

Procedure Title: Acceptability Criteria for Hematopoietic Stem Cell Components Submitted for Processing

Procedure #: HSC.B301.01

1. Procedure:

A. Visual inspection of components

1. Each unit prior to processing shall be visually inspected to ensure that unusual observations are noted in the laboratory record. The visual inspection will be documented on the appropriate processing worksheet.
2. Any unusual observations must be communicated to the Laboratory Director. These observations may include:
 - a. Clotting
 - b. Evidence of hemolysis or discoloration
 - c. Break in the integrity of the outer container

Any necessary actions will be discussed with the Laboratory Director.

B. For bone marrow stem cells

1. A preharvest bone marrow specimen must be tested for immunocytological evidence of Neuroblastoma tumor by the Neuroblastoma Resource Laboratory within 30 days of the scheduled bone marrow harvest.
 - a. If the preharvest bone marrow result is zero tumor cells per 10^5 cells, proceed with Neuroblastoma tumor purging using the standard (direct) method of purging.
 - b. If the preharvest bone marrow result is at least one tumor cell per 10^5 cells, notify the Laboratory Director immediately. Perform an indirect purging of the bone marrow component at the discretion of the Laboratory Director.

2. An adequate number of nucleated cells must be harvested in order to attain sufficient cell numbers after purging. Approximately 1×10^9 cells/kg body weight should be harvested for hematopoietic stem cell purging. For components submitted that have less than 1×10^9 cells/kg, discuss with the Laboratory Director prior to processing.

D. For peripheral blood stem cell components

An adequate number of CD34 stem cells must be collected in order for the procedure to be initiated. A minimum of approximately 5×10^6 CD34/kg body weight should be collected (use CD34/kg quantity reported to us by the laboratory used by the collection facility). For components submitted that have CD34/kg values that are close to 5×10^6 CD34/kg, consult with the Laboratory Medical Director prior to processing.

E. Acceptable time limits for receipt of hematopoietic stem cell components

1. Hematopoietic stem cell components from any cell source must be processed within one day of the collection date. For PBSC, two components may be pooled and processed on a given processing date. When two components are pooled into one component, processing may occur within one day of the collection date of the most recently collected component.

Note: If a clinical decision is made to only collect one PBSC component for processing, that component must be processed within one day of the collection date. Notify the Laboratory Director if this cannot be accommodated.

2. If the component(s) are not received within an acceptable time frame:
 - a. Document the date and time received on the appropriate Cell Processing Worksheet.
 - b. According to routine procedure, inspect the component(s) visually and note any unusual observations (eg. color, hemolysis, and clotting). Perform percent viability on the component before processing.
 - c. Notify the Laboratory Director of the delay in processing and the test results and visual inspection. Document the instructions for future processing from the Laboratory Director on the Cell

Processing Worksheet.