Methodist Health Services Corporation
& UnityPoint Health Methodist
Department of Pathology
Peoria, IL 61636

Effective: May 20, 2012
Revised: March 19, 2017

# Quality Control Schedule for Cell Processing Laboratory Equipment

## I. Principle
To ensure equipment is in proper working order.

## II. Clinical Significance
Equipment needs to be in proper working order so that the hematopoietic progenitor cell product is of the highest quality possible to ensure engraftment in the recipient.

## III. Specimen
NA

## IV. Reagents
NA

## V. Instrumentation/Equipment
See individual instructions

## VI. Calibration
NA

## VII. Quality Control
See individual instructions

## VIII. Procedure

A. Record each day of use and at least weekly:
   1. Refrigerator
      a. 1-6º C Record on refrigerator.
   2. Refrigerator Freezer
      a. <0º C Record on refrigerator.
   3. LN2 Storage/LN2 tanks
      a. Units must be locked when not in use . Unlock both units for daily QC. Wearing cryogloves, use LN2 measuring stick to measure LN2 level in unit III. The stick is touching bottom of unit correctly if it measures 34 inches at top of unit. Level should be approximately 7½-11½ inches. Make sure power cord and remote power source (black rectangular box) are plugged in. Check control panel

making sure power switch is lit. For units III and IV, read temperature reading from mounted wall graph lit display. (On graph itself, unit III is designated as"3", but unit IV is designated as "1".) For unit IV also read lid temperature from unit IV display on unit itself and the LN2 level (13-23 inches) from same display. Temperatures in all areas should read below <-150C. Lift lid of unit IV to check for vapor presence. Record this information on Liquid Nitrogen Storage Units Levels Temperatures and Functions Form (CP:065) on processing clipboard.

b. The LN2 supply tanks should have enough LN2 to last overnight (approx. 1/8 on gauge). If it does not have this amount, switch to another tank. Upon delivery of each tank, the gauge is read and recorded on the LN2 use tank sheet (CP: 070) located on the clipboard. The gauge should read approx. 22 PSI. If it reads <15 or >35 PSI, call LN2 tank supplier to notify them of a possible problem and follow their directions. (Per Form Scientific, manufacturer of the storage units, as long as the PSI is < 100 the solenoid valves will not blow.)

B. <u>Weekly</u>:

(Record on Liquid Nitrogen Storage Unit, Temperatures and Function Forms (CP: 065) on clipboard.)

1. Solenoid valve function
    a. Push manual fill buttons and listen for opening on LN2 storage units of valves and LN2 entering units.
2. Temperature chart recorder
    a. 2. Change chart every Monday
        i. By pushing chart key
        ii. for storage units pulling up on pen lifter
        iii. removing used chart from retaining clips
        iv. installing new chart under the 5 retaining clips making sure small hole is over pin near center of chart.
        v. pushing pen lifter down, and
        vi. pushing chart key. Record your initials and date on graph when placing chart and when removing chart.

C. <u>Day of Use:</u>

1. Laminar flow hood
    a. Turn on fan. Wipe entire surface twice with disinfecting towelette. Leave fan on until hood is no longer needed. Read magnehelic gauge. Reading should be no more than 1.50 inches of water. A lower reading is fine. Record on CP: 069 Quality Control for Recorder, Freezing Chamber, LN2 Tank, Tube Sealer, Balance, Cryomed Freezing Process. A reading of >1.50 inches of water indicates the Hepa filter needs to be changed. Phone Biomed or Clean Air Flow, Inc. for advice if a filter change does not solve the problem.

2. Terumo tube sealer
    a. Check for completeness of seal each time used. Silver clips and sealer located in Blood Bank are to be used for sealing only if necessary. Hemodialysis has a heat sealer attached to one of their Cobe Spectra machines that can be used for heat sealing the final product if time allows. Record on CP: 069 Quality Control.
3. Cryomed recorder
    a. Check calibration by touching SAMP to move pen to 180 and CHAM to bring it back to zero. Use the zero dial to adjust if necessary. Record on QC (CP: 069) on back of door. Scroll through the program to make sure it hasn't erased.
4. Model 1010 controller/LN2
    a. For each new LN2 tank delivery that will be attached to the tank freezing chamber, run 2-3 minutes of freezing program 1.1 to verify its accuracy, plus to check the LN2 tank function and solenoid valve function. The temperature of the freezing chamber should decrease. Shut off and turn back on to scroll through program to make sure it is correct. Record on CP: 069.
5. Freezing chamber
    a. Visually check probe for cleanliness and plug connection. Record on QC sheet (CP: 069) on back of door. Solenoid valve function is confirmed when new LN2 tank is run to check the freezing program - the valve will open and close as the temperature drops in the chamber as seen on model 101 display.
6. OHAUS balance
    Check known 147.5g weight. Range +/= 1 %. Clean as needed. Record on CP: 069.

D. <u>Annually:</u>

1. Timer
    a. Check expiration date. Re-order as necessary.

2. Thermometers
    a. Refrigerator and freezer thermometers are checked against NIST thermometers. Blood Bank personnel perform and document temperatures in Blood Bank QC book.
3. LN2 Temperature Probes
    a. The probes are checked against the Omega temperature in Storage Units probe from Biomed. The Omega probe is calibrated annually by Biomed. Arrange white coiled cord of Omega probe on unit III so the bottom of it is right at the top of the storage unit. At this point the bottom of the Omega probe will be even with the LN2 storage unit probe. Close lid on unit. Turn the Omega probe on and leave in the storage unit several minutes until the

temperature stabilizes. Compare the Omega temperature display to the storage unit display on the wall. The readings should be within 10%. Repeat with unit IV.

4. LN2 unit alarms
   a. High – For unit III, hold solenoid switch on until high alarm sounds on unit and in main lab. Unit III will have a 20 minute delay for remote alarm. High indicator light should be lit. Record level on LN2 level alarm checks sheet. Horn will have to be kept off and remote power source disconnected until LN2 level falls to normal levels. Check daily for light to go off. May take 2-3 days. At that time, turn horn on and plug in remote power source. The electrical plug will also have to be disconnected until level is at normal range. Record on CP: 067 Annual Liquid Storage Unit Alarm Check Validations and Temperature Probe Calibration Unit III.

      Low – For unit III, when daily reading is close to 8 – 8 ½ inches, shut off LN2 supply until the low alarm sounds on unit and in main lab. Low indicator light should be lit. Record on alarm checks sheet the LN2 level at which the alarm sounds. 7 inches is the minimum. Turn on LN2 tank and make sure unit fills properly. Record on CP: 067 Annual Liquid Nitrogen Storage Unit Alarm Check Validation and Temperature Probe Calibration Unit III. Check power switches by shutting off and on. Remote alarm in main lab should sound. Check off on alarm checks sheet. Unit III will have a 20 minute delay before remote alarm sounds. These are checked monthly. For unit IV high and low alarm verification and temperature display verification, see page 31 of Custom Biogenic Systems 2300 LN2 Storage Unit Set-Up & Technical Manual at end of this procedure. For power off alarm, unplug unit from the wall. Record on CP: 068 Annual Liquid Nitrogen Storage Unit Alarm Check Validations and Temperature Probe Calibration Unit IV.

5. Transport Cooler – Dry
   b. Using Biomed's Omega temperature probe, place probe end into Temperature transport cooler (property of transplant unit) along with approximately 5 lbs. of dry ice when HPC canisters are being picked up. Record # of canisters present along with canisters are less than 12, fill in with mock canisters stored in cryobank freezer so 12 canisters are present. Continue recording temperature every time a canister is removed from the cooler until the cooler is empty. Maximum # canisters for pickup at a time is 12. Maximum storage time is 1 hour, 10 minutes. Temperature to be maintained at or below -80ºC while canisters are present in cooler. Record on CP: 066 Transport Cooler / Dry Ice QC.

6. Model 1010 Controller
    c. Using the Omega temperature probe, fit the cord through the top side of the front door. Place temperature display on counter. Run program 1.1 as usual. Record chamber temperature from freezing curve graph paper peak of each spike) and temperature from Omega display simultaneously. Depending on rate of change, record every 10 minutes until temperature change occurs. Continue every minute thereafter recording both temperatures as they occur. Readings should be within 10% during Sections 1.1 and 1.2. Readings are not accurately measured during Section 1.3 due to rapid infusion of LN2. (The Omega probe does not reflect changes as rapidly as the changes occur.) Readings should be within 20% during Sections 1.4, 1.5, and 1.6 Record on CP:078 Microcomputer Model 1010 Quality Control.
7. Ohaus Balance
    d. Calibration performed by Biomed using annually calibrated weights.
8. Room Air Quality
    a. Place an open blood agar plate and fungal plate on the clean work counter for one hour. Lid can be face up next to plate. Fill out an Epidemiology / Environmental Cultures sheet and give to Microbiology with the closed plates. Record on CP: 062 Annual Equipment Maintenance Log, Audits, and Chart Review Verification.
9. Laminar Flow Hood
    a. Inspection performed by outside company. For sterility check, place open blood agar plates in each of the four corners of hood after cleaning with fan on. Fill out an Epidemiology / Environmental Cultures sheet and give to Microbiology with the closed plates. Record on CP: 062.

## IX. Calculations

NA

## X. Objectives / Acceptable Endpoints / Range of Expected Results

See individual steps of procedure.

## XI. Reporting Results

Record on appropriate log sheets located on clipboard or on back of door.

## XII. Procedural Notes/Problem-Solving Tips

A. Any equipment not performing up to standards will be promptly evaluated and corrected before use. Steps taken should be documented on “Equipment Problem Log”.
B. If equipment is not able to be corrected before use or not in compliance in accordance

with the maintenance schedule, this will be indicated by a note on the equipment AND by verbal notification to all personnel. The appropriate backup equipment will be in use as listed under Procedural Notes in CP: 005.

C. In the event of a cryostorage unit solenoid valve failure, see Alarms for Cryostorage Units and Storage Unit Failure CP: 014. Phone the Service Center and ask for Biomedical Engineering assistance to correct the solenoid valve problem.
D. In the event a storage unit cannot contain the LN2 and thus keep the canisters at the proper temperature, see Policy CP: 011 "Product Storage, Including Monitoring and LN2 Alarm System."
E. In cases of suspected thawing of cryopreserved products, the patient's primary transplant physician must be notified and a decision made regarding continued storage of the product.

## XIII. References


Forma Scientific, Inc. CRYOSERIES Liquid Nitrogen Storage System Manual N0. 7000740 Rev.0
Forma Scientific, Inc. Operation and Maintenance Manual Cryomed Model 1010
Cryomed Operator Manual for Flat-Bed Recorder, 1989
Clean Air Flow, Inc. Service Representative, Howard Cutter, 2003
Terumo Heat Sealer Instructions for Use
OHAUS Electronic Balance Directions for Use and Maintenance
Custom Biogenic Systems 2300 LN2 Storage Unit Set-Up & Technical Manual, July 2008


## IX. Distribution

A hard copy of this procedure is located in the Cell Processing manual at the Cell Processing bench

| ***POLICY CREATION :*** | | | |
|---|---|---|---|
| ***Author:*** | ***Deb Rinne, CLS (ASCP)*** | | ***November 15, 1999*** |
| ***Medical Director:*** | ***Douglas McGrady, MD*** | DMcGrady MD | ***November 15, 1999*** |

| ***MEDICAL DIRECTOR*** | | |
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| March 4, 2017 | Elizabeth A. Bauer-Marsh, M.D. | Elizabeth A. Bauer-Marsh MD |
| ***SECTION MEDICAL DIRECTOR*** | | |
| May 13, 2016 | Julia Adams, M.D. | Julia Adams, M.D. |
| | | |

| REVISION HISTORY (began tracking 2011) | | | |
|---|---|---|---|
| **Rev** | **Description of Change** | **Author** | **Effective Date** |
| .09 | Centrifuge changed to 10 minutes for timer, omitted Confirm program and changed % difference requirements for 1010 Controller | D. Rinne | |
| .10 | Changed LN2 levels for storage units and updated timer expiration | Deb Rinne | 3/3/16 |
| .11 | Change fridge temp, QC form name | Deb Rinne | 01/31/17 |

**Reviewed by**

| Lead | Date | Coordinator/Manager | Date | Medical Director | Date |
|---|---|---|---|---|---|
| Deb Rinne | 12/11/02 | | | Douglas McGrady M.D. | 12/11/02 |
| Deb Rinne | 12/01/03 | | | Douglas McGrady M.D | 12/03 |
| Deb Rinne | 2/04/04 | | | Douglas McGrady M.D. | 2/05/04 |
| Deb Rinne | 10/13/04 | | | Douglas McGrady M.D. | 10/14/4 |
| Deb Rinne | 12/5/05 | | | Douglas McGrady M.D. | 12/05 |
| Deb Rinne | 10/1/06 | | | Douglas McGrady M.D. | 10/06 |
| Deb Rinne | 10/25/07 | | | Douglas McGrady M.D. | 10/07 |
| Deb Rinne | 11/5/08 | | | Douglas McGrady M.D. | 11/5/08 |
| Deb Rinne | 2/18/09 | | | Douglas McGrady M.D. | 2/18/09 |
| Deb Rinne | 2/16/10 | | | Douglas McGrady M.D. | 2/2010 |
| Deb Rinne | 6/22/12 | | | DMcGrady MD | 6/26/12 |
| Deb Rinne | 4/11/14 | | | DMcGrady MD | 4/11/14 |
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