Policy
Dignity Health Central Coast Service Area

SUBJECT: Reagent Receipt, Inspection, and Final Disposition

ORIGIN: Laboratory-Transfusion Service

NUMBER: 7540.BB.CC.200

Applies to:		
☒ Santa Maria Campus, Marian Regional Medical Center	☒ Arroyo Grande Campus, Marian Regional Medical Center	☒ French Hospital Medical Center
☐ St. John's Pleasant Valley Hospital	☐ St. John's Regional Medical Center	

I. PURPOSE:

This policy provides instruction for the documentation and performance of the receipt, inspection, and final disposition of transfusion service reagents.

II. DEFINITIONS:

Critical Materials: A material that can directly affect the quality of the facility's products or services.

III. POLICY:

Critical materials, such as reagents and supplies that are used in the transfusion service must be documented and inspected when received and documented when they are discarded.

A. Receipt and Inspection of Reagents and Supplies

1. The reagents received will be documented on the Transfusion Service Critical Materials Receipt Log (7540.BBF.CC.200.1).
2. Date stamp all reagents on the day they were received in the transfusion service.
3. The critical materials received will be compared to the packing list provided by the supplier. The packing list will be reviewed and compared with the materials received for the following items:
   a) Description
   b) Lot number
   c) Expiration date
   d) Ordered and shipped quantities.
4. The packing list will be initialed and dated by the clinical laboratory scientist unpacking the critical materials and the quantities received will be acknowledged.
5. The materials will be visually inspected for the following:
   a) Shipped according to manufacturer's recommendations, which is depicted by a thermometer with the acceptable storage temperature range.

b) Materials are clearly labelled.

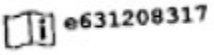
c) Evidence of alteration of the intended product such as unexpected turbidity, color change, precipitate, and possible bacterial contamination that would indicate the deterioration of the product.

d) Evidence of damage such as broken, dented, or containers or seals that appears tampered.

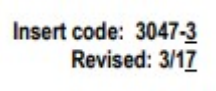
e) If visual inspection is unacceptable, then notate “N” under Visual Inspection Acceptable and quarantine the reagent, complete 7540.BBF.CC.200.3 Critical Supplier Problem Report, and notify the supervisor.

6. The package insert will be compared to the current package insert in use.

a) The  symbol is present on the box if a package insert is not included along with a reference number associated with the version of the applicable package insert.



b) If a package insert is included, then the package insert reference number will be present on the insert.



c) Compare the package insert reference number with the package insert currently in use.

d) Document that the packages insert was checked on the Transfusion Service Critical Materials Receipt Log (7540.BBF.CC.200.1).

e) If the package insert is new and is not available, then print a new package insert from the manufacturer’s website and notify the supervisor.

f) The supervisor will review the new package insert for changes and update procedures and practice as necessary. The supervisor will write, “Reviewed by (Initials and Date).”

g) Label the critical material with a “NEW PACKAGE INSERT” label.

h) When the reagent with a “NEW PACKAGE INSERT” label is placed in use, then remove the old package insert from the binder and write, “Removed by (Initials and Date) and place in the supervisor’s review box. Write “Placed in use by (Initials and Date)” on the new package insert before placing it in the binder.

7. Disposition

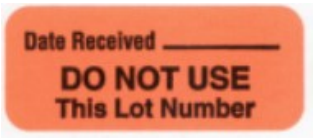
a) If the information on the packing list agrees with the reagent received and the shipping conditions and the visual inspection are acceptable, then the reagents can be released for use.

b) If the information on the packing list does not agree with the reagent received and/or the shipping conditions and/or the visual inspection are unacceptable, then the reagents must be quarantined.

1) If the reagents must be quarantined, then place the reagents in the quarantine box and complete 7540.BBF.CC.200.3 Critical Supplier Problem Report and notify the supervisor.

8. Additional QC Required

a) If the reagent or supply requires quality control to be performed prior to being used for patient testing, then place “DO NOT USE THIS LOT NUMBER” stickers on the reagents and write “Y” in the appropriate box on 7540.BBF.CC.200.1 Transfusion Service Reagent and Supply Receipt Log.



b) If the supply does not require quality control, e.g. blood transfusions filters, then write “N” in the appropriate box on 7540.BBF.CC.200.1 Transfusion Service Reagent and Supply Receipt Log and place “THIS LOT IS READY FOR USE” stickers on the boxes.

9. If additional QC is required, then once completed specify if it is acceptable or unacceptable. If the QC is unacceptable, then refer to procedure step 10 in 7540.BB.CC.201 Reagent Quality Control –Daily. Do not report any patient testing until resolution of unacceptable QC is investigated and resolved.

10. Use the comment section to explain any discrepancies or unacceptable responses.

11. Attach the packing list to the completed 7540.BBF.CC.200.1 Transfusion Service Reagent and Supply Receipt Log.

B. Final Disposition of Reagents and Supplies

1. The discarded reagents will be documented on the Transfusion Service Reagent and Supply Discard Log (7540.BBF.CC.200.2).

2. Log the following information on the form:

a) Manufacturer

b) Reagent name

c) Lot number

d) Expiration date

e) Quantity

f) Discard date and employee initials

g) Discard Disposition

1) Refer to the key to determine the reason the reagent or supply is being discarded.

a. H=Hemolyzed

i. Reagent is markedly hemolyzed and is unacceptable for use. Discard the vial and open a new visually acceptable vial.

b. O=Outdated

i. Reagent is expired.

c. C=Contaminated

i. Reagent is contaminated by bacteria, precipitate or cross contamination and is unacceptable for use.

d. E=Empty

i. No more reagents in the same lot number are available.

e. B=Broken

i. Container or associated components are broken and not acceptable for use.

f. U= Unacceptable storage temperature

i. Reagent or supply was not stored according to manufacturer's recommendations and must be discarded due to the quality being compromised.

g. R= Recalled per manufacturer

i. Recalled due to manufacturing that has compromised the safety, purity, and potency of the product.

2) Use the comment section to explain any discrepancies or unacceptable responses.

3) Discard the reagents or supplies in the appropriate receptacles.

IV. REFERENCES:

A. Fung, M.K. (Current Edition). *Technical Manual*. Bethesda, MD: AABB.

B. *Standards for Blood Banks and Transfusion Services* (Current Edition). Bethesda, MD: AABB.

V. ASSOCIATED DOCUMENTS:

A. 7540.BBF.CC.200.1 Transfusion Service Critical Materials Receipt Log

B. 7540.BBF.CC.200.2 Transfusion Service Critical Materials Discard Log

C. 7540.BBF.CC.200.3 Transfusion Service Critical Supplier Problem Report

Dignity Health Central Coast Service Area

☐ Santa Maria Campus, Marian Regional Medical Center ☐ Arroyo Grande Campus, Marian Regional Medical Center ☐ French Hospital Medical Center

Transfusion Service Reagent and Supply Receipt Log

Manufacturer	Reagent Name	Lot Number	Expiration Date	Quantity	Received		Shipping Conditions Acceptable (Y/N)	Visual Inspection Acceptable (Y/N)	Package Insert Checked (Y/N/*New)	Disposition (R/Q)	Additional QC Required (Y/N)	Additional QC Acceptable (Y/N)
					Date	Initials						

Key:
Y=Yes
N=No
R=Released for use
Q=Quarantined

Acceptable Results:
1. Shipped according to manufacturer's recommendations.
2. Visual inspection: Reagents are clearly labeled and with no evidence of bacterial contamination, tampering, or damage. If visual inspection is unacceptable, then quarantine the reagent and complete the Critical Supplier Problem Report (7540.BBF.CC.200.3).
3. Package insert checked with manufacturer's insert in use. *If the package insert is new, then print the new package insert and notify the supervisor.

Comments:_____

_____

Reviewed by:_____

Date:_____

7540.BBF.CC.200.1 Transfusion Service Reagent and Supply Receipt Log
Version 1

Dignity Health Central Coast Service Area

☐ Santa Maria Campus, Marian Regional Medical Center ☐ Arroyo Grande Campus, Marian Regional Medical Center ☐ French Hospital Medical Center

Transfusion Service Reagent and Supply Discard Log

Manufacturer	Reagent Name	Lot Number	Expiration Date	Quantity	Discarded		Discard Disposition Code (See Key)
					Date	Initials	

Key:
H=Hemolyzed/Discarded
O=Outdated
C=Contaminated
E=Empty (No more lot number available)
L=Lot number change
B=Broken
U=Unacceptable storage temperature
R=Recalled per manufacturer

Comments:_____

_____

_____

Reviewed by:_____

Date:_____

7540.BBF.CC.200.2 Transfusion Service Reagent and Supply Discard Log

Dignity Health Central Coast Service Area

☐ Santa Maria Campus, Marian Regional Medical Center ☐ Arroyo Grande Campus, Marian Regional Medical Center ☐ French Hospital Medical Center

Critical Supplier Problem Report

Supplier: Click here to enter text.

Purchase Order Number: Click here to enter text.

Date of discovery: Click here to enter a date.

Name of Reporter: Click here to enter text.

Problem Category:

☐Product Quality

☐Product Availability

☐Incorrect Order

☐Delivery/Shipping

☐Technical

☐Other Click here to enter text.

Product Involved: Click here to enter text.

Brief description of problem: Click here to enter text.

Has this problem occurred before? ☐ Yes ☐ No

If yes, how many times and how long ago? Click here to enter text.

Vendor contacted? ☐ Yes ☐ No

If yes, who did you speak to? Click here to enter text.

Date:Click here to enter a date. Time: Click here to enter text.

Product return to vendor required? ☐ Yes ☐ No

If yes, Date returned to vendor: Click here to enter a date.

If No, was the product discarded? ☐Yes ☐No

Comments: Click here to enter text.

Follow up with vendor required? ☐ Yes ☐ No

Whom did you follow up with? Click here to enter text.

Date: Click here to enter a date. Time: Click here to enter text.

Comments: Click here to enter text.

Were the sales representative/customer service personnel helpful and courteous in resolving the problem? ☐ Yes ☐ No

Was the problem resolved? ☐ Yes ☐ No