

# Blood Bank Practice Alert



## Practice Updates: Granulocytes and other Exceptional Release Blood Products

**Audience:** All Blood Bank Team Members

**Level of Education:** Level II

**Date:** Feb 11, 2026

A new policy has been created to provide guidance to clinical and blood bank team members on the process for ordering, obtaining and transfusion of granulocytes and other Exceptional Release blood products.

### WHAT TO KNOW...

- **Exceptional Release Blood Product** = any blood product that is received from the donor center with incomplete infectious disease testing.
  - These products **MUST** have Transfusion Medicine MD approval prior to dispensing product from the Blood Bank.
  - These products may include granulocytes, red cells or platelets
  - **Updated Form** BBCP-F012: Exceptional Release of Blood Products to be completed by Blood Bank team member
- **New Form** BBCP-F031: Approval to Receive Blood Products with Incomplete Infectious Disease Testing (Consent) is to be completed by ordering provider with the patient and a copy sent to Blood Bank.
  - Completed form must be received by Blood Bank prior to ordering Granulocytes or any other exceptional release blood product from ARC.
  - Transfusion Medicine MD **MUST** review the order and confirm receipt of BBCP-F031 prior to ordering product from supplier.
  - This approval form is valid for the series of products ordered for the patient during a single admission.
- **Components Exceptional Release Binder** = located in Component area of lab. Used to store all paperwork (alphabetically by patient last name).
- **Notification of completed Infectious Disease Results:** when results of completed Infectious Disease is received in Blood Bank, notify the Transfusion Medicine MD on-call so they can notify clinician of results.
  - Attach results to the Exceptional Release of Blood Product Form (BBCP-F012) and place in BB Supervisor Tray for MD Signature and documentation of provider notification.

### WHAT TO DO...



Review and acknowledge appropriate procedures for competency & understanding of new process



March 1, 2026



### Approval to Receive Blood Products with Incomplete Infectious Disease Testing

Select the blood product the patient will be receiving:

- Granulocytes
- Red Blood Cells
- Platelets
- Other: \_\_\_\_\_

Per FDA requirements, blood products must be tested for the following organisms prior to transfusion: HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, syphilis, *Babesia* (if applicable), and *Trypanosoma cruzi* (if applicable). In instances when the blood product expires before testing is complete, like in granulocyte products, or when there is urgent clinical need for the product, this requirement can be waived.

Infectious disease testing for the organisms listed above will be completed, but not until after the product has been transfused. The Blood Bank and clinical team will be notified when the results of the infectious disease testing are available. This is generally a couple of days after the transfusion has occurred.

Patients requiring “CMV negative” blood products will receive products from donors who have historically tested negative for CMV. The product will also be tested for CMV; however, this testing will not be complete at the time of transfusion. Therefore, the product will not be labeled as “CMV negative.”

The risk of receiving a blood product with incomplete infectious disease testing is transmission of an infectious disease through the transfusion.

This approval is valid for all blood products with incomplete infectious disease testing ordered by my provider during this admission.

#### RECIPIENT (or PARENT/LEGAL GUARDIAN)

The potential risks of receiving blood products with incomplete infectious disease testing have been explained to me. I understand these risks, and I have had the opportunity to ask questions and have them answered.

By signing below, I agree to receive these blood products as part of my (or my child’s) treatment plan.

Patient (or Guardian) Name: \_\_\_\_\_ Patient (or Guardian) Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Relationship to Patient (if Guardian signed): \_\_\_\_\_

Interpreter name/ID: \_\_\_\_\_

#### TREATING PHYSICIAN

I have explained the risks of blood products with incomplete infectious disease testing as listed above. I understand that I will be notified of the infectious disease results when they are made available to the blood bank.

Physician Name: \_\_\_\_\_ Physician Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_



### Exceptional Release of Blood Products

Patient label
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Unit DIN#	Component

By FDA standards or guidelines, the following infectious disease tests are incomplete for the product above: HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, syphilis, *Babesia* (if applicable), and *Trypanosoma cruzi* (if applicable).

I have verified that the “Approval to Receive Blood Products with Incomplete Infectious Disease Testing” form has been completed and signed by the patient and their physician.

\_\_\_\_\_  
 Transfusion Medicine  
 Physician Initials

Due to the clinical need and the timing of the product expiration, I approve the exceptional release of the product from Blood Bank.

\_\_\_\_\_  
 Transfusion Medicine Physician Signature                      Date                      Time

The infectious disease tests results have been completed by the donor center (see attached documentation). The following provider has been notified of these results.

\_\_\_\_\_  
 Name of Provider Notified                      Date                      Time

\_\_\_\_\_  
 Notification Performed By (Name)                      Notification Performed By (Signature)

 <b>Indiana University Health</b>	<b>Original Creation Date:</b> 01/31/2025	<b>Publication Date:</b> Not Set
	<b>Owner:</b> Elaine Skipworth (Director- Lab Transfusion Medicine)	<b>Next Review:</b> Not Set
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	<b>Education:</b> Level 3	
<b>Approval Signatures:</b> No Users		
<h2>Procedure: Granulocytes Preparation for Issue</h2>		

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Reference # 103767

## I. PURPOSE

This procedure details the steps for ordering, receiving, and preparing granulocyte products.

## II. SCOPE

This SOP covers all granulocytes products released from AHC Blood Banks. All Blood Bank team members will comply with this procedure.

## III. STATEMENTS/REQUIREMENTS

- A. Granulocyte products are provided by the American Red Cross.
- B. The granulocyte product must be crossmatch-compatible with the recipient's plasma due to the volume of red blood cells in the product.
- C. Granulocyte products are stored at 20 - 24 °C without agitation.
- D. Granulocyte products have a shelf life of 24 hours from collection and should be infused as soon as possible, due to deterioration of function in storage.
- E. Granulocyte products must be irradiated to prevent transfusion associated graft versus host disease.
- F. CMV seronegative granulocytes should be provided for CMV seronegative recipients, when available. If a CMV seronegative granulocyte product is not available, notify blood bank MD on call.
- G. Granulocytes must NOT be leukoreduced but administered with a standard blood infusion set with a 170-to-260-micron filter.
- H. Since the results of donor infectious disease testing are generally unavailable within 24 hours of collection granulocyte products require an [Form BBP-F012: Exceptional Release of Blood Products](#) prior to dispense of the product.
- I. All granulocyte transfusions will be documented on the Transfusion Document. These products are not set up in Bridge.

## IV. DEFINITIONS

**AABB:** Association for the Advancement of Blood & Biotherapies

**ARC:** American Red Cross- Blood Product Supplier

**CMV:** Cytomegalovirus

**SOP:** Standard Operating Procedure

## V. EQUIPMENT/RESOURCES

None

## VI. PROCEDURE

### A. Granulocyte Orders / Patient Approval

1. Clinicians will place an order for "Granulocytes" in Cerner.
2. When a Cerner order for "Granulocytes" is received in Blood Bank, notify on-call Transfusion Medicine MD via Backline Diagnoses by using the "@oncall" tag in the Blood Bank Team room.
3. Transfusion Medicine MD or MD designee will confirm that the product is indicated and that patient has signed the [Form: BBCP-F031 Approval to Receive Blood Products with Incomplete Infectious Disease Testing](#) .
  - a. A copy of this form must be sent to blood bank prior to ordering the granulocytes from ARC.
  - b. When received, scan this approval form via email to the Transfusion Medicine MD on call or upload to the Backline Diagnoses Blood Bank Team Room.
4. Once Transfusion Medicine MD has approved the order and confirmed receipt of the [Form: BBCP-F031 Approval to Receive Blood Products with Incomplete Infectious Disease Testing](#) , the MD will reach out to the Blood Bank Leader on call to place the order with ARC.
  - a. Refer to [Job Aid: BBCP-JA017 Standard Work for Ordering Granulocytes from American Red Cross](#)
  - b. The order will require an indication and frequency.
  - c. Reach out to Transfusion Medicine MD on-call, if these have not already been provided.
5. Place Cerner order and copy of [Form: BBCP-F031 Approval to Receive Blood Products with Incomplete Infectious Disease Testing](#) in "Components Exceptional Release Binder".
  - a. File by last name alphabetically.

### B. Product Receipt

1. Refer to SOP [Procedure: Components Received from Blood Suppliers and Other Institutions](#) for receipt of granulocytes.
2. Granulocytes are stored on the designated platelet rotator shelf at 20 - 24°C without agitation.
  - a. Ensure the agitation is turned off for this storage shelf.

### C. Preparation for Issue

1. Check for current Type & Screen sample.
  - a. If sample is not available, request sample and complete testing.
2. Irradiate product according to SOP [Procedure: Irradiation of Blood Products: RS 3400](#) .
3. Crossmatch product according to [Procedure: Routine Crossmatch](#) with current patient sample.
4. Send a paper Transfusion Document with each granulocyte product.
5. Follow SOP [Procedure: Exceptional Release of Blood Products](#) to complete the [Form BBCP-F012: Exceptional Release of Blood Products](#) and obtain approval to dispense granulocyte product.
6. Once Transfusion Medicine MD approved the release of the granulocyte product, notify clinical team that the product is available.

### D. Infectious Disease Results

1. When infectious disease testing has been completed, the results will be sent to the blood bank.
2. When the results are received in blood bank, notify Transfusion Medicine MD on-call, so they can notify clinician of the results.
3. Attach infectious disease results to the corresponding [Form BBCP-F012: Exceptional Release of Blood Products](#) that is located in the "Exceptional Release Binder" located in the Components area.
  - a. Place these forms in the Supervisor Review tray for MD signature and provider notification.

## VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

### A. Clinical indications for granulocyte transfusions:

1. Severe neutropenia with absolute neutrophil count (ANC) < 500/ $\mu$ L or impaired granulocyte function, such as chronic granulomatous disease.
2. Documented evidence of fungal or bacterial infection that is unresponsive to appropriate antimicrobial therapy for at least 24 to 48 hours.

## VIII. REFERENCES

AABB standards, current edition.

AABB: Circular of Information for the Use of Human Blood and Blood Components, current version

## IX. FORMS/APPENDICES

[Form BBCP-F012: Exceptional Release of Blood Products](#)

## X. APPROVAL BODY

None

APPROVED

 <p>Indiana University Health</p>	<b>Original Creation Date:</b> Not Set	<b>Publication Date:</b> Not Set
	<b>Owner:</b> Elaine Skipworth (Director- Lab Transfusion Medicine)	<b>Next Review:</b> Not Set
	<b>Category:</b> Lab Methodist, Lab Riley, Lab University	
	<b>Education:</b> Level 2	
<b>Approval Signatures:</b> No Users		
<h2>Procedure: Exceptional Release of Blood Products</h2>		

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Reference # 111073

## I. PURPOSE

This procedure details the steps for obtaining approval to dispense blood products with incomplete infectious disease testing.

## II. SCOPE

This SOP applies to all blood products with incomplete infectious disease testing. All Blood Bank team members will comply with this procedure.

## III. STATEMENTS/REQUIREMENTS

- A. Any blood product that is received from the donor center with incomplete infectious disease testing must have Transfusion Medicine MD approval for prior to dispensing product from Blood Bank.
- B. By FDA standards or guidelines, the following infectious disease tests are required for blood and component products: HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, syphilis, *Babesia* (if applicable), and *Trypanosoma cruzi* (if applicable).
- C. These products may include granulocytes, red blood cells, or platelets.

## IV. DEFINITIONS

**AABB:** Association for the Advancement of Blood & Biotherapies

**FDA:** Food and Drug Administration

**DIN:** Donation Identification Number

**SOP:** Standard Operating Procedure

## V. EQUIPMENT/RESOURCES

None

## VI. PROCEDURE

### A. Documentation

1. Fill out the Form BBCP-F012: Exceptional Release of Blood Products.
2. Complete the following fields:
  - a. Patient name and MRN
    - i. Use patient label
  - b. Unit DIN
    - i. Sticker from the unit can be used here.
  - c. Component
3. Get approval to dispense the product by notifying the Transfusion Medicine MD via Backline Diagnoses by using the "@oncall" tag in the Blood Bank Team room.
4. Scan a copy of the Form: BBCP-F031 Approval to Receive Blood Products with Incomplete Infectious Disease Testing to the Transfusion Medicine MD.
  - a. This approval form is valid for the series of granulocyte products ordered for the patient during this admission.
5. Once the Transfusion Medicine MD has given approval for release, the product can be dispensed to the floor according to Procedure: Dispense and Return Products.
6. Make a copy of Transfusion Medicine MD's approval from Backline Diagnoses and attach to the completed Form BBCP-F012: Exceptional Release of Blood Products.
7. Place the form in the Supervisor review tray for Transfusion MD signature on next business day.
8. Once Transfusion Medicine MD has signed the form, place in the "Exceptional Release Binder" with the other completed forms.

## VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

## VIII. REFERENCES

AABB Standards, Blood Banks and Transfusion Services, current edition.

FDA, 21 CFR 610.40 and 21 CFR630.3(h).

## IX. FORMS/APPENDICES

Form BBCP-F012: Exceptional Release of Blood Products

## **X. APPROVAL BODY**

None