PROCEDURE
Corewell Health East - Receipt of Critical Blood Bank Reagents and Materials - Farmington Hills

This Procedure is Applicable to the following Corewell Health sites:
*Sites:, Corewell Health Farmington Hills Hospital

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

The Blood Bank must comply with several regulatory requirements relating to the inventory and receipt of reagents and critical materials. For example, all new lots of reagents and critical materials must be inspected and tested, as applicable, before use, with documentation of acceptance. In addition, the Blood Bank must review all manufacturer's instructions and printed materials to ensure that all reagents and materials shall be stored and used in accordance with the manufacturer's instructions. The Blood Bank maintains binders in which the current manufacturer's inserts are stored. When changes to an insert are noted, the appropriate procedures are updated as necessary.

This document will provide guidance and procedures that are to be followed when receiving critical reagents and supplies in the Blood Bank in order to comply with all applicable regulatory requirements.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Definitions

A. Critical Supplies: Those supplies and reagents that impact the safety and quality of the blood supply. The critical items include, but are not limited to: serological antisera, reagent red blood cells, ID-MTS™ reagents (cards and diluent), rare antigen typing sera, elution kits, test tubes, pipettes, normal saline, Rh Immune Globulin and an adequate supply of blood components and tissues.
B. Reference numbers: A general term for the revision date and other numbers that are printed on manufacturers' inserts and packaging supplies. The Blood Bank uses these reference numbers to help determine whether a manufacturer has revised the insert for a reagent.
C. Invoice: The itemized document for Blood Bank reagents or supplies that is provided by the supplier, includes quantities and sometimes includes prices.
D. IF: Inventory Form

4. Quality Control

A. All new lots of reagents must be physically tested and pass all QC requirements, including visual inspections, before actual use in patient testing. The reagents may be tested upon

receipt or upon physically opening the reagent. Refer to Transfusion Medicine policy, Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals

5. Procedure

A. Reagent Inventory Record
   1. All reagents that are received into the Blood Bank must be documented on their *Reagent Inventory Record*. Generally, all reagents are considered critical materials, as they are a good or supply used in the testing of blood components that directly affects quality or patient safety. It is not necessary to document non-reagent materials on a Reagent Inventory Record.

B. Reagent / Supply Invoice
   1. The invoice that accompanies the shipment needs to be initialed and dated by the Medical Technologist (MT) who opens the box in which the reagents were shipped. The initials of the MT indicate that the visual inspection of the shipment is satisfactory; if the inspection is unsatisfactory, then a variance report must be submitted, and the reagents must be quarantined.

C. Visual Inspection of Reagents
   1. The visual inspection is documented on each unique reagent's form as “S” (satisfactory) or “U” (unsatisfactory).
   2. All reagents must be visually inspected. Unsatisfactory visual inspection includes:
      a. Broken vials, leakage, or damaged shipping boxes.
      b. Reagents were shipped at inappropriate temperatures / conditions, noncompliance with any directions supplied by the manufacturer on the shipping container, etc. Note that all Ortho® reagents and Immucor® cellular reagents must be shipped with a coolant. Immucor® non-cellular reagents with four-day shipping do not require a coolant.
      c. Gel cards that are lying on their side (instead of upright) when they are received or that appear damaged.
      d. Solutions that are cloudy, contain particulate matter, are leaking or are not properly sealed.
   3. If the visual inspection fails, the reagent must be placed into quarantine, and a variance report should be submitted.

D. Label Verification
   1. Blood product labels received from an outside manufacturer (i.e. Shamrock) must be inspected for content, legibility, color, etc. before use. This inspection is documented on the attached *Blood Product Label Inspection Log*.

E. Use of the “Received/Date” Sticker
   1. The Blood Bank should be able to determine the date that any reagent was received. The “Received/Date” sticker will be affixed to reagents upon receipt.
   2. If multiple quantities are received in a box/container, then this sticker will be affixed to the storage box or plastic sleeves (e.g., tube antisera, panels, gel cards). These reagents must remain in common box.
   3. Individual bottles not in containers must have a Received/Date sticker attached to each bottle.

F. Use of the Color Sticker
   1. Reagents requiring Quality Control (QC) before use will be labeled with appropriate color sticker to visually indicate the QC status for a reagent.
      a. The ORANGE "DO NOT USE" sticker will be used to indicate a new lot or a reagent that is not in use or has not been tested for Quality Control.
      b. The GREEN "THIS LOT IS READY FOR USE" stickers are reserved for lots in use and can be placed on items after the appropriate QC has been completed.

G. Manufacturers' Insert Binder

1. Reagent manufacturers must supply product information which includes storage requirements, testing procedures, etc. This information may be in the form of printed material and package inserts with reagents or electronically through vendor websites.
2. The Blood Bank maintains this product information in the Manufacturers' Inserts Binder.
3. All reagents and supplies received have their own *Reagent Inventory Record* sheets placed behind the manufacturers insert.

H. Comparison of Manufacturer's Inserts
1. The Blood Bank documents the reference numbers printed on manufacturers' inserts, packaging supplies or boxes on the *Reagent Inventor Record.* These reference numbers are used to help determine whether a manufacturer has revised the insert for a reagent.
   a. For Ortho reagents, the reference numbers include the revision date, the REF number, and/or the electronic number (the e number appears in the format e123456789_EN). These reference numbers appear on the reagent's box. Note that Ortho has not yet assigned both REF and e numbers to all reagents. Note also that Ortho does not typically send inserts with reagents, but may do so if a revision to the insert has recently been made. Ortho inserts include a text box in which the specific revision is listed.
   b. For Immucor / Gamma reagents, the reference numbers include the Insert Code and the revision date, as they appear on the inserts that are routinely sent with the reagents. Revisions made by Immucor on an insert are typically underlined.
   c. Directions for viewing or printing manufacturer's inserts are located in the Manufacturers' Inserts Binders for those vendors who no longer provide printed materials with the reagents.
2. For each reagent that is received by the Blood Bank, the reference number on the packaging must be compared to the reference number on the insert in the Manufacturer's Insert Binder.
   a. This comparison is documented on the *Reagent Inventory Record*. Note: In some cases, two product inserts may appear in the binder for the same reagent if there are two lot numbers currently in use and each lot number has different reference numbers.
3. The reagent packaging must not be discarded until the reference numbers have been recorded on the Reagent Inventory Record.
4. If the reference number on the reagent packaging does not match the reference number on the insert in the Manufacturer's Insert Binder, the technologist must:
   a. Determine the nature of the revisions to the insert and alert the MT Lead/Supervisor of the revision no matter how insignificant the revision may seem.
   b. The technologist receiving the reagent will await the decision from MT Lead/Supervisor on whether to place the reagent in quarantine or not and record corrective actions on the Reagent Inventory Record.
      1) Reagent NOT placed in quarantine: Minor revision only. It has been determined the manner in which the insert has been revised is acceptable to use the reagent consistent with current procedures, despite the revision. For example, a revised logo on the insert.
      2) Reagent placed in quarantine: It has not been determined the manner in which the insert has been revised, or has determined that the use of the current procedure is not advised due to the revision (i.e. entire methodology change). The reagent is placed into quarantine by affixing an orange Quarantine sticker to the reagent or box of reagents. Refer to the policy 5.I. *Placement of Reagents into Quarantine*.
5. Upon notification of a reference number change, the MT Lead/Supervisor will:

a. Determine the nature of the revision to the insert.
b. Determine whether product any related procedures need to be revised and/or validated. If necessary, the reagent/product will be placed into quarantine.
c. Place a copy of the revised insert in the Manufacturer's Insert Binder.
d. Remove the previous version of the insert only if the all vials of the reagent corresponding to the previous insert are expired or exhausted.
e. If applicable, initiate QC testing of the reagent and remove the reagent from quarantine.

I. Placement of Reagents into Quarantine
1. Reagents that have been received in the Blood Bank are considered to be in quarantine until all steps of the Procedure are complete. In addition, reagents shall be placed into quarantine in the following situations:
a. If QC is required at the time of reagent receipt and the QC fails.
b. If the visual inspection fails.
c. If directed by Lead MT/Supervisor after discovery of change in reagent reference numbers, as described in the policy 5.H. *Comparison of Manufacturer's Inserts.*
2. If a reagent is placed in quarantine, the following apply:
a. The orange Quarantine sticker shall be affixed to the reagents by the receiving technologist.
b. A variance report shall be submitted (unless the reason for placement of the reagent in quarantine is that the reference numbers do not match).
c. The quarantined reagent should be stored at the appropriate temperature and conditions, as described by the manufacturer.

J. Unpacking Reagents/Moving to Storage Location in Laboratory
1. All reagents should be received into inventory as soon as possible after delivery from the supplier.
2. Reagents requiring refrigeration should be placed on the "Incoming Not Processed Reagent shelf" until all required steps of the procedure have been completed. Once all steps have been completed, they can be moved to the correct reagent storage location.
3. Gel cards requiring room temperature storage should be sequestered from in use Reagents and affixed with an ORANGE sticker.

K. Antigrams for Antibody Screens and Panels
1. When Selectogen sets, Surgiscreen sets and antibody panels are received, they should be documented on the *Reagent Inventory Record.* Copies of each antigram will be made and distributed/managed as follows:
a. Multiple copies of each antigram will be placed in a sheet protector and placed in the Antigram Binder to be used for antibody investigations. Mark one copy as a "Master" with a highlighter.
b. Each lot number will be kept for 3 months after the expiration date before removal from the binder.

L. Documentation
1. Document the following on Reagent Inventory Record:
a. Received Date
b. Tech
c. Manufacturer
d. Lot Number
e. Expiration Date
f. Quantity
g. Quantity Matches Invoice
h. Visual Inspection
i. Manufacturers Insert Reference Number
j. Manufacturers Insert Changed
k. NOTES – Anything needing an explanation

2. Document the quantity of reagents received; include a description of the quantity. For example: x number of vials, y number of boxes of gel cards, etc. Also document the log with a check mark to indicate that the quantity received matches the quantity from the invoice. If the quantity received does not match the quantity from the invoice, then investigate the discrepancy and take appropriate actions (for example, submit a variance).
3. Visually inspect the shipment of reagents. Document the visual inspection as S (satisfactory) or U (unsatisfactory). If the visual inspection is unsatisfactory, Place the reagent in quarantine and document a variance. For example: an unsatisfactory inspection would include broken vials, leakage, or damaged shipping boxes; reagents that were not shipped at appropriate temperatures/conditions; visible contamination; non-compliance with any directions supplied by the manufacturer on the shipping container, etc.
4. Document the reference numbers from the box/packaging.
    a. For Ortho document the reference number/e number.
    b. For Immucor/Gamma document the insert code and the revision date.
    c. For any other reagents, identify the applicable reference numbers/dates from the Manufacturers' Inserts Binders and identify these numbers/dates on the incoming box/packaging. Refer to policy section 5.H. *Comparison of Manufacturer's Inserts.*
5. Compare the reference numbers on the reagent's packaging with the reference numbers on the insert in the Manufacturer's Insert Binders; and determine whether the reference numbers match.
    a. If reference numbers match, document the "MFG Insert Changed?" column as N (NO).
    b. If reference numbers do NOT match mark the box, document the "MFG Insert Changed?" column as Y (YES).
        1) Determine the nature of the revisions to the insert and alert the MT Lead/Supervisor of the revision no matter how insignificant the revision may seem.
        2) The technologist receiving the reagent will await the decision from MT Lead/Supervisor on whether to place the reagent in quarantine or not and record corrective actions on the Reagent Inventory Record. Refer to the policy section 5.H. *Comparison of Manufacturer's Inserts*.
        3) If the decision to quarantine can not be made timely, place the reagent in quarantine by affixing an orange quarantine label to the reagent and place on appropriate quarantine shelf. Document the corrective action on the Reagent Inventory Record. Refer to the policy section 5.H.*Comparison of Manufacturer's Inserts*.
6. Affix a "Received/Date" sticker to each supply or reagent; document the Reagent Inventory Record with a check mark. Refer to the policy section 5.E. *Use of the "Received/Date" Sticker*.
7. Affix appropriate color sticker to signify the reagent computer delivery and QC testing status. Refer to the policy IV.F. *Use of the Color Sticker.*
8. Move the supplies or reagents to the correct storage location in the Blood Bank.
9. Once all steps of this procedure have been performed satisfactorily, the reagent is acceptable for use (after appropriate quality control has been performed).
10. Document the Reagent Inventory Record with any applicable Notes.
11. File the completed record behind the designated reagent package insert in the Manufactuers' Binder in the department.

6. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

7. References

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

A. AABB, Technical Manual, current edition
B. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.

8. Procedure Development and Approval

Document Owner:
Leisa Haughney (Clinical Policy Program Analyst)

Writer(s):
Susan Pelley (Contracted Consultants)

Reviewer(s):
FAPC LABORATORY, Amy Knaus (Contracted Consultants), Elzbieta Wystepek (Contracted Consultants), Jennifer Yaker (Contracted Consultants), Kelly Sartor (Mgr, Division Laboratory), Laura Judd (Contracted Consultants), Ryan Johnson (OUWB Clinical Faculty), Terri Lovins (Contracted Consultants)

Approver:
John Pui (Chief, Pathology), Sarah Britton (VP, Laboratory Svcs)

9. Keywords

Not Set