

## HIM.2.4 Respond to Lookback Investigations

Procedure Area: Hospital Inventory Management Procedures (HIM)

Version: 1.3

### Purpose

To discard blood components from a donor who tested reactive or repeatedly reactive for a qualifying disease marker on a subsequent donation.

### Scope

Customers

### Materials

- ✓ Partially completed *Inventory Discard/Supplemental Testing Notification* form (initiated in **QA.2.8**)
- ✓ *Issue/Complaint Report*, if needed (initiated in **HIM.2.1**)

### Procedure Notes

- Refer to [21 CFR 610.46\(b\)](#) for HIV lookback requirements for consignees of blood components.
- Refer to [21 CFR 610.47\(b\)](#) for HCV lookback requirements for consignees of blood components.

### Procedure Steps

1. Receive the faxed *Inventory Discard/Supplemental Testing Notification* form. See [Figure 1](#) for an example.
2. Print your name and then sign and date the form. Keep in mind that by signing the form, you are acknowledging receipt of the *Inventory Discard/Supplemental Testing Notification* form, including the component information listed on the form.
3. Determine the disposition of the blood component listed in the Component section of the *Inventory Discard/Supplemental Testing Notification* form, and handle as follows:

In inventory?	Then this
Yes	<ul style="list-style-type: none"><li>• Discard/destroy the component.</li><li>• Complete an <i>Issue/Complaint Report</i> as detailed in <b>HIM.2.1</b> for the component.</li><li>• Fax the <i>Issue/Complaint Report</i> with a copy of the completed <i>Inventory Discard/Supplemental Testing Notification</i> form to the blood center servicing your facility.</li></ul>
No	Proceed to the next step.

4. Fax the completed *Inventory Discard/Supplemental Testing Notification* form to the fax number printed at the bottom of the form.
5. You will be notified via certified mail generally within 45 days of the reactive test results if the donor's test results were confirmed and recipient notification is required. Contact Quality Assurance using the phone number provided on the *Inventory Discard/Supplemental Testing Notification* form if you have any questions.

### Related Documents

- [HIM.2.1 \(Report an Issue/Complaint\)](#)
- [QA.2.8 \(Perform Lab Review\)](#)

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## Inventory Discard/Supplemental Testing Notification LifeSouth Community Blood Centers

Case File Number: W11512412345A

To: Childrens Hospital	Date notification sent: 09/25/2024
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Our records indicate that the blood component(s) below were shipped to your facility. All of the components were NONREACTIVE/NEGATIVE for viral marker testing at the time of distribution. However, on a subsequent donation the donor tested reactive for the following test(s):

Test Name	Test Result
HBsAg	Reactive

### Component

Unit Number / DIN	Product Code	Expiration Date	Date Shipped	Transaction Number	Box #	BOL #
W11512498765Z	E0701V00	04/20/2025	04/27/2024	12345-67890	001	N/A

### Confirmation/Supplemental Testing

- Additional results pending (this form will be resent with supplemental results upon completion)
- No further testing

Name of Test	Test Results	Date Tested
HBsAg Neutralization	Reactive	09/24/2024

Please acknowledge receipt of this information by signing and returning form to LifeSouth by FAX at 352-334-7782.

Form Completed By: Denise Hinman Date: 09/25/2024  
(print name)

Signature: \_\_\_\_\_

If you have questions, please contact LifeSouth's Quality Assurance department at 1-866-592-8678, Monday through Friday, 9 a.m. to 5 p.m. (ET).

QA.2.8

Effective: 01 Aug 2024

Figure 1, Inventory Discard/Supplemental Testing Notification Form

Not Under Document Control if Printed

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### Version History

#	Significant Changes	Approved by	Approved	Implemented
1.3	<ul style="list-style-type: none"> <li>Added procedure notes with references to CFR sections with HIV and HCV lookback requirements for consignees of blood components.</li> <li>Updated <i>Inventory Discard/Supplemental Testing Notification</i> form example in Figure 1.</li> </ul>	Phuc Huynh, Corporate Quality Assurance Coordinator III	05 Dec 2024	05 Dec 2024
1.2	<ul style="list-style-type: none"> <li>Added Figure 1 as an example of <i>Inventory Discard/Supplemental Testing Notification</i> form.</li> <li>Updated references to <i>Inventory Discard/Supplemental Testing Notification</i> form.</li> </ul>	Dr. Juan Merayo-Rodriguez, Medical Director Dr. Chris Lough, Medical Director Lori Masingil, VP of Quality	05 Mar 2021	23 Mar 2021
1.1	<ul style="list-style-type: none"> <li>Changed <b>QA.2.4</b> references to <b>QA.2.8</b>.</li> <li>Changed contact for customer questions from Medical Office to Quality Assurance.</li> </ul>	Dr. Juan Merayo-Rodriguez, Medical Director Dr. Chris Lough, Medical Director Matt Audette, QA Manager CBCC Medical Director	13 Dec 2016	17 Jan 2017
1.0	<ul style="list-style-type: none"> <li>Replaced <i>Request for Credit</i> form with <i>Issue/Complaint Report</i>.</li> <li>Added version information.</li> </ul> <p><b>Note:</b> Prior versions of this document may exist; version numbers were applied to policies and procedures beginning in ~Jan. 2015.</p>	Dr. Juan Merayo-Rodriguez, Medical Director Dr. Marek Fried, Medical Director Richard Jones, QA Manager CBCC Medical Director	03 Jun 2015	23 Jun 2015