Recombigen HIV-1 Latex Agglutination (LA) Test (8/1/89)

Date: August 1, 1989

From: Director, Center for Biologics Evaluation and Research

Subject: Use of the Recombigen HIV-1 Latex Agglutination (LA) Test

To: All Registered Blood and Plasma Establishments

On February 1, 1989 this office issued a memorandum regarding the use of the Recombigen HIV-1 LA test in blood and plasma establishments. This memorandum is intended to clarify certain statements in the February 1 memorandum. In addition, this memorandum addresses FDA recommendations concerning the use of rapid tests for "pre-collection screening."

1. Clarifications to the memorandum of February 1, 1989

Our February 1 memorandum stated that the latex agglutination test is not recommended for routine use in blood and plasma establishments because of procedural difficulties in testing large numbers of donor samples. This recommendation has been misinterpreted to mean that the test is not suitable for any use in blood and plasma establishments. As previously stated, the latex agglutination test may be used, with the exercise of medical discretion, in situations in which screening by EIA is impractical or unavailable. For example, in emergency situations, the latex test could be used to screen whole or rare blood donors. It might also be used for testing previously-screened platelet donors. Results from a latex screen will determine the HIV-1 status of the donor; repeatably reactive donors must be deferred, although they remain eligible for reentry.

The prior memorandum mentioned circumstances which could give rise to false positive results. This test requires subjective reading and interpretation, necessitating proper training of personnel to insure correct results. Because blood bank technicians may not have occasion to use the test on a regular basis, the interpretation panel should be used periodically, as recommended in the package insert. Clinical trials performed in blood banks by properly trained operators showed the latex test to be 99.5% specific.

2. Use of rapid screening tests for "pre-collection screening" Following the licensure of a rapid screening test for antibodies to HIV-1, this office received inquiries about the possibility of screening donors of blood or plasma prior to collection. Such a

practice might be useful to avoid performing lengthy and expensive apheresis procedures on donors whose donations would be subsequently discarded. Tests used to determine donor suitability may be performed prior to the collection, but on the same day (21CFR 640.3(a)). If an HIV-1 antibody test is performed in the "pre-collection screening" mode, it would become improper to draw a unit from a person with a repeatably reactive result.

Tests performed "pre-collection" do not obviate the performance of required tests at the time of collection on the unit or on the donor (2lCFR 640.4(g)(2), and 2lCFR 640.5). If a situation should occur in which another licensed test for HIV-1 antibodies is performed and found to be repeatedly reactive on a unit from a donor who tested negative in a "pre-collection screen," the unit should be discarded and the donor deferred despite the negative result of the pre-collection test.

The Medical Director, in using tests in the circumstances outlined above, should pay special attention to the potential for difficulties in maintaining confidentiality and of inadvertent de facto donor notification in the absence of additional testing for specificity.

Paul D. Parkman, M.D.
Director
Center for Biologics
Evaluation and Research