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

Figures Used to Summarize the Candidate Reference Laboratory Results for the October 7, 1996 Shipment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
Public Health Practice Program Office
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Report of the October 7, 1996 Human T-lymphotropic virus types I and II (HTLV-I/II) Performance Evaluation Sample Testing Results Provided by Candidate Reference Laboratories in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

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Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program
Human T-Lymphotropic Virus Types I and II (HTLV-I/II) Testing
October 7, 1996 Candidate Reference Laboratory Shipment

Vial Label Number	CDC Donor Number	CDC Result[2]	Laboratory Interpretation[1] EIA INIT.[3]	EIA FINAL[4]	WB	IIF
01	12	Negative	___	___	___	___
02	03	Positive	___	___	___	___
03	06	Positive	___	___	___	___
04	01	Positive	___	___	___	___
05	09	Positive	___	___	___	___
06	13	Negative	___	___	___	___
07	04	Positive	___	___	___	___
08	07	Positive	___	___	___	___
09	02	Positive	___	___	___	___
10	08	Positive	___	___	___	___
11	14	Negative	___	___	___	___
12	10	Positive	___	___	___	___
13	05	Positive	___	___	___	___
14	11	Negative	___	___	___	___

[1] Laboratory Interpretation space (to be completed by candidate reference laboratory) provided to facilitate comparison of candidate reference 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

CDC Western Blot (WB) Testing Results for the
October 7, 1996 Candidate Reference Laboratory Panel Samples

Vial Label Number	CDC Donor Number	CDC Western Blot Test Results Major WB Bands Detected[1]	WB Test Kit Manufacturer	CDC Laboratory Interpretation[2]
01	12	NO BANDS	Both Manufacturers	Negative
02	03	r21*, 19, 24, 46	Cambridge Biotech	Positive
		GD21*, 19, 24, 46, r46-I*	Genelabs Diagnostics	Positive
03	06	r21, 19, 24	Cambridge Biotech	Positive
		GD21, 19, 24, r46-II*	Genelabs Diagnostics	Positive
04	01	r21, 19, 24, 46	Cambridge Biotech	Positive
		GD21, 19, 24, 46, r46-I	Genelabs Diagnostics	Positive
05	09	r21, 19, 24, 46	Cambridge Biotech	Positive
		GD21, 19, 24, 46, r46-I	Genelabs Diagnositcs	Positive
06	13	NO BANDS	Both Manufacturers	Negative
07	04	r21, 19, 24, 46,	Cambridge Biotech	Positive
		GD21, 19, 24, 46, r46-I	Genelabs Diagnostics	Positive
08	07	r21, 24	Cambridge Biotech	Positive
		GD21, 24, r46-II	Genelabs Diagnostics	Positive
09	02	r21, 19, 24, 46	Cambridge Biotech	Positive
		GD21, 19, 24, 46, r46-I	Genelabs Diagnostics	Positive
10	08	r21, 19, 24, 46	Cambridge Biotech	Positive
		GD21, 19, 24, 46, r46-I	Genelabs Diagnostics	Positive
11	14	NO BANDS	Both Manufacturers	Negative
12	10	r21, 19, 24, 46	Cambridge Biotech	Positive
		GD21, 19, 24, r46-I	Genelabs Diagnostics	Positive
13	05	r21, 19, 24	Cambridge Biotech	Positive
		GD21, 19, 24, r46-II	Genelabs Diagnostics	Positive
14	11	NO BANDS	Both Manufacturers	Negative

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

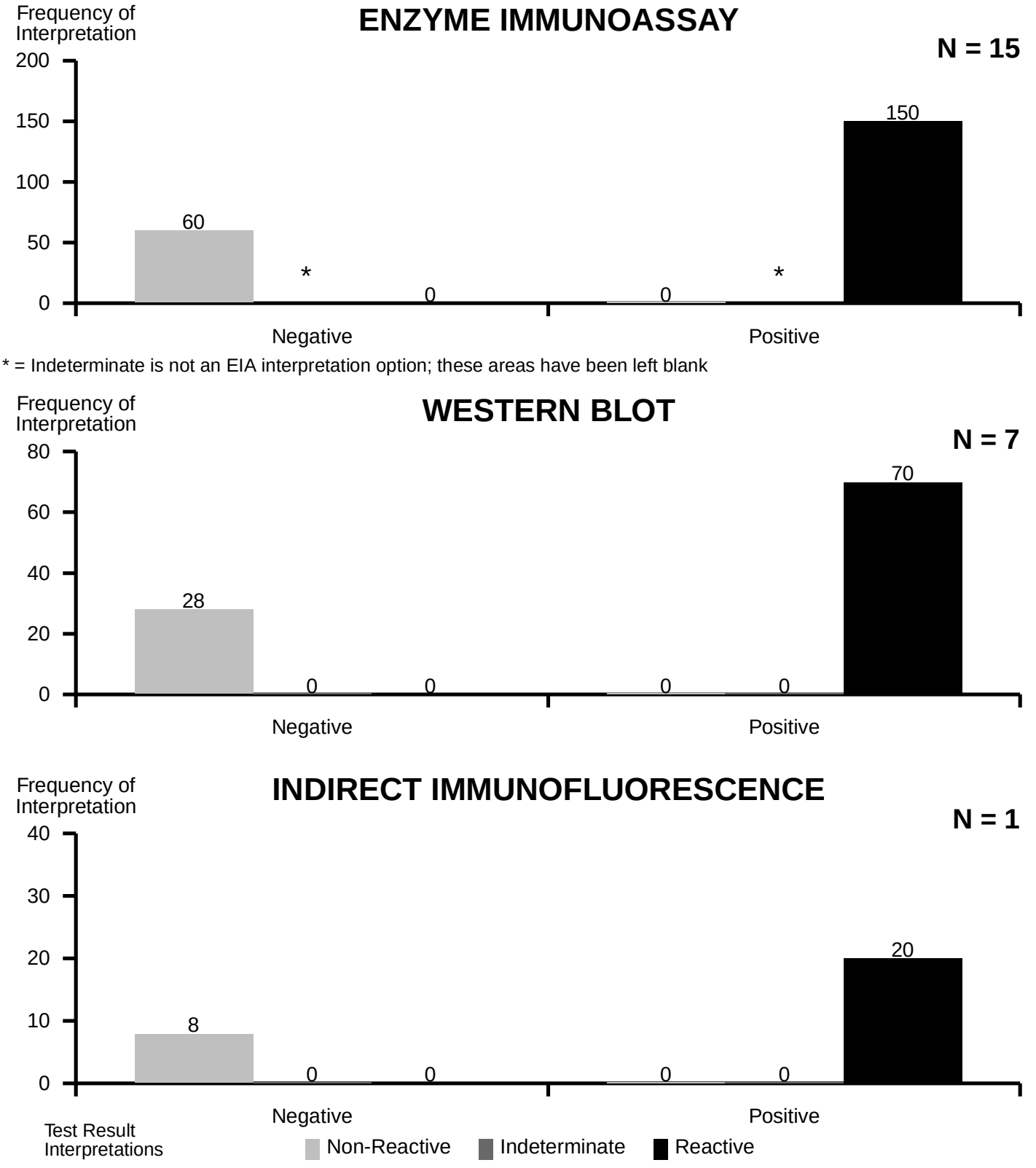
[2] The CDC interpretation is consistent with the kit manufacturers' criteria for interpretation of WB results.

* 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, 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 reference laboratories for the October 7, 1996 shipment



CDC Model Performance Evaluation Program
HTLV-I/II Antibody Testing

Figure 2. Percentage of HTLV-I/II reference laboratories, by laboratory type, that reported results to the CDC for the October 7, 1996 shipment

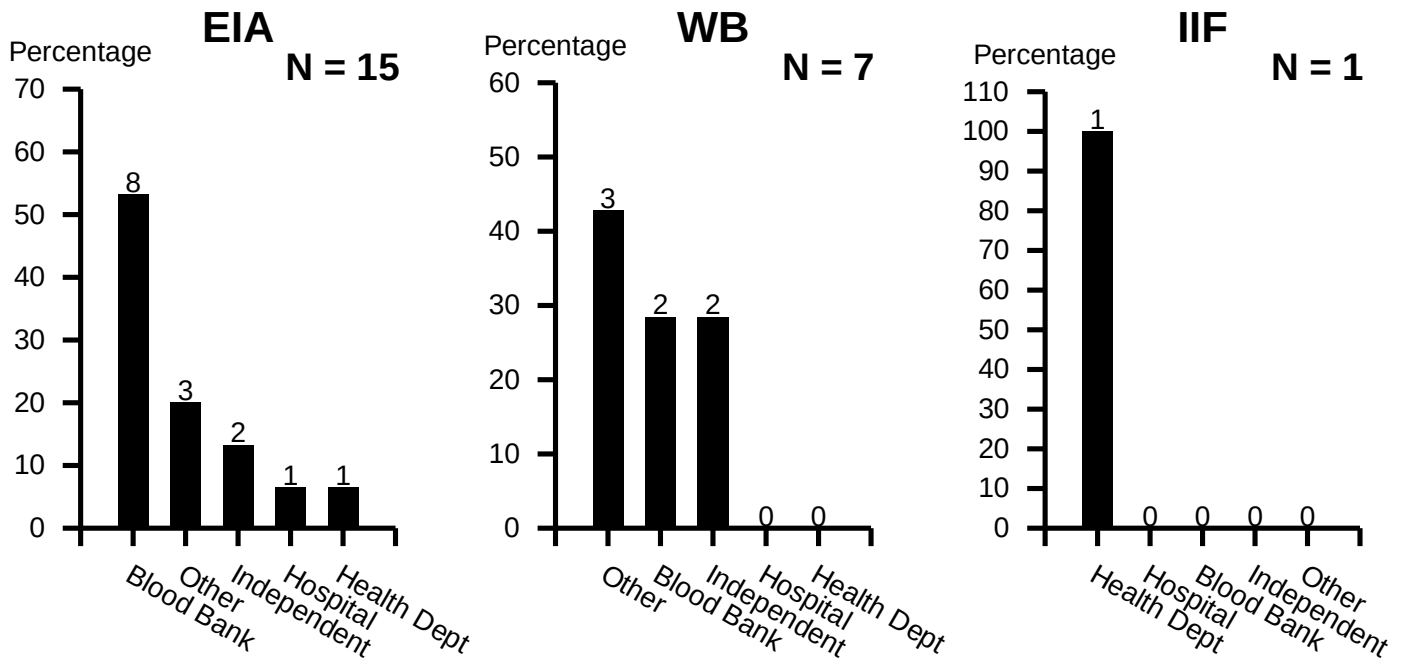


Figure 3. Combination of HTLV-I/II tests reported by reference laboratories for the October 7, 1996 shipment

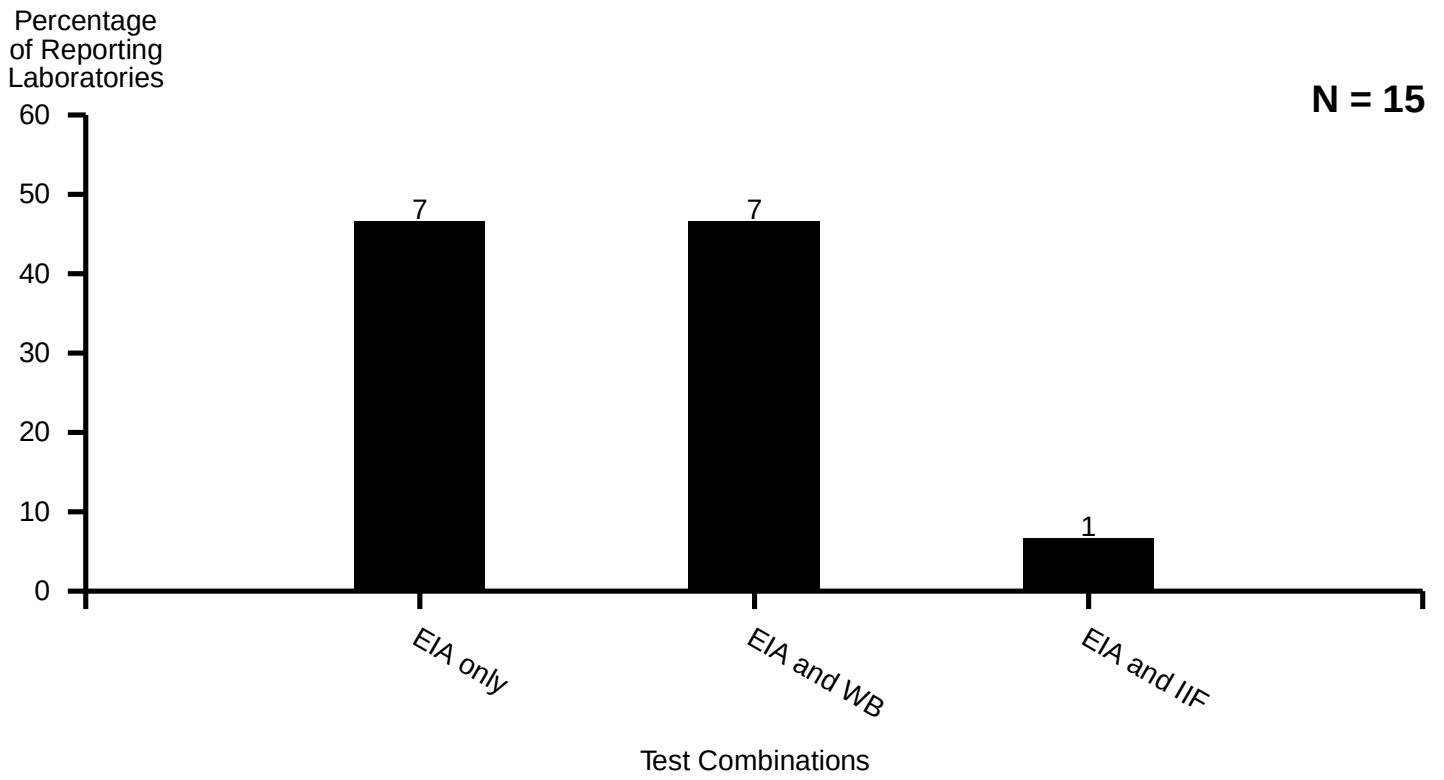
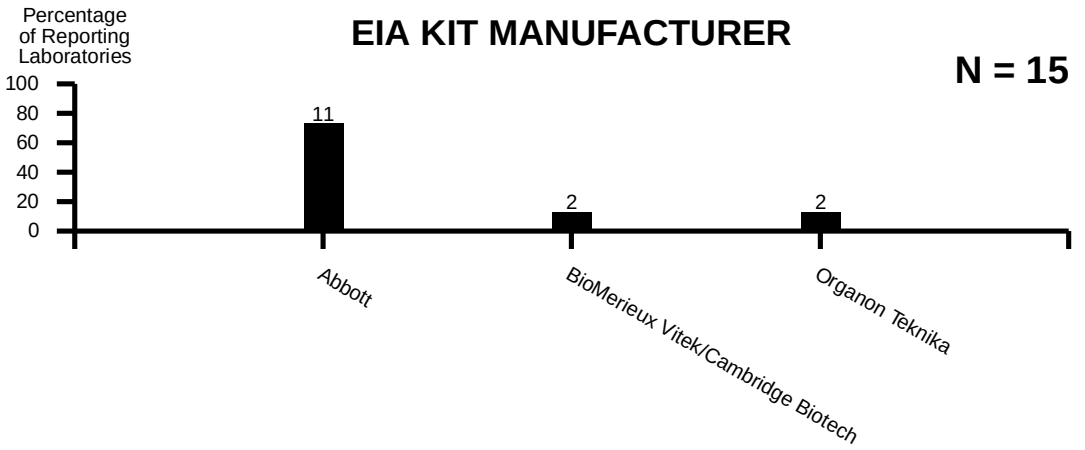
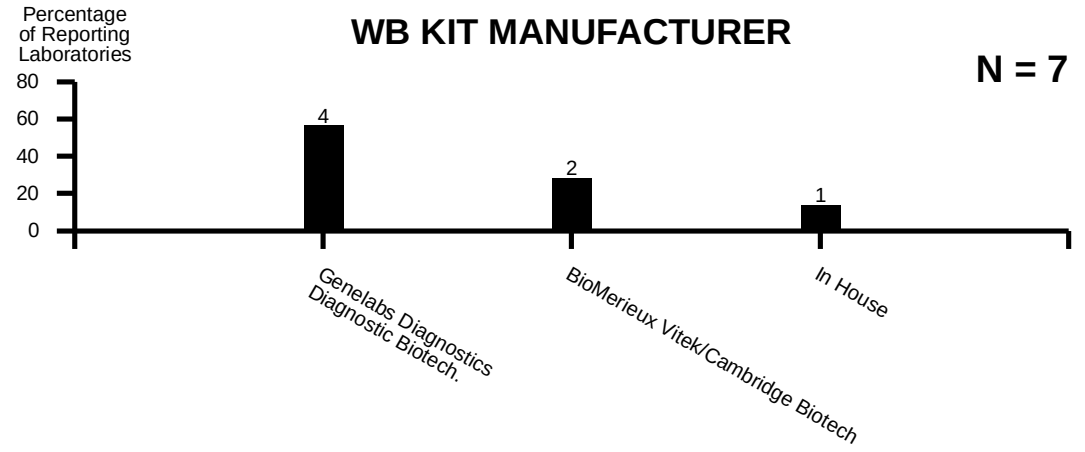


Figure 4. Types of HTLV-I/II kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the October 7, 1996 shipment





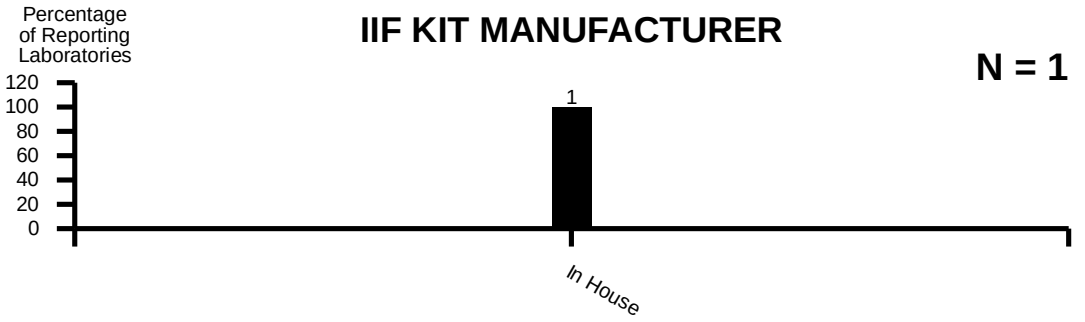
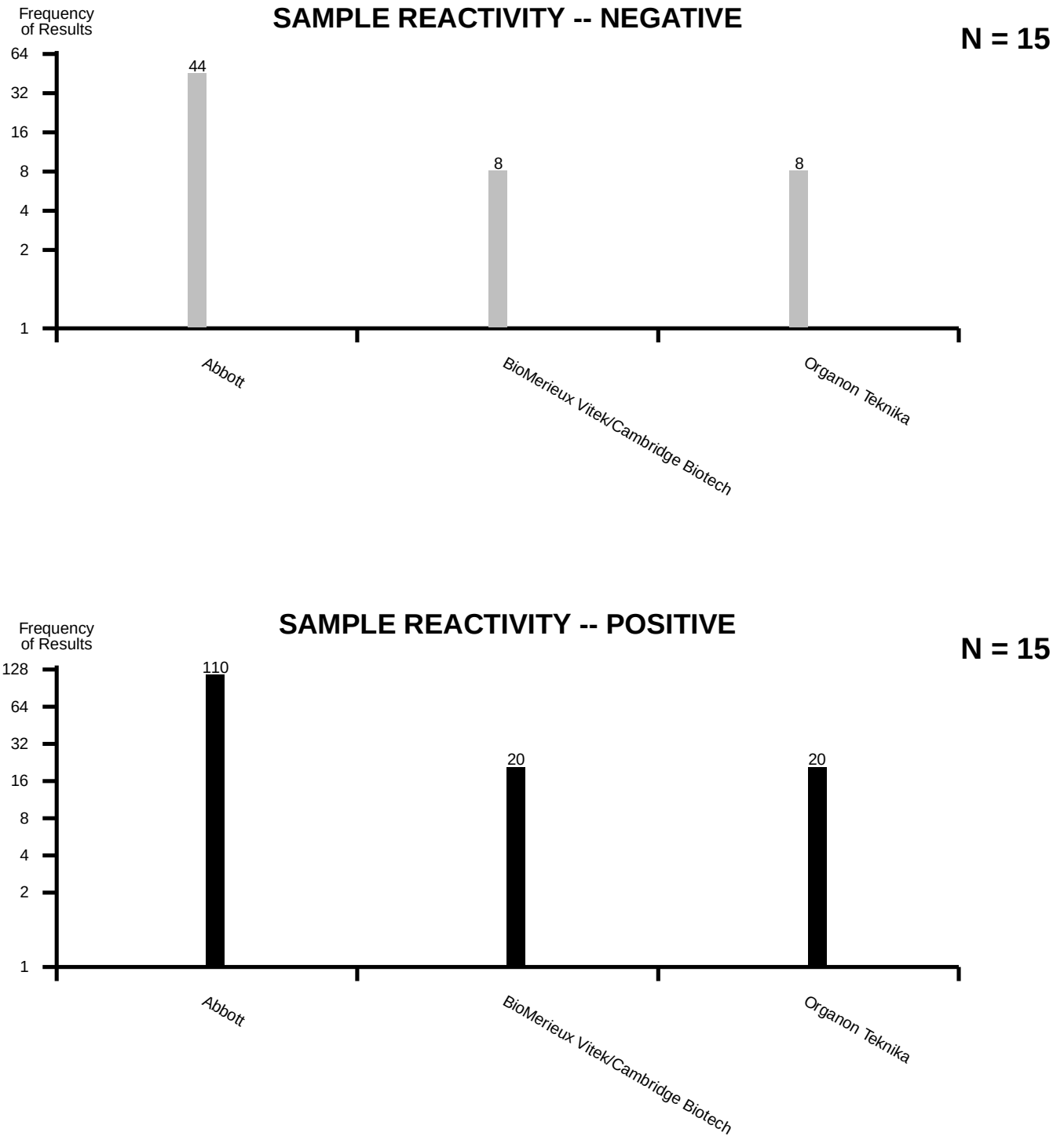


Figure 5. Enzyme immunoassay HTLV-I/II results, by kit manufacturer, reported by reference laboratories for the October 7, 1996 shipment



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HTLV-I/II Antibody Testing

Figure 6. Western blot HTLV-I/II results, by kit manufacturer, reported by reference laboratories for the October 7, 1996 shipment

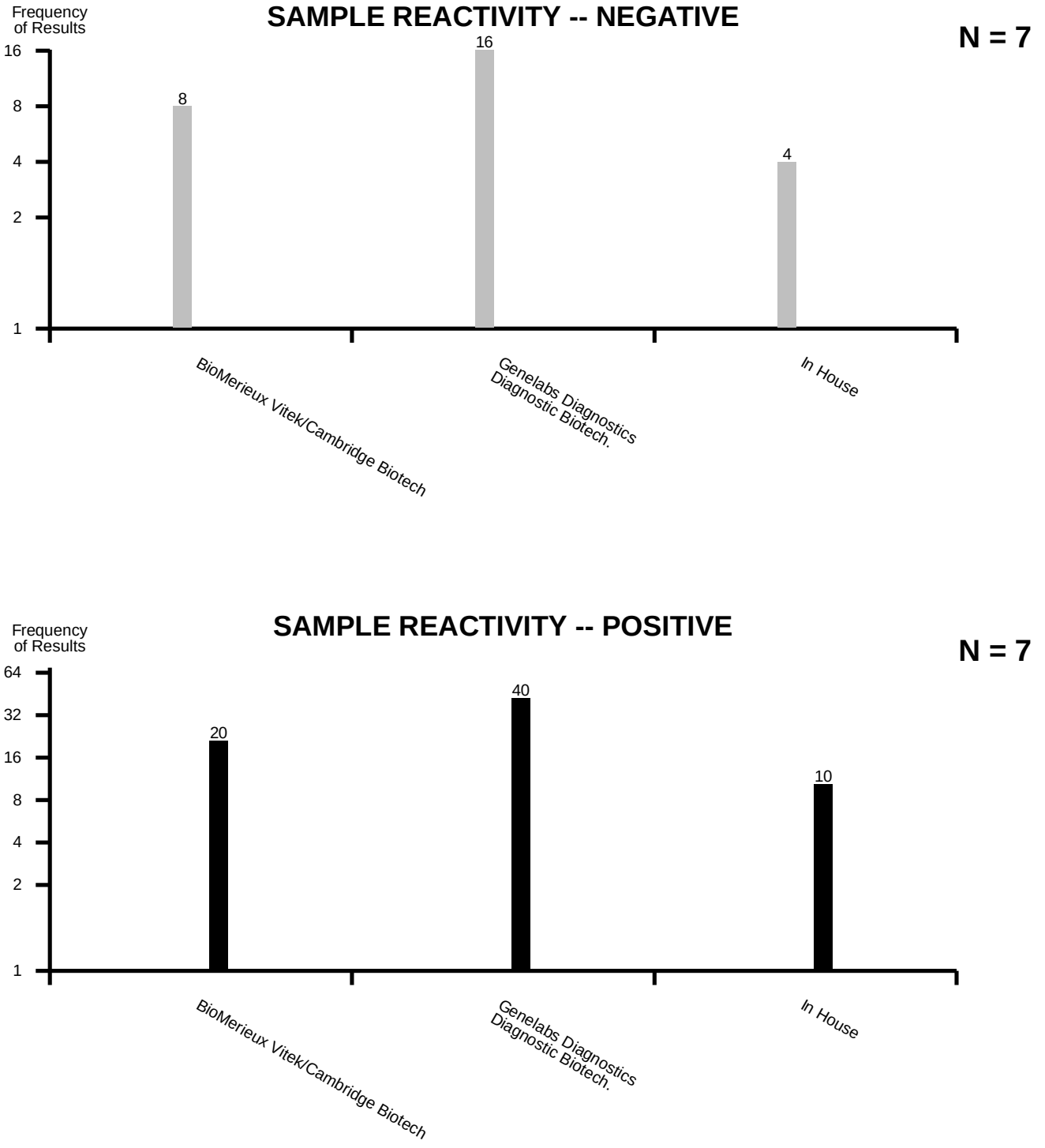
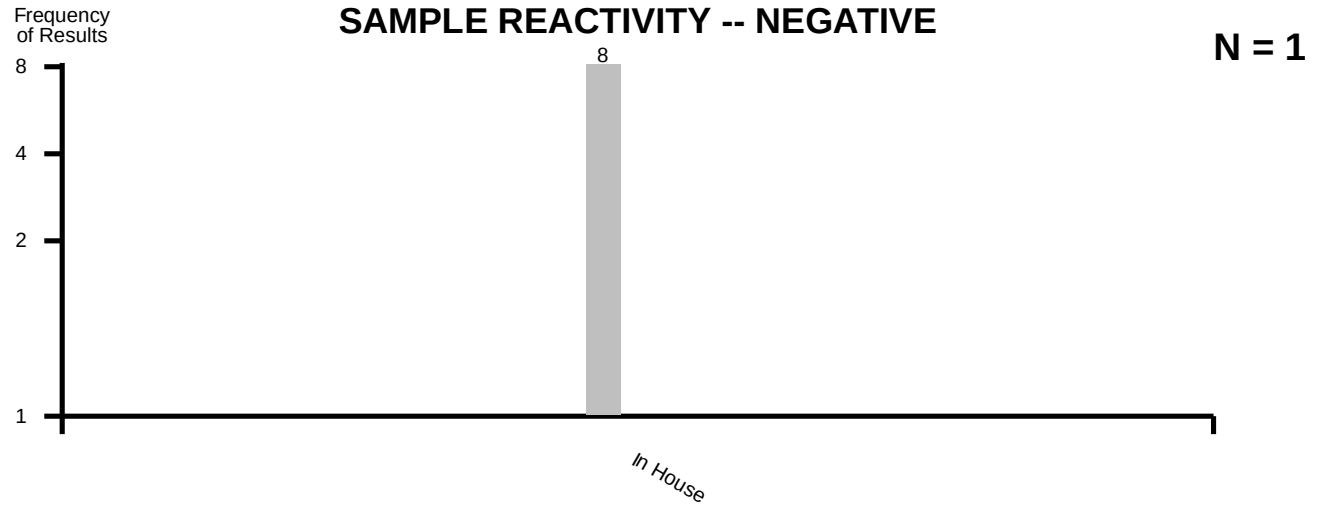
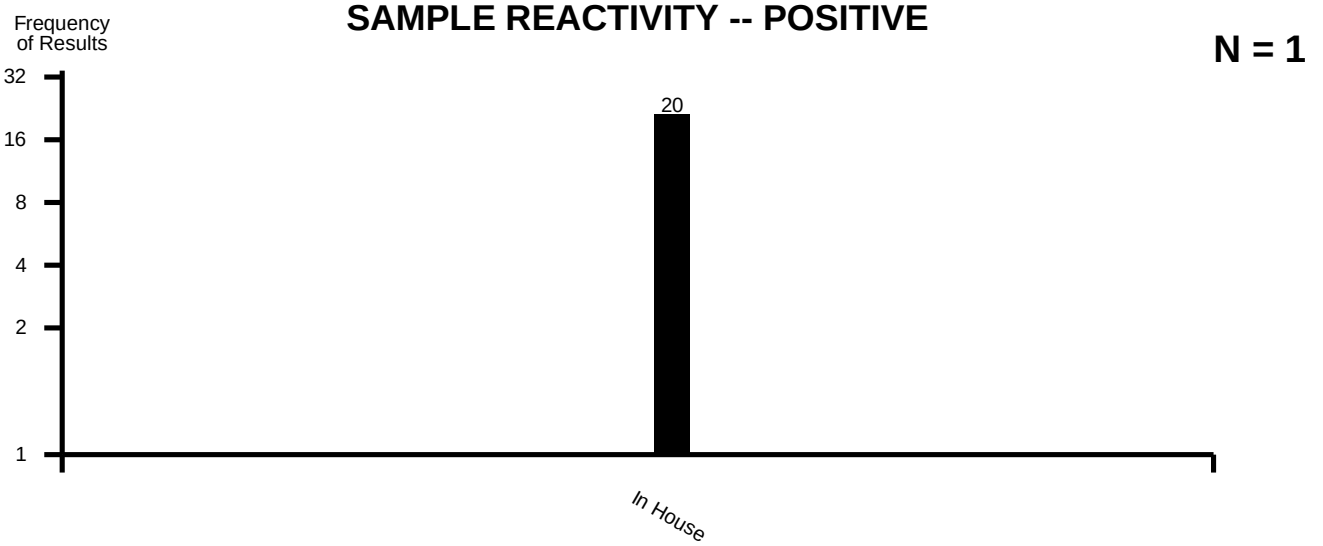


Figure 7. Indirect immunofluorescence HTLV-I/II results, by kit manufacturer, reported by reference laboratories for the October 7, 1996 shipment



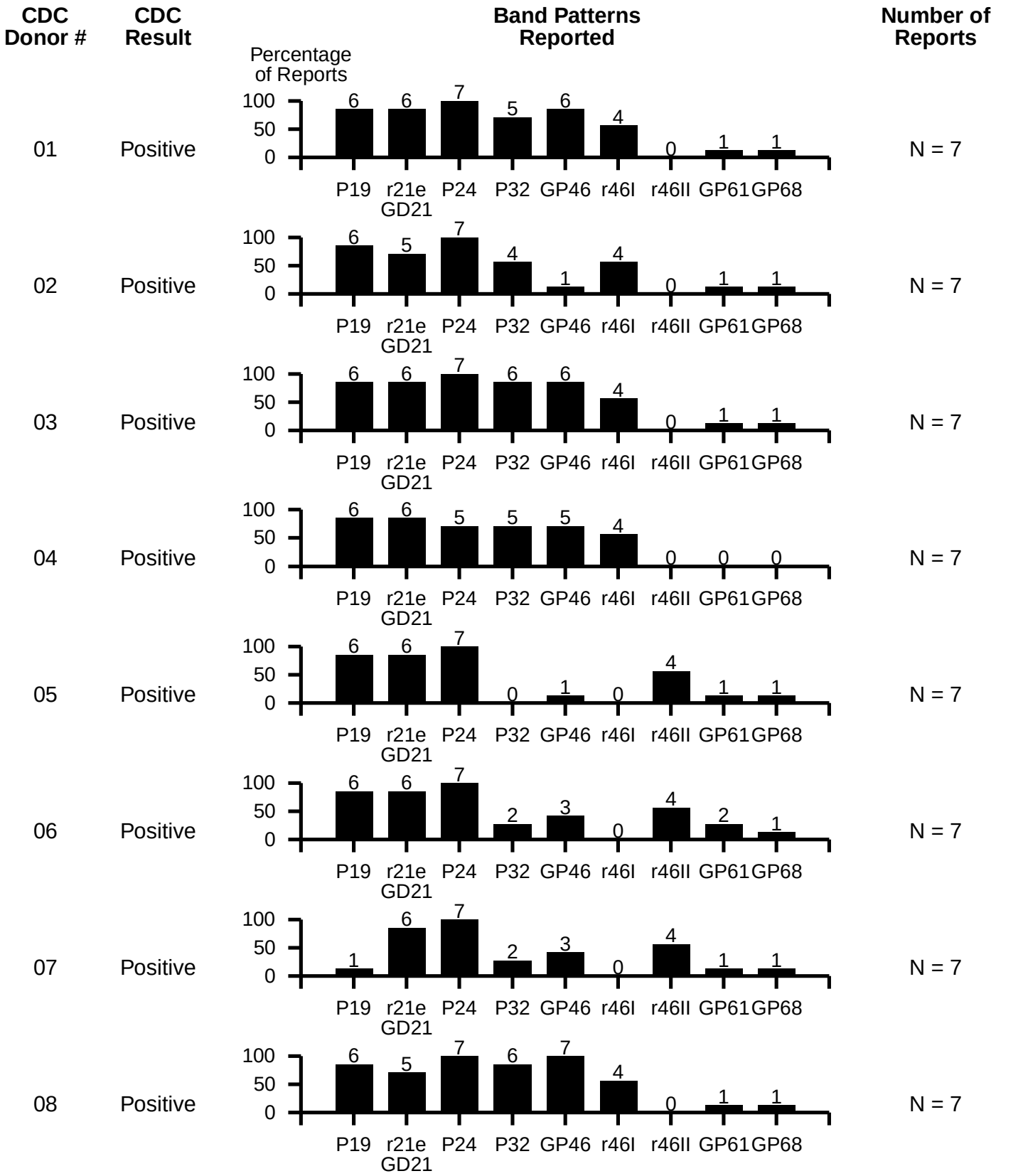


Test Result Interpretations

Non-Reactive Indeterminate Reactive

CDC Model Performance Evaluation Program
HTLV-I/II Antibody Testing

Figure 8. Western blot HTLV-I/II band patterns reported to CDC by reference laboratories for the October 7, 1996 shipment



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HTLV-I/II Antibody Testing

Figure 8. Western blot HTLV-I/II band patterns reported to CDC by reference laboratories for the October 7, 1996 shipment

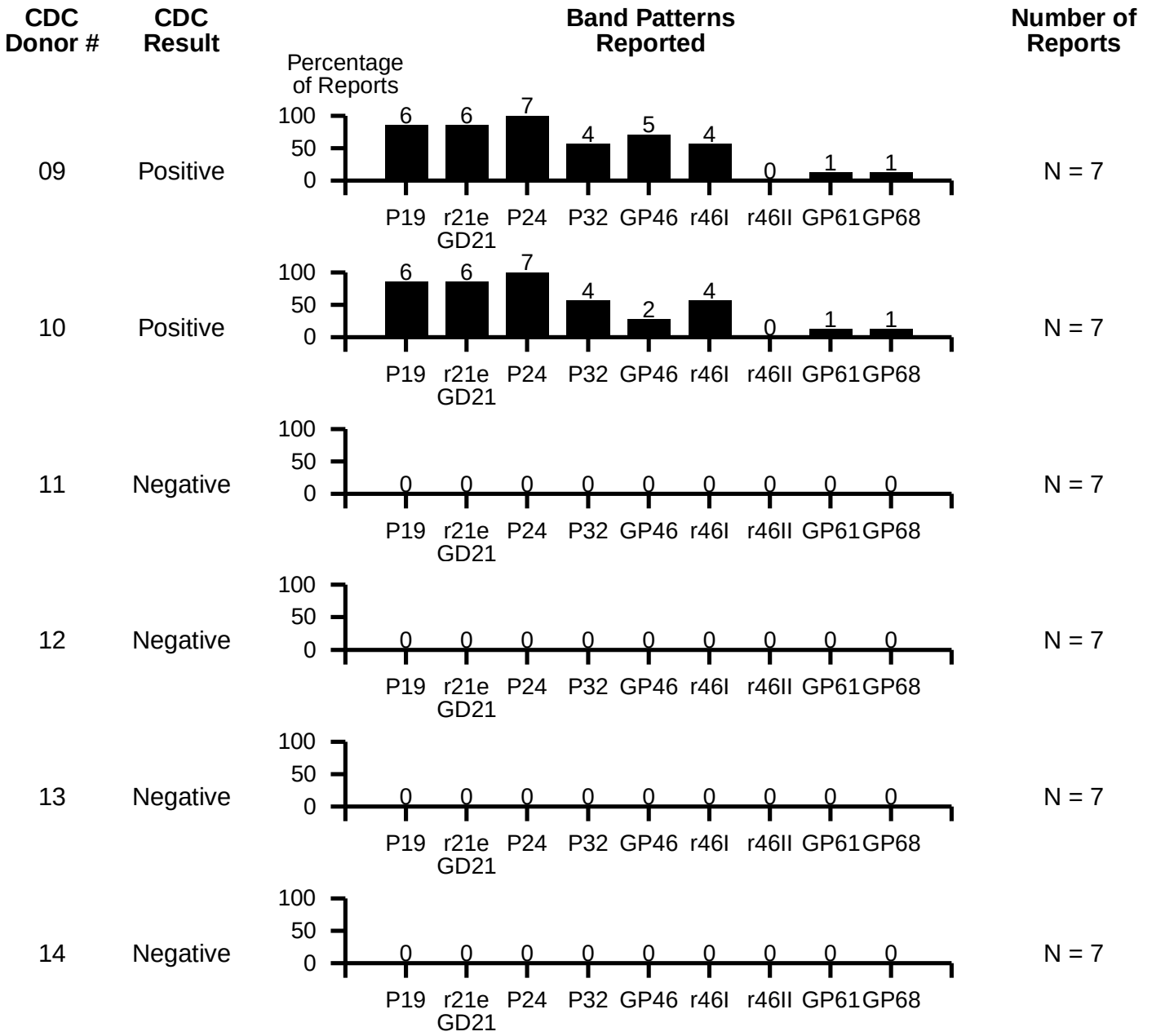

Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by reference laboratories for the October 7, 1996 shipment

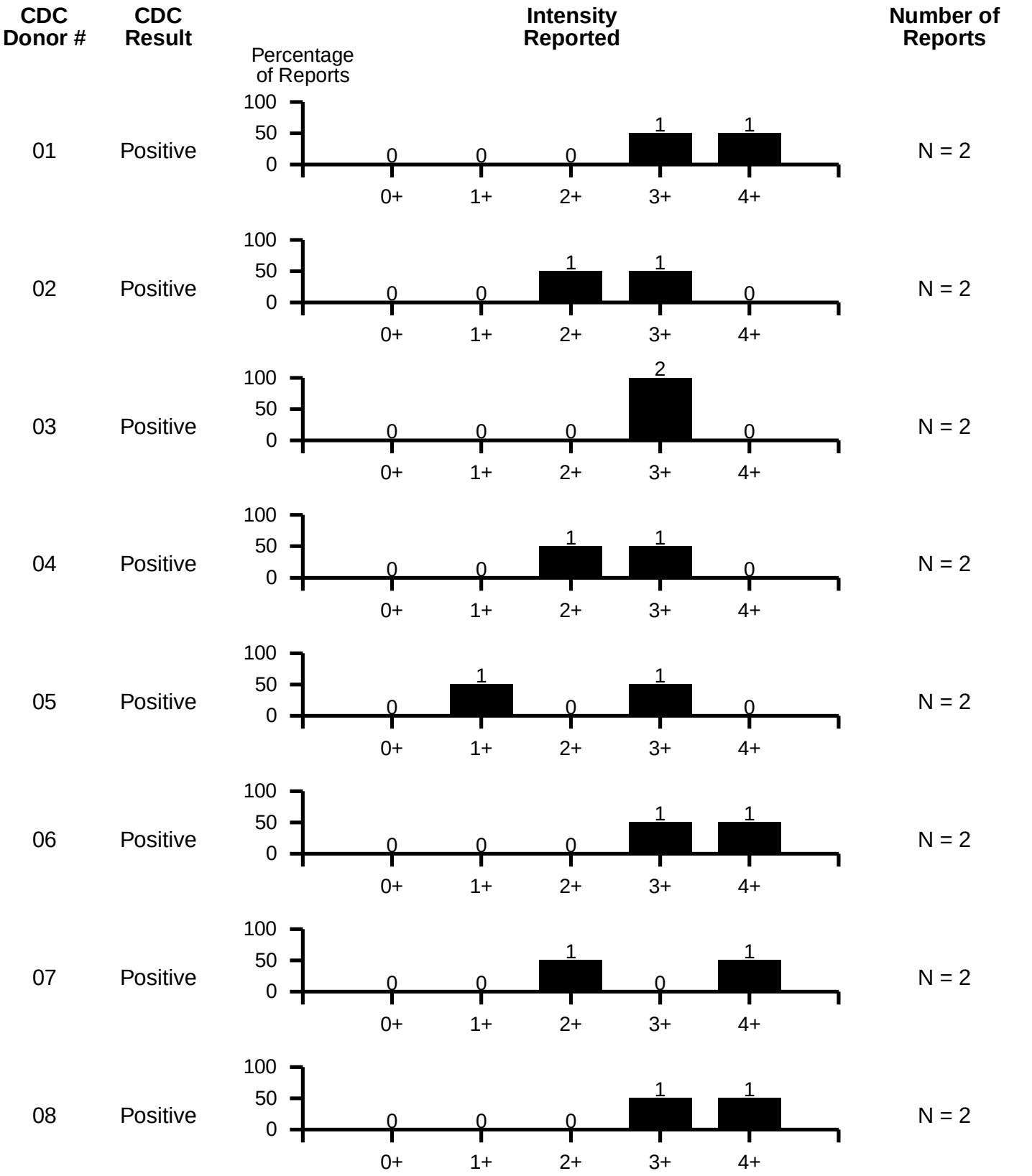

Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by reference laboratories for the October 7, 1996 shipment