



**University of Washington Medical Center
1959 NE Pacific Street. Seattle, WA 98195
Transfusion Services Laboratory
Policies and Procedures Manual**

**Original Effective Date:
08-09-2019**

Revision Effective Date:

**Number:
SS-0001.01**

TITLE: Critical Materials Inventory Management

PURPOSE:

To provide a process for ordering and tracking the use of critical materials

PRINCIPLE & CLINICAL SIGNIFICANCE:

Managing and maintaining an adequate inventory of reagents and supplies is essential to keep the transfusion laboratory functional for patient safety

POLICIES:

- Critical materials are reagents or supplies used in the preservation, storage, preparation or testing of blood components and patient samples that directly affects quality or patient safety.
 - Examples of critical materials:
 - Reagents used in the performance of testing such as antisera, red cell reagents, gel card, saline
 - Supplies used in the performance of testing such as test tubes, plastic pipettes, pipette tips
 - Supplies used in component preparation of blood components such as component bags, syringes, saline
 - Examples of non-critical materials
 - Office supplies, lab furniture, computers, personal protective gear, etc.
- The following information is documented on the *Critical Materials Inventory Log* for all critical materials:
 - Date Received
 - Quantity Received
 - Unit
 - Lot Number
 - Expiration Date
 - Visual inspection results
 - Manufacturer's package insert version number and comparison to current version
 - Date item is placed into use
- Package inserts
 - Are reviewed upon receipt of critical materials to verify the most current version is in use.
 - New and old versions are compared for changes that may affect internal policies or procedures and appropriate changes made prior to use.
 - Retired package inserts will be retained for a time to meet regulatory and laboratory retention requirements
- Critical materials found to be unacceptable for use should be quarantined and/or discarded as appropriate. This includes:
 - Critical materials recalled by the manufacturer

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- Unopened materials and reagents (this does **NOT** include reagents in use that expire before the container is empty)
- Damaged items
- Items failing visual inspections
- Items not store under required conditions (refrigerator items not stored at acceptable temperatures)
- Notify the UWMC TSL Safety Officer when a new chemical is purchased

SPECIMEN REQUIREMENTS:

N/A

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
N/A	<ul style="list-style-type: none"> ● <i>Critical Materials Inventory Log</i> ● <i>Package Insert Review form</i> ● <i>Inventory Reorder Card</i> 	<ul style="list-style-type: none"> ● Label Gun

QUALITY CONTROL:

NA

INSTRUCTIONS:

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Receiving Critical Materials

STEP	ACTION	
1	Verify the shipping container is addressed to UWMC TSL	
	If	Then
	Addressed to UWMC TSL	Go to next step
2	Not addressed to UWMC TSL	<ul style="list-style-type: none"> ● Verify with loading dock if shipment was meant for TSL ● Have shipment picked up by Supply Chain Logistics Receiving and Transportation team located at the loading dock
	Unpack the shipment and verify contents were shipped at the appropriate conditions and temperature – refer to manufacturer insert if needed	

STEP	ACTION		
	If temperature	Then	
	Acceptable	Go to next step	
	Not acceptable	<ul style="list-style-type: none"> Quarantine shipment at appropriate storage Contact the manufacturer to determine if shipment is acceptable for use 	
		If deemed	Then
		Acceptable for use	Ask for written documentation of acceptability from the manufacturer
Not acceptable	Follow manufacturer's instruction to discard or return items Notify manager or lead		
3	Reconcile the materials received with the packing list		
	If packing list and shipment	Then	
	Match	Document today's date and tech code on the packing list and file the packing list in the purchasing file under "Received Packing List" folder NOTE: Documentation of tech code and filing the packing list indicates items received matches the items on the packing list	
Do not match	Notify lead or purchaser for resolution		
4	Document the following on the <i>Critical Materials Inventory Log</i> : <ul style="list-style-type: none"> Date Received Quantity Unit (ie. box, bottle) Lot Number Expiration Date 		
5	Visually inspect material and document the result on the <i>Critical Materials Inventory Log</i> . Inspect for but not limited to: <ul style="list-style-type: none"> Damage to container Contamination and spill NOTE: The reagent package insert should be followed for additional visual inspection requirements such as hemolysis for red cells reagents		
	If visual inspection	Then	
	Passes	<ul style="list-style-type: none"> Document 'P' for Pass on the log Go to next step 	
Fails	<ul style="list-style-type: none"> Document 'F' for Fail on the log Quarantine the material Notify a lead or purchaser Document the specifics on a QI Contact the manufacturer to determine if material should be returned or discarded – document the manufacturer's response on the QI 		

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STEP	ACTION						
6	Document the manufacturer's package insert version number on the <i>Critical Materials Inventory Log</i> NOTE: Package inserts for Ortho reagents must be retrieved on-line – see Appendix 1: Retrieving Ortho Reagents Package Insert						
7	Verify the new package insert matches the current version in the Package Insert binder						
	<table border="1"> <thead> <tr> <th>If inserts</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Match</td> <td> <ul style="list-style-type: none"> Document 'Y' for yes on the log Go to next step </td> </tr> <tr> <td>Do NOT match</td> <td> <ul style="list-style-type: none"> Document 'N' for no on the log Complete a <i>Package Insert Review</i> form and attach a copy of the new package insert to the form Submit <i>Package Insert Review</i> form for management review Go to next step <p>Note: Notify TSL manager directly if material is needed for immediate use</p> </td> </tr> </tbody> </table>	If inserts	Then	Match	<ul style="list-style-type: none"> Document 'Y' for yes on the log Go to next step 	Do NOT match	<ul style="list-style-type: none"> Document 'N' for no on the log Complete a <i>Package Insert Review</i> form and attach a copy of the new package insert to the form Submit <i>Package Insert Review</i> form for management review Go to next step <p>Note: Notify TSL manager directly if material is needed for immediate use</p>
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8	Label the containers with a receipt date label using the label gun NOTE: Label only the outside container/box, do NOT label individual bottles						
9	Place item in the appropriate storage area in order of expiration date (earliest expiring in front)						
	<table border="1"> <thead> <tr> <th>If the new lot expires</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>After the current in-use lot</td> <td>Place in order of expiration behind the current in-use lot</td> </tr> <tr> <td>Before the current in-use lot</td> <td>Notify a lead to help coordinate changing of lots including QC prior to use</td> </tr> </tbody> </table>	If the new lot expires	Then	After the current in-use lot	Place in order of expiration behind the current in-use lot	Before the current in-use lot	Notify a lead to help coordinate changing of lots including QC prior to use
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10	Attach the Inventory Reorder Card to the container that when removed for use will leave the minimum inventory level on the shelf						

Placing a New Lot Number in Use

STEP	ACTION
1	Verify there are no remaining items of the current lot in use
2	Document the following for the matching entry on the <i>Critical Materials Inventory Log</i> <ul style="list-style-type: none"> Date lot number of item is placed in use Tech ID
3	Place an original copy of the corresponding antigram in the Antigram Binder if the item is Antibody Screening or Panel cells
4	Perform and document any required quality control for the item CRITICAL: If two lots of the same reagent are in use at the same time, ensure both lots are quality controlled and all shifts are aware there are two lots in use

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Requesting Reorders

STEP	ACTION	
1	Remove the Inventory Reorder Card from the item	
2	Write the current date on the card with a dry erase marker	
3	Place the card in the "Inventory Reorder" folder	
	If the order	Then
	Is STAT	<ul style="list-style-type: none"> Notify the lead or purchaser in person Place the card in the "Inventory Reorder" folder
	Is NOT STAT	Place the card in the "Inventory Reorder" folder

Ordering Critical Materials

STEP	ACTION
1	Order the quantity of item required to meet PAR level in the purchasing system – only designate person, including the TSL manager, have access to this system
2	Erase the date from the Inventory Reorder Card
3	Place the Inventory Reorder Card on the "Pending Receipt" board

Discarding Expired Critical Materials

STEP	ACTION	
1	If the item is	Then
	Antibody Panel and Screening Cell Reagents	<ul style="list-style-type: none"> Remove all copies of the antigram from the in-use section of the Antigram Binder and place the original in the expired section Move the expired reagent panel to the expired reagents shelf. Discard the following in a biohazard bin: <ul style="list-style-type: none"> Panels not visually acceptable (ie: hemolyzed, bacterial contamination) Panels 3 month past expiration
	Reagents, gel cards, and Kits, saline (ex. Anti-sera, FMH)	<ul style="list-style-type: none"> Retain the minimal amount of unopened expired reagents need for training (TSL & students), write "for training" on the bottle, rubber band them together and place in the Training refrigerator Discard the remaining expired reagents in a red biohazard bin.

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	Chemicals (ex. Sodium Hydroxide)	<ul style="list-style-type: none"> Request a pickup from UWMC Environmental Health and Safety at https://ehs.washington.edu/chemical/mychem Click on <Chemical Waste Disposal> from the list of item on the left of the screen Scroll to the middle of the page and click on <Online Chemical Waste Collection Request from> Login using your UWMC ID and password Fill in the required fields and follow the directions. Print screen shot of the order number and attach a copy with the chemicals for pickup. 	
	Other Critical Materials (ex. Transfer bags, aliquot syringes)	If	Then
		Not contaminated with biohazard material	Discard in a regular trash bin
Contaminated	Discard in the red biohazard bins		

CALIBRATION:

N/A

PROCEDURE NOTES AND LIMITATIONS:

- Required quality control of critical material should be performed prior to use (does not apply to antibody panels)
- Refer to package insert for
 - Acceptable shipping and storage conditions
 - Visual inspection requirements
- Reagents or supplies may be borrowed from affiliate facilities if inventory is critically low. Borrowed supplies should be recorded in the Critical Materials Inventory log following this procedure. If borrowed, record the amount, name and where the item was borrowed in the communication log including whether replacement items should be sent to the lender when available.
- In the event, use of an item requires a SOP revision is needed before the change can be made, obtain approval from the TSL/QA Manager and document on QI
- Copies of the package inserts may be found on the manufacturer’s website when not included with item – for Ortho reagents see [Appendix 1: Retrieving Ortho Reagent Package Inserts](#)

REFERENCES:

N/A

RELATED DOCUMENTS:

Critical Materials Inventory Log
 Package Insert Review Form
 Inventory Reorder Card

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UWMC SOP Approval:	
UWMC CLIA Medical Director	_____ Date _____
	Mark H. Wener, MD
Transfusion Service Manager	_____ Date _____
	Nina Sen
Compliance Analyst	_____ Date _____
	Christine Clark
Transfusion Service Medical Director	_____ Date _____
	Monica Pagano, MD
UWMC Biennial Review:	
	_____ Date _____
	_____ Date _____

TRANSFUSION

APPENDIX:

Appendix 1: Retrieving Ortho Reagent Package Inserts

STEP	ACTION										
1	Go to https://www.orthoclinicaldiagnostics.com/										
2	Hover over the 'Solutions & Products' tab										
3	Click <Reagents> under 'Immunoematology'										
4	Click <Resources> (in red text)										
5	Click <Technical Documents> (in bluetext)										
6	Click on <Instructions for Use> under 'Immunoematology'										
7	Select the following:										
	<table border="1"> <thead> <tr> <th>Field</th> <th>Select</th> </tr> </thead> <tbody> <tr> <td>Country</td> <td>United States and US Territories</td> </tr> <tr> <td>Language</td> <td>EN-English</td> </tr> <tr> <td>Product</td> <td>Transfusion Medicine</td> </tr> <tr> <td>Cat. No., Product code REF</td> <td>Enter the product REF from the reagent box</td> </tr> </tbody> </table>	Field	Select	Country	United States and US Territories	Language	EN-English	Product	Transfusion Medicine	Cat. No., Product code REF	Enter the product REF from the reagent box
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	Country	United States and US Territories									
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Product	Transfusion Medicine										
Cat. No., Product code REF	Enter the product REF from the reagent box										
8	Click <Submit>										
9	Open link and print the package insert										