PROCEDURE
Corewell Health East - Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuge, and Diluent Dispensers

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

Reference #: 33942

Version #: 2

Effective Date: 11/12/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle
The purpose of this document is to provide instructions for quality control (QC) and maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuge, and Diluent Dispensers.

2. Responsibility
Personnel who have completed the competency requirements will perform these tasks.

3. Definitions
A. Tachometer: An instrument for determining speed, especially the rotational speed of a shaft.
B. Rotor Head: Top of the rotating part of an electrical or mechanical device
C. RPM: Rotations per minute.
D. Daily: On a given calendar date.
E. Weekly: Within 7 days ± 2 days.
F. Monthly: Within the first 2 weeks of each calendar month.
G. Quarterly: Every 3 months ± 2 weeks; typically, in the calendar months January, April, July and October.
H. Bi-Annually: Every 6 months ± 1 month.
I. Yearly: Every 12 months ± 1 month.
J. QC: Quality Control

4. Reagent/Equipment Needed
A. QC/Maintenance of the Ortho MTS Incubator
   1. Ortho MTS incubators
   2. Mild detergent (or other solution as approved by Clinical Pathology)
   3. 70% isopropyl alcohol
   4. Lint-free cloth

5. Fuse with a rating of 1.0 Amp 250 VAC 5x20 mm

B. QC/Maintenance of the Ortho MTS Centrifuge
   1. Ortho MTS centrifuge
   2. Reflective tape
   3. Traceable electronic digital tachometer
   4. Timing device

C. QC of the MTS Diluent Dispensers
   1. MTS diluent dispensers (0.5 mL and 1.0 mL dispensers)
   2. Deionized (DI) water
   3. 70% isopropyl alcohol
   4. 10 mL graduated cylinder

D. QC/Maintenance of the Ortho MTS Gel Workstation
   1. Ortho Workstation for ID-MTS™ Gel Cards (1 in the laboratory)
   2. Unused gel card
   3. Calibrated, thin wire digital thermometer
   4. Mild detergent (or other solution as approved by Clinical Pathology)
   5. 70% isopropyl alcohol
   6. Lint-free cloth
   7. Deionized (DI) water
   8. Reflective tape
   9. Traceable electronic digital tachometer
   10. Timing device

5. Policies

A. Daily QC checks shall be performed on each day that the instrument will be used and documented on:
   1. Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
   2. All other sites: *Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers*.

B. The centrifuges and diluent dispensers will be cleaned weekly and documented on :
   1. Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
   2. All other sites: *Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers.*

C. The Ortho MTS Centrifuge and the Ortho MTS Gel Workstation centrifuge calibration verification maintenance, performed annually, semi-annually, and after repairs, may be performed by the Biomedical department. If the Biomedical department does not perform the calibration verification, the Blood Bank will be responsible for performing the centrifuge calibration verifications. Refer to Corewell Health East – Centrifuge RPM and Timer Check – Blood Bank – All Beaumont Hospitals.

D. The QC passes if the observed results match the expected results and fails if the observed results do not match the expected results defined in this procedure. If the QC or maintenance fails, repeat the QC testing (if applicable). If the QC fails even after repeating it, then the following apply:
   1. Do not use the incubator, centrifuge, or diluent dispenser on which the QC failed.
   2. Tag the incubator, centrifuge, or diluent dispenser with Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals, *Equipment Out of Service* form.
   3. Notify the Blood Bank Supervisor, Medical Technologist Lead, or designee assigned to Quality Control.
   4. If applicable, the Blood Bank Supervisor, Medical Technologist Lead, or designee shall arrange for repair from Ortho Clinical Diagnostics or from Corewell Health Biomedical.
   5. Document a variance form and submit it.

6. Procedure

A. Procedure for Performing QC and Maintenance of the Ortho MTS Incubator

1. Daily Temperature Checks
   a. The temperature of each of the MTS incubators will be checked at least daily. The thermometers used to take the temperatures of the incubators will be rotated each day of the week. The thermometers are placed in test tubes that are filled with saline or water to the level of the incubator block top surface. Documentation of the temperature checks for the MTS incubator may be documented on *QC and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.
   b. The expected results of the temperature of the Ortho MTS Incubator should be 37°C±1°C.
2. As Needed Cleaning
   a. The Ortho MTS incubators will be cleaned with a lint-free cloth and mild detergent (or other solutions as approved by Clinical Pathology) as-needed.
   b. As needed, the fuse will be replaced as follows:
      1) Set the power switch to OFF and disconnect the power cord from the power supply. Warning: Serious injury or electric shock may occur if the power cord is not unplugged.
      2) Locate the fuse holder beside the power cord socket on the rear panel. Remove the fuse holder by inserting a small screwdriver into the slot at the bottom of the holder to pull the fuse out.
      3) Replace the old fuse with a new fuse with the rating 1.0 Amp 250 VAC 5x20 mm.
      4) Replace the fuse holder; it should snap into place.
      5) Reconnect the power cord and power ON the incubator.

B. Procedure for Performing QC and Maintenance of the Ortho MTS Centrifuge

1. Daily Confirmation that the RPM and Timer Display Function Properly
   a. Each day after pressing the START button and allowing the balanced or empty centrifuge to reach its maximum speed, check that the displayed RPM is 895 ± 25. Also check that the timer begins at 10:00 minutes and counts down to zero, at which time the display becomes blank. Document this on:
      1) Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
      2) All other sites: *Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.
2. Semi-Annual and Annual Centrifuge Calibration Verification and Timer Check
   1) Refer to Corewell Health East – Centrifuge RPM and Timer Check – Blood Bank – All Beaumont Hospitals
3. Annual Inspection of the Cable Sub-assembly and Drive Belt
   a. Note that this inspection may be performed by either Corewell Health Biomedical or the Blood Bank. Each year, the cable sub-assembly and drive belt are inspected as follows:
      1) Remove the rotor head from the centrifuge.
      2) Turn the power off, making sure to leave the drawer open, and disconnect the power cord from the power supply. Warning: Serious injury or electric shock may occur if the power cord is not unplugged.
      3) Turn the instrument upside down and extend the drawer out to see the back Retractile Cable Sub-Assembly extended from the rear of the instrument to the inside of the drawer.
      4) Inspect the Retractile Sub-Assembly; see Expected Results, below.
      5) Remove the 4 screws from the panel to see the drive belt.
      6) Inspect the drive belt; see Expected Results, below.
      7) Document this on the *Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.

8) If the observed results do not match the expected results, the Blood Bank Supervisor, Medical Technologist Lead, or designee may need to contact Ortho for a Retractile Cable Replacement kit or for a Belt Spares Replacement kit.

Yearly Inspection of the Cable Sub-assembly and Drive Belt

Expected Results: Cable Sub-Assembly	• No visible nicks, cuts, or tears on the cable's black surface. No exposure of the green, white, or black wires on the inside of the sub-assembly. • The retractile cable has not lost its coil • The green, white or black wires that extend out from each side of the sub-assembly have not been nicked or cut to the point where the metal wire inside is exposed.
Expected Results: Drive belt	No nicks, tears, or areas that appear to be stretched thin on the drive belt.

4. As Needed Cleaning
   a. The Ortho MTS centrifuges will be cleaned with a lint-free cloth and mild detergent (or other solutions approved by Clinical Pathology) as-needed.

C. Procedure for Performing QC and Maintenance of the Ortho MTS Gel Workstation
1. Daily temperature checks and confirmation that the RPM and timer displays function properly will occur and may be documented on:
   a. Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
   b. All other sites: *Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.
2. Each day, press the START button and allow the balanced or empty centrifuge to reach its maximum speed
   a. Check that the displayed RPM is 1032 ± 10.
   b. Check that the timer display begins at 10:00 minutes and counts down to zero, at which time the display becomes blank
   c. Check the temperature of the heat block:
      1) Remove the foil from the top of an unused well on a gel card.
      2) Fill the reaction chamber of an empty microtube with 100uL of distilled water.
      3) Place sensor wire of a thin wire thermometer into the reaction chamber.
      4) Place the card into a slot of the incubator and route the sensor wire out under the lid through the small slot on the right side. Ensure the card is seated completely in the incubator slot after closing lid.
      5) Incubate the card for 15 minutes
      6) Read the temperature. Expected temperature results should be 37ºC ± 2ºC.
      7) Verify the incubator temperature status display light is GREEN.
      8) Record the temperature and check of the status display light on:
         a) Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
         b) All other sites: *QC & Maintenance of the MTS Manual Workstation, Centrifuges, Incubators, and Dispensers* log.
3. Weekly cleaning
   a. Turn off the instrument and unplug the power cord.
   b. Clean all obvious materials from the outside of the system, inside the rotor well using a moistened cloth with mild detergent and then with 70% isopropyl alcohol. The centrifuges are cleaned with 70% isopropyl alcohol.
   c. Clean the centrifuge lids with distilled water.
   d. Allow all surfaces to air dry completely.
   e. Plug in the power cord and turn the instrument on. Do not use bleach for cleaning.

f. Document on:
   1) Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
   2) *All other sites: Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.

4. Semi-Annual and Annual Centrifuge Calibration Verification and Timer Check
   1) Refer to Corewell Health East – Centrifuge RPM and Timer Check – Blood Bank – All Beaumont Hospitals
5. As Needed Cleaning
   a. The MTS Incubator does not require any special maintenance other than checking the card slots and tube holders for loose items and basic cleanliness. Use a mild detergent with a cloth to clean the incubator.
   b. When cleaning, unplug the cord.
   c. Do not immerse instrument in water.
   d. Do not spill liquids over the instrument.
   e. Do not use alcohol on the cover.

D. Procedure for Performing QC and Maintenance of the MTS Diluent Dispenser
1. Cleaning on the MTS diluent dispensers will occur weekly
   a. Remove the dispenser from the diluent bottle. Dispense diluent until the outlet line is empty.
   b. Rinse and decant the inside of the cap with 70% Isopropyl Alcohol.
   c. Rinse and decant the inside of the cap with copious amounts of deionized or distilled water.
   d. Aspirate with 70% Isopropyl Alcohol a minimum of 15 times through the dispenser into a waste receptacle.
   e. Remove dispenser from the 70% Isopropyl Alcohol solution.
   f. Dispense into a waste receptacle the remaining 70% Isopropyl Alcohol that is left in the tubing until the outlet line is empty.
   g. Wipe the inlet tubing with a paper towel so as not to contaminate the deionized or distilled water with the 70% Isopropyl Alcohol solution
   h. Flush the dispenser with freshly drawn deionized or distilled water a minimum of 20 dispenses into a waste receptacle.
   i. Remove the dispenser from deionized or distilled water.
   j. Dispense into a waste receptacle the remaining water that is left in the tubing until the outlet line is empty.
   k. Wipe dry the inlet tubing and outer dispenser surface with a paper towel.
   l. If ready for use, prime line a minimum of one time, with appropriate diluent to be dispensed. If the dispenser is not used for a while, store dry.
   m. Document on:
      1) Royal Oak: On form 33902-1 *Daily Temp QC Record*, refer to procedure Corewell Health East - Daily Temperature and Quality Control Record - Blood Bank - Royal Oak
      2) *All other sites: Quality Control and Maintenance of the Ortho MTS Gel Workstation, Incubator, Centrifuges, and Diluent Dispensers* log.
2. A quarterly calibration check should be done as part of a routine laboratory quality control schedule and after each repair and may be documented on *Quarterly QC of the Ortho MTS Diluent Dispensers* log.
   a. Dispense 10 times into a clean, dry 10.0 ml graduated cylinder and record volume.
   b. Record the actual volume dispensed on QC & Maintenance of the MTS Manual Workstation, Centrifuges, Incubators, and Dispensers.
   c. Evaluate the performance of the dispenser by comparing the actual dispensed volume with the acceptable volumes listed below.
   d. Expected total volume from 10 dispenses:

1) 0.5 mL Dispenser 4.7 mL – 5.3 mL
2) 1.0 mL Dispenser 9.5 mL – 10.5 mL

e. In the event the MTS Dispenser does not meet the required specification during the Calibration check, quarantine the dispenser and DO NOT use for testing. Calibration of the MTS Dispenser is set by the manufacturer and cannot be adjusted by the user. Contact Ortho Diagnostic Testing Inc.

7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

8. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [33890 Corewell Health East – Maintenance of the Ortho MTS Equipment – Grosse Pointe, 33826 Corewell Health East – QC & Maintenance of the Ortho MTS Gel Workstations – Blood Bank – Dearborn, Farmington Hills, Troy, RC.BB.QC.PR.329 Royal Oak Paper Policy: Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers, 33945 Corewell Health East - Quality Control of the Manual Gel System Reagents - Blood Bank - Taylor, Trenton, Wayne]

9. References

A. AABB Standards for Blood Banks and Transfusion Services, current edition.
B. AABB Technical Manual, current edition.
C. College of American Pathologists, Transfusion Medicine Checklist, current edition.
D. ORTHO™ workstation, ID-MTS™ Gel Cards Reference Guide, 09/2013
E. Micro Typing Systems, Inc. MTS Incubator™ User's Guide, 06/30/2004
F. Micro Typing Systems, Inc. Centrifuge User's Guide, Pub. No. 6902118, 10/15/2008

10. Procedure Development and Approval

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11. Keywords

Not Set