Status **Scheduled** PolicyStat ID **13365656**

Origination	3/16/2022
Last Approved	7/7/2023
Effective	8/6/2023
Last Revised	7/7/2023
Next Review	7/6/2025

Document Contact	Brooke Klapatch: Medical Technologist Lead
Area	Laboratory-Blood Bank
Applicability	Royal Oak

Daily Temperature and Quality Control Record - Blood Bank Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies and procedures relating to the daily temperature checks and quality control (QC) that are documented on the *Daily Temperature and Quality Control Record*.

II. SCOPE:

The scope of this document includes the following daily QC measures:

A. Inspection of the dry ice tissue coolers.
B. The level and temperature of the liquid nitrogen tank.
C. The temperatures of the refrigerated centrifuges.
D. The temperatures of the blood processing room, storage room, and freezer room.
E. The Rees reports and temperatures.
F. Completion of billing.
G. Verification that billing was completed.
H. Cleaning of the Sterile Connection Device (SCD) as described in Transfusion Medicine policy, *Sterile Connection device: Weld Integrity Test and Cleaning*.
I. Cleaning of the heat sealer as described in this document.
J. Cleaning of the Micro Typing System (MTS) diluent dispensers as described in Transfusion

Medicine policy, *Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers*.

K. Verification that the expected Soft Bank Backup files have been created, as described in Transfusion Medicine policy, *Using the Soft Bank Backup File During Computer Downtimes*.

L. Running of a Condition mode cycle on the Rad Source RS 3400 blood irradiator, as described in Transfusion Medicine policy, *Irradiation of Blood Components using the Rad Source RS 3400 Blood Irradiator*.

M. Verification that all vials of Rh Immune globulin (RhIG) that have been set up on previous dates have been issued, as described in Transfusion Medicine policy, *Rh Immune Globulin Evaluation*.

N. The temperatures of the triage room and the tissue cabinet.

O. QC of the triage plasma baths: the temperature and appearance (observe for contamination, cloudiness, odor, and the water level), and cleaning of the water baths. For additional information refer to Transfusion Medicine policy, *Helmer DH8 Plasma Thawing System*.

P. The temperatures of the four MTS incubators, Ortho Workstation, and of the one heat block. Note that these temperatures are recorded each shift.

Q. The temperature and water level of the processing room water bath.

R. The weights of the four Blood Bank scales.

S. Rotation of the 3 O negative RBC units that are used as described in Transfusion Medicine policy, *Downtime Emergency Issue*.

T. Rotation of the O negative neonatal RBC unit that is used as described in Transfusion Medicine policy, *Downtime Emergency Issue*.

U. The Helmer UltraCW™ system flush and rotor fill port inspection as described in Transfusion Medicine policy, *Helmer UltraCW™ Automatic Cell Washing System Preventative Maintenance*.

V. Checking for growth in units that were sent to the microbiology laboratory as described in Transfusion Medicine policy, *Suspected Bacterial Contamination of a Transfused Component*.

W. The RPM and timer checks for the MTS and Ortho Workstation centrifuges described in Transfusion Medicine policy, Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers.

III. DEFINITIONS / ACRONYMS:

A. **Rotor Head**: The top of the rotating part of an electrical or mechanical device.

B. **Tachometer**: An instrument for determining speed, especially the rotational speed of a shaft.

C. **RPM**: Rotations per minute.

D. **Daily**: On a given calendar date.

E. **Weekly**: Within 7 days ± 2 days.

F. **Monthly**: Within the first two weeks of each calendar month.

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

H. **Yearly**: Within a 12 month ± 1 month time span.

IV. POLICIES:

The *Daily Temperature and Quality Control Record* is used each day by each shift to document QC measures listed in the *Scope* section of this document. A Medical Technologist will document the form each shift. If a Laboratory Assistant is available on the day shift, then they may assist by performing and documenting the form with the following exceptions:

A. Verification that all vials of RhIG have been dispensed.

B. Weekly rotation of the O negative neonatal RBC unit.

C. Billing Completion.

D. Weekly cleaning of the diluent dispensers.

E. Weekly cleaning of the sterile connection device.

F. Checking the SoftBank backup files.

A. Medical Technologist QC Review

1. Each day, a Medical Technologist will review the QC.
    a. The reviewing technologist will verify that all QC measures for the given date have been documented on the *Daily Temperature and Quality Control Record,* and that all QC measures were within the expected range.
    b. If any QC measures were not documented or were not within the expected range, the reviewing technologist should take appropriate actions. For example, the QC measure will be documented, or the *Notes / Adjustments to Equipment / Additional Actions* column should be documented accordingly, or a variance report should be submitted.
    c. For each date, the technologist who documents the QC review must be a different technologist than the one who documents the QC measures.
    d. A Medical Technologist (MT), and not a Laboratory Assistant, will document the QC review.

B. Failing QC

1. The expected results for each QC measure are defined in the *Expected Results* section of this document and on the *Daily Temperature and Quality Control Record.* The QC passes if the observed results are within the expected results range, and the QC fails if the observed results are not within the expected range. If the QC fails, repeat the QC testing (if applicable). If the QC fails after the repeat:
    a. Do not use the item (equipment, reagent, instrument, etc.) on which the QC failed.
    b. Tag the item with the *Equipment Out of Service* form.
    c. Notify the Medical Technologist Lead or designee assigned to Quality Control (MT Lead QC).
    d. If applicable, the MT Lead QC shall arrange for repair from Beaumont Health

Biomedical or the applicable manufacturer.

e. Document and submit a variance.

f. Document the *Notes / Adjustments to Equipment / Additional Actions* column of the *Daily Temperature and Quality Control Record* accordingly.

C. Record of Equipment at Blood Bank Workstations

1. The *Record of Equipment at Blood Bank Workstations* is used to keep track of the Beaumont Health System property numbers for the MTS and table-top centrifuges, MTS incubators, and heat blocks. If any of these pieces of equipment are moved or replaced, then the *Record of Equipment at Blood Bank Workstations* should be updated accordingly. A current copy of this form is maintained along with this policy in the Transfusion Medicine Procedure Manual.

V. PROCEDURE:

A. Documentation of the *Daily Temperature and Quality Control Record*: All Shifts

1. MTS Incubators, Ortho Workstation (gel card) incubator, and the Heat Block
    a. Document the *Daily Temperature and Quality Control Record* with the temperature of each of the MTS incubators, the Ortho Workstation (gel card) incubator, and of the one heat block, as displayed on each thermometer.
        i. The MTS incubators are labeled #1, #2, #5, the Ortho Workstation (gel card) incubator is #4, and the heat block is labeled as #3. These are located at the type and screen, crossmatching, and antibody problems workstations.
        ii. The Ortho Workstation (gel card) incubator is monitored by a digital thermometer placed into a gel card, that is left in the incubator at all times.

2. Running of a Condition Mode Cycle on the Rad Source RS 3400 Blood Irradiator
    a. A Medical Technologist or Laboratory Assistant will run a Condition mode cycle on the Rad Source RS 3400 blood irradiator at the start of every shift as described in Transfusion Medicine policy, *Irradiation of Blood Components using the Rad Source RS 3400 Blood Irradiator*.
    b. Document the *Daily Temperature and Quality Control Record* with an "S" (satisfactory) or "U" (unsatisfactory) and employee initials to indicate that they have performed this Condition mode, and that the Condition Light is not illuminated after running the Condition mode.

3. Liquid Nitrogen Level and Temperature
    a. Document the *Daily Temperature and Quality Control Record* with the liquid nitrogen level and temperature, as it appears on the display panel or remote tracking program display.
    b. If the level is low, a new tank should be ordered.

c. The liquid level and temperatures can be monitored remotely on the SenseAnywhere website, or recorded from the liquid nitrogen tank display.

4. Verification that the Expected SoftBank Backup Files have been Created
    a. A Medical Technologist or Laboratory Assistant will access the SoftBank Backup File and verify that the expected files appear on one fo the six designated PCs; the full backup file should have been created each morning shortly after midnight, and incremental files should be continuously created every 30 minutes (on the top and bottom of each hour). Document the *Daily Temperature and Quality Control Record* with an "S" (satisfactory) or "U" (unsatisfactory) and employee initials to indicate that the files appear as expected.
    b. If the expected files have not been created or for additional information refer to Transfusion Medicine policy, *Using the SoftBank Backup File During Computer Downtimes*.

5. Notes / Adjustments to Equipment / Additional Actions
    a. This column should be documented with the equipment name, if applicable. Record any adjustments, the post-adjustment recheck, whether the post-adjustment recheck is within the acceptable range, any additional actions, and the employee initials.

6. Medical Technologist or Laboratory Assistant to Initial the *Daily Temperature and Quality Control Record*
    a. The Medical Technologist or Laboratory Assistant should document their initials on the *Daily Temperature and Quality Control Record* to indicate that all QC measures that appear on the applicable page have been documented.

7. Medical Technologist QC review
    a. This reviewing technologist will document the *MT QC Review* column of the *Daily Temperature and Quality Control Record* with a "✓" and their initials to indicate that this review has been performed.

B. Documentation of the *Daily Temperature and Quality Control Record*: Day Shift

All tasks described in *Documentation of the Daily Temperature and Quality Control Record: All Shifts* must be performed, as well as the shift-specific tasks below.

1. Temperatures of the Triage Room and Tissue Cabinet
    a. Document the *Daily Temperature and Quality Control Record* with the temperatures of the triage room and tissue cabinet.
        i. The triage room thermometer is located on the counter closes to the helicopter computer station.
        ii. The thermometer for the tissue cabinet is located in cabinet C on the underside of shelf 1.

2. Triage Plasma Baths

a. Document the *Daily Temperature and Quality Control Record* with the temperatures from the display of each plasma bath.

b. Evaluate the appearance of the water in each plasma bath for contamination, cloudiness, odor, and water level. Document as "S" (satisfactory) or "U" (unsatisfactory).

c. Cleaning of the plasma baths:

    i. For the dates on which the plasma baths are cleaned, document with the date and initials of the Laboratory Assistant or Medical Technologist.

    ii. For the dates on which cleaning of the plasma baths is not required, document with "NR" to indicate that cleaning is not required.

d. If the temperature is not within the expected range, or if the appearance is unsatisfactory, or if the plasma bath need cleaning refer to Transfusion Medicine policy, *Helmer DH8 Plasma Thawing System QC and Maintenance*.

3. Refrigerated Centrifuges

    a. Document the *Daily Temperature and Quality Control Record* with the temperatures of the Sorvall RC 3B PLUS and Sorvall BP 8 refrigerated centrifuges.

        i. Located in the blood processing room.

        ii. The Sorvall RC 3B PLUS centrifuge is set to maintain cold temperatures for RBC centrifugation, and the Sorvall BP 8 centrifuge is set to room temperature for platelet processing.

4. Processing Room Water Bath

    a. Document the *Daily Temperature and Quality Control Record* with the temperature of the water bath, as displayed on the thermometer. Observe the water level, and document as "S" (satisfactory) or "U" (unsatisfactory)

        i. If the water level is unsatisfactory, add more distilled water as needed and recheck the temperature after sufficient time has elapsed for the temperature to stabilize. Document the *Notes / Adjustments to Equipment / Additional Actions* column accordingly.

5. Temperatures of the Blood Processing Room, Storage Room, and Freezer Room

    a. Document the *Daily Temperature and Quality Control Record* with the temperatures of the blood processing room, storage room, and freezer room.

        i. The thermometer for the blood processing room is located on the counter near the plasma extractors.

        ii. The digital thermometer for the storage room is located next to the light switch.

        iii. The thermometer for the freezer room is located in the cabinet.

6. Rees

    a. View the Rees monitor and verify that all temperatures are within normal range, as indicated by green lighting for each node. Staple the previous day's *Event Report* to

the *Daily Highs, Lows, Averages Report* (these reports print automatically each morning), stamp / initial the report, and submit the reports to the MT Lead QC for review. Document the *Rees* column on the *Daily Temperature and Quality Control Record* with an "S" (satisfactory) or "U" (unsatisfactory) to indicate that the Rees Temp Logs were acceptable.

i. If Rees indicates that any of the temperatures are not within normal range, a Medical Technologist should be notified. They should proceed as described in Transfusion Medicine policy, *Response to an Alarm Condition*.

7. Rotate O Negative Neonatal RBC used for Downtime Emergency Issue
    a. Document the *Daily Temperature and Quality Control Record* as follows:
        i. For the dates on which a new neonatal RBC is set up, document with the technologist's initials.
        ii. For the dates on which setting up a new neonatal RBC is not required, document with "NR" to indicate that it is not required.
    b. A new O negative RBC should be set up each Monday; it must be rotated weekly (within 7 days ± 2 days).
    c. The freshest available O negative neonatal RBC should be irradiated and set up each time.
    d. For additional information, refer to Transfusion Medicine policy, *Downtime Emergency Issue*.
8. Cleaning of the Sterile Connecting Device
    a. Document the *Daily Temperature and Quality Control Record* as follows:
        i. For the dates on which the SCD is cleaned, document with the technologist's initials.
        ii. For the dates on which cleaning of the SCD is not required, document with "NR" to indicate that cleaning is not required.
    b. The SCD is cleaned each Monday; it must be cleaned weekly (within 7 days ± 2 days).
    c. For cleaning directions, refer to Transfusion Medicine policy, *Sterile Connecting Device: Weld Integrity Test and Cleaning*.
9. Cleaning of the Heat Sealer
    a. Document the *Daily Temperature and Quality Control Record* as follows:
        i. For the dates on which the heat sealer is cleaned, document with the technologist's initials.
        ii. For the dates on which cleaning of the heat sealer is not required, document with "NR" to indicate that cleaning is not required.
    b. The heat sealer is cleaned each Monday; it must be cleaned weekly (within 7 days ± 2 days).

c. Clean the heat sealer as follows:
    i. Turn off the power to the heat sealer and unplug the device. Wait 30 seconds.
    ii. Clean the open sealing region and adjacent areas with isopropyl alcohol on a cotton swab. Immediately dry the sealing region with a dry cotton swab.
    iii. Wipe down the exterior case of the heat sealer with isopropyl alcohol and gauze.
    iv. Make sure the heat sealer is completely dry, then plug the power bord back into the device and turn the power on.

10. Cleaning of the Diluent Dispensers
    a. Document the *Daily Temperature and Quality Control Record* as follows:
        i. For the dates on which the dispensers are cleaned, document with the technologist's initials.
        ii. For the dates on which cleaning of the dispensers is not required, document with "NR" to indicate that cleaning is not required.
    b. The diluent dispensers are cleaned on each Monday; they must be cleaned weekly (within 7 days ± 2 days).
    c. For cleaning directions, refer to Transfusion Medicine policy, *Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers*.
11. Verification that all RhIG Vials have been Issued
    a. Each morning, the technologist who is assigned to prepare RhIG will verify that all vials that were set up on previous dates have been dispensed from the Blood Bank. If any vials have not been dispensed, the patient's caregivers should be notified. For additional information, refer to Transfusion Medicine policy, *Rh Immune Globulin Evaluation*.
    b. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate that the technologist has performed this verification, and if any notifications are required then document the notifications in the *Notes / Adjustments to Equipment / Additional Actions* column.
12. Completion of Billing
    a. A Medical Technologist will be responsible for completing the billing required for the previous day.
        i. Refer to the Blood Bank Billing CDM's for further instructions.
    b. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate the technologist has performed this task.
13. Eyewash Weekly Inspection and Cleaning
    a. A Medical Technologist or Laboratory Assistant will perform a weekly flush and inspection of the department Eyewash Stations in accordance with the Laboratory

Emergency Eyewash and Shower Equipment policy.

b. This will be documented using the Eyewash Weekly Inspection Form attached to the Eyewash Stations and Shower Equipment policy.

C. Documentation of the *Daily Temperature and Quality Control Record*: Afternoon Shift

All tasks described in *Documentation of the Daily Temperature and Quality Control Record: All Shifts* must be performed, as well as the shift-specific tasks below.

1. Scale Checks
    a. Weigh the standard 200 g weight on each of the four Blood Bank scales and record the weight on the *Daily Temperature and Quality Control Record*.
        i. Each scale is numbered.
            i. Scale # 1: Seca, located in the blood processing room.
            ii. Scale # 2: Acculab, located in the triage area, near the sterile connecting device.
            iii. Scale # 3: Sunbeam, located at the stand-up triage area.
            iv. Scale # 4: Sunbeam, located at the stand-up triage area.
2. Rotate O Negative RBCs used for Downtime Emergency Issue
    a. Monitor the expiration dates of the O negative units that are reserved for downtime emergency issue. If the units are within one week of expiring, they should be placed in general inventory and replaced with fresher units. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate that this step has been performed.
3. Check for Growth in Units Sent to Microbiology for Culture
    a. Each day a technologist will review the *Suspected Bacterial Contamination of a Transfused Component Log*. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate that the log has been reviewed.
        i. The *Suspected Bacterial Contamination of a Transfused Component Log* is reviewed as described in Transfusion Medicine policy, *Suspected Bacterial Contamination of a Transfused Component*.
4. Flush the Helmer UltraCW™ Cell Washer and Inspect the Rotor Fill Ports
    a. Document the *Daily Temperature and Quality Control Record* as follows:
        i. For the dates on which the cell washer is flushed and the rotor fill ports are inspected, document with the technologist's initials.
        ii. For the dates on which the cell washer flush and rotor fill port inspection is not required, document with "NR" to indicate that cleaning is not required.
    b. The cell washer is flushed and the rotor fill ports are inspected each Friday; they must be cleaned weekly (within 7 days ± 2 days).

c. For additional information refer to Transfusion Medicine policy, *Helmer UltraCW™ Automatic Cell Washing System Preventative Maintenance*.

5. Inspection of the Dry Ice Tissue Coolers
    a. Each day a technologist will inspect the inside of each dry ice tissue cooler to ensure no tissues were left inside of them upon return to the Blood Bank. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate the dry ice tissue coolers were checked.
    b. If any are found in the dry ice tissue coolers, place the tissues in quarantine and submit a variance.
6. Verification that Billing was Completed
    a. Each day a technologist will verify that billing was completed. Document the *Daily Temperature and Quality Control Record* with the technologist's initials to indicate that billing has been reviewed.

D. Documentation of the Daily Temperature and Quality Control Record: Midnight Shift

All tasks described in *Documentation of the Daily Temperature and Quality Control Record: All Shifts* must be performed, as well as the shift-specific tasks below.

1. MTS and Ortho Workstation (Gel) Centrifuges: RPM and Timer Checks
    a. Perform the RPM and timer checks of the MTS and Ortho Workstation centrifuges and record the results on the *Daily Temperature and Quality Control Record.*
    b. Refer to Transfusion Medicine policy, Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers.

VI. EXPECTED RESULTS:

QC Measure	Expected Results
Temperature of Triage Room	18°C - 25°C
Temperature of Tissue Cabinet	15°C - 25°C
Temperature of Triage Plasma Baths	36°C ± 1°C
Appearance of Water in Triage Plasma Baths	Clear, not cloudy and without an odor or other signs of contamination
Water Level in Triage Plasma Baths	The level should not exceed the upper slotted line and should remain at or just below the lower slotted line
Cleaning of Triage Plasma Baths	Must be cleaned every 7 days ± 2 days
Temperatures of MTS Incubators and Heat Block	37°C ± 1°C
Ortho Workstation (gel card) incubator	37°C ± 2°C
Liquid Nitrogen Level	Greater than 12" and less than 20"
Liquid Nitrogen Temperature	-200°C to -165°C
RC 3B PLUS Refrigerated Centrifuge Temperature	1°C - 4°C
Sorvall BP 8 Refrigerated Centrifuge Temperature	20°C - 24°C
Temperature of the Processing Room Water Bath	36°C ± 1°C
Water Level in the Processing Room Water Bath	Halfway full
Temperature of the Blood Processing Room	18°C - 25°C
Temperature of the Storage Room	18°C - 25°C
Temperature of the Freezer Room	18°C - 25°C
Rees	All temperatures are within normal range, as indicated by green lighting for each node
Rotate Downtime Neonatal RBC	Must be done every 7 days ± 2 days
Cleaning of Sterile Connection Device and Heat Sealer	Must be cleaned every 7 days ± 2 days
Cleaning of Diluent Dispensers	Must be cleaned every 7 days ± 2 days
RhIG Vials Issued	All RhIG should be dispensed within 24 hours from the time set up or the caregiver should be notified
SoftBank Backup Files	Full backup file: created each morning shortly after midnight. Increment files: continuously created every 30 minutes (on top and bottom of each hour)

Irradiator Condition Mode	Performed successfully at the start of every shift
Dry Ice Tissue Coolers	Should only contain dry ice, not tissues
Billing	Billing should be completed each day
Scale Weights	200g ± 10 g
Expiration Date of O Negative RBCs Used for Emergency Issue	Should not be within one week of expiring
Units Sent to Microbiology Laboratory for Cultures	Growth checked
Helmer UltraCW™ Flush and Rotor Fill Port Inspection	Must be done every 7 days ± 2 days
MTS and Ortho Workstation Centrifuge RPM Checks	MTS: 895 ± 25 RPM / Ortho Workstation: 1032 ± 10 RPM
MTS and Ortho Workstation Timer Checks	Timers start at 10 minutes, count down to zero

VII. INTERPRETATION:

The QC passes if the observed results are within the range of the expected results, and the QC fails if the observed results are not within the range of the expected results. If the QC fails, refer to the *Failing QC* section of this document.

VIII. REFERENCES:

1. Micro Typing Systems, Inc. MTS Incubator™ User's Guide, 06/30/2004.
2. Micro Typing Systems, Inc. Centrifuge User's Guide, Pub. No. 6902118, 10/15/2008.
3. MTS Dispenser™ Repetitive Dispenser PK No. 079-E, Rev. date 10/13/2008, distributed by Ortho-Clinical Diagnostics.
4. Helmer Plasma Thawing System Operation-Service-Maintenance Manual, Noblesville, IN 46060.
5. Terumo Teruseal Tube Sealer Operating Instructions, Somerset, NJ 08873.
6. Ortho Workstation for ID-MTS™ Gel Cards Reference Guide, 09/04/2013.

Attachments

Daily Temperature and Quality Control Record

Record of Equipment at Blood Bank Workstations

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	7/7/2023
	Kristina Davis: Staff Physician	7/6/2023
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	5/4/2023
	Kelly Sartor: Mgr, Division Laboratory	5/4/2023
	Brooke Klapatch: Medical Technologist Lead	5/3/2023