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Reagent/Supplies Inspection & Receiving

I. PURPOSE

To provide instruction for documenting inspection and receipt of reagents, critical materials and labels.

II. SCOPE

This SOP addresses procedural steps for documenting receipt and inspection of reagents, critical materials, and labels into inventory by recording items into the Receiving Log Book. This SOP is intended for all Transfusion Medicine Staff.

III. EXCEPTIONS

1. This SOP does not apply to receipt of blood components.
2. This SOP does not apply to materials that are received and inspected by Supply Chain.

IV. DEFINITIONS

1. Reagent: Any of the necessary substances that produce or catalyze reactions that allow an analyte to be detected and measured. Calibrators and quality control materials are also considered reagents.
2. Critical Material: Non-reagent materials that are necessary for the Blood Bank to perform testing or perform further manufacturing of blood products which have specified characteristics that are critical to the outcome of a procedure.
3. Package Insert and Instructions for Use (IFU): While these two documents have different meanings to regulatory bodies, for the purposes of this procedure, Package Insert is used to refer to any set of instructions provided by the manufacturer that describe the appropriate use of the item.

V. POLICY STATEMENTS

1. Traceability: Lot numbers of critical materials and reagents are recorded upon receipt and on procedural control logs at time of use.
2. Inspection of critical materials and reagents and review of Package Inserts is performed upon receipt.

3. When workload does not permit immediate inspection/log-in of any product, the incoming item(s) may be placed in appropriate Quarantine location/storage, while keeping the packing slip with the shipment for later login/receiving documentation.
4. Quality Control (QC): Some reagents require additional testing before being placed into use. See Procedure statements below. For all other reagents, QC is performed and documented on new lots at time of use and **each day of use** as described in SOP BBQC-002, BBT- 010 and elsewhere when indicated.

VI. PRINCIPLE/BACKGROUND

None

VII. MATERIALS

Incoming reagents and supplies with all supporting documentation.

VIII. SPECIMEN REQUIREMENTS

None

IX. PROCEDURE

1. Each reagent and critical material is assigned its own Receiving Log.
    1. Ensure that the item name and manufacturer matches the item that is being received.
    2. When initiating a new log, document:
        1. The item name and manufacturer on the top of the form.
        2. Mark "N/A" in the **Pulled Panel/Screen Sheet to File"** box for all columns if the reagent is not a panel or screen.
        3. Document N/A in all rows for Insert Version Date if there is no Insert.
2. REAGENTS: (red cells, antisera, and panels)
    1. Record on the Reagent Receiving Log:
        1. Date Received
        2. Number of Vials/Boxes/Units
        3. Lot Number and Expiration Date
            i. Perform Visual Inspection of the incoming reagent and ✓ the box corresponding to if the reagent passes or fails visual inspection.

Criteria	Pass	Fail
Clarity	Clear solution or supernatant	Cloudy solution or supernatant
Hemolysis (if applicable)	Not hemolyzed	Hemolysis present
Leakage	Not leaking	Leaking or

		broken vials
Seal Integrity	Intact seals	Leaking or punctured seals
Temperature	Temperature consistent with shipping/storage conditions. **Example:** If reagents are shipped with an ice pack, the ice pack should be cold. If there are any questions about acceptable receiving temperature, consult with the vendor. Some vendors have validated shipping temperatures that are outside of the recommended storage range.	Too warm or too cold.

NOTE: If the reagent fails inspection, check with the supervisor or designee for corrective action.

2. Document the Version number or date on the Receiving Log. Compare the version date of the new insert received with the version/date currently in use. **NOTE:** ORTHO Reagents: see Job Aid Printing of Ortho Instruction for Use

Same Version?	**Then…**
Yes	No action needed

No	▪ Document the date and your initials on the new version.
	▪ Make a copy of the current version and return the original document to the binder.
	▪ Give a copy of the new and current version to the Supervisors to review for impact.
	  ▪ Minor changes may be approved for immediate use.
	  ▪ If major changes are identified that require SOP revision, then SOPs must be revised, or a Temporary Procedure put into place, and communication to all Testing Personnel must be completed before that reagent lot may be used. Place the reagent into the applicable Quarantine location until all changes are implemented per Change Control procedure.

3. Pull Screen and Panel Reaction Sheets (Anagram/Master List) for file: (Check box marked **N/A** if this step does not apply)

   NOTE: If only one set arrives, make copies and place original in **Master Panel** book-- place copy with reagent.

   1. Screen Cells: Remove Screen reaction sheets to be placed in:
      1. **Master Panel** book (Permanent storage)
      2. **New Lot File Folder - this will hold the paperwork until the Antibody Screen is put into use**

2. Panel Cells: Remove Panel reaction sheets to be placed in:
    1. **Master Panel** book (Permanent storage)
    2. Working **Clipboard** (Ortho and Immucor Panocell Only)
3. EXTENDED Typing results sheets are to be placed in **Extended Typing** notebook; appropriate section by vendor
4. Place a ✓ in the **Done** box in **Pulled Panel Sheet to file** column when completed.
5. Panel Sheet Distribution:

Anagram/Master List	Copy for Master panel book	Copy of Antibody Screen Antigram Placed in designated folder	Copy on Clipboard for Selected Cells
Immucor Antibody Screen, RS3	X	X	
Immucor Ready ID	X		
Immucor Extend I/ II	X		
Immucor Panocell Screen	X	X	
Immucor Panocell 10/20	X		X
0.8% Screen	X	X	
Ortho Panel 0.8% A/B	X		X
Quotient Panel 10	X		X
Quotient Panel 16	X		X

4. Selected reagents require additoinal testing:
    1. SickleDex and FMH Kit: Perform Lot-to-Lot testing as described in Lot-to-Lot Comparison for Sickle-Dex and FMH Kit .
    2. Ortho Resolve panels A and B: Perform QC as described in BBQC-047.
5. Determine if the items can be released for use:

If…	Then…
▪ Visual inspection passed ▪ Insert version is the same OR approved for immediate use via Change Control ▪ Panel/Screen sheets have been distributed (as	Check the box marked **Yes** and document your initials. Complete Sections 5.0 and 6.0 of this procedure.

applicable)	
Visual inspection does not pass.	Check the box marked **No**, document your initials, and notify management. Reagents must be stored in appropriate quarantine until further resolution.
Insert Version Date does not match and management review shows major changes that require SOP revision.	Check the box marked **No**, document your initials, and place the reagents into quarantine storage. Note in the Remarks column that the reagents were placed into Quarantine pending SOP revision.

3. CRITICAL MATERIAL INSPECTION
    1. Record on the Form: Critical Material Receiving Log Form:
        1. Date Received
        2. Number of Boxes
        3. Lot Number and Expiration Date
    2. Perform Visual Inspection of received items and ✓ the box corresponding to if the solution passes or fails Visual Inspection.

Criteria	**Pass**	**Fail**
Integrity	Packaging is intact and not damaged	Package is damaged

3. Compare the version date of the insert received with the version date currently in use**.**

Same Version?	**Then…**
Yes	No action needed

No	▪ Document the date and your initials on the new version.
	▪ Obtain a copy of the current version
	▪ Give a copy of the new and current version to the Supervisors to review for impact.
	  ▪ Minor changes may be approved for immediate use via Change Control.
	  ▪ If major changes are identified that require SOP revision, then SOPs must be revised, or a Temporary Procedure put into place, and communication to all Testing Personnel must be completed before that lot may be used. Place the reagent into a Quarantine location.

No Insert	Document **N/A** in the **Insert Version Date** column.

4. Determine if the items can be released for use:

If…	**Then…**
▪ Visual inspection passed ▪ Insert version is the same OR approved for immediate use via Change Control OR is not applicable	Check the box marked **Yes** and document your initials. Complete Sections 5.0 and 6.0 of this procedure

Visual inspection does not pass.	Check the box marked **No**, document your initials, and notify management. Reagents may be stored in quarantine until further resolution.
Insert Version Date does not match and management review shows major changes that require SOP revision.	Check the box marked **No**, document your initials, and place the reagents into quarantine storage. Note in the Remarks column that the reagents were placed into Quarantine pending SOP revision.

4. Labels and Forms Receiving: Complete Form Label QC Record.
    1. Attach Label or Form to a blank sheet of paper or make copy of packing slip/invoice. Three hole punch paper and **Record**:
        1. Received date
        2. Tech Initials
        3. Vendor
        4. Name or description of Label
        5. Quantity received
        6. Lot # (when applicable)
        7. Purchase Order Number (PO#) of order
        8. Affix Example of **old** and **new** label or form
           NOTE: "Old" and "New" are needed for comparison next to each other. Several label/form sets can be placed on each sheet; space permitting.
    2. Inspect Labels and Forms for acceptance: (as appropriate for form/label)
        1. Spelling and Format match the previous label or form
        2. IU Health Logo is correct (if applicable),
        3. Barcode Present and Tested (if applicable)
        4. Label Glue sticks to intended surface(s) adequately
        5. Perforation tears between forms correctly
        6. Perforation tears within form correctly
        7. Mylar tape positioned correctly on Transfusion Document
        8. Glue is adequate with uniform application on Transfusion Document
        9. Appropriate changes were made when indicated
        10. Barcode is present and test to insure that the LIS system is able to scan and translate the barcode into eye readable format.
    3. Following QA/Supervisory Review:
        1. Document Release for Use when inspection has been completed and the label is acceptable for use
        2. Document Do Not Release for Use when inspection has been completed and the label is not acceptable. Notify the Vendor for unacceptable findings.
5. Packing Slip/Invoice:
    1. Check item and quantity of reagents and materials received is listed appropriately on packing slip/

invoice.

2. Record "✓" by each item received
3. Date and Initial Packing Slip/Invoice
4. Document on packing slip any discrepancies or inspection errors.
   If discrepancies or inspection errors are noted, make COPY of packing slip and refer problems to supervisor for review.
5. Place Packing Slip in Director's in box for review.

6. Reagent and Material Storage and Usage
   1. Fill in and Attach "Date Received" sticker to each product set/box before placing in appropriate storage locations
   2. Designated Refrigerated storage locations:
      1. Place New lot reagents in drawers labeled "New Lot Reagent" (as appropriate)
      2. Rotate "oldest" received lots to front of drawer and place newly received lots towards back of drawer
   3. Designated Room Temp storage locations:
      1. Place New lot materials/reagents onto shelves (as appropriate)
      2. Rotate inventory so that "oldest" received dates are used first.

         NOTE: Rotation of inventory will ensure timely use of product and reduce wastage due to expiration.
7. Problem Resolution
   1. Items placed into quarantine due to failed visual inspection should be held in quarantine until the vendor indicates resolution.
      1. Items that are indicated as able to be released for use: Complete Change Control and attach any applicable documentation from the manufacturer.
      2. Items that are indicated as not able to be released for use: Follow vendor instructions to either return to the vendor or destroy.
   2. Items placed into quarantine due to package insert changes should be held in quarantine until SOP changes are made via Change Control and/or a Temporary Procedure is developed and communication to staff has been distributed.

X. APPENDICES/ATTACHMENTS/FORMS/ LABELS

Reagent Receiving Log
Quarantine Material Notification
Label QC Record
Form: Critical Material Receiving Log
Printing of Ortho Instruction for Use
Logging In CAP Surveys

XI. REFERENCES/CITATIONS

Quality System, AABB/IU Health.
AABB Technical Manual, current edition. AABB Standards, current edition.

Policy #:

BBQC – 052