

DRAFT  
REVIEWERS' GUIDE  
DISEASE ASSOCIATED ANTIBODY COLLECTION PROGRAM

I. INTRODUCTION

This reviewers' guidance on disease associated antibody collection serves to elaborate on the requirements of 21 CFR 640.63. It is designed to assist the reviewer in determining whether a license application/supplement includes this information, and does not change any current statutory or regulatory requirements and recommendations.

II. RECOMMENDATIONS

Requests to collect Source Plasma from donors who have detectable levels of the disease associated antibodies listed below will now require that notification be sent to CBER that the establishment plans to institute such a deliberate collection program. This notification should be submitted no less than 30 days in advance of instituting such a program and should include the following:

- a. A statement that the Source Plasma will be collected only from otherwise suitable donors who meet all the required/recommended donor suitability criteria that pertain to normal Source Plasma donors.
- b. A statement that the donor will be informed that his/her plasma is being collected because it contains a specific antibody and that the level of this antibody will be monitored periodically in order to determine that the donor may continue participating in this program.
- c. A statement that the plasma will be collected from a donor in a convalescent state of disease, if applicable, and not during acute illness. The primary indicator of this is the presence of IgG antibody. Programs for the collection of plasma containing IgM antibodies will continue to require review and approval of a supplement to the licensee's Source Plasma product license application.
- d. Examples of labeling that accurately describe each product.

If all information requested above is submitted, the incoming cover letter will be stamped acknowledged and a copy returned to the Responsible Head. The licensee may begin the collection of the product. However, shipment of Source Plasma from donors participating in the specific disease associated antibody programs included in the notification category cannot begin prior to the licensee's receipt of notification of approval of labeling from CBER.

The following list contains the disease associated antibodies that will be considered under the 30-day notification process:

C-Reactive Protein  
Mononucleosis (Epstein Barr)  
Cytomegalovirus (CMV)  
Herpes Type I  
Herpes Type II  
Varicella Zoster  
Coccidioidomycosis  
Histoplasmosis  
Pseudomonas  
Rubella  
Mumps  
Hepatitis A (Anti-HAV)  
Hepatitis B (Anti-HBs)  
Hepatitis B core (Anti-HBc)\*

\* Anti-HBc collections are included in this category only when the donor is known to also have anti-HBs. Anti-HBc repeatedly reactive, without anti-HBs, might indicate an infectious unit for HBV infection.

Toxoplasmosis  
Rubeola  
Respiratory Syncytial Virus (RSV)  
Chlamydia  
Hemophilus influenza

Although not disease associated, Source Plasma from donors who have specific human leukocyte antibodies (HLA), red blood cell antibodies (that are not currently stimulated in a immunization program) and platelet antibodies may be similarly collected and shipped. For donors with pre-existing red blood cell antibodies, the licensee should submit, in addition to the information requested above, a statement attesting to the fact that the donor is not currently in an immunization program and has not been immunized, either deliberately or by transfusion, within the previous twelve months.

Please note that the above conditions apply only to plasma collected from donors who otherwise meet all required/recommended donor suitability criteria for Source Plasma. Plasma collected from high-risk donors and plasma collected as a by-product of therapeutic procedures may only be collected and shipped following review and approval of specific product license applications or supplements to existing applications.