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 5, 1998 Shipment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention Public Health Practice Program Office Division of Laboratory Systems Atlanta, Georgia 30333





Use of trade names is for identification only and does not constitute endorsement by the Public Health Service or by the U.S. Department of Health and Human Services.

Report of the October 5, 1998 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).

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	Thomas L. Hearn, Ph.D., Acting 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 HTLV Performance Evaluation	Laurina O. Williams, Ph.D.,
	HTLV Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-8130 or (770) 488-8098.

#### Centers for Disease Control and Prevention (CDC) Model Performance Evaluation Program Human T-Lymphotropic Virus Types I and II (HTLV-I/II) Testing October 5, 1998 Candidate Reference Laboratory Shipment

Vial Label Number	CDC Dono Number	r CDC Result <sup>2</sup>	Laboratory Interpretation <sup>1</sup> EIA			
	. turns of		INIT. <sup>3</sup> F	INAL⁴	WB	llF
01	03	Positive, HTLV-I				
02	06	Positive, HTLV-II				
03	13	Negative				
04	16	Negative				
05	15	Negative				
06	10	Negative				
07	02	Positive, HTLV-I				
08	08	Positive, HTLV-II				
09	01	Positive, HTLV-I				
10	09	Negative				
11	14	Negative				
12	11	Negative				
13	05	Positive, HTLV-II				
14	12	Negative				
15	04	Positive, HTLV-I				
16	07	Positive, HTLV-II				

#### Table 1

<sup>1</sup> Laboratory Interpretation space (to be completed by candidate reference laboratory) provided to facilitate comparison of candidate reference laboratory result with CDC result.

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

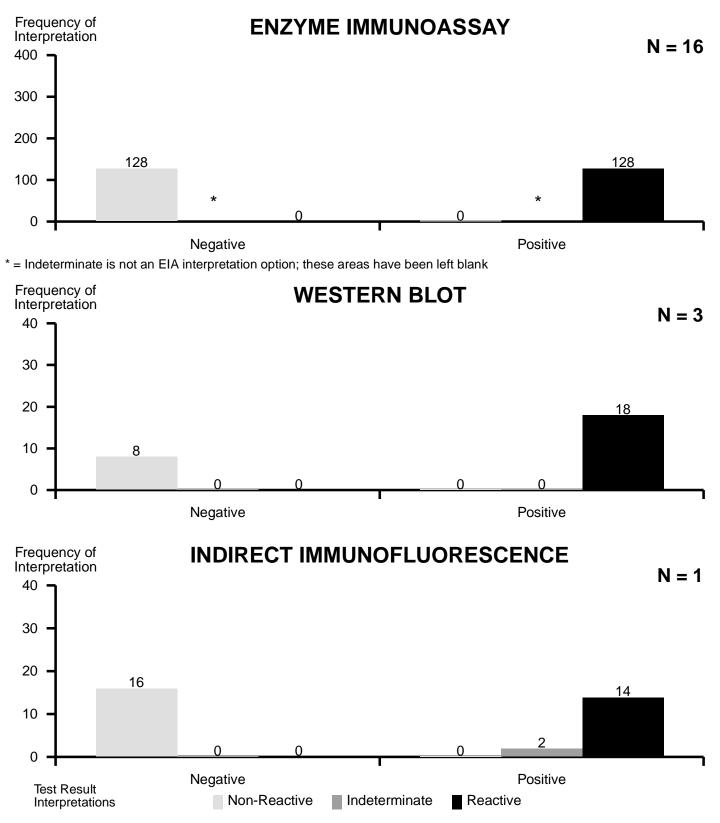
<sup>3</sup> Initial EIA interpretation

<sup>4</sup> Final EIA interpretation

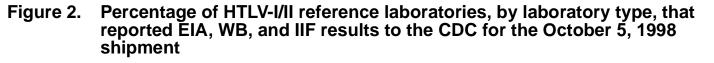
#### SUPPLEMENTAL INFORMATION FOR COMPREHENDING THE NUMBERS USED TO LABEL FIGURES IN THIS REPORT

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 enzyme immunoassay (EIA), Western blot (WB), and indirect immunofluorescence (IIF), reported by reference laboratories for the October 5, 1998 shipment



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



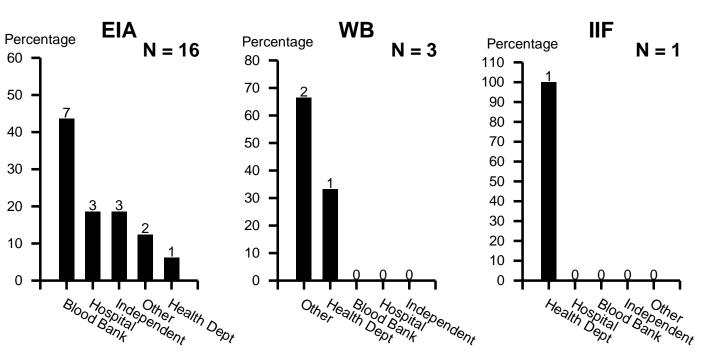
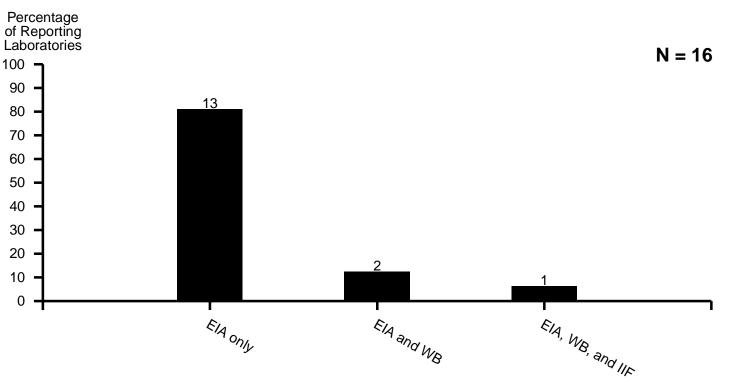


Figure 3. Combination of HTLV-I/II antibody tests reported by reference laboratories for the October 5, 1998 shipment



**Test Combinations** 

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

Figure 4. Types of HTLV-I/II antibody test kits used for enzyme immunoassay, Western blot, and indirect immunofluorescence, as reported by reference laboratories to the CDC for the October 5, 1998 shipment

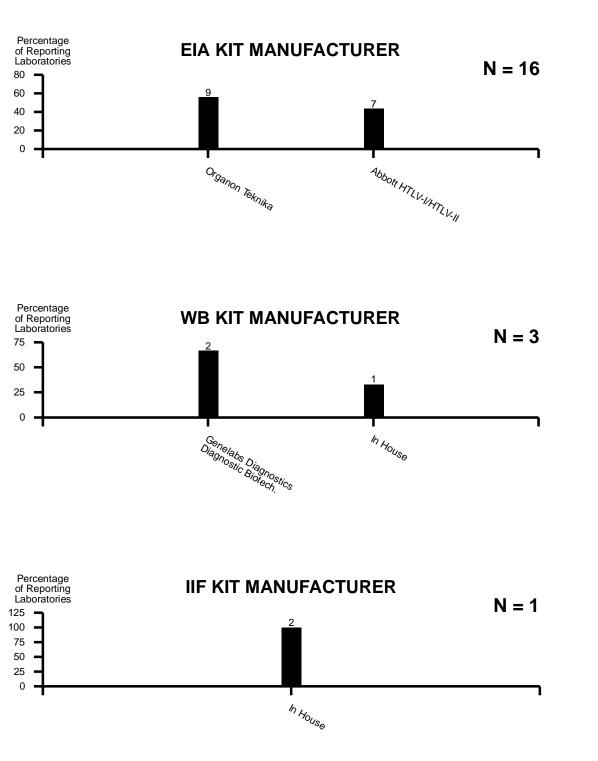
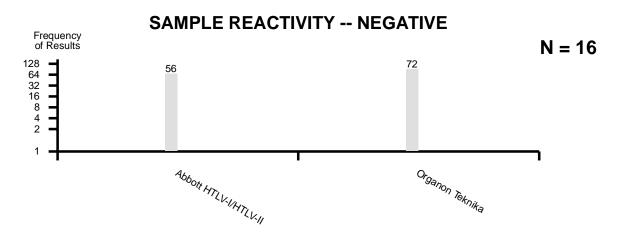
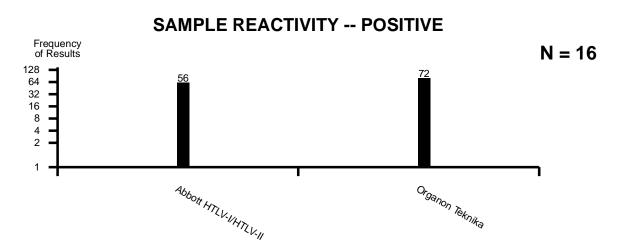


Figure 5. Enzyme immunoassay HTLV-I/II antibody test results, by kit manufacturer, reported by reference laboratories for the October 5, 1998 shipment

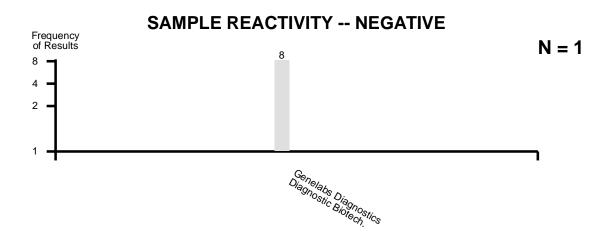


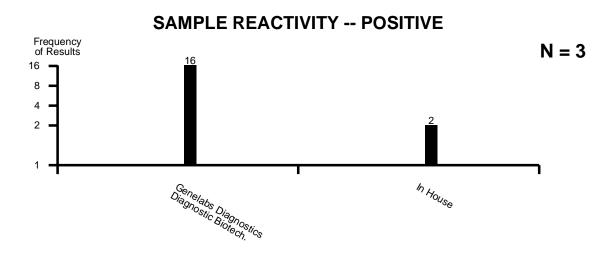


Test Result Interpretations

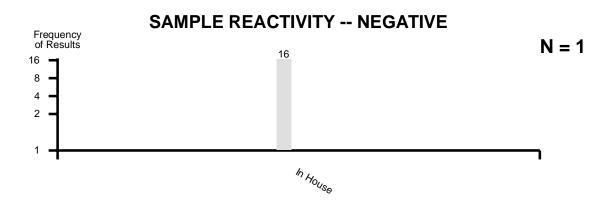
Non-Reactive Reactive

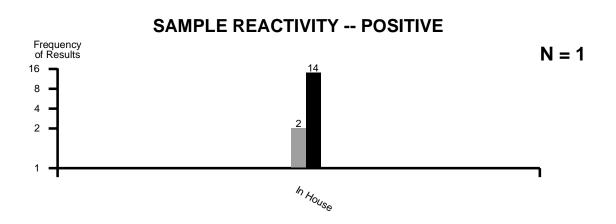
Figure 6. Western blot HTLV-I/II antibody test results, by kit manufacturer, reported by reference laboratories for the October 5, 1998 shipment





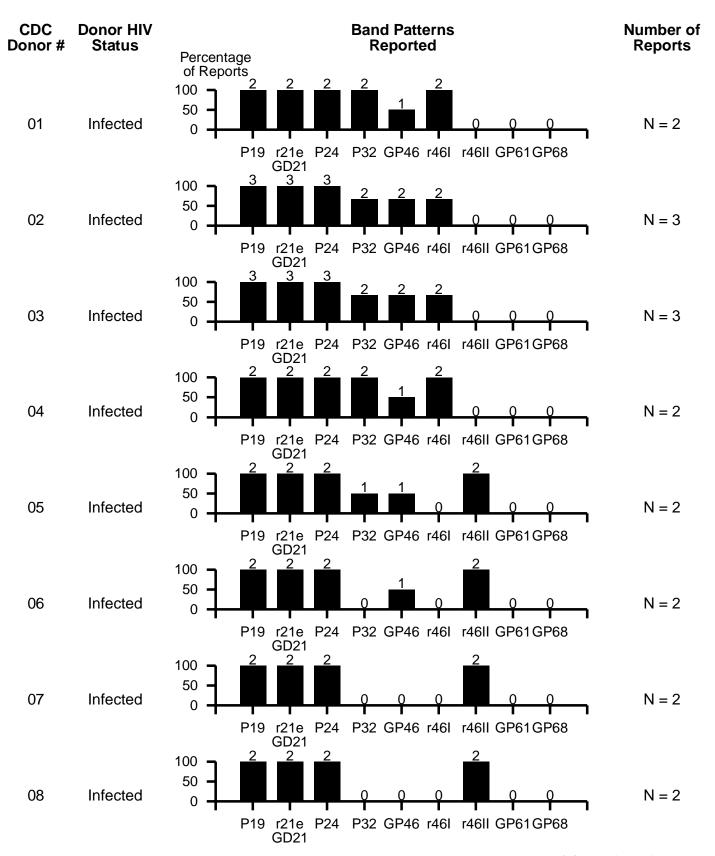
Test Result Interpretations Figure 7. Indirect immunofluorescence HTLV-I/II antibody test results, by kit manufacturer, reported by reference laboratories for the October 5, 1998 shipment





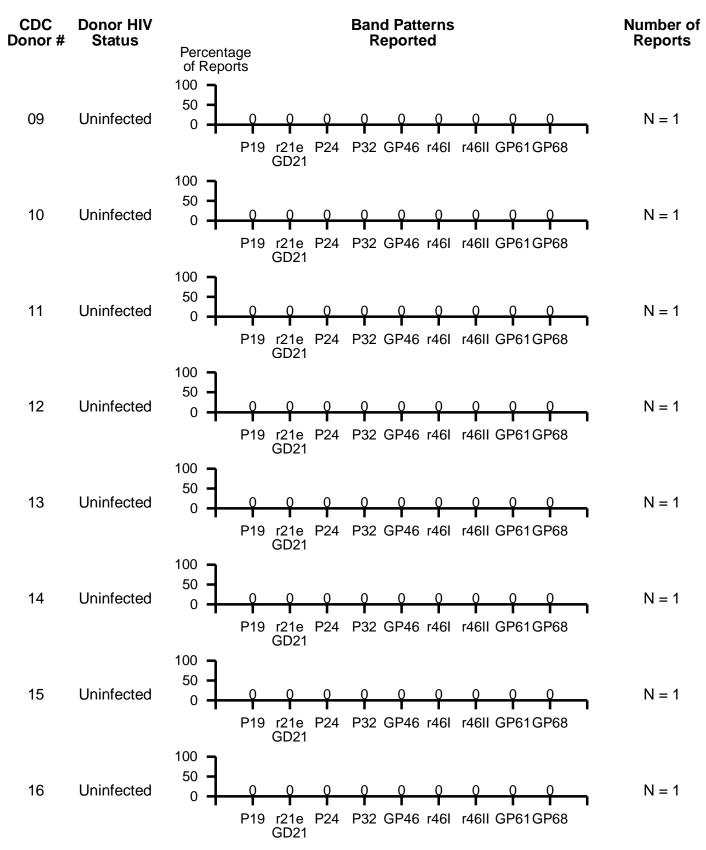
Test Result Interpretations

Non-Reactive Indeterminate Reactive



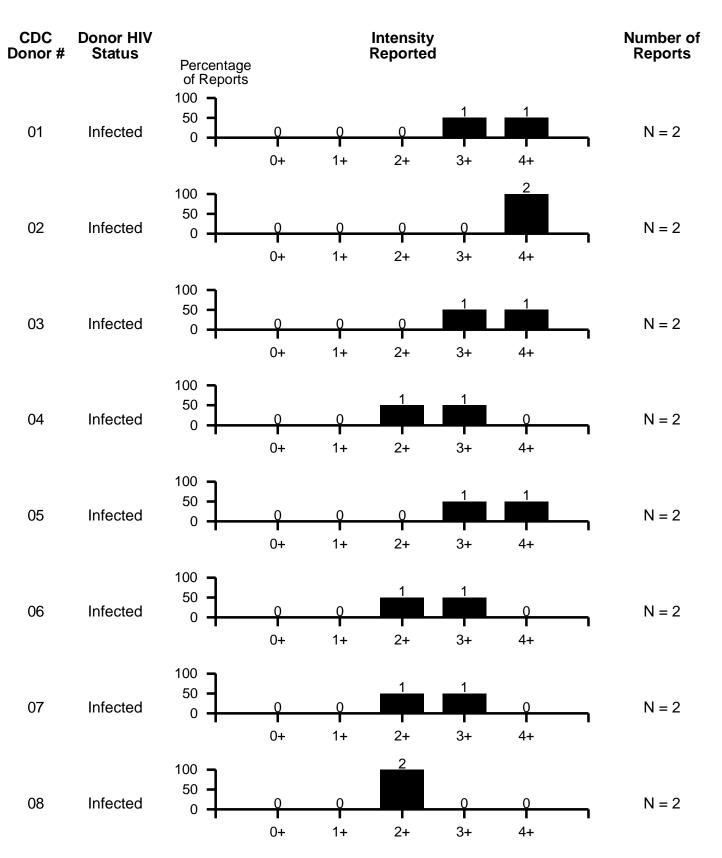
### Figure 8. Western blot HTLV-I/II antibody band patterns reported to CDC by reference laboratories for the October 5, 1998 shipment

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



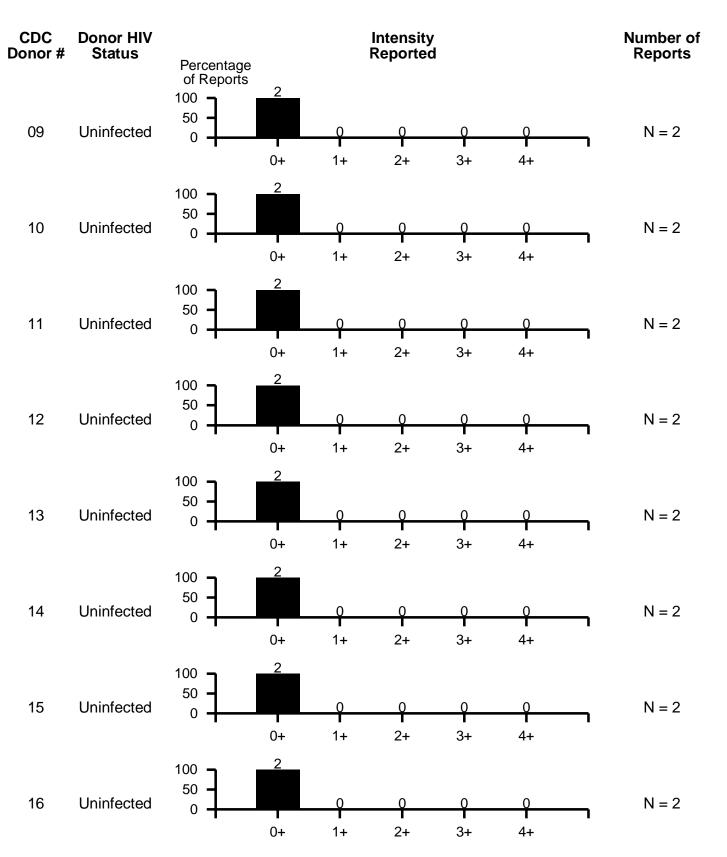
### Figure 8. Western blot HTLV-I/II antibody band patterns reported to CDC by reference laboratories for the October 5, 1998 shipment

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



# Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by reference laboratories for the October 5, 1998 shipment

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



# Figure 9. Fluorescence intensity patterns, of HTLV-I/II-infected cells, for IIF results reported to CDC by reference laboratories for the October 5, 1998 shipment

CDC Model Performance Evaluation Program HTLV-I/II Antibody Testing Figure 10. Types of 'Other' HTLV antibody test kits used and results reported by reference laboratories to the CDC for the October 5, 1998 shipment

