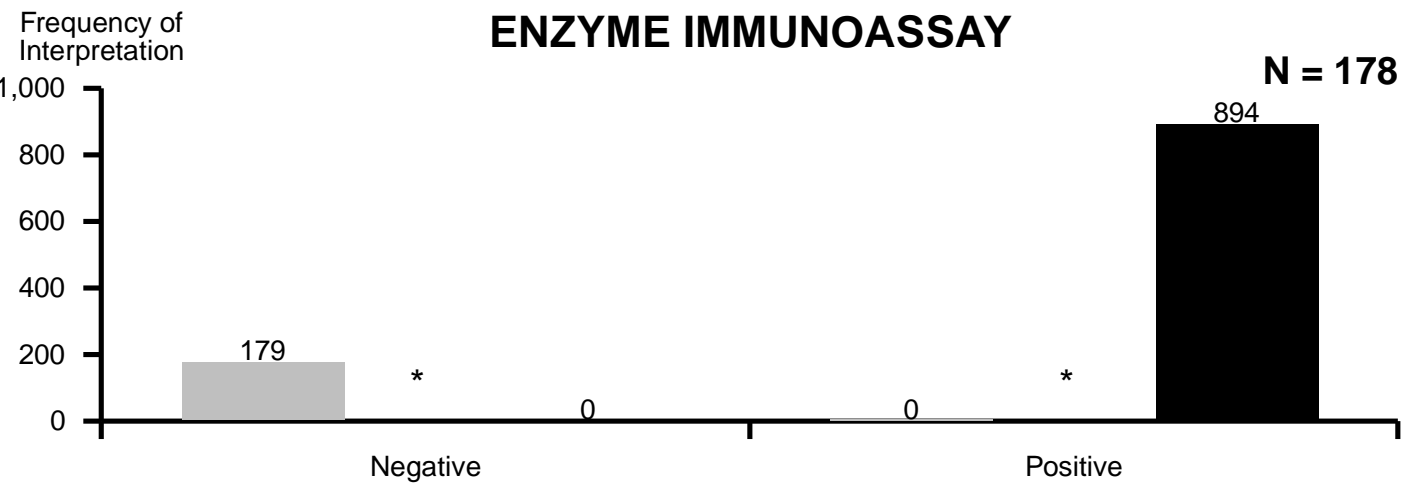
² The CDC interpretation is consistent with the kit manufacturers' criteria for interpretation of WB results.

* Denotes WB band detected for recombinant antigens (recombinant gp21 = r21 and GD21; recombinant HTLV Type I gp46 = r46-I; recombinant HTLV Type II gp46 = r46-II).

**SUPPLEMENTAL INFORMATION FOR COMPREHENDING
THE NUMBERS USED TO LABEL FIGURES
IN THIS REPORT**

The "N=" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test; therefore, the number of results may exceed the actual number of laboratories providing reports. In figures 1-7 and 10, the vertical axis is labeled either as frequency or percentage of results; in figures 8 and 9, this axis is labeled as percentage of reports. However, in all figures, the number appearing directly above or within each bar represents a frequency of results only.

Figure 1. Frequency of HTLV-I/II antibody test result interpretations, by sample type (reactivity), for the enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by participant laboratories for the November 4, 1996 shipment



* = Indeterminate is not an EIA interpretation option; these areas have been left blank

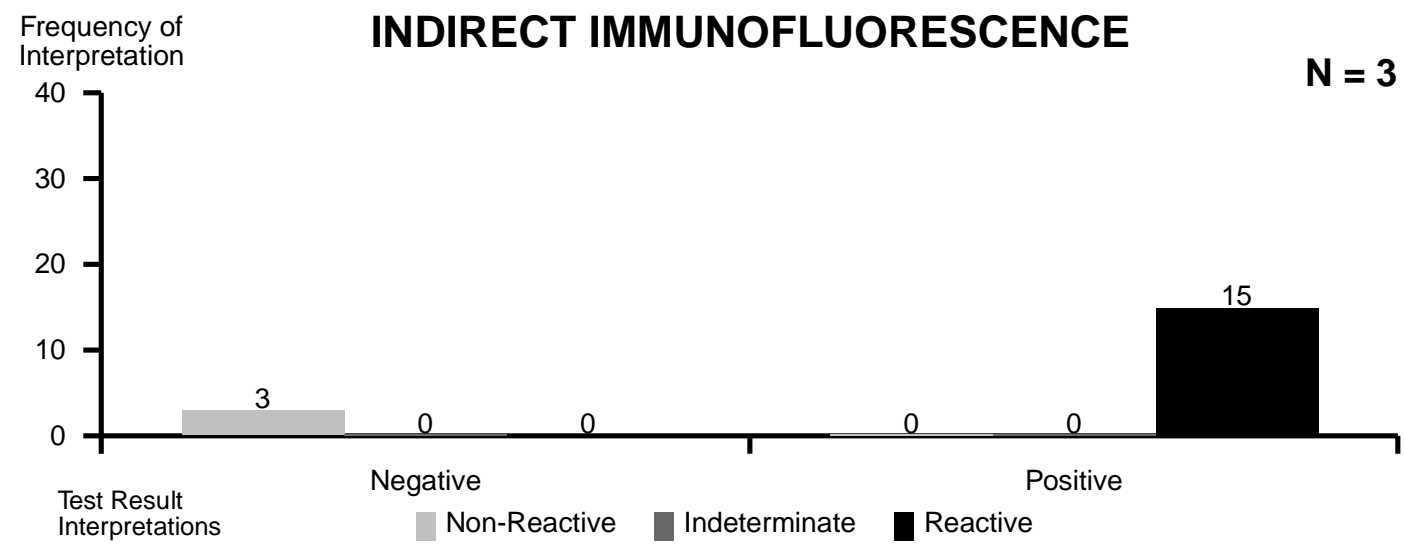
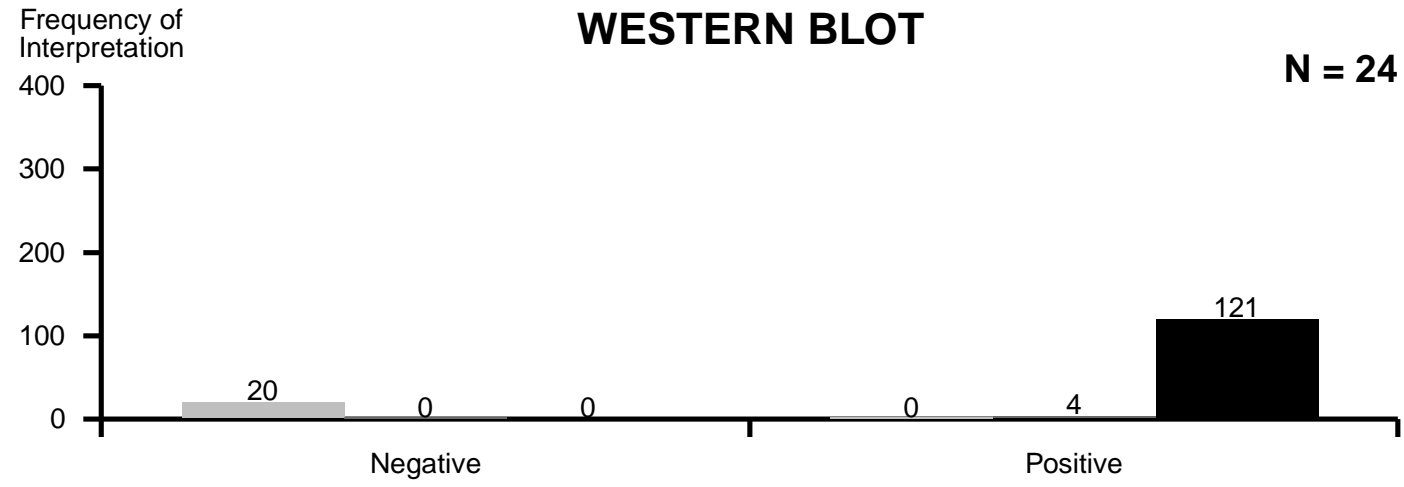


Figure 2. Percentage of HTLV-I/II participant laboratories, by laboratory type, that reported results to the CDC for the November 4, 1996 shipment

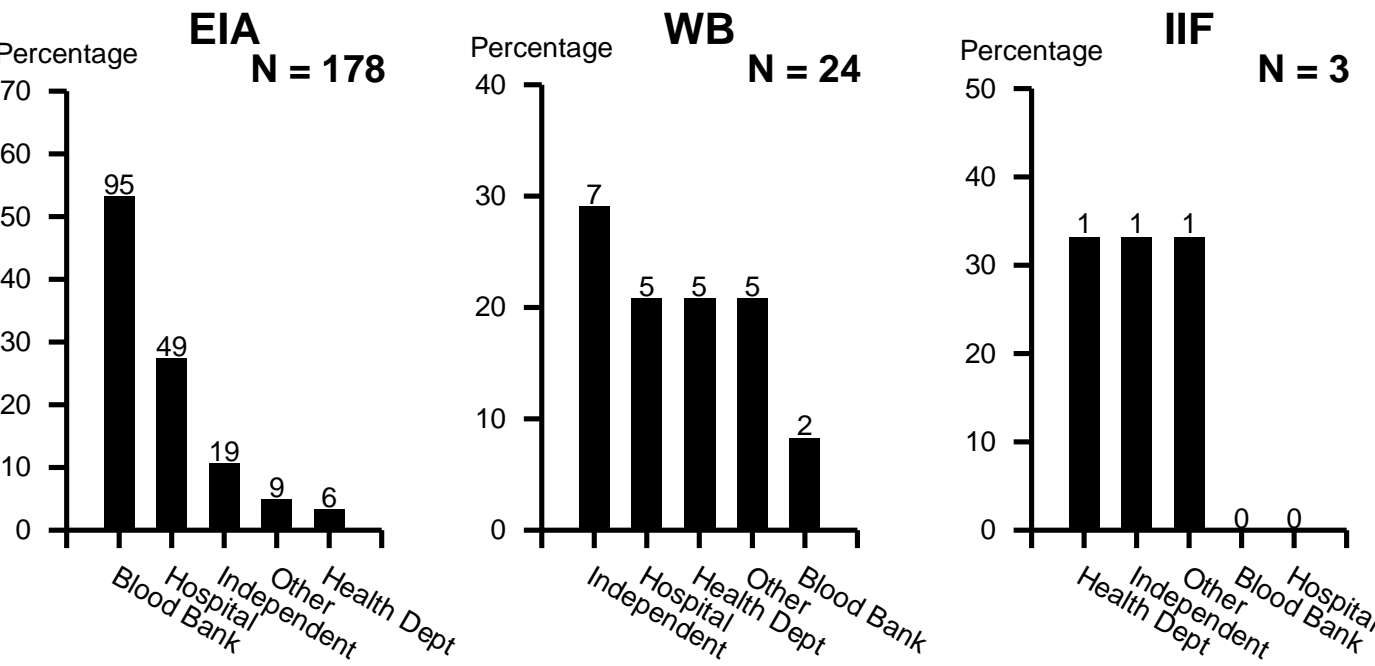


Figure 3. Combination of HTLV-I/II tests reported by participant laboratories for the November 4, 1996 shipment

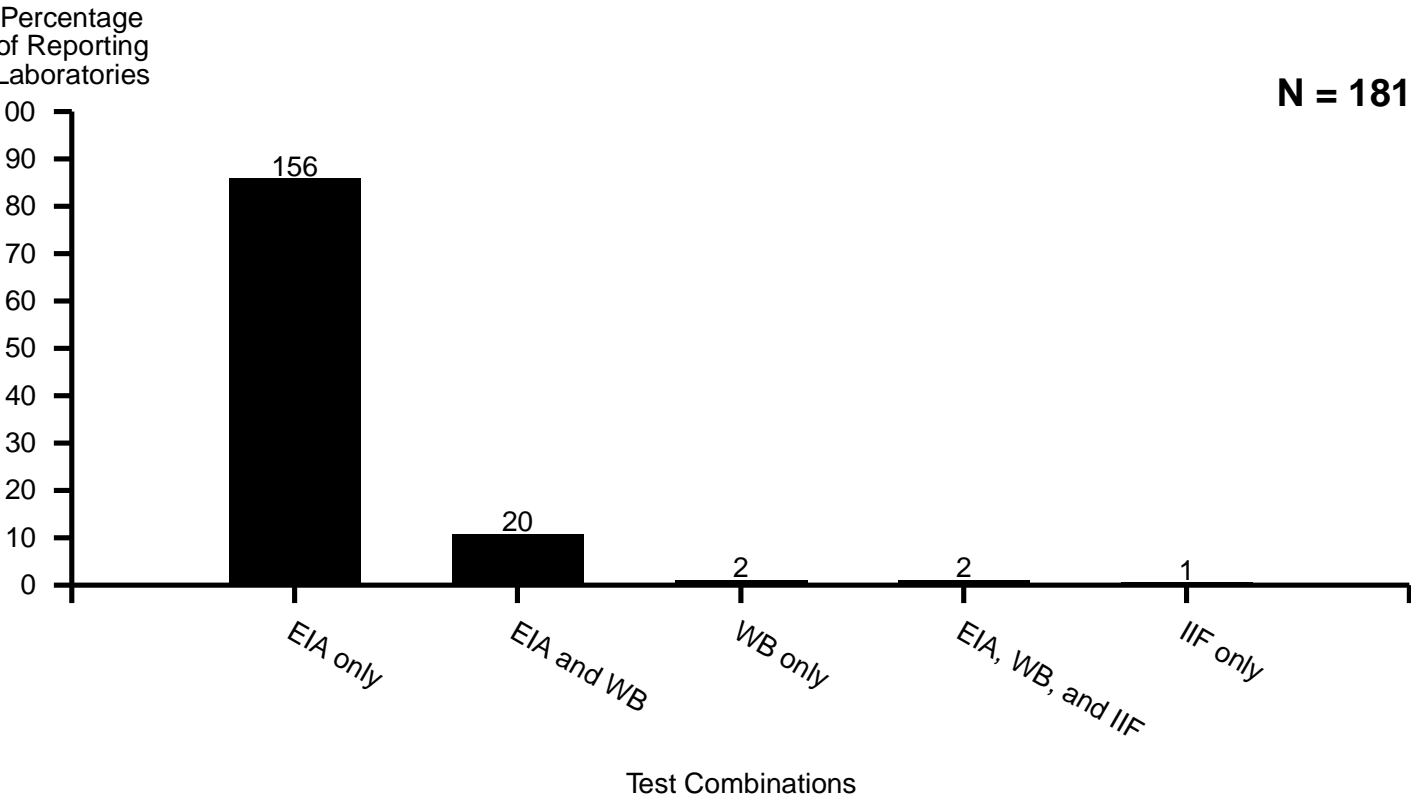


Figure 4. Types of HTLV-I/II kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by participant laboratories to the CDC for the November 4, 1996 shipment

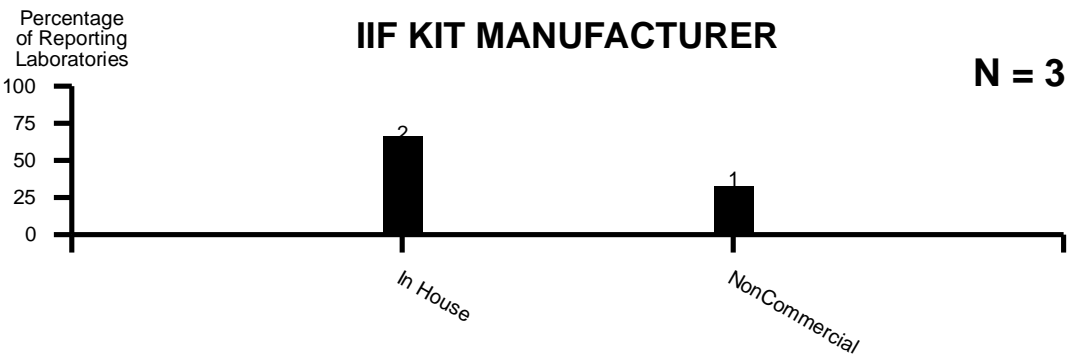
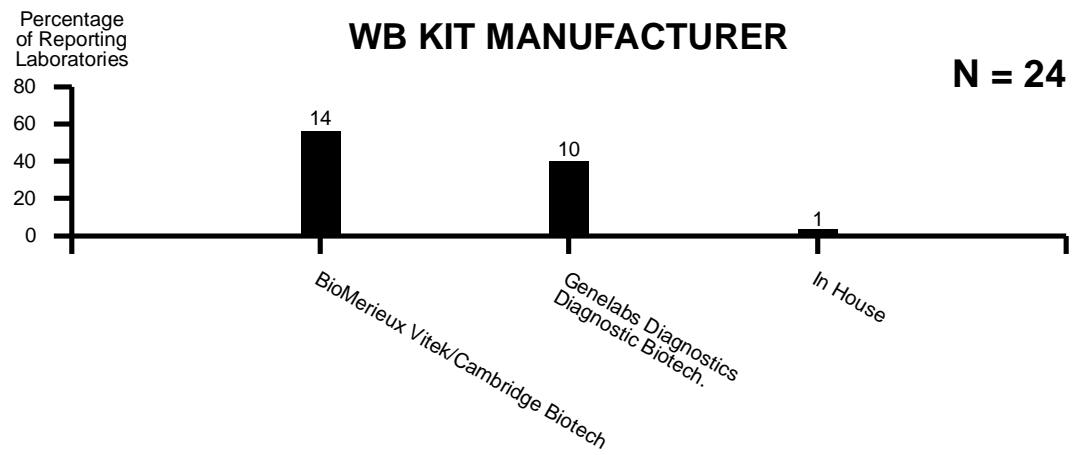
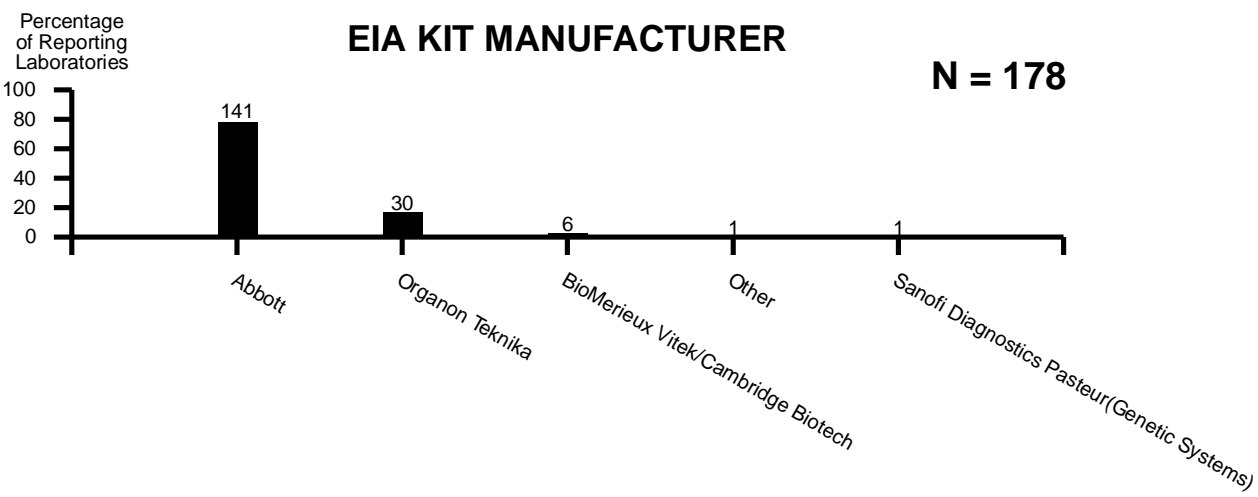
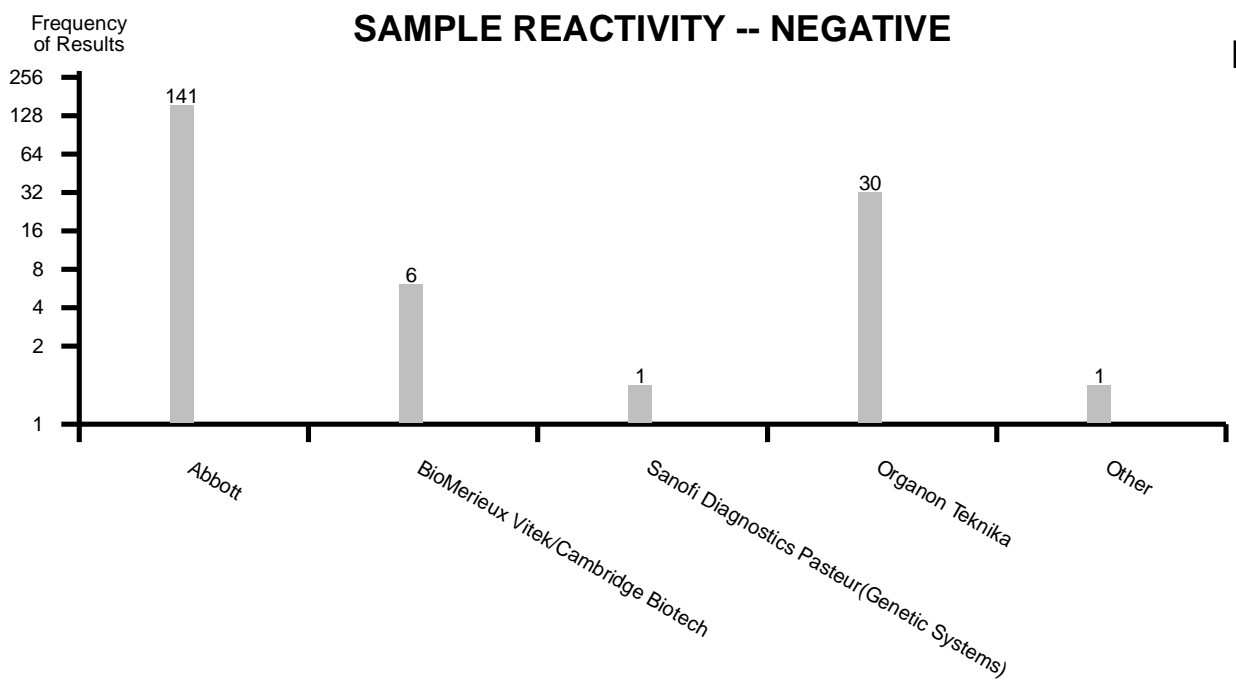


Figure 5. Enzyme immunoassay HTLV-I/II results, by kit manufacturer, reported by participant laboratories for the November 4, 1996 shipment

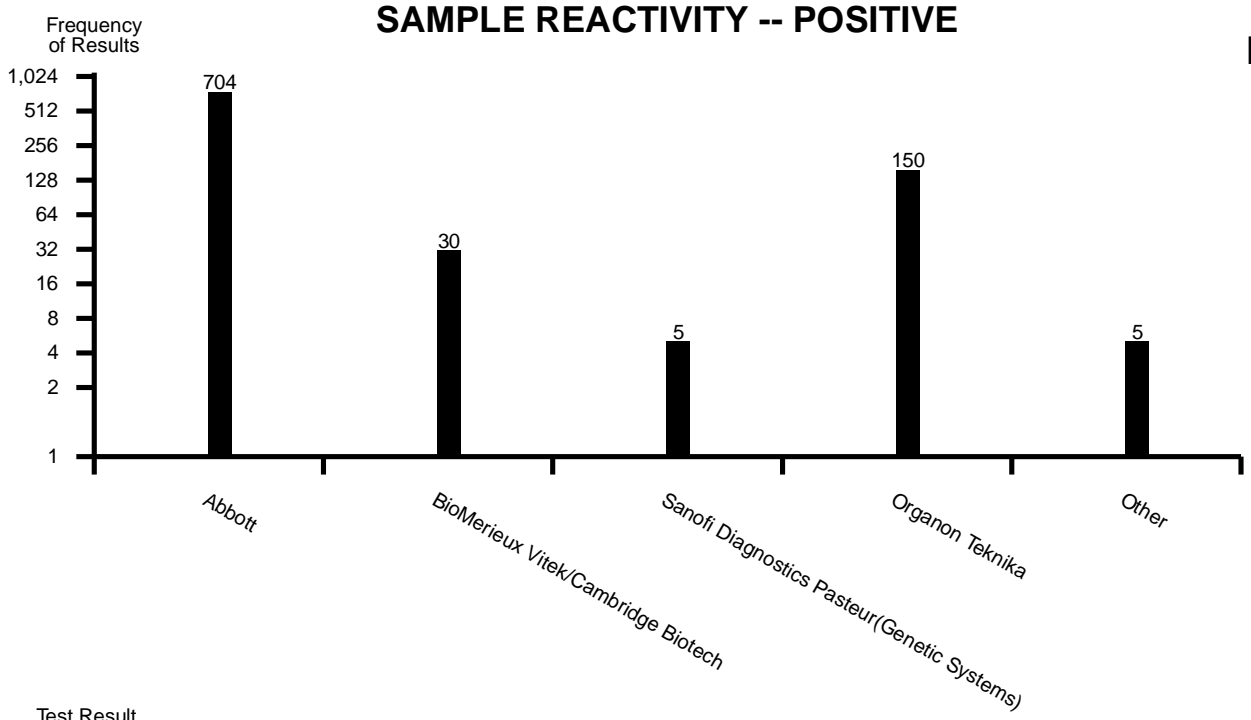
SAMPLE REACTIVITY -- NEGATIVE

N = 178



SAMPLE REACTIVITY -- POSITIVE

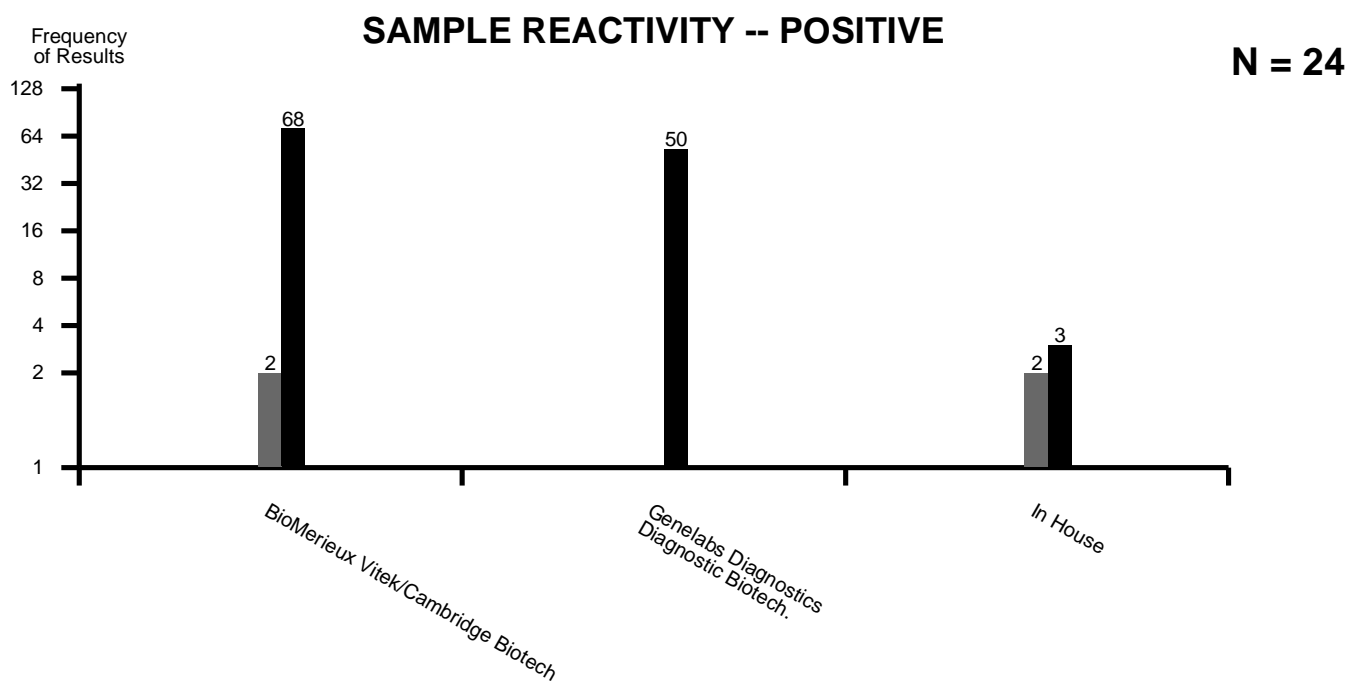
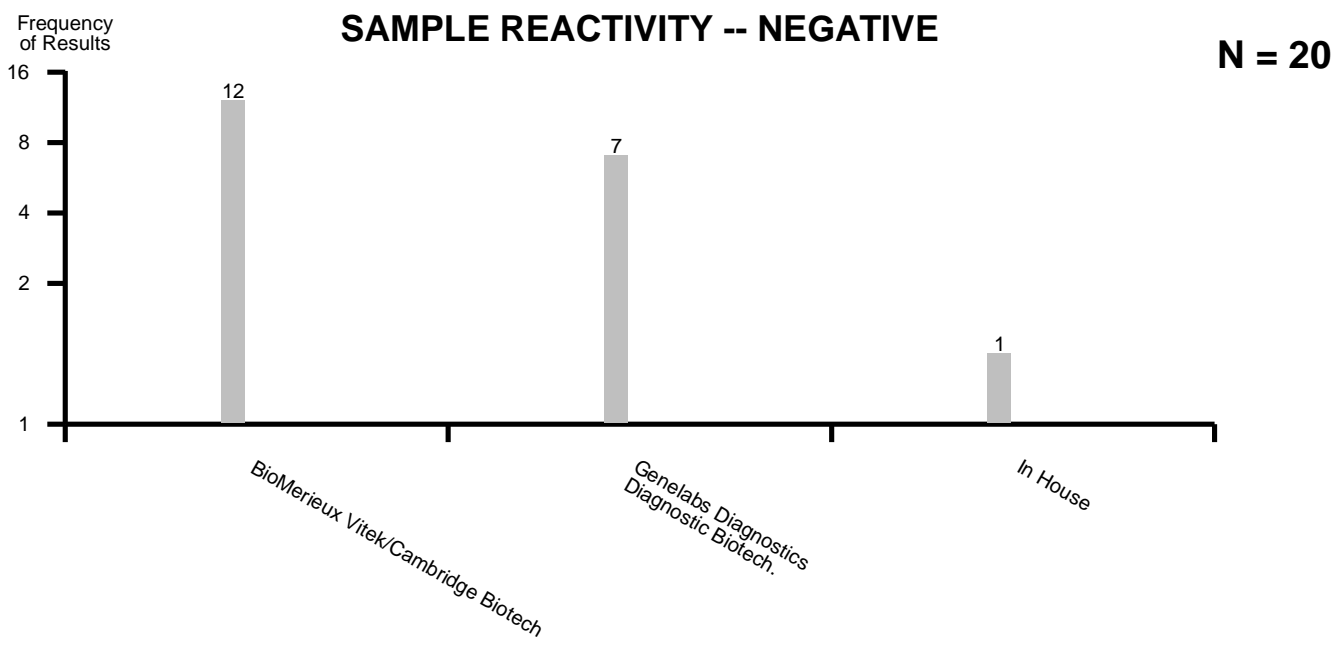
N = 178



Test Result Interpretations

■ Non-Reactive ■ Reactive

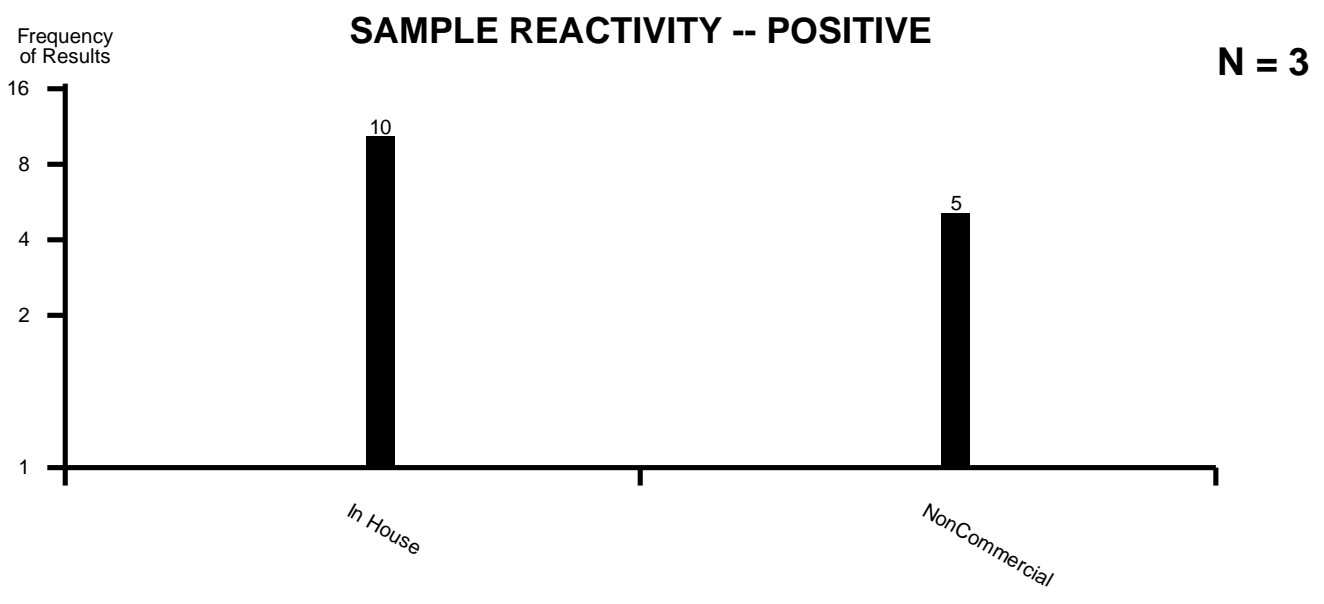
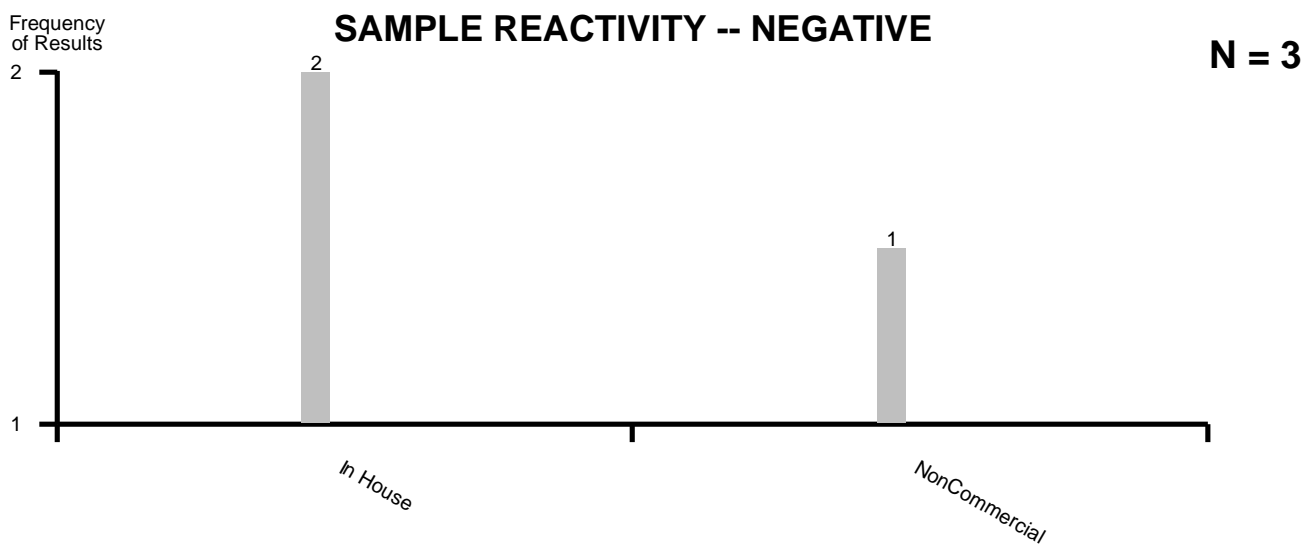
Figure 6. Western blot HTLV-I/II results, by kit manufacturer, reported by participant laboratories for the November 4, 1996 shipment



Test Result Interpretations

- Non-Reactive
- Indeterminate
- Reactive

Figure 7. Indirect immunofluorescence HTLV-I/II results, by kit manufacturer, reported by participant laboratories for the November 4, 1996 shipment



Test Result Interpretations

Non-Reactive
 Indeterminate
 Reactive

Figure 8. Western blot HTLV-I/II band patterns reported to CDC by participant laboratories for the November 4, 1996 shipment

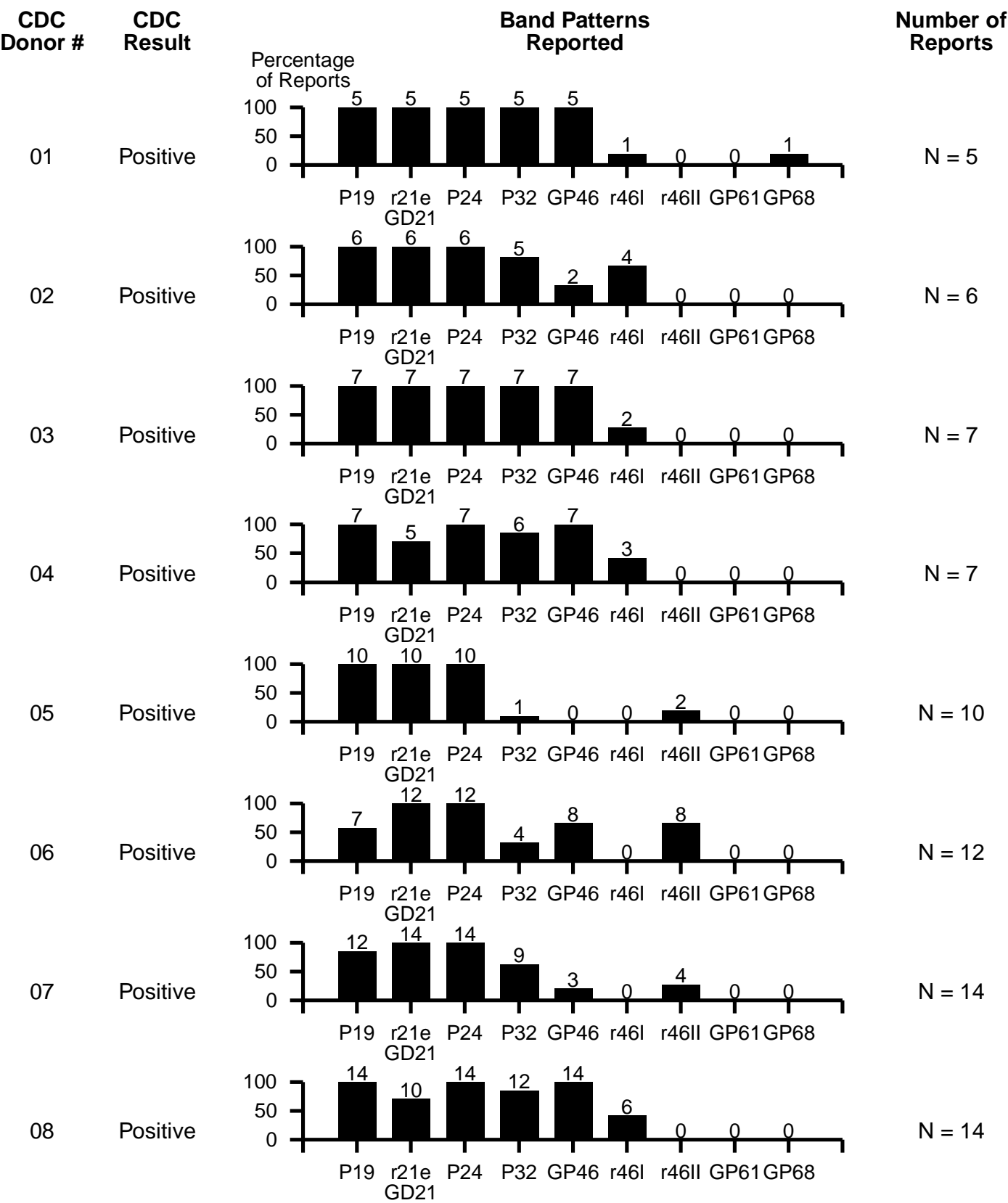


Figure 8. Western blot HTLV-I/II band patterns reported to CDC by participant laboratories for the November 4, 1996 shipment

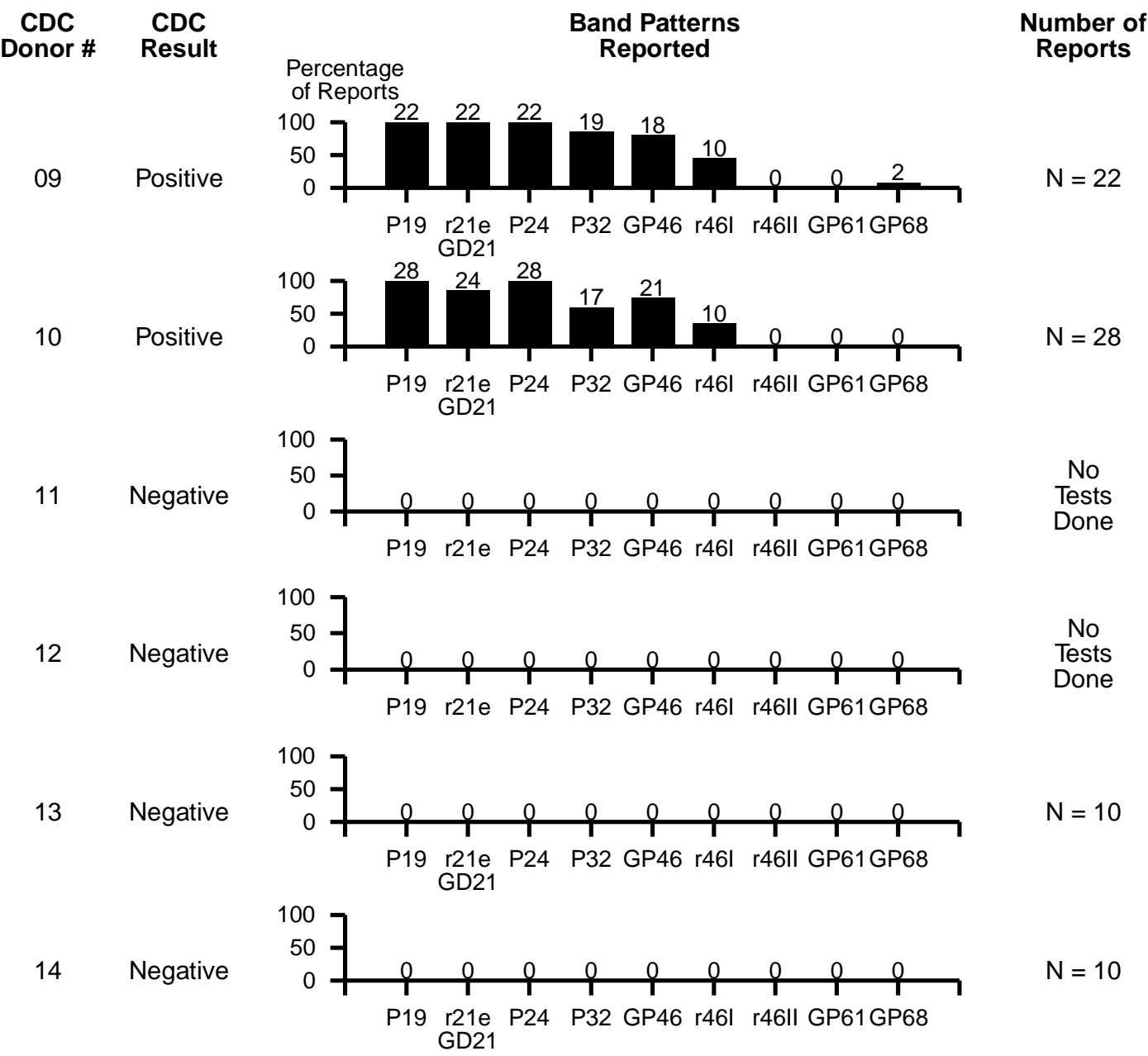


Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by participant laboratories for the November 4, 1996 shipment

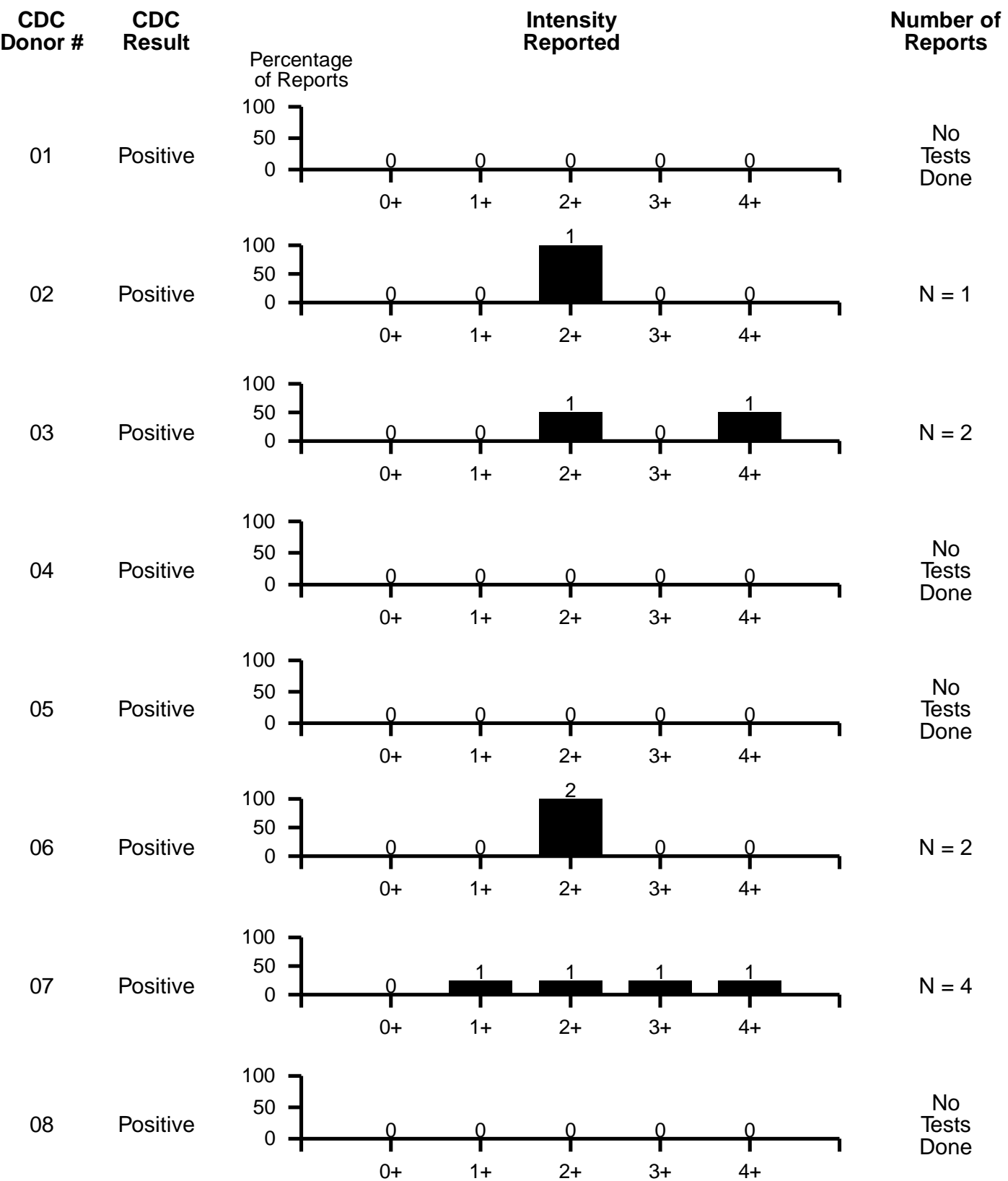


Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by participant laboratories for the November 4, 1996 shipment

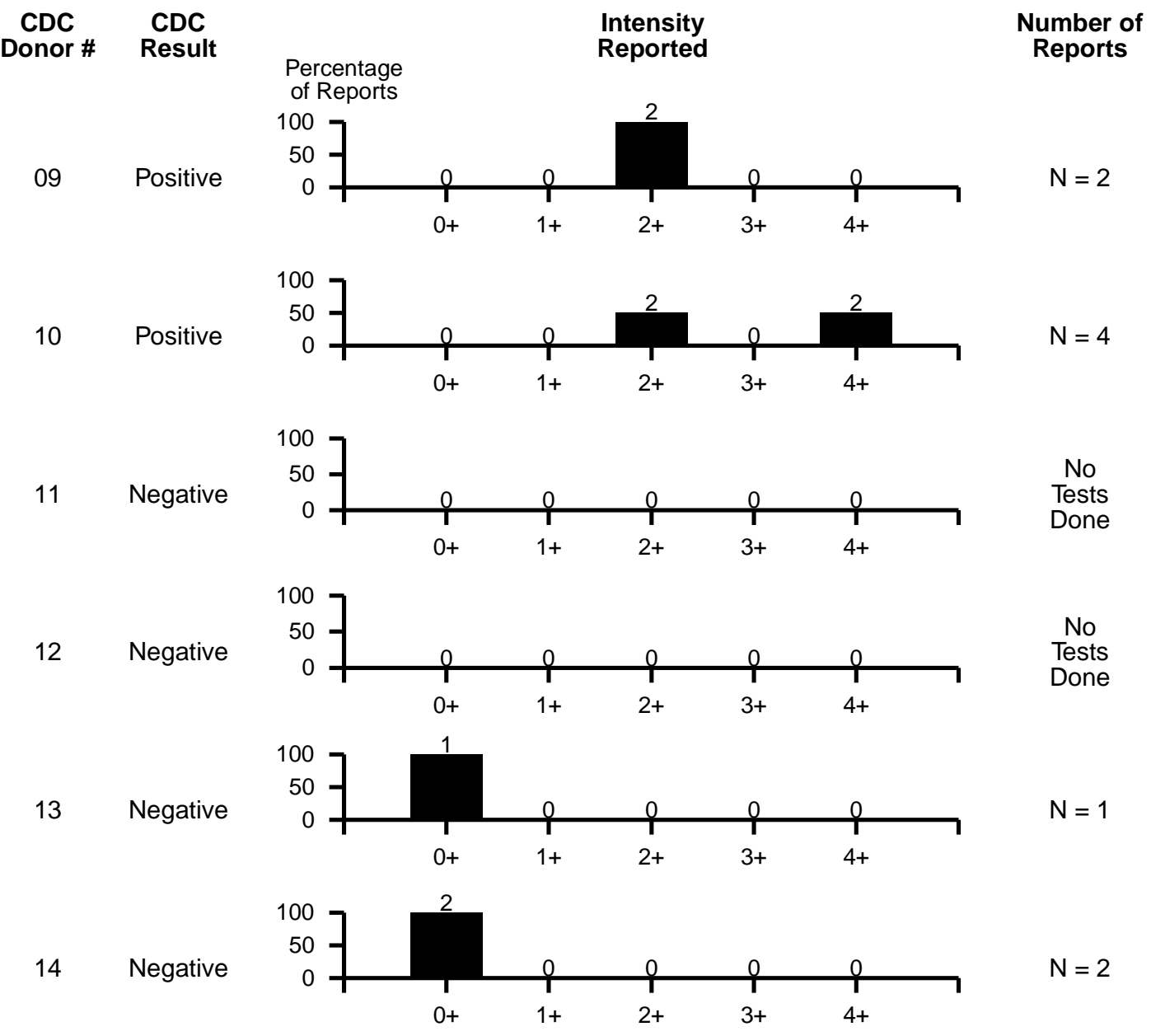


Figure 10. Types of 'Other' HTLV test kits used and results reported by participant laboratories to the CDC for the November 4, 1996 shipment

