

Non-Technical SOP

<b>Title</b>	<b>Component Selection to Reduce the Risk of Transfusion Associated CMV (Cytomegalovirus) Disease</b>	
<b>Prepared by</b>	Stephanie Codina	Date: 2/14/2010
<b>Owner</b>	Stephanie Codina	Date: 2/14/2010

<b>Laboratory Approval</b>		
<b>Print Name and Title</b>	<b>Signature</b>	<b>Date</b>
<i>Refer to the electronic signature page for approval and approval dates.</i>		
<b>Local Issue Date:</b>		<b>Local Effective Date:</b>

<b>12 month (or new) management review and approval:          Signature acknowledges SOP version remains in effect with NO revisions.</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

## TABLE OF CONTENTS

1. PURPOSE.....	2
2. SCOPE.....	2
3. RESPONSIBILITY.....	3
4. DEFINITIONS.....	3
5. PROCEDURE.....	3
6. RELATED DOCUMENTS .....	5
7. REFERENCES .....	6
8. REVISION HISTORY.....	6
9. ADDENDA AND APPENDICES.....	6

### 1. PURPOSE

Transfusion of cellular blood products from donors who have been exposed to the CMV virus may be capable of transmitting CMV. Transmission rates are dependent upon the status of the recipient's immune system. CMV rarely causes problems in immunocompetent individuals but can be fatal in immunocompromised recipients. CMV-seronegative blood products have been tested and found negative for antibodies to CMV and can be issued to patients who require CMV-negative blood products. Leukocyte-reduced blood products can be an alternative to CMV-seronegative blood products in some clinical situations.

### 2. SCOPE

CMV-seronegative cellular blood products will be automatically issued by the blood bank in the following situations:

- When the recipient is <4 months in age
- When the blood product is for intrauterine transfusion

**Other than those patients listed above, CMV-seronegative blood products are never indicated for recipients who test positive for antibodies to the CMV virus.**

Cellular blood products may be ordered and issued as CMV-seronegative blood products in the following situations:

- When requested by the treating physician for the following reasons:
  - Recipient has undergone a hematopoietic progenitor cell transplant (bone marrow, cord blood, or peripheral blood progenitor cells)
  - Recipient will likely undergo a hematopoietic progenitor cell transplant (bone marrow, cord blood, or peripheral blood progenitor cells)
  - Recipient is CMV-seronegative and has received a solid organ from a CMV-seronegative donor (R=/D=)
  - Recipient is HIV-positive
  - Recipient is currently pregnant
- When requested by the treating physician **and** approved by a pathologist for severe immunosuppression and reasons otherwise not listed

### 3. RESPONSIBILITY

All Blood Bank employees are required to understand the indications for CMV seronegative products and the steps that must be taken if CMV-seronegative blood products are requested/required.

### 4. DEFINITIONS

CMV (cytomegalovirus) is a double-stranded DNA virus that resides in leukocytes, specifically monocytes expressing the CD13 marker. CMV can be transmitted via transfusion of cellular blood products (plasma and platelet products do not need to be tested for CMV antibodies).

Cellular blood products = Red blood cells, leukocytes, and platelets.

### 5. PROCEDURE

Step	Action
1	<p>When a physician requests CMV-negative blood products for a recipient and the recipient meets established hospital criteria, a marker will be placed into the patient's blood bank historical data and <b>all current and subsequent transfusions must be CMV-seronegative until transfusion of CMV-negative blood products is no longer clinically necessary per treating physician.</b></p> <p><b>Exceptions:</b></p> <ul style="list-style-type: none"><li>A. The CMV marker will be automatically removed from a neonate when he/she reaches the age of 4 months (120 days).</li><li>B. The CMV marker will be automatically removed from a pregnant recipient as soon as she delivers.</li></ul>
2	<p>When CMV-seronegative blood products are ordered for the first time, we must determine the CMV status of the recipient.</p> <p>Note: CMV testing is not required for neonates under the age of 120 days or patients undergoing intrauterine transfusion.</p> <p>Note: Blood bank will issue CMV-seronegative blood products while CMV antibody testing is pending.</p>

Step	Action
	<p>A. Review the patient's laboratory results using Sunquest function Laboratory Inquiry.</p> <p>B. Search for CMV antibody test results (note all send-out tests begin with an X).</p> <ul style="list-style-type: none"><li>a. If the CMV antibody is negative, the patient is a candidate for CMV-seronegative blood products. Proceed to step 3 and add the CMV marker.</li><li>b. If the CMV antibody is positive, the patient does not require CMV-seronegative blood products.<ul style="list-style-type: none"><li>i. Notify the ordering provider that CMV-seronegative blood products will not be issued based on patient's test results.</li><li>ii. Place a comment in the patient's blood bank history that CMV-seronegative blood products were ordered by Dr. X but are not indicated because patient tested positive for CMV antibodies on <i>date</i>.</li></ul></li><li>c. If the patient does not have CMV antibody results,<ul style="list-style-type: none"><li>i. Order a CMV IgG antibody test on the patient.</li><li>ii. Notify the ordering provider that blood bank will automatically stop giving CMV-seronegative blood products if the patient demonstrates antibodies to CMV.</li><li>iii. Add a comment to the patient's blood bank administrative data file indicating the CMV testing was ordered on date.</li><li>iv. Document the CMV order in the communication log and check for return of test results. Follow steps a and b above based on the testing results.</li></ul></li></ul>
3	<p>Enter the CMVN attribute into the LIS system with a comment per procedure, "Entering Special Transfusion Attributes into the LIS."</p> <p>The CMVN attribute should be automatically removed from the patient's blood bank administrative data file in the following situations.</p> <ul style="list-style-type: none"><li>A. When a neonate who had been receiving CMV-seronegative blood products reaches an age of 4 months (120 days).</li><li>B. When a pregnant woman who was receiving CMV-seronegative blood products during pregnancy delivers or is no longer pregnant.</li></ul>

Step	Action
4	<p>CMV-seronegative blood products may be difficult to obtain in situations where the patient has other special transfusion needs (Antigen-negative blood products, HLA-matched platelets, etc).</p> <p><b>When CMV-seronegative blood products are not available:</b></p> <p>A. Notify the nurse or physician treating the patient in a timely manner.</p> <p>a. Ask the physician if leukocyte-reduced blood products can be substituted for CMV-seronegative blood products.</p> <p>i. If the physician does not want to substitute products, notify the Blood Bank Medical Director or Clinical Pathologist on-call.</p> <p>ii. If the physician approves substitution with leukocyte-reduced blood products, ascertain how long the substitution is valid (one transfusion, one week, one admission, etc).</p> <p>iii. Document the substitution in patient's historical blood bank data file. Note: Not all techs have access to the patient's BAD file. Notify the blood bank supervisor or administrator on-call for guidance if needed.</p> <p>a. Access Sunquest function "Blood Bank Administrative Data Entry."</p> <p>b. At the "Lookup by" prompt, click on the dropdown menu and select "Patient ID."</p> <p>c. At the "Value" prompt, type in the patient's medical record number and click the "Search" button.</p> <p>d. Press the "Tab" key until your cursor is in the "Comment" field.</p> <p>e. Type a semicolon ";" and free text a comment in indicating which physician approved substitution with leukoreduced blood products and how long the substitution is good for.</p> <p>f. Press the "Save" button.</p> <p>B. Document the notification in the Blood Bank Communication Log.</p>
5	<p>Allocate and crossmatch the blood product to the patient per procedure, "Crossmatch."</p>

**6. RELATED DOCUMENTS**  
SOP - Entering Special Transfusion Attributes into the LIS

**7. REFERENCES**

1. Roback, J.D., Combs, M.R., Grossman, B.J., Hillyer, C.D. 2011. Technical Manual of the AABB, 17<sup>th</sup> ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 27<sup>th</sup> ed. 2011. AABB Publishing, Bethesda, Maryland.
3. Circular of information for the use of human blood and blood components. Prepared by AABB, the American Red Cross, America's Blood Centers, and the Armed Services Blood Program. Bethesda, MD: AABB, 2009.

**8. REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
000	2/14/2010	Updated owner Sections 1 & 2: simplified content Section 5: added patient testing for CMV status and LIS documentation Section 7: updated to current	S. Codina	N. Cacciabeve
001	6/15/2012	Section 2: Updated scope and indications for CMV-seronegative blood products. Section 4: Added definitions. Section 5: Updated some wording in procedure for clarification.	S. Codina	N. Cacciabeve

**9. ADDENDA AND APPENDICES**

- A. Indications for the Use of CMV-Seronegative Blood Products

## **Appendix A**

### **Indications for the use of CMV-Seronegative Blood products**

In most situations, there is no benefit to giving CMV-seronegative blood products to patients who have been previously exposed to CMV as evidenced by positive CMV antibody levels. Testing for IgG CMV antibodies is required at the time CMV-seronegative blood products are ordered and every 2 years for subsequent transfusions. Blood bank will automatically remove the CMV requirement for any patient who demonstrates antibodies to CMV. Except those in category I below.

#### **Category I**

##### **Indications for CMV-seronegative blood products regardless of CMV status:**

1. All neonates under the age of 4 months will automatically receive CMV-seronegative blood products. Blood bank will remove the CMV requirement for these infants when they reach the age of 4 months.
2. All patients undergoing intrauterine transfusion.

#### **Category II**

##### **Indications for CMV-seronegative blood products in CMV-negative recipients:**

3. Recipients of allogeneic hematopoietic progenitor cell transplant (bone marrow, cord blood, peripheral blood progenitor cells).
4. Patients who will likely undergo allogeneic hematopoietic progenitor cell transplant in the future.
5. Solid organ transplant recipients who received CMV-negative organs (R=D=).
6. HIV-positive patients.
7. Patients who are currently pregnant. Blood bank will remove the CMV marker as soon as the patient delivers.
8. Severely immunosuppressed patients after consultation with the on-call pathologist.

**CMV-seronegative blood products may be requested for reasons other than those listed after consultation with the on-call pathologist.**