



## STEM CELL LABORATORY (STCL)



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Processing of ABO Incompatible Cellular Products

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**Author:** WATER002

**Owner:** WATER002

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## **STCL-PROC-002**

# **PROCESSING OF ABO INCOMPATIBLE CELLULAR PRODUCTS**

### **1 PURPOSE**

- 1.1 To describe the necessary steps for processing ABO incompatible cellular products.

### **2 INTRODUCTION**

- 2.1 Depending on the ABO blood types of both the donor and the recipient, a cellular product may need to be manipulated to remove incompatible red blood cells, plasma, or both.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 The Medical Directors, Laboratory Manager, Quality System Unit, and laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met.

### **4 DEFINITIONS/ACRONYMS**

- 4.1 QSU Quality Systems Unit
- 4.2 ISBT International Society Blood Transfusion
- 4.3 RBC red blood cell
- 4.4 QC quality control

### **5 MATERIALS**

- 5.1 300 mL transfer bags
- 5.2 Sampling site couplers
- 5.3 6% Hetastarch
- 5.4 60 mL syringes
- 5.5 25% Albumin
- 5.6 Plasmalyte-A
- 5.7 Tie tags
- 5.8 ISBT labels

### **6 EQUIPMENT**

- 6.1 Refrigerated Centrifuge
- 6.2 Plasma Expresser
- 6.3 Heat Sealer (Sebra)
- 6.4 Sterile Docker (Terumo)

## 7 SAFETY

- 7.1 Wear all appropriate personal protective equipment when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, etc.
- 7.2 **NOTE:** A technologist will only handle/process one cellular product in the biological safety cabinet at any given time.

## 8 PROCEDURE

- 8.1 Receipt of the product in the Stem Cell Laboratory.
- 8.1.1 Upon receipt of the product, complete the appropriate Chain of Custody form and inspect the product to ensure the labeling is accurate, there are no obvious signs of contamination, and no leaks or tears are identified in the product container.
- 8.1.2 Assign barcode (*if applicable*) to cellular product and complete the ISBT Barcode Release Log.
- 8.1.3 Review signed doctor's orders and follow processing instructions as written. Products will be processed as follows based on ABO/Rh compatibility.
- RBC depleted
  - Plasma depleted
  - Plasma and RBC depleted

**NOTE: TO DETERMINE HOW CELLS SHOULD BE PROCESSED:**

Refer to the signed processing or infusion orders for instructions regarding the processing that is required. The recipient and donor blood types must be taken into consideration in an effort to minimize exposure to ABO incompatible cellular products. See **Table 1** for processing instructions for all donor / recipient combinations.

O Donor / O Recipient	<b>NO manipulation required</b>
O Donor / A Recipient	Plasma reduce
O Donor / B Recipient	Plasma reduce
O Donor / AB Recipient	Plasma reduce
A Donor / O Recipient	RBC reduce
A Donor / A Recipient	<b>NO manipulation required</b>
A Donor / B Recipient	RBC and plasma reduce
A Donor / AB Recipient	Plasma reduce
B Donor / O Recipient	RBC reduce
B Donor / A Recipient	RBC and plasma reduce
B Donor / B Recipient	<b>NO manipulation required</b>
B Donor / AB Recipient	Plasma reduce
AB Donor / O Recipient	RBC reduce
AB Donor / A Recipient	RBC reduce
AB Donor / B Recipient	RBC reduce
AB Donor / AB Recipient	<b>NO manipulation required</b>

**Table 1**

- 8.1.4 For cellular products with the same recipient and donor blood types, no manipulation is required
- 8.1.5 If NO manipulation is required, proceed to Step 8.2 *QC and Labeling of product for infusion*.
- 8.1.6 For cellular products requiring **RED CELL DEPLETION** only
- 8.1.6.1 Before manipulating the product, perform a cell count and cultures so the percent recovery can be determined after processing has been completed and sterility of the product can be determined before the product was manipulated in the STCL.
- 8.1.6.2 Transfer the product to a 300 or 600 mL transfer bag and heat seal tubing being sure to leave enough to sterile dock to another 300 or 600 mL transfer bag.
- 8.1.6.3 Add 1 mL of 6% hetastarch for every 5 mLs of cellular product to your 300 or 600 mL transfer bag, and hang the bag on the plasma expresser. This will need to sit undisturbed for 30-60 minutes on the plasma expresser. If a good separation is not achieved after that time period, the product may be spun at 700 rpm for 10 minutes (with brake OFF) in the refrigerated centrifuge.



- 8.1.6.4 Express the white cells and plasma off and heat seal the tubing. The remaining red blood cells should be retained for QC and cultures and then discarded.
- 8.1.6.5 Add Plasmalyte-A® to achieve a final product volume that is appropriate based on the weight of the recipient.
- 8.1.7 For cellular products requiring **PLASMA DEPLETION** only:
  - 8.1.7.1 Before manipulating the product, perform a cell count and cultures so the percent recovery can be determined after processing has been completed and sterility of the product can be determined before the product was manipulated in the STCL.
  - 8.1.7.2 Transfer the product to a 300 or 600 mL transfer bag and heat seal tubing being sure to leave enough to sterile dock to another 300 or 600 mL transfer bag. Sterile dock a second 300 or 600 mL bag to cells. Balance transfer bag(s) in centrifuge buckets of the refrigerated centrifuge, and spin using program 3 (1800 rpm for 20 minutes).
  - 8.1.7.3 After centrifugation cycle is complete, express off the plasma and heat seal tubing. Retain plasma bag for sterility testing.
  - 8.1.7.4 Measure the remaining volume in the bag and add 25 mLs of 25 % human albumin to the product.
  - 8.1.7.5 Add Plasmalyte-A® to achieve a final product volume that is appropriate based on the weight of the recipient.
- 8.1.8 For cellular products requiring **RED CELL AND PLASMA DEPLETION**:
  - 8.1.8.1 Complete steps 8.1.6 thru 8.1.7.
- 8.1.9 Document supplies, reagents and equipment used in processing of the cells on the appropriate *Processing Lot Numbers* form.
- 8.2 **QC and Labeling** of product for infusion:
  - 8.2.1 Remove a small aliquot from the product. If a dilution is necessary, place 100 microliters of sample in a tube containing 800 microliters of Cellpack (1:9 dilution) for cell count. If NO dilution is required, place 200 microliters of samples in a tube for cell count. Record results on processing worksheet.
  - 8.2.2 Remove a small aliquot from the product, if straight split or plasma depleted, to perform ABO testing. Record results on the blood bank worksheet and on the processing worksheet.
  - 8.2.3 Perform viability. Record results on processing worksheet.
  - 8.2.4 Perform sterility testing using 1 mL product if straight split, 2 mLs of red blood cells, if RBC depleted, or 5 mLs of plasma (if plasma

depleted). These volumes are different due to the WBC content; false positives can occur if the WBC count is too high.

- 8.2.5 Demand 128 labels will need to be prepared per *COMM-PAS-003 Labeling Cellular Therapy Products* and placed on each bag for infusion or freezing. A tie tag with both the recipient and donor information must be affixed to the bottom of the bag.
- 8.2.6 If the product is a direct infusion, place an assigned barcode on *STCL-FORM-056 Cellular Therapy Infusion Request Form* and record the volume, expiration date and appropriate cell numbers. Photocopy the *STCL-FORM-056 Cellular Therapy Infusion Request Form* to allow for one copy to remain with the product and for one copy to remain in the lab to file. *APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing* must also be copied, barcoded, and assigned a product collection date to accompany the product for infusion. Place product in a biohazard bag along with the appropriate forms.
- 8.2.7 The designated infusion site should be contacted to arrange an infusion time. Courier services are available to the lab until 4:30 PM. Every effort should be made to deliver the product before 5:00 PM. Call the designated courier to make arrangements for pickup and delivery of the product to the infusion site. If cells cannot be infused before the courier leaves for the day, alternate arrangements will need to be made.

### 8.3 Problems Encountered

#### 8.3.1 **Clotting:**

- 8.3.1.1 If the product clots during processing, contact the medical director immediately to get processing instructions. If benzonase (200 IU units/vial) is to be used, note the number of vials to be added to the product. Rotate the product for at least 30 minutes.
- 8.3.1.2 Filter product using a 150-170 micron filter set.
- 8.3.1.3 Perform a cell count and record the information on the infusion form that accompanies the product
- 8.3.1.4 Refer to *STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition* procedure and complete *STCL-QA-007 FRM1 Non-Conforming Products* form.

#### 8.3.2 **Leaking:**

- 8.3.2.1 If the product container is found to be leaking, identify the source of the leak and make every effort to contain the leak in an effort to maintain product sterility. Notify the medical director (or designee) and get instructions regarding how to proceed with the product. Consult with the lab manager who will consult with the QSU to determine if a *STCL-QA-007 FRM1 Non-Conforming Product* or *STCL-SOP-045*



*FRM1 Record of Discard* should be completed based on the instructions from the medical director or designee.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
- 9.2 Appropriate Processing Lot Numbers forms
- 9.3 COMM-PAS-003 Labeling Cellular Therapy Products
- 9.4 COMM-QA-042 Deviations and Investigations
- 9.5 STCL-FORM-056 Cellular Therapy Infusion Request Form
- 9.6 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
- 9.7 STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition.
- 9.8 STCL-QA-007 FRM1 Non-Conforming Products
- 9.9 STCL-SOP-045 FRM1 Record of Discard

## 10 REFERENCES

- 10.1 AABB Technical Manual, Current Edition
- 10.2 Standards for Blood Banks and Transfusion Services, Current Edition

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
10	Barb Waters-Pick	<ul style="list-style-type: none"> <li>• Added “See <b><u>Table 1</u></b> for processing instructions for all donor / recipient combinations” after NOTE in Section 8.1.3</li> <li>• Deleted information following the NOTE between sections 8.1.3 and 8.1.4</li> <li>• ADDED <b><u>Table 1</u></b> after NOTE in Section 8.1.3 to accommodate discussion following NMDP Biobank audit for CCBB Lab on February 2, 2023.</li> </ul>

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**STCL-PROC-002 Processing of ABO Incompatible Cellular Products****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		04 Feb 2023, 08:58:45 AM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		04 Feb 2023, 08:59:07 AM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		04 Feb 2023, 11:01:47 AM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch De Gracia (IMS19)		06 Feb 2023, 07:23:27 PM	Approved

**Document Release**

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Sandra Mulligan (MULLI026)		07 Feb 2023, 11:39:45 AM	Approved