UPDATE

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Patricia Newman
301-496-6641

BLOOD TEST FOR AIDS PROVES RELIABLE AND PRACTICAL

A team of National Cancer Institute (NCI) and collaborating scientists has demonstrated that a simple blood test for the virus called HTLV-III, the probable cause of AIDS, is a reliable, specific, and sensitive tool for screening large numbers of blood samples for antibodies to HTLV-III.

The blood test used in this study is a prototype, similar but not identical to those under development for commercial use. The findings reaffirm the usefulness of such a test for initial screening of blood samples for evidence of HTLV-III exposure. A total of 1,236 coded blood samples were analyzed between April-September 1984.

The NCI scientists have now reported that this test will be useful for identifying people who have been exposed to the virus and have developed an antibody response. A majority of these people may be virus carriers, or they may have immunologic abnormalities associated with HTLV-III infection.

The research was reported in the January 11, 1985, Journal of the American Medical Association by NCI scientists Stanley H. Weiss, M.D., James J. Goedert, M.D., Robert C. Gallo, M.D., William A. Blattner, M.D. and M. G. Sarngadharan, Ph.D.; Anne J. Bodner, Ph.D., of Biotech Research Laboratories, Rockville, Maryland; and a group of NCI and collaborating scientists in the AIDS seroepidemiology area.

The partially automated blood test used for the study is the research assay developed in the laboratory of Dr. Robert C. Gallo, who discovered the HTLV-III virus. Based on an ELISA (enzyme-linked immunosorbent assay) test

for antibodies to the HTLV-III virus, the NCI assay also used a robot to pipette equivalent amounts of coded blood samples into tiny wells on a tray, thus reducing risk to lab personnel, and shortening the time required to do the test. The levels of HTLV-III antibodies in each well was then measured by machine and recorded automatically by computer.

NCI's Dr. Stanley Weiss said a positive blood test "...indicates a person probably has been infected by HTLV-III and that the body's immune system has responded by producing antibody to the virus." Because ELISA assays can produce slightly variable results, making data from different laboratories difficult to interpret, the scientists first calibrated their assay by determining the range of ELISA results among volunteer blood donors. This control group, carefully selected from the normal population, provided scores for comparison with other test groups in the study.

Only 1 percent of 297 volunteer blood donors were positive, 6 percent were borderline, and 93 percent were negative. The blood test confirmed the presence of antibody in 72 of 88 AIDS patients. Fourteen were borderline (falling between the clear positive and clear negative results), and two were negative.

Using a second, more complex test for HTLV-III antibodies, known as a Western blot, the borderline blood donors were negative. AIDS patients with borderline ELISA results are positive for HTLV-III antibody when tested by Western blot.

The reliability of the ELISA test was confirmed further by showing that groups of people with non-AIDS illnesses, whose blood might have cross-reacted, scored negative on the test.

Included were blood samples from groups with antibodies to other HTLV viruses, patients with chronic hepatitis or cancers of the lymph system, and individuals with high levels of other antibodies.

"Our study findings further strengthen the epidemiologic association between HTLV-III and AIDS," said Dr. Weiss, "and lay essential groundwork for the commercial assays under development."

Importantly, the study showed that laboratory personnel working directly with HTLV-III in NCI and certain collaborating laboratories, as well as health care personnel caring for AIDS patients at NIH, do not have antibody to HTLV-III. Although 7 of 188 laboratory and hospital workers scored positive or borderline on the ELISA screening test, all were negative on the confirmatory Western blot test. "This finding confirms other research showing that current laboratory and hospital procedures are effective in protecting against HTLV-III virus transmission," said Dr. Weiss.

A new finding was that 26 of 56 (46.4 percent) of drug abusers from New York City whose samples were taken in 1981 and 1982 had HTLV-III antibodies, as measured by the ELISA test. The study also found that 53.3 percent of 75 New York City homosexuals and in 8.8 percent of 250 homosexuals in Denmark whose blood samples were taken during the same time period scored positive for HTLV-III antibodies.

The United States Public Health Service currently is developing guidelines concerning the clinical application and interpretation of ELISA-type HTLV-III antibody tests.

The authors recommend that an ELISA-type test be used as an initial screening and monitoring tool. They point out, however, that the sensitivity of the test (and the number of persons scoring as positives) increases as lower antibody levels are scored as positive on the ELISA test. "Because the Western blot is difficult to do and expensive, clinical science needs a simpler confirmatory assay. Clinical pathologists will also turn to additional laboratory tests to confirm the physician's clinical findings and the results of ELISA-type tests," said Dr. Weiss.

"Based on recent data, tests for antibody to HTLV-III will be important for blood screening, but the assays would miss those HTLV-III carriers who did not respond with antibody. Apparently such individuals do exist in some high-risk groups, but it is at present uncertain how many people who carry the virus react in this manner. Additional tests for the presence of small amounts of virus or its products in blood will be needed," said Dr. Peter J. Fischinger, the NCI member of the NIH Executive Committee on AIDS.

Other collaborating scientists on this study included: Robert J. Biggar, M.D., Jeffrey W. Clark, M.D., Mark H. Greene, M.D., and Deborah M. Winn, Ph.D., of the NCI Environmental Epidemiology Branch; Mikulas Popovic, Ph.D., Marjorie Robert-Guroff, Ph.D., and W. Carl Saxinger, Ph.D., of the NCI Laboratory of Tumor Cell Biology; and Edward P. Gelmann, M.D., NCI Medicine Branch; Roger Y. Dodd of the American Red Cross Blood Services Laboratories, Bethesda, MD; Jose S. Giron, M.D., of Flushing Hospital, Flushing, NY; Mads Melbye, M.D., of the Institute of Cancer Research in Aarhus, Denmark; and Michael Simberkoff, M.D., Department of Infectious Disease, New York Veterans Administration Medical Center, NY.