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Receipt of Critical Blood Bank Reagents and Materials - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and procedures that are to be applied when receiving critical reagents in the Blood Bank and for reviewing manufacturers' printed materials for reagents that are received.

II. INTRODUCTION:

A. 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. Manufacturers' provide their customers with various printed materials so quality is not compromised and that products are used as recommended. The laboratory must have a procedure so that the most current manufacturers' inserts are in use. The Blood Bank maintains several reference binders in which the current manufacturers' inserts are stored. When changes to an insert are noted, the appropriate policies are updated as necessary.

III. DEFINITIONS:

A. **Critical material**: A good or supply used in collection, preservation, storage, preparation, or testing of blood components that directly affects quality or patient safety.

B. **Receipt traveler**: A Beaumont document that is brought to the Blood Bank by the dock delivery personnel; usually includes price and quantity.

C. **Invoice**: The itemized document for Blood Bank reagents or supplies that is provided by the

supplier; includes quantities and sometimes included price.

D. **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 references numbers to help determine whether a manufacturer has revised the insert for a reagent.

E. **Designee**: Employee trained.

IV. POLICIES:

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.

A. Documentation of the Reagent Receipt Log

1. Reagents that are received from the manufacturer must be documented on the *Reagent Receipt Log*.
2. Directions for documenting this log are located in the *Procedure* section of this document.
3. Generally, all reagents should be documented on this log; items that are considered reagents are included in the *Quality Control of Reagents upon Receipt* section of this document.
4. Note that it is not necessary to document supplies or any items not listed in the *Quality Control of Reagents upon Receipt* section of this document on the *Reagent Receipt Log*.

B. Visual Inspection of the Reagents and Materials

1. Each shipment of reagents must be visually inspected at the time of receipt. A satisfactory visual inspection of the shipment is documented in the computer by marking the "Receipt Criteria Met" box as the reagents are registered. Unsatisfactory visual inspection includes:
    a. Broken vials, incorrect volume, 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.
    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, leaking, or that are not properly sealed.
2. Note that as described throughout this document each individual vial, gel card, etc. will also be visually inspected at the time of testing as part of routine quality control (QC) testing.

C. Policies Relating to the Receipt Traveler and Invoice

1. Receipt travelers should be initialed and time-stamped by the employee who accepts the shipment from the dock delivery personnel. One copy will be retained by the delivery personnel, the other copy should be placed in the shipping box. Any employee may accept the shipment. It is this employee's responsibility to place the shipment at the appropriate temperature, or to ask a technologist for assistance.

2. The invoice that accompanies the shipment should be initialed and time-stamped 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 should be submitted.
3. Once all steps of the procedure have been completed, the receipt traveler and invoice should be submitted to a Laboratory Assistant.

D. 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 the reagents upon receipt.
    a. If multiple quantities are stored in a common box, then this sticker will be affixed to the storage box (e.g., gel cards).
    b. If reagents are removed from the box, then the sticker will be affixed to each individual reagent vial (e.g., reagent and typing sera, MTS diluents, etc.).

E. Label Verification

1. Blood product labels received from outside manufacturer (i.e. Shamrock tags) must be inspected for content, legibility, color, etc. before use. In addition, ABO stickers will be scanned into the computer system to verify that the barcode is accurate. This inspection is documented on the attached *Blood Product Label Inspection Log*, which is stored in the *Reagent Receipt Binder.*
    a. Note that Rad-Sure® tags will be documented on the *Reagent Receipt Log*, NOT on the *Blood Product Label Inspection Log*.
2. If the inspection of any blood product label is unsatisfactory, the label may not be used and appropriate actions must be taken. For example:
    a. If the label is printed at this facility then reprint the labels, or notify the Medical Technologist Lead assigned to draft labels and policies, etc.
    b. If the label is supplied from an outside source, then return the labels to the manufacturer, request a replacement, submit a variance report, etc.

F. Manufacturers' Inerts Binder / Notecards

1. Reagent manufacturers must supply printed materials (inserts) which include storage requirements, testing procedures, etc. The Blood Bank maintains these inserts in the *Manufacturers' Inserts Binders*. The Blood Bank also maintains notecards along with many of the inserts in these binders. These notecards provide helpful information; e.g., acceptable inert controls, warnings that a test should not be centrifuged, warnings that a reagent should be tested only by the IgG gel card method, etc. These notecards are prepared and updated by a Medical Technologist Lead.
    a. Only a Medical Technologist Lead may place a notecard in the binder or revise a notecard.
    b. The reagent name and reference number should be included on each notecard.

c. As revisions to the insert are made by the manufacturer, the notecards must be updated as appropriate.

d. Notecards should be removed from the binders only by a MT Lead.

G. Reference Numbers / Indicate Whether an Insert has been Revised

1. The term reference number is a general term for the revision date and other numbers that are printed on manufacturers' inserts and packaging supplies. The Blood Bank documents the reference numbers on the Reagent Receipt Log and in the computer and uses these reference numbers 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.
    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. For **Bio-Rad reagents**, the reference numbers include a REF number, the revision date, and another number listed on the insert before the revision date.
    d. For any other reagents, identify the applicable reference numbers / dates from the *Manufacturers' Inserts Binders*. These numbers / dates are usually highlighted.

H. Comparison of Reference Numbers when Reagents are Received

1. Note that some manufacturers have recently discontinued the practice of sending inserts with reagents. Directions for viewing or printing manufacturers' inserts are located in the Ortho or Immucor/Gamma *Manufacturers' Inserts Binders*.
2. The Blood Bank maintains printed copies of current manufacturers' inserts in the Ortho or Immucor/Gamma *Manufacturers' Inserts Binders*.
3. 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 *Manufacturers' Insert Binder*. This comparison is documented on the *Reagent Receipt Log*. This comparison is also documented in the computer by marking the "Package Insert Reviewed" box as the reagents are registered.
    a. Note that in some cases, two current inserts may appear in the binder for the same reagent; e.g., two lot numbers are currently in use and each lot number has different reference numbers.
4. The reagent packaging must not be discarded until the reference numbers have been recorded on the *Reagent Receipt Log* and in the computer.
5. If the reference number on the reagent packaging does not match the reference number on the insert in the *Manufacturers' Insert Binder*, the technologist must document the *Revision Made*

to Manufacturer's Insert sticker and will affix this sticker on the communication log. This sticker must be documented for all manufacturers' revisions, no matter how insignificant the revision may seem. This sticker will alert a MT Lead or Designee to perform the actions described in *Actions upon Revision to Manufacturers' Insert*. In some cases, it may be necessary to update the corresponding policy or notecard. The technologist receiving the reagent has the option of whether to place the reagent in quarantine or not, and will mark the corresponding box on the *Reagent Receipt Log*.

a. Reagent NOT placed in quarantine; minor revision only. The technologist has determined the manner in which the insert has been revised and is comfortable to use the reagent consistent with standard operating procedures, despite the revision. For example, a revised logo on the insert.

b. Reagent placed in quarantine. The technologist may place the reagent in quarantine by affixing an orange Quarantine sticker to the reagent or box of reagents. A reagent should be placed into quarantine if the technologist has not determined the manner in which the insert has been revised, or is not comfortable to use the reagent consistent with standard operating procedures, due to the revision. For example, the entire test methodology has been revised. See the *Placement of Reagents into Quarantine* section of this document.

I. Actions upon Revision to Manufacturer's Insert

1. Determine the nature of the revision to the insert.
2. Determine whether the corresponding policy and *Manufacturer's Insert Notecard* should be revised, and update the policy and notecard as necessary.
3. Place a copy of the revised insert in the *Manufacturers' Insert Binder*. Remove the previous version of the insert only if the all vials of the reagent corresponding to the previous insert are expired or exhausted.
4. After each of these steps have been performed, the MT Lead / Designee will:
    a. Initial and date the *Reagent Receipt Log*.
    b. Initial and date the *Revision Made to Manufacturer's Insert* sticker, which was placed on the communication log.
    c. If applicable, initiate QC testing of the reagent and remove the reagent from quarantine.
    d. The MT Lead / Designee will document the *Review of Manufacturers' Revisions* form, which is stored in the quality control folders.

J. Placement of Reagent 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. The technologist may place a reagent into quarantine if the reference numbers on the reagent packaging do not match those in the current *Manufacturers' Insert Binder*, as described in the *Comparison of Reference Numbers when Reagents are Received* section of this document.

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 shall be submitted (unless the reason for placement of the reagent in quarantine is that the reference numbers do not match; in this case a MT Lead / Designee will take the actions described in the *Actions upon Revision to Manufacturer's Insert* section of this document).
    c. The quarantined reagent should be stored at the appropriate temperature and conditions, as described by the manufacturer. For example, on the reagent quarantine shelf in the walk-in refrigerator, if applicable.

K. Unpacking Reagents / Moving to Storage Location in the Laboratory

1. Reagents should be received into inventory as soon as possible after delivery from the supplier.
2. Reagents should be left in the delivery box and should be stored at the temperature indicated by the manufacturer until all required steps of the *Procedure* have been completed. Once all steps have been completed, the reagents should be removed from the delivery boxes and placed in the correct reagent storage location.

L. Antigrams for Antibody Screens and Panels

1. When Selectogen sets, Surgiscreen sets and antibody panels are received they should be documented on the *Reagent Receipt Log*, delivered into Soft, and imported into the Antigen Plus program as described in Transfusion Medicine policy, *Using the Antigen Plus Program*. One copy of each antigram will be initialed and dated by the receiving technologist. Several copies of each initialed / dated antigram will be made. The antigrams are distributed / managed as follows:
    a. One copy of each antigram will be placed in the *Panels to be Imported into Antigen Plus* folder, located in the bottom right drawer at the problem workstation.
    b. One copy of each antigram will be placed in the applicable *Ortho or Immucor/ Gamma Antibody Screens and Panels* reference binder.
    c. Several copies of each antigram will be placed in the Special Studies forms drawer, to be used for patients' antibody investigations. If there are antigrams from a previous lot in the Special Studies forms drawer, paper clip the new copies to keep them separated.
    d. After the antibody screen or panel has expired, the antigram should be removed from the Special Studies forms drawer.

e. After the antibody screen or panel has been discarded (the last 3 lots of each screen/panel type are kept), the antigram should be removed from the reference binder.

M. Registering and Opening Reagents in the Blood Bank Computer System

1. Some reagents are registered and opened in the Blood Bank computer system upon receipt or upon physically opening the reagent, while other reagents aren't brought into the Blood Bank computer system at all. Use the following table to determine if a reagent is brought into the Blood Bank computer system.

Reagent / Supply		Registered / Opened in the Computer?	When to Register / Open in the Computer
0.8% Panels 0.8% Selectogens 3% Affirmagens 3% Panels 3% Surgiscreens A_2 Cells ABO/Rh Tube Type Reagents AHG Reagents Anti-IgG Gel Cards	Antisera Check Cells DAT Reagents Diluent 2 Fetal Cell Screen Kit LISS Rh Gel Cards RhIG (as a supply)	Yes	Upon receipt
AlbaQ-Chek Kits Hgb S Controls Hgb S Solubility Kit	Saline Cubes 7% Bovine Albumin (BSA)	Yes	Upon opening each individual reagent
0.8% Affirmagens 22% Bovine Albumin ABD/Reverse Gel Cards Anti-D Gel Cards Control Gel Cards Diluent 2 Plus	DTT Reagent Eluate Kit Irradiation Indicators PGD Reagents WARM Reagent Buffered Gel Cards	No	N/A

N. Quality Control of Reagents upon Receipt

1. QC for some reagents is required at the time of receipt; for other reagents QC is not required at the time of receipt but QC may be required to test in parallel with testing of patient and donor samples. Use the following table to determine whether QC testing is required at the time of receipt and, if applicable, the location where QC is documented.

NOTE: If QC is documented in a rack in the computer, make a printout of the rack and attach the printout to the *Reagent Receipt Log*.

Reagent	Examples	Is QC Required at Time of Receipt?	Location of QC Documentation
Tube testing ABO/Rh reagents	Anti-A, Anti-B, Anti-D, Rh control, reverse cells	Yes	RQ3 rack in SoftBank
AlbaQ-Chek Kit vials	AlbaQ-Chek Kit vials	No	N/A
Vision reagents (except Anti-D / Control gel cards)	IgG and ABO/Rh gel cards, MTS Diluent 2 Plus, MTS Diluent 2, Affirmagen and Selectogen cells	Yes	Attach Vision printout to the *Reagent Receipt Log*
A_2 Cells	A_2 Cells	N/A	N/A
Antisera or gel cards for antigen typing	Anti-C, Anti-Fy^a, Anti-A_1, Rh gel cards, Anti-D gel cards, MTS™ Control cards, Buffered gel cards	No	N/A
Surgiscreen cells and LISS	Surgiscreen cells and LISS	Yes	RQLIS rack in SoftBank
Antiglobulin and DAT reagents	Polyspecific, IgG, and C3 antiglobulin, check cells	Yes	RQDAT rack in SoftBank
Ortho Panel A 0.8%	Ortho Panel A 0.8%	No, upon opening	Problems Clipboard
Fetal Cell Screen Kit	Fetal Cell Screen Kit	Lot to Lot comparison required upon receipt.	On the *FMH Lot to Lot Comparison* form
All other reagents	Sickle cell testing, other panels, warm autoantibody removal medium (WARM), eluate kit, Pan Genera Detection (PGD), 22% bovine albumin, DTT, 7% BSA	No	N/A
Supplies	Glycerolyte solution, syringes, Rh Immune Globulin, etc.	No	N/A

V. PROCEDURE:

A. Documentation of the *Reagent Receipt Log*

1. Document the following on the *Reagent Receipt Log*:

a. Current date and initials of technologist receiving the reagent
b. Reagent name (e.g., Anti-A, reverse cells, fetal cell screen kit, etc.)
c. Reagent manufacture (e.g., Ortho, Immucor/Gamma, BioRad, etc.)
d. Reagent Lot Number
e. Reagent expiration date

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.
4. Document the reference numbers from the box / packaging.
    a. For Ortho document the revision date, REF number, and the e number.
    b. For Immucor/Gamma document the insert code and the revision date.
    c. For Bio-Rad reagents document the REF number, the revision date, and the number listed on the insert before the revision date.
    d. 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.
5. Compare the reference numbers on the reagent's packaging with the reference numbers on the insert in the Manufacturers' Insert Binders; and determine whether the reference numbers match. Mark the applicable box:
    a. Reference numbers match
    b. Reference numbers do NOT match
6. Perform step 6 only if the reference numbers DO NOT match.
    a. Document the *Revision Made to Manufacturer's Insert* sticker and affix this sticker on the Communication Log. This sticker must be documented for all manufacturers' revisions, no matter how insignificant the revision may seem. This sticker will alert a MT Lead / Designee to perform the actions described in the *Actions upon Revision to Manufacturer's Insert* section of this document.
    b. The technologist receiving the reagent has the option of whether to place the reagent in quarantine or not, and will mark the corresponding box on the log.
        i. Reagent NOT placed in quarantine; minor revision only
        ii. Reagent placed in quarantine. The technologist may place the reagent in quarantine by affixing an orange Quarantine sticker to the reagent.
    c. A MT Lead or designee will complete the actions described in the *Actions upon Revision to Manufacturer's Insert* section of this document. Place a copy of the

revised insert in the *Manufacturers' Insert Binder*. Remove the previous version of the insert only if the all vials of the reagent corresponding to the previous insert are expired or exhausted.

7. Affix a “Received / Date” sticker to each supply or reagent; document the form with a check mark.
8. Register and open the reagent in the Blood Bank computer system, if applicable; document the form with a check mark or NA.
9. Perform QC testing or lot to lot testing, if indicated, and mark the applicable box on the Reagent Receipt Log. Attach a Vision or Soft printout of the QC, when QC is indicated. Indicate the new reagent that is being QC’d on the printout by highlighting or circling it. Fill out the appropriate lot to lot comparison form if indicated.
    a. Passed, Soft printout attached
    b. Passed, Lot to Lot comparison attached
    c. Passed, Vision printout attached
    d. Failed, quarantine, variance
    e. QC NR (QC not required)
10. Move the supplies or reagents to the correct storage location in the laboratory; document the form with a check mark.
11. Once all steps of this *Procedure* have been performed satisfactorily, the reagent is acceptable for use. Document the form with a check mark and the technologist’s initials to indicate that the reagent is acceptable for use.
12. Document the *Reagent Receipt Log* with any applicable *Notes*.

B. Documentation of the *Blood Product Label Inspection Log*

1. Obtain the *Blood Product Label Inspection Log*, located in the *Inventory binder.*
2. Document the log with the receipt date and the number of rolls or sheets, and affix a label to the log.
3. Inspect the label for content, legibility, and color. Document the inspection as S (satisfactory) or U (unsatisfactory).
4. If the label is an ABO barcode sticker, access SoftBank / Inventory / In/Out / Delivery / scan in the barcode in the ABO/Rh field. The ABO/Rh that populates the field must match the ABO/Rh on the sticker.
5. Document the log with the technologist’s initials and the inspection date.
6. Move the supplies or reagents to the correct storage location in the laboratory.

VI. NOTES:

A. Copies of the Job Aids *Obtaining Ortho Technical Documents Online* and Obtaining Immucor/

Gamma Technical Documents are located in the applicable *Manufacturers' Inserts Binders*.

VII. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. College of American Pathologists, *Transfusion Medicine Checklist,* current edition.

Attachments

Blood Product Label Inspection Log

Manufacturers Insert Notecard

Reagent Receipt Log

Review of Manufacturers Revisions

Revision Made to Manufacturers Insert Sticker

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	9/15/2022
	Jeremy Powers: Chief, Pathology	9/15/2022
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	9/12/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	9/8/2022
	Rebecca Thompson: Medical Technologist Lead	9/8/2022
	Brooke Klapatch: Medical Technologist Lead	8/18/2022