

Guidance for Industry

Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens

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For questions on the content of the draft document contact Dr. Ruth Solomon, 301-827-0078.

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I. INTRODUCTION

The purpose of this guidance document is to inform all establishments or persons engaged in the testing of donations of human tissue intended for transplantation and regulated under 21 CFR Part 1270 of the availability of two licensed donor screening tests labeled for use with cadaveric (post-mortem) blood specimens.

II. BACKGROUND

In the Federal Register of July 29, 1997 (62 FR 40429), FDA published a final rule on human tissue intended for transplantation. The final rule, which became effective on January 26, 1998, requires that donor specimens be tested and found negative for the communicable disease viruses: HIV-1, HIV-2, Hepatitis B, and Hepatitis C, using FDA licensed donor screening tests in accordance with manufacturers' instructions. Specifically, 21 CFR 1270.21(d) states that "FDA licensed screening tests labeled for cadaveric specimens must be used when available." The preamble to the rule explains that FDA is aware of the need to clarify the appropriateness of using cadaveric specimens, i.e., a blood specimen taken from a donor whose heartbeat has ceased, with the currently licensed test kits. Generally, the concern has been that test results based on testing of cadaveric blood specimens that exhibit some degree of hemolysis and/or lipemia may not be accurate. At the time of publication of the final rule, no kits specifically labeled for cadaveric specimens were available. However, FDA states in the preamble that once FDA approval has been given and the labeling of the test kit has been modified to specifically indicate the use of cadaveric blood specimens, such screening tests are to be used.

Recognizing the need for specifically labeled test kits, FDA has worked with manufacturers towards validation of assays for cadaveric specimen use. To facilitate this, FDA issued letters to test kit manufacturers on January 12, 1995, and on May 2, 1995, which suggested a minimum protocol to follow for such validation. Since that time, one manufacturer, Genetic Systems Corporation, has submitted adequate validation data and has received approval for specific labeling of two screening tests for testing of cadaveric blood specimens.

¹ This guidance document represents the agency's current thinking and recommendations on *in vitro* testing of cadaveric blood samples. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

III. AVAILABILITY OF SPECIFICALLY LABELED TEST KITS

On December 28, 1999, FDA approved the Genetic Systems Corporation's Supplement to its Product License Application for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal) Enzyme-Linked Immunosorbent Assay (ELISA) to modify the intended use of the Genetic Systems HBsAg EIA 2.0 and the Genetic Systems HBsAg Confirmatory Assay 2.0 to include the testing of cadaveric serum samples.

On February 9, 2000, FDA approved the Genetic Systems Corporation's Supplement to their Product License Application for Human Immunodeficiency Virus Types 1 and 2 (Synthetic Peptide) to modify the intended use of the Genetic Systems HIV-1/HIV-2 Peptide EIA to include the testing of cadaveric serum samples.

These specifically labeled test kits are now available for commercial use.

IV. IMPLEMENTATION

Pursuant to 21 CFR 1270.21(d), FDA expects that testing of cadaveric samples for HIV-1, HIV-2 and Hepatitis B should be performed using test kits specifically labeled for screening of cadaveric blood specimens as soon as feasible, but not later than January 31, 2001. It is not necessary to retest the cadaveric samples from donors which have already been tested prior to the implementation date.