Unlicensed Anti-HCV Supplemental Test Results (8/19/93)

Date: August 19, 1993

From: Acting Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research

Subject: Clarification of the Use of Unlicensed Anti-HCV Supplemental Test Results in Regard to Donor Notification

To: All Registered Blood and Plasma Establishments

This memorandum transmits a clarification to the Revised Recommendations for Testing for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV) in Blood Establishments, August 5, 1993, in regard to donor notification (Section I.A.3.c., page 3a).

A donor who was tested with an unlicensed anti-HCV supplemental test prior to August 5, 1993, may be notified of those results providing certain statements are included in the notification. This notification should state that such results have been generated from a test which was unlicensed, but similar in principle, to the currently licensed supplemental test and that if the donor's physician has concerns regarding the accuracy of such results, repeat testing using the licensed test could be considered.

After August 5, 1993, for donor notification (beyond test results obtained with a licensed ELISA), tests on donors who are repeatedly reactive by ELISA should be performed with licensed anti-HCV supplemental tests.

Only licensed supplemental tests should be used for attempting donor re-entry.

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