

## Reconstituted Red Blood Cells

### US Guidance

Reconstituted Red Blood Cells refer to red cells to which plasma is added, often to a specific hematocrit. The following information reflects communication ICCBBA has had with the FDA and reflects current thinking.

#### 1 Selecting a Product Description Code

Depending on the way in which they are made, these products are encoded as follows.

IF	THEN
The product is made by adding blood group-compatible plasma to Red Blood Cells	Product is encoded as Red Blood Cells with the Attribute "Plasma Added"
The product is made by first removing additive from the Red Blood Cells and then adding blood group-compatible plasma	Product is encoded as Red Blood Cells with the Attribute "Supernatant removed/Plasma added"
The product is made by removing some of the plasma from Red Blood Cells and then adding blood group-compatible plasma	Product is encoded as Red Blood Cells with the Attribute "Plasma reduced/Plasma added"

## 2 Donation Identification Number

The Donation Identification Number (DIN) can either be that of the Red Blood Cells or may be a newly assigned Pool Number, depending on the computer system requirements of the facility. The text name and location of the facility that appears beneath the DIN should correspond to the Facility Identification Number within the DIN. That means, if the original DIN of the Red Blood Cells is used, the name beneath the DIN should correspond to the collection facility. If a new pool number is assigned to the product, the DIN should have the Facility Identification Number of the pooling facility and the name beneath the DIN should be that of the pooling facility. Regardless of which method is chosen, traceability of the original DINs for the Red Blood Cells and the Plasma through facility records must be assured. See Figure 1 and Figure 2.

Figure 1 Reconstituted Red Blood Cells, Pool Number Assigned

FIN A9999 corresponds to St. Mary's

A9999 17 123456 8 9

St. Mary's Hospital  
Anywhere, USA  
FDA Registration Number 1234567  
Properly identify intended recipient.  
See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents.  
Rx only

VOLUNTEER DONOR

B0001V00

0170311515

31 JAN 2017 15:15

Expiration Date/Time

RECONSTITUTED  
RED BLOOD CELLS

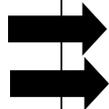
SUPERNATANT REMOVED/PLASMA  
ADDED  
Approx. 55 mL Irradiated,  
Leukocytes Reduced Red Blood Cells  
from 500 mL CPD Whole Blood and  
45 mL CPD AB+ Plasma

Red Blood Cells Negative for  
antibodies to CMV; Plasma not  
tested for antibodies to CMV.

Store at 1 to 6 C

Figure 2 Reconstituted Red Blood Cells, Original RBC DIN Retained

FIN W0000  
corresponds  
to Accurate  
Blood Center



	
W0000 17 123456 8 <b>G</b>	5100
<p>Accurate Blood Center Anywhere, USA FDA Registration Number 7654321 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only</p>	
<p><b>Rh POSITIVE</b></p>	
<p><b>VOLUNTEER DONOR</b></p>	
	
E8988V00	0170311515
RECONSTITUTED RED BLOOD CELLS	Expiration Date/Time <b>31 JAN 2017 15:15</b>
<p>SUPERNATANT REMOVED/PLASMA ADDED Approx <u>53</u> mL Leukocytes Reduced Red Blood Cells from 500 mL CPD Whole Blood and <u>42</u> mL <b>CPD</b> <b>AB+</b> Plasma Store at 1 to 6 C</p>	<p>Red Blood Cells Negative for antibodies to CMV; Plasma not tested for antibodies to CMV.  St. Mary's Hospital Same City Anywhere, USA</p>

Note: The name of the modifying facility in the lower right quadrant is required ONLY if the product leaves the modifying facility.

### 3 ABO/Rh, anticoagulant and volume

The ABO/Rh, anticoagulant, and volume of both the Red Blood Cells and the plasma must be on the label. For the plasma, this information appears in the lower left quadrant as shown Figure 2 and Figure 3.

### 4 Number of donors

The US has chosen not to use an Attribute indicating the number of donors in this product.

### 5 Hematocrit

Hematocrit may optionally appear on the label in the lower left quadrant.

### 6 Modifiers

The proper name of this product is Reconstituted Red Blood Cells. If Modifiers apply, they should be printed before Reconstituted Red Blood Cells. That is, if the Red Blood Cells were washed, the name of the product becomes Washed Reconstituted Red Blood Cells.

### 7 Special testing and processing of Reconstituted RBCs

Because the testing of the red blood cells and plasma may not be the same, labeling must reflect the actual status.

CMV Testing of Reconstituted Red Blood Cells:

IF	THEN Text in Lower Right Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma have been screened and found negative for antibodies to CMV	Negative for antibodies to CMV	N0008 or other Special Testing Code indicating product is CMV negative (Note: Bar coding of this information is optional.)
Red Blood Cells CMV negative; Plasma NOT tested for CMV	Red Blood Cells Negative for antibodies to CMV; Plasma not tested for antibodies to CMV (See Figure 3, lower right quadrant)	No code for this—use text only

## 8 Hemoglobin S:

Labeling of Reconstituted Red Blood Cells for Hemoglobin S should be based on the test results of the red blood cells. If the red blood cells have been found to be Hemoglobin S negative, it is acceptable to label the combined product as Hemoglobin S negative. N0106 (or other Special Testing Code indicating the product is Hemoglobin S negative) could be used if the facility chooses to bar code this information.

## 9 Leukocyte Reduction of Reconstituted Red Blood Cells:

IF	THEN Text in Lower Left Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma are leukocytes reduced (or the combined product is leukocytes reduced)	<p>“LEUKOCYTES REDUCED” in Attribute line</p> <p>(See Figure 4, lower left quadrant)</p>	<p>Select a Product Description Code with the Attribute “ResLeu:&lt;5E6”</p>
Red Blood Cells leukocytes reduced; Plasma NOT leukocytes reduced (or production method has not been validated to ensure that the residual leukocyte count of the plasma is below the requisite level)	<p>“Leukocytes Reduced” shall NOT appear as Attribute text. It shall appear as additional text. For example “Approx ____ mL Leukocytes Reduced Red Blood Cells from 450 mL CPD Whole Blood”</p> <p>(See Figure 3, lower left quadrant)</p>	<p>Select a Product Description Code with the Attribute “ResLeu:NS” (“NS” in this context means: Residual Leukocyte Content Not Specified: a procedure has been used to reduce the leukocyte count of the product but the target count is not specified.)</p>

## 10 Irradiation of Reconstituted Red Blood Cells:

IF	THEN Text in Lower Left Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma are irradiated (or the combined product is)	<p>“IRRADIATED” in Attribute line</p> <p>(See Figure 4, lower left quadrant)</p>	Select a Product Description Code with the Attribute “Irradiated”
Red Blood Cells irradiated; Plasma NOT irradiated	<p>“RBC IRRADIATED” in Attribute line</p> <p>(See Figure 5, lower left quadrant)</p> <p>OR</p> <p>“Irradiated” shall NOT appear as Attribute text. It shall appear as additional text. For example “Approx ___ mL Irradiated Red Blood Cells from 450 mL CPD Whole Blood”</p> <p>(See Figure 3, lower left quadrant)</p>	<p>Select a Product Description Code with the Attribute “ RBC irradiated”</p> <p>OR</p> <p>Use a local Product Description Code</p>

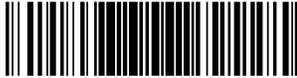
Figure 3 Only RBCs Irradiated, Leukoreduced, and Tested for CMV – Local Product Code

<p>A9999 17 123456 8 <b>9</b></p>	<p>5100</p>	
<p>St. Mary's Hospital Anywhere, USA FDA Registration Number 1234567 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only</p>		<p><b>O</b> Rh POSITIVE</p>
<p>VOLUNTEER DONOR</p>		
		<p>Expiration Date/Time</p>
<p>B0001V00</p>	<p>0170311515</p>	<p>31 JAN 2017 15:15</p>
<p>RECONSTITUTED RED BLOOD CELLS</p>		<p>Red Blood Cells Negative for antibodies to CMV; Plasma not tested for antibodies to CMV.</p>
<p>SUPERNATANT REMOVED/PLASMA ADDED Approx <u>55</u> mL Irradiated, Leukocytes Reduced Red Blood Cells from 500 mL CPD Whole Blood and <u>45</u> mL CPD <u>AB+</u> Plasma</p>		
<p>Store at 1 to 6 C</p>		

Figure 4 Combined Product Irradiated and Leukocytes Reduced

<p>W0000 17 123456 8 <b>G</b></p>	<p>5100</p>	
<p>Accurate Blood Center Anywhere, USA FDA Registration Number 7654321 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only</p>		<p><b>O</b> Rh POSITIVE</p>
<p>VOLUNTEER DONOR</p>		
		<p>Expiration Date/Time</p>
<p>E5529V00</p>	<p>0170311515</p>	<p>31 JAN 2017 15:15</p>
<p>RECONSTITUTED RED BLOOD CELLS</p>		<p>St. Mary's Hospital Same City Anywhere, USA</p>
<p>IRRADIATED LEUKOCYTES REDUCED SUPERNATANT REDUCED/PLASMA ADDED Approx <u>53</u> mL Red Blood Cells from 450 mL CPD Whole Blood and <u>42</u> mL CPD <u>AB+</u> Plasma</p>		
<p>Store at 1 to 6 C</p>		

Figure 5 RBC Irradiated Attribute

 A9999 17 123456 8 9 St. Mary's Hospital Anywhere, USA FDA Registration Number 1234567 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only <b>VOLUNTEER DONOR</b>	 5100  <b>Rh POSITIVE</b>
 E8989V00 <b>RECONSTITUTED  RED BLOOD CELLS</b> RBC IRRADIATED SUPERNATANT REMOVED/PLASMA ADDED Approx <u>55</u> mL Leukocytes Reduced Red Blood Cells from 500 mL CPD Whole Blood and <u>45</u> mL <u>CPD</u> <u>AB+</u> Plasma Store at 1 to 6 C	 Expiration Date/Time 31 JAN 2017 15:15

- E8989 = RED BLOOD CELLS|CPD>AS1/500mL/refg|**RBC irradiated**|ResLeu:NS|Supernat rem/Plasma added