

HIM.2.3 Respond to Market Withdrawals and Recalls

Procedure Area: Hospital Inventory Management Procedures (HIM)

Version: 1.0

Purpose

To respond to recalls due to post donation information about the donor or the blood component.

Scope

Customers

Materials

- ✓ *Blood Component Market Withdrawal/Recall Notification* form (initiated in **HS.5.2**)
- ✓ *Hospital Return* form, if needed (initiated in **HIM.1.2**)

Procedure Notes

A credit will not be issued for components returned due to a recall without a completed *Blood Component Market Withdrawal/Recall Notification* form.

Procedure Steps

1. Receive the faxed *Blood Component Market Withdrawal/Recall Notification* form (see [Figure 1](#)). Note that you will receive a call alerting you that the form was faxed.
2. Determine the disposition of each blood component listed in the Component Details section of the *Blood Component Market Withdrawal/Recall Notification* form.
3. Complete the To Be Completed by Customer section of the *Blood Component Market Withdrawal/Recall Notification* form as follows:
 - a. Enter your name as the **Person Completing Form**.
 - b. Enter your job title as the **Title**.
 - c. Indicate the **Final Disposition** of each component listed on the *Blood Component Market Withdrawal/Recall Notification* form, and handle as follows:

If component is	Do this
In inventory	<ul style="list-style-type: none">• Complete a <i>Hospital Return</i> form and arrange for return per HIM.1.2.• On the <i>Blood Component Market Withdrawal/Recall Notification</i> form select the “Returned to Blood Center” disposition, and write the date you returned the component in the Date of Final Disposition field.• Enclose a copy of the <i>Blood Component Market Withdrawal/Recall Notification</i> form with the component being returned.
Discarded/destroyed	Select the “Destroyed at your facility” disposition, and write the date you discarded/destroyed the component in the Date of Final Disposition field.
Transfused	Select the “Transfused prior to notification” disposition, and write the date the component was transfused in the Date of Final Disposition field.
Shipped	<ul style="list-style-type: none">• Select the “Shipped to another facility” disposition, and write the date you shipped the component in the Date of Final Disposition field.• Indicate the facility that received the component in the Additional Comments field.
Kept	Explain why the component was kept in the Additional Comments field.

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4. Sign and date the *Blood Component Market Withdrawal/Recall Notification* form. By signing the form, you are assuring that the component disposition information indicated on the form is accurate.
5. Fax or email the completed *Blood Component Market Withdrawal/Recall Notification* form to the number or email address listed on the form as soon as possible.

Related Documents

[HIM.1.2 \(Return Components for Normal Inventory Rotation\)](#)

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Clear Fields



Blood Component Market Withdrawal/Recall Notification LifeSouth Community Blood Centers

Form Initiated by: PVH1	Region: NEWBE
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Customer Information

Notification Date: 03/18/2021	Contact Name: John Doe
Facility: Blood Bank Hospital	Phone Number: (352) 224-1611
	Fax Number: (352) 224-1111

Component Details

#	DIN	Product Code	ABO/Rh	Date Shipped	Date Expires
1	W115121046180D	E9749V00	O=	05 MAR 2021	19 FEB 2022
2					
3					
4					

Reason for Market Withdrawal/Recall

<input type="checkbox"/> Bacterial testing failed <input type="checkbox"/> Co-component associated with a report of adverse transfusion event <input checked="" type="checkbox"/> Co-component has fibrin strands <input type="checkbox"/> Co-component has visual signs of bacterial contamination (cloudy, clumps, frothy, or clots) <input type="checkbox"/> Imported product: exporter initiated recall: _____ <input type="checkbox"/> Incorrect volume on product label	<input type="checkbox"/> pH out of range in component or co-component <input type="checkbox"/> Product QC: low platelet count: _____ x10e11 <input type="checkbox"/> Product QC failure noted after component shipped <input type="checkbox"/> QA Investigation: _____ <input type="checkbox"/> Other reason: _____
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Email this form to QA@lifesouth.org at the same time that you fax or email this form to the customer

TO BE COMPLETED BY CUSTOMER

Person Completing Form: John Doe	Title: Medical Technologist
Signature: <i>Johndoe</i>	Date: 03/18/2021

Indicate the Final Disposition of each component listed (check applicable):

#	Returned to Blood Center	Destroyed at your facility	Transfused prior to notification	Shipped to another facility (designate where)	Component Kept (include comment)	Date of Final Disposition
1	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	03/18/2021
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Additional Comments:

- As soon as possible, return this form to QA at QA@lifesouth.org or fax at (352) 334-7782.
- Credit for discarded components may be issued upon request. Request credit by submitting the Issue/Complaint Form (accessible at www.lifesouth.org).

Contact the LifeSouth Quality Assurance department at 1-866-592-8678 if you have questions.

HS.5.2

Effective: 02 Feb 2021

Figure 1, Blood Component Market/Withdrawal Notification form

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Version History

#	Significant Changes	Approved by	Approved	Implemented
1.0	<ul style="list-style-type: none">Added "Component Kept" to the if/then table in step 3.Updated step 5 so staff have the option to email the completed <i>Blood Component Market Withdrawal/Recall Notification</i> form.Added example of completed <i>Blood Component Market/Withdrawal Notification</i> form <p>Note: <i>Prior versions of this document may exist; version numbers were applied to policies and procedures beginning in –Jan. 2015.</i></p>	Phuc Huynh, Corporate Quality Assurance Coordinator	18 Mar 2021	18 Mar 2021