Memorial Hospital

# BBQC 3.0-Receipt of Supplies and Reagents

## A. Principle

Documentation of receipt and acceptability of supplies and reagents must be maintained. Changes in manufacturer package inserts must be incorporated into current Standard Operating Procedures.

## B. General Policies

a. All supplies and reagents will be inspected for acceptability prior to use.
b. Personnel receiving supplies or reagents are responsible for documentation on the receiving log.

## C. Specimen Collection and Preparation

N/A

## D. Equipment

N/A

## E. Supplies

N/A

## F. Reagents

N/A

## G. Quality Control

N/A

## H. Safety

Refer to Chemical Hygiene and Blood Borne Pathogen Plan for Memorial Hospital Laboratory.

## I. Procedure

a. Document receipt of reagents and supplies on receipt log *BBF 24.0-Supplies and Reagents Receipt Log*.
    i. **Date rec'd**- Enter date received into blood bank inventory.
    ii. **Tech**- Enter initials of staff member documenting receipt.
    iii. **Description**- Enter name and manufacturer of supply or reagent.
    iv. **Lot number-** Enter lot number if applicable. Enter "N/A" if supply or reagent doesn't have a lot number.
    v. **Expiration date**- Enter expiration date if applicable. Enter "N/A" if supply or reagent doesn't have an expiration date.

vi. **Pkg. Insert Date**- Enter package insert date, if applicable. (This will be located on the bottom or back of the package insert.) Enter "N/A" if supply or reagent doesn't have a package insert date.

vii. **Pkg. Insert Change? (Y/N)**-
   1. Enter "N" if the package insert date is the same as the previous shipment.
   2. Enter "Y" if the package insert date has changed since the previous shipment and proceed to step viii.2.
   3. Enter "N/A" if supply or reagent doesn't have a package insert date.

viii. **Acceptable (Y/N)**-
   1. Enter "Y" if
      a. The reagent looks as described in package insert
      b. Reagent/supply is not expired
      c. "N" is entered into the **Pkg. Insert Change? (Y/N)** column.
   2. Enter "N" and proceed to step ix.2, if
      a. The reagent doesn't look as described in package insert or appears contaminated, **or**
      b. Reagent/supply is expired, **or**
      c. "Y" is entered into the **Pkg. Insert Change? (Y/N)** column.

ix. **Date in Use**-
   1. Enter current date, if "Y" is entered into **Acceptable** column.
   2. Enter "N/A" if "N" is entered into **Acceptable** column and proceed to step c.

b. If a date is entered into "Date of Use" column, place supply or reagent in appropriate storage depending on required conditions (i.e. refrigerator or room temperature).

c. If "N/A" is entered into "Date of Use" column,
   i. Retrieve form *BBF 25.0-Supplies and Reagents Changes Tracking Log*. One (1) form for each supply/reagent.
   ii. Copy same information from *BBF 24.0* in the first four (4) columns onto *BBF 25.0.*
   iii. If problem is with appearance or issue other than package insert, comment under "Problem & Resolution" what the problem is.
   iv. Place supply/reagent into refrigerator or room temperature quarantine and document tech initials and date in **Quarantine In Initials/Date** column on *BBF 25.0.*
   v. Place *BBF 25.0* form into Supervisor or designee's inbox for review and follow up.
   vi. Put note in communication log about quarantined supplies/reagents

Memorial Hospital

**Supervisor or Designee Follow-up**

d. Retrieve *BBF 25.0* from inbox and compare to *BBF 24.0* with the same information and communication log.
e. If supply or reagent failed appearance inspection, contact manufacturer for further instructions. Consult supervisor if necessary to resolve.
    i. Record any steps to resolution with date and initials under "Problem & Resolution" section.
    ii. If the problem with the current shipment is resolved without getting a new shipment,
        1. Circle "Y" to "Supply/Reagent problem resolved?"
        2. Circle "N" to "Were new supplies/reagents ordered and current destroyed or returned to manufacturer?"
        3. Record "N/A" in "Pkg. Insert Review Initials/Date" column
        4. Record "Y" in "Problem Resolution" column
        5. Record initials and date under "Quarantine Out/Destroyed Initials/Date"
        6. Place supply/reagent out for use
        7. Record date in "Date in Use" column.
        8. File Form.
    iii. If problem is not resolved with current shipment and a new shipment must be ordered,
        1. Circle "N" to "Supply/Reagent problem resolved?"
        2. Circle "Y" to "Were new supplies/reagents ordered and current destroyed or returned to manufacturer?"
        3. Record "N/A" in "Pkg. Insert Review Initials/Date" column
        4. Record "N" in "Problem Resolution" column
        5. Record initials and date under "Quarantine Out/Destroyed Initials/Date" when supply/reagent is removed from quarantine to be returned or destroyed.
        6. Destroy or return supply according to manufacturer or supervisor instruction.
        7. Record "N/A" in "Date in Use" column.
        8. File Form.
f. If supply has a change to the package insert, review insert for any changes between current insert and previous insert.
    i. Record any steps to resolution with date and initials under "Problem & Resolution" section deemed necessary by reviewer.
    ii. If changes to package insert do not require changes to any current procedures,
        1. Place new package insert in binder and document on insert sticker in binder.
        2. Discard old package insert.

3. Circle “N” to “Change to package insert require procedure change?”
4. Circle “N/A” to “Procedure changed and reviewed?”
5. Circle “Y” to “New package insert added to package insert binder and old insert discarded?”
6. Record initials and date in “Pkg. Insert Review Initials/Date” column
7. Record “N/A” in “Problem Resolution” column
8. Place supply/reagent out for use
9. Record initials and date under “Quarantine Out/Destroyed Initials/Date”.
10. Record current date in “Date in Use” column.
11. File Form.

iii. If changes to package insert do require changes to any current procedures,

1. Notify supervisor to review and change any current procedures and place form in supervisor inbox.
2. Once procedures are revised, reviewed and ready for use according to laboratory document control procedures, supervisor or designee will retrieve form and proceed to step 3.
3. Place new package insert in binder and document on insert sticker in binder.
4. Discard old package insert.
5. Circle “Y” to “Change to package insert require procedure change?”
6. Circle “Y” to “Procedure changed and reviewed?”
7. Circle “Y” to “New package insert added to package insert binder and old insert discarded?”
8. Record initials and date in “Pkg. Insert Review Initials/Date” column
9. Record “N/A” in “Problem Resolution” column
10. Place supply/reagent out for use
11. Record initials and date under “Quarantine Out/Destroyed Initials/Date”.
12. Record current date in “Date in Use” column.
13. File Form.

g. Any problems or procedures not covered by this procedure are to be resolved by blood bank supervisor, laboratory director, and/or laboratory medical director as needed at their discretion.

**J. References**

a. Standards for Blood Banks and Transfusion Services, AABB, current edition, Bethesda, MD.
b. Technical Manual, AABB, Current Edition, Bethesda, MD.
c. CAP Accreditation Requirements, TRM. 31375, 2011.

Memorial Hospital

# PROCEDURE AND FORM CHANGE CONTROL

| Title: BBQC 3.0-Receipt of Supplies and Reagents | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Written | | Validated | | Path Review | | Review | | Effective | | Reason for Revision |
| Date | By | Date | By | Date | By | Date | By | Date | By | |
| 3/2/10 | PAB | 3/9/10 | GJM | 3/10/10 | ESB | | | 4/1/10 | PAB | |
| Revised | | | | | | | | | | |
| 3/6/12 | PAB | | | 3/8/12 | ESB | | | 3/9/12 | PAB | Document date of use per CAP |
| 2/11/15 | JLH | | | 2/11/15 | ESB | | | 2/11/15 | JLH | Removed QC of supplies/reagents. Added document control. Added form for tracking. Added instructions for use of supply log and tracking log. |
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Location of any copy(s) of the procedure:

**Out of use:**

**Date:_____By:_____Reason:_____**