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| Area | Laboratory-Blood Bank |
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# Preventative Maintenance and Quality Control of the COBE 2991 Blood Cell Processors



Document Type: Procedure

# I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies and procedures relating to the quality control (QC) and preventative maintenance (PM) for washing and deglycerolizing red blood cells (RBCs) using the COBE 2991 Blood Cell Processor.

# II. INTRODUCTION:

A. Quarterly QC and PM for Washing and Deglycerolizing RBCs

1. The Quarterly QC includes:
    a. Washing and deglycerolizing RBCs on each of the two cell processors, submitting samples from these processed RBC units to the Chemistry and STAT Laboratories for analysis, and reviewing the results provided.
2. Refer to the *Procedure* section of this document / *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs.*
3. Additional PM and QC measures are also taken each time a RBC unit is washed or deglycerolized (e.g., the hemolysis check, cleaning the red cell detector, as needed cleaning, priming the hydraulic system, etc.). For additional information refer to Transfusion Medicine policy, W*ashing and Deglycerolizing Red Blood Cells using the COBE 2991 Blood Cell Processor*.

B. Yearly Preventative Maintenance Performed by Terumo BCT

1. All additional PM activities are performed by Terumo BCT (previously Caridian BCT).

For a complete list of these activities refer to the COBE 2991 Cell Processor Preventative Maintenance Procedure. The Medical Technologist Lead assigned to quality control (MT Lead) or designee will review and maintain records of all PM activities submitted by Terumo.

2. In addition to performing the PM and QC described in this document quarterly, the PM and QC is also performed:
    a. After the yearly maintenance is performed by Terumo, and
    b. Before returning the cell processors to use, in cases where the cell processors were taken out of service.

# III. DEFINITIONS:

A. **Quarterly**: Within the calendar months of January, April, July, and October.

B. **Yearly**: Every 12 months ± 1 month.

C. **Designee**: Any Medical Technologist Lead or the Blood Bank Manager

# IV. POLICIES:

## A. RBC Units Used for Quarterly QC

1. In order to conserve the frozen and liquid rare RBC inventory, units that were discarded, but which are not yet expired, are used for quarterly QC as described in this document.
2. Units that are frozen specifically for QC purposes are not suitable for transfusion purposes. Important: The hematocrit of the unit before freezing must be obtained for QC purposes; this process is described in Transfusion Medicine policy, *Freezing Red Blood Cells*. The Blood Bank maintains a separate inventory of frozen RBCs that are used specifically for this quarterly QC. The following measures are taken to assure that these inventories will remain separated:
    a. The units are stored in the freezer on a shelf clearly labeled as Units for QC Only.
    b. *For QC or Training Only / Do Not Transfuse* sticker is affixed to the face label of each unit that is frozen specifically for QC purposes. This yellow sticker is also affixed to each log (*RBC Processing Log: Freezing & Deglycerolizing*).
    c. These logs are stored in the *Frozen Units for QC Only / Do Not Transfuse* binder, to separate them from the binders for Frozen Autologous Units and volumes of Rare Frozen Units.

## B. Failing Quality Control

1. If any of the measurements taken as part of the quarterly QC or PM are not within the acceptable range, then:
    a. Take the cell processor out of service.
    b. Tag the cell processor with an *Equipment out of Service* form.
    c. Notify a MT Lead or designee.

d. Document and submit a variance. Refer to Transfusion Medicine policy, Variance Reporting.

2. Actions of the MT Lead if an instrument is found to be out of conformance during quarterly QC:
    a. Review previously processed units for their pre-weight and post-weight.
    b. Check instrument QC logs after the previous quarterly QC.
    c. If required, the MT Lead or designee shall arrange for investigation or repair from Terumo.

# C. Documentation / MT Lead Review

1. Quarterly cleaning and all quarterly QC for washing and deglycerolizing RBCs is documented on the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form.
2. The MT Lead or designee reviews and maintains records of all PM tasks submitted by Terumo or Biomedical.
3. The MT Lead or designee also reviews all QC relating to freezing, thawing, washing and deglycerolizing the units. For example, the MT Lead verifies that the hemolysis check was satisfactory, that the inspection of all tube welds and seals were satisfactory, that the retype was performed (if indicated), that the prime was performed, etc. This QC is documented on the following forms, which are submitted to the MT Lead along with the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form.
    a. *Washed Red Blood Cells Processing Log*
    b. *RBC Processing Log: Freezing & Deglycerolizing*
    c. *Prime (Hydraulic System Check) and As Needed Cleaning of the COBE 2991 Cell Processors*



# D. Calculating Percent RBC Recovery for Deglycerolized RBCs

1. The percent RBC recovery is calculated for deglycerolized RBCs as part of quarterly QC. The formula to calculate percent RBC recovery is:

$$\%\ \text{RBC Recovery} = \frac{(\text{Post net weight} \times \text{Post hct})}{(\text{Pre net weight} \times \text{Pre hct})} \times 100$$

2. All factors used in this calculation are defined on page 2 (the reverse side) of the form, *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs*.

# E. Approved Cleaners

1. The COBE 2991 cell processors are cleaned quarterly as described in the Procedure section of this document. Use only hospital approved cleaners (e.g., Sparquat or 70% isopropyl alcohol)

as described in P051, Blood Bank Environmental and Personnel Safety.

2. The red cell detector (RCD) should be cleaned with an alcohol swab. Do not use bleach as damage to the lens will occur if bleach is used on the RCD, which may affect processing outcomes.

# V. SPECIMEN COLLECTION AND HANDLING:

A. Samples from a washed unit and from a deglycerolized unit are collected as described in the Procedure section of this document, and are tested by the Chemistry and STAT Labs.

# VI. SUPPLIES:

A. Refer to Transfusion Medicine policy,

B. Hospital approved cleaner; e.g., Sparquat or 70% isopropyl alcohol

C. Cleaning cloth or gauze

D. Alcohol swabs

# VII. PROCEDURE:



## A. Quarterly Quality and Preventative Maintenance for Washing and Deglycerolizing RBCs

1. Wash a unit of RBCs. Before the unit is removed from the cell processor prepare samples for Chemistry and STAT Lab as described in step 3.
2. Thaw and deglycerolize a unit of frozen RBCs. Before the unit is removed from the cell processor prepare samples for Chemistry, STAT Lab, and the Blood Bank as described in step 3.
3. Preparation of Samples for Chemistry, STAT Lab, and Blood Bank

| Processing Method | Required Tests | Sample Labeling | Testing Location |
|---|---|---|---|
| Wash | Total protein | Label a red top tube with the donor number and "run as fluid" | STAT Lab |
| | Hematocrit | Label a plastic 12 x 75 mm tube with the donor number and "hematocrit" | STAT Lab |
| Deglycerolize | Osmolality, | Label a red tip tube with the donor number and "run as fluid" | Main Chemistry |
| | Hematocrit | Label a plastic 12 x 75 mm tube with the donor number and "hematocrit" | STAT Lab |
| | Hemolysis check | Label a plastic 12 x 75 mm tube with the donor number and "hemolysis check" | Blood Bank |

a. Obtaining “Run as fluid” samples: As the unit is removed from the cell processor, use

the tube sealer to make a segment (approximately 2 inches long) of the tubing as close to the waste bag as possible, so that the segment contains primarily the supernatant and not packed RBCs. Empty the contents of the tubing into the plastic tube labeled "run as fluid," then cap the tube.

b. Obtaining "Hematocrit" and "Hemolysis Check" samples: Obtain a transfer bag. Use the spike on the transfer bag to spike the donut bag. Allow the tubing of the transfer bag to fill with RBCs from the donut bag. Make several segments with the tube sealer. Note that RBC units tested for QC purposes are not used for transfusion purposes, so it is not necessary to use the sterile connection device. Empty the contents of the segments into the plastic tubes that were labeled as described in the table, above. Cap the plastic tubes.

4. Begin to document the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form. Place a mark in the applicable boxes to indicate which cell washer was used and to indicate which tests should be performed by Main Chemistry and STAT Lab. Also document the donor numbers on the form.
5. Submit samples and the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form to STAT Lab and Main Chemistry as indicated in the table above. For deglycerolized RBCs, the Blood Bank will perform the hemolysis check and will document the results on the *RBC Processing Log: Freezing & Deglycerolizing.*
6. Once the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form is returned to the Blood Bank, calculate the percent RBC recovery for the deglycerolized RBCs. The formula for this calculation is included on the QC form; refer also to the additional information on the reverse side of the QC form.
7. For each QC measure, mark the applicable box to indicate whether the QC passed or failed. Also document the Blood Bank technologist's initials and the date.
8. Clean the external portions of each cell washer quarterly as follows:
    a. Use an alcohol swab to clean the tubing slot of the red cell detector (RCD).
    b. Using a hospital approved cleaner (e.g., Sparquat or 70% isopropyl alcohol) and gauze, clean the seal weight's vertical posts These 2 posts may be located by lifting the seal weight. The contacting surfaces should be clean and free of debris and nicks. Do not use any lubricants on the seal weight or the vertical posts.
    c. Clean the outer rim of the centrifuge bowl and centrifuge bowl cover.
    d. Document the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form with the employee's initials and the date to document this quarterly cleaning.
9. Attach the following to the *Quarterly Quality Control and Preventative Maintenance for Washing and Deglycerolizing RBCs* form:
    a. *Washed Red Blood Cells Processing Log*
    b. *RBC Processing Card: Freezing & Deglycerolizing*
    c. *Prime (Hydraulic System Check) and As Needed Cleaning of the COBE 2991 Cell Processors*

10. Repeat the above steps for the second COBE 2991 cell processor.
11. Submit all documentation to the MT Lead or designee for review.

# VIII. ACCEPTABLE RANGE:

| RBC Processing Method | QC Measure | Acceptable Range |
|---|---|---|
| Wash | Total protein (g/dL) | ≤ 2 g/dL |
| Wah | Hematocrit | 65 - 80% |
| Deglycerolize | Osmolality (mOsm) | <500 mOsm |
| Deglycerolize | Specific gravity | <1.3384 |
| Deglycerolize | Refractive index | <28 |
| Deglycerolize | Plasma hemoglobin (mg/dL) | <50 mg/dL |
| Deglycerolize | % RBC recovery | ≥80% |
| Deglycerolize | Hemolysis check | No hemolysis |

A. QC is considered passing if the QC measure is within the acceptable range.
B. QC is considered failing if the QC measure is not within the acceptable range. Take the appropriate actions as described in the *Failing Quality Control*.

# IX. REFERENCES:


1. College of American Pathologists Transfusion Medicine TRM.44100, *Open System Preparation Usage*, 2012
2. College of American Pathologists Transfusion Medicine TRM.44150, *Deglycerolization Requirements*, 2010
3. COBE 2991 Cell Processor, *Essentials Guide*, CardianBCT, 06/2008
4. Caridian *2991 Cell Processor Preventative Maintenance Procedure*.
5. AABB, *Technical Manual*, current edition.




## Attachments

For QC or Training Only / Do Not Transfuse sticker

Quarterly Quality Control and Preventative Maintenance for Washing and Delgycerolizing RBCs

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|

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|---|---|---|
| | Ann Marie Blenc: System Med Dir, Hematopath | 8/18/2023 |
| | Kristina Davis: Staff Physician | 8/14/2023 |
| Policy and Forms Steering Committe (if needed) | Kelly Sartor: Mgr, Division Laboratory | 7/24/2023 |
| | Kelly Sartor: Mgr, Division Laboratory | 7/24/2023 |
| | Brooke Klapatch: Medical Technologist Lead | 7/10/2023 |