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Comparison of Six Commercial Human T-Cell Lymphotropic Virus Type I (HTLV-I) Enzyme Immunoassay Kits for Detection of Antibody to HTLV-I and -II

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Three licensed and three research human T-cell lymphotropic virus type I (HTLV-I) enzyme immunoassay (EIA) kits were evaluated with a panel of 213 serum or plasma samples which were previously tested by the indirect immunofluorescence method for HTLV-I and -II antibodies. The three research kits were found to be more sensitive and specific than the three licensed kits.

A relatively high rate of antibody to human T-cell lymphotropic virus type II (HTLV-II) has been demonstrated in intravenous drug user (IVDU) populations in various regions in the United States, including California (3, 4, 8, 9). An HTLV-I enzyme immunoassay (EIA) screening test is usually used to test for antibody, but HTLV-I and HTLV-II share cross-reacting antigens, and the EIA can not differentiate antibodies to these two agents. In studies done by techniques which can distinguish HTLV-I from HTLV-II infection, such as the polymerase chain reaction, it has been confirmed that the majority of antibody found in IVDU populations in the United States is to HTLV-II (4, 6–9).

In the present study, we evaluated six commercial HTLV-I EIA kits in their configurations as of September 1989. Three of the kits, Abbott Laboratories (North Chicago, Ill.), Cellular Products, Inc. (CPI; Buffalo, N.Y.), and E. I. du Pont de Nemours & Co., Inc. (DuPont; Wilmington, Del.), are licensed by the U.S. Food and Drug Administration; and three of the kits, Cambridge BioScience (CAMB; Worchester, Mass.), Genetic Systems Corp. (GSC; Seattle, Wash.), and Organon Teknika Corp. (OTC; Durham, N.C.), are for research only.

The kits were evaluated with a panel of 213 serum or plasma samples which were screened by immunofluorescence assay (IFA) on both HTLV-I- and HTLV-II-infected cells as described previously (3). The panel consisted of 35 IFA-negative and 110 IFA-positive samples from patients attending drug treatment centers and 66 IFA-negative and 2 IFA-positive samples from blood bank donors. Specimens that gave discrepant results between EIA and IFA were tested by Western immunoblot (WB) and radioimmunoprecipitation (RIPA), if necessary, as described previously (2); and the reactions were interpreted as positive, negative, or indeterminate according to the criteria of the Centers for Disease Control (1).

Table 1 provides results of EIA, IFA, and the confirmatory tests. The three research kits detected all 112 samples that were positive by IFA. Only 102, 62, and 58 of these samples were reactive with the Abbott, DuPont, and CPI kits, respectively.

Of the 101 IFA-negative specimens, 3 were reactive with the OTC and Abbott kits; 4 were reactive with the CAMB kit; and 9, 17, and 27 were reactive with the CPI, GSC, and DuPont kits, respectively. The majority of these discrepant specimens were found to be negative by WB, although a few displayed core band reactions which were interpreted as indeterminate or had an insufficient quantity for testing. The results of this study indicate that there are appreciable differences in the sensitivities and specificities of these commercial HTLV-I EIA kits.

These EIA kits are designed to detect antibody to HTLV-I. Kline et al. (5) determined the sensitivities and specificities of seven HTLV-I antibody kits, five of which

TABLE 1. Results for 112 IFA-positive and 101 IFA-negative specimens obtained with six HTLV-I EIA kits

EIA	No. of specimens					
	IFA result		WB and RIPA results on discrepant specimens			
	Positive	Negative	Positive	Negative	Indeterminate	QNS[a]
OTC						
Positive	112	3	0	1	2	
Negative	0	98				
CAMB						
Positive	112	4	0	4	0	
Negative	0	97				
GSC						
Positive	112	17	0	13	3	1
Negative	0	84				
Abbott						
Positive	102	3	0	0	3	
Negative	10	98	9	0	0	1
DuPont						
Positive	62	27	0	20	4	3
Negative	50	74	37	0	7	6
CPI						
Positive	58	9	0	5	3	1
Negative	54	92	41	0	7	6

[a] QNS, quantity not sufficient.

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were evaluated in the present study, with sera from pregnant Haitian women. One would assume from the results of past serosurveys done in the Caribbean that the women in the study of Kline et al. (5) were infected with HTLV-I. The three licensed kits detected antibody in 93.2 to 94.9% of the reactive samples in the panel of sera from Haitian women, which was a much higher sensitivity rate than was found in our study.

HTLV-II has not been firmly linked to any disease. However, until data are available to show that HTLV-II does not cause disease, blood centers and diagnostic laboratories should be performing screening antibody tests that are sensitive to both viral types. The excellent sensitivities of the three research kits evaluated in this study indicate that more reliable HTLV-I and -II screening tests are available for this purpose.

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