Abbott Laboratories' HIVAG-1 test (10/4/89)

DATE: October 4, 1989

FROM: Director, Center for Biologics Evaluation and Research

SUBJECT: Abbott Laboratories' HIVAG-1 test for HIV-1 antigen(s) not recommended for use as a donor screen.

TO: All Registered Blood Establishments

On August 3, 1989, the Food and Drug Administration licensed Abbott Laboratories, North Chicago, Illinois, to manufacture and distribute an enzyme-linked immunoassay for the qualitative, in-vitro, detection of HIV-1 antigen(s) in human serum or plasma. The test is called HIVAG-1. As stated in the package insert, "It is intended to be used as an aid in the diagnosis and prognosis of patients with HIV-1 infection." The label does not include an indication for donor screening.

The FDA does not recommend the use of this test for screening of donations of either whole blood or source plasma. The purpose of this memorandum is to declare this position, and explain its rationale.

The indications for licensure of Abbott's antigen test were discussed at a public meeting of the Blood Products Advisory Committee on March 23, 1989 in Bethesda, Maryland. At this meeting the FDA received endorsement of its positions: a) that screening of source plasma would not add significantly to the safety of plasma derivatives, b) that screening of whole blood would not add measurably to the safety of the blood supply, and c) that the test has value for prognosis and other clinical diagnostic uses. The arguments can be summarized as follows:

a) argument against screening of source plasma donations

Although a study conducted by Abbott Laboratories (S. L. Straemer, et al., JAMA 1989; 262:64-69) demonstrated the presence of HIV antigen prior to antibody in four out of seven source plasma donors who seroconverted and had samples stored from previous donations, there is overwhelming evidence that plasma derivatives no longer transmit HIV. Thus, the antigen test is unnecessary for screening of plasma intended for further manufacture into derivatives.

b) argument against screening of whole blood donations

The efficacy of the antigen test for "early" detection of HIV-1 infection prior to seroconversion in donors of whole blood has been examined in Europe

and the United States. Studies in West Germany and Austria failed to reveal a single case of "early" HIV detection in approximately 595,000 screened donations between March 1987 and April, 1988. In the United States, a study of over 200,000 (now updated to exceed 500,000) whole blood donors screened since January, 1989 was also negative. In addition, retrospective testing of the repository of the Transfusion Safety Study failed to reveal a case positive for HIV antigen and negative for HIV antibody among 2,292 samples from male donors in areas of high antibody prevalence who were drawn between September 1984 to February, 1985. Collectively, these studies show that detection of antigen without antibody is rare event in the whole blood donor population (less than one per million). Thus, routine use of the antigen test would not add significantly to the safety of the blood supply, even though a person with recent HIV infection could donate prior to the development of antibodies.

c) licensure as a clinical diagnostic test

The FDA accepted the data of Abbott Laboratories which indicated efficacy of the HIVAG-1 test for early diagnosis of HIV-1 infection in individuals at high risk, and as a prognostic test to estimate the risk of progression to ARC or AIDS in asymptomatic, seropositive persons. The test was therefore licensed for its diagnostic and prognostic use.

A similar recommendation against antigen testing of blood donors was publicized by a Select Committee of Experts of the Council of Europe which met in March, 1989 in Innsbruck, Austria. That group stated that "currently available HIV-antigen tests will not add to the security gained by screening of donors with current anti-HIV-1 tests, though the danger of HIV transmission by donations taken before seroconversion still exists."

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