Antibody to HTLV-1 - Release Panel 1 (10/18/88)

October 18, 1988

From: Director, Center for Biologics Evaluation and Research, FDA

Subject: Antibody to Human T- Cell Lymphotropic Virus, Type I (HTLV-1) Release Panel 1

To: Manufacturers of HTLV-I Antibody Test Kits

A new FDA lot release panel for antibody to Human T-Cell Lymphotropic Virus, Type I (HTLV-I Release Panel 1) is now available for distribution by the Center for Biologics Evaluation and Research, FDA. The purpose of Panel 1 is for the qualitative and semi-qualitative evaluation of in vitro tests to detect antibody to HTLV-I in human serum or plasma. It is a regulatory panel similar to the HTLV-III Reference Panel 2. The HTLV-I Release Panel 1 is designed to provide a release criterion for lots of HTLV-I antibody detection kits produced by licensed manufacturer or lots of produced by manufacturers pursuing licensure of such tests and should not be used for experimental or other reference purposes. Due to the expected large number of requests for this panel, Center for Biologics Evaluation and Research will limit the distribution of the panel when necessary.

The HTLV-I Release Panel 1 is derived from six human sera reactive for antibody to HTLV-I which were provided by the National Center Institute and the American Red Cross. These sera were obtained from two Japanese blood donors in Japan, two American blood donors in the United States and two Jamaican Blood donors in Jamaica. Each serum has been found to contain antibodies to GAG, ENV, ana TAX gene products by both immunoblot and radioimmunoprecipitation assay as well as being reactive by p.24 radioimmunoprecipitation assay and indirect immunofluorescence using chronically infected cells lines (HUT 102.B2 and MT-2).

The HTLV-I Release Panel 1 consists of twelve samples: (a) Ten are reactive sera that have been diluted in normal human sera negative for antibodies to HTLV-I. Eight of these ten sample are reactive for antibodies to HTLV-I by an enzyme-linked immunosorbent assay (ELISA), and have been confirmed as specific for HTLV-I by immunoblot and radioimmunoprecipitation assay out have a borderline ELISA reactivity. (b) Two are normal human sera that contain no detectable antibody to HTLV-I. A description of the individual samples in the panel is attached to this memorandum.

USE: HTLV-I Release Panel 1 samples should be kept frozen for extended storage. It is suggested that samples be aliquotted into smaller volumes for routine use. Thimerosal has been added as a microbial inhibitor (0.01% however, care should be taken to

minimize contamination.

CAUTION: These samples have not been treated to inactivate viruses. All samples should be labeled and handled as infectious material.

Information and requests regarding this panel should be directed to:

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Center for Biologics Evaluation and Research
HTLV-I Release Panel 1
(Reference Antibodies to HTLV-I)

Panel Member	Source	Dilution	Expected Reactivity*
1	JA 238 (Jamaica)	1:8	+
2	JA 246 (Jamaica)	1:32	+
3	ARCFDA 02 (USA)	1:2	+
4	ARCFDA 03 (USA)	1:16	+
5	ARCFDA 03 (USA)	1:6	+
6	ARCFDA 02 (USA)	1:16	+/-
7	ARCFDA 02 (USA)	1:8	+
8	ARCFDA 03 (USA)	1:100	+/-
9	A121-1392	1:2	+

	(JAPAN)		
10	A0504-8754 (JAPAN)	1:64	+
11	N1 pooled sera NSA+NSB+NSC+NSD (USA)	undil	-
12	N1 human serum NSK (USA)	undil	-