



Sutter Roseville Medical Center

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Owner: *Nadera Poirier: Spvr, Transfusion Services*
Policy Area: *Lab - Transfusion Service*
References:
Applicability: *Sutter Roseville Medical Center*

Managing Market Withdrawals, Recalls, and Quarantining of Blood Products and Reagents

PURPOSE

To provide instructions on how to process requests for market withdrawals, recalls, or the quarantine of blood products from the blood supplier and reagents.

POLICY

- The Transfusion Services Supervisor will notify the supplier of reagent or product issues.
- Following notification of a product investigation, confirm product status and respond as soon as possible, preferably within 1 business day of receipt.
- Products that are still in date will be quarantined until further direction can be provided by supplier.
- Notifications of lookback will be performed by the Transfusion Services Supervisor.

PROCEDURE

Blood Products

Step:	Action:
1.	Launch Sunquest, and select <i>Blood Bank Inquiry</i> (BBI). Look up the status of the unit number(s) found on notification form from the blood supplier.
2.	Complete the appropriate fields on the form using information garnered from BBI and fax completed form back to blood supplier.

3. Follow the instructions provided by the blood supplier for returning or discarding unused products.

If:	Then:
Product is still in inventory	<ul style="list-style-type: none"> • Refer to SOP: <i>Quarantining Blood Products</i> • Complete required documentation for returns/transfers to blood supplier and return product with next blood delivery, as indicated by blood supplier instruction
Product was placed in <i>Issued</i> status within the last 4 hours	<ul style="list-style-type: none"> • Immediately identify recipient and location of product • Contact nursing staff and request product transfusion be discontinued immediately and returned to Transfusion Services <ul style="list-style-type: none"> ◦ If product is being discarded due to suspected bacterial contamination, perform blood cultures on blood product • Notify patient's clinician and Pathologist of the reason for return and any potential clinical impact on patient <ul style="list-style-type: none"> ◦ If product is being discarded due to suspected bacterial contamination, request that the clinician order blood cultures on the patient ◦ Document communication as a chartable comment (BBC) in the accession • If retrieved and blood supplier requests return, complete required documentation for returns/transfers to blood supplier and return product with next blood delivery
Product status is : Issued Final (IF), Discarded (DS), Outdated (OD)	<ul style="list-style-type: none"> • No additional action is needed at this time

4. Print BBI for unit(s) after taking above action and leave with notification form from blood supplier for Transfusion Services Supervisor or Technical Coordinator for review and follow up.

Reagents

To be used when issues arise with reagents causing them to be unusable (i.e. repeated QC failure).

Step:	Action:
1.	Upon discovery, remove reagent lot from use until issue is resolved.
2.	If immediate testing need exists, contact surrounding Sutter affiliates to determine availability of properly functioning lot/reagent to borrow until issue is resolved. <ul style="list-style-type: none">• If alternative product is not available for use, consult available or on-call supervisor to arrange send out testing until replacement is available• If no immediate need exists for testing, proceed to step 3
3.	Leave documentation of issue and resolution for the Transfusion Services Supervisor for follow up.

RELATED DOCUMENTS

Quarantining Blood Products

All revision dates:

Attachments

No Attachments

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