

Procedure Title: Infectious Disease Testing Requirements for Patients Scheduled for Hematopoietic Stem Cell Component Collection

Procedure #: HSC.D492.01

1. Principle:

In compliance with national accreditation requirements, a panel of infectious disease tests must be completed for each patient within thirty days of a scheduled hematopoietic stem cell collection or harvest. Documentation must be sent to the CHLA Hematopoietic Stem Cell Processing Laboratory before the date of processing. This procedure describes the procedural changes that need to be addressed for patients that are tested positive or reactive for one of the infectious disease tests in the panel.

2. Abbreviations:

- A. Anti- HIV-1: Antibody to Human Immunodeficiency Virus 1
- B. Anti- HIV-2: Antibody to Human Immunodeficiency Virus 2
- C. HIV-1 Ag: Human Immunodeficiency Virus antigen
- D. Anti- HTLV: Antibody to Human T Lymphotropic Virus
- E. HBsAg: Hepatitis B Virus Surface Antigen
- F. Anti- HBc: Antibody to Hepatitis B Core Antigen
- G. Anti-HCV: Antibody to Hepatitis C Virus
- H. Anti- CMV: Antibody to Cytomegalovirus

3. Procedure:

- A. Documentation of all of the test results listed in the abbreviation section of this procedure needs to be received by the Hematopoietic Stem Cell Processing Laboratory from the collection facility or treating hospital prior to the processing date. The testing must be from blood sample collected within thirty days of the collection date of the stem cell component.

- B. Patients that test negative or non- reactive for all infectious disease markers:
 - 1. Ensure that all of the required results have been tested and reported.
 - 2. File the documentation in the laboratory patient file
- C. Patients that test positive or reactive for at least one of the infectious disease marker (excluding anti-CMV)

Note: Anti- CMV positive result for a patient does not require labeling as BIOHAZARD.

- 1. Label the patient laboratory file with a brightly colored label that clearly communicates to all laboratory staff that patient tested positive for an infectious disease marker.
- 2. Labeling the final cryocyte freezing bags

Note: Refer to Labeling procedure, HSC.E301, for specific details regarding labeling after processing. The following steps are in addition to procedure HSC.E301 when patient is positive for an infectious disease marker.

- a. Place a biohazard label firmly to each cryocyte freezing bag
- b. In red ballpoint ink, write BIOHAZARD on each label that is attached to the cryocyte freezing bags prior to lamination.
- 3. Select a liquid nitrogen storage location designated for storage of infectious disease positive components. All units are stored in the vapor phase of liquid nitrogen. A rack that is closest to the top of the LN storage tank is preferred for storage of these units as they are least likely to be submerged in liquid nitrogen in the event of a tank overfill malfunction.
- 4. Follow guidelines established for transportation of dangerous goods when shipping frozen components that are positive for an infectious disease marker.