DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

FEB 27 1985

TO: State and Territorial Public Health Laboratory Directors
State and Territorial Epidemiologists

SUBJECT: Availability of Control Reagents for AIDS Serologic Tests and Reference Tests for HTLV-III Antibody

This memorandum is to inform you of the Center for Infectious Diseases (CID) plans to provide reference reagents and to make available reference tests for HTLV-III antibody to State health department laboratories. Beginning March 15, 1985 the following candidate reference or control sera may be requested from the Biological Products Program, CID by submitting Requisition Form CDC 51.6 Rev 11-83. The distribution policy will be similar to that of other reference or standard material.

Catalog No. VS 2151 - HTLV-III positive antiserum, human
Catalog No. VN 2152 - HTLV-III negative serum, human

Because supplies are limited, the control sera will be available in reference amounts only.

The HTLV-III antigen for use in the Western blot test can be made available by any of the companies that receive approval from FDA for distribution of the ELISA kits. It is anticipated that the HTLV-III antigen will be sold by one or more of these companies for "investigational use only." The positive and negative serum controls listed above may be used for reference purposes with the commercial ELISA kits as well as for checking the reliability of commercially obtained antigen for usein the Western blot antibody assay. If persistent problems with the Western blot antibody assay are encountered or if additional information on HTLV-III reference testing is needed, please contact:

Charles A. Schable
AIDS Serology Laboratory, AIDS Branch
Division of Viral Diseases
Center for Infectious Diseases
Centers for Disease Control
Atlanta, GA 30333
(404) 329-3040

If as a result of consultation inactivated HTLV-III virus is determined to be needed, reference amounts will be provided by the AIDS Branch, Division of Viral Diseases.

Beginning March 15, CID will provide reference service to State laboratories for ELISA and Western blot assay for HTLV-III antibody. These services will be provided primarily to assist State and local laboratories in gaining proficiency with the tests. The anticipated demand for the tests and the commercial availability of kits for the ELISA test, preclude CDC accepting serum specimens for diagnostic purposes. We ask that specimens submitted be accompanied by a completed request form (CDC 50.34 Rev. 8-84). Patient confidentially can be preserved by placing an identifying number or code where the name is requested.

We will continue to keep you informed of any additional information in this rapidly developing activity.

Walter R. Dowdle, Ph.D.
Director
Center for Infectious Diseases

cc:
Director, Laboratory Program Office
Director, Epidemiology Program Office