Daily Quality Control and Preventive Maintenance of the Neo

A. Principle

Daily quality control of all reagents must be performed to ensure the equipment is operating as expected. Preventive maintenance must be performed to ensure that the equipment continues to function as designed. Many of the daily tasks are programmed into the Neo software and will not allow testing to begin until completed.

B. General Policies

a. Daily quality control and maintenance tasks must be performed a minimum of every 24 hours. If tasks are not completed, assays will not run.
b. Designated first shift personnel are responsible for deleting historic plate entries.
c. Third shift personnel are responsible for the remaining QC & PM tasks.

C. Specimen Collection and Preparation

N/A

D. Equipment

a. Neo
b. Transport frame

E. Supplies

a. Capture strips and trays

F. Reagents

a. 0.9% Phosphate Buffered Saline, pH 6.5-7.5
    i. Preparation: Ensure that pH is between 6.5-7.5 by testing with pH paper.
        1. If out of range, pHIX buffer must be added.
        2. Add 100ml to 10 liter cube of saline.
        3. Mix well and label appropriately.
        4. Only use for Neo or Echo testing.
    ii. Storage: 20-24C
    iii. Expiration: One (1) month from opening not to exceed original expiration date.
b. Anti-A
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer.
c. Anti-B
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer

d. Anti-D series 4
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
e. Anti-D series 5
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
f. Monoclonal Control
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
g. Commercial A1 cells
    i. Preparation: Using the provided dispenser, place one stir ball in the vial.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
h. Commercial B cells
    i. Preparation: Using the provided dispenser, place one stir ball in the vial.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
i. Capture LISS
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
j. Capture-R Control Serum (positive and negative)
    i. Preparation: Use as supplied.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer
k. DAT Positive Control Cell
    i. Preparation: Using the provided dispenser, place one stir ball in the vial.
    ii. Storage: 1-8C when not in use
    iii. Expiration: 7 days from opening
l. Capture Indicator cells
    i. Preparation: Using the provided dispenser, place one stir ball in the vial.
    ii. Storage: 1-8C when not in use
    iii. Expiration: 24 hours from opening
m. corQc EXTEND control cells
    i. Preparation: Using the provided dispenser, place one stir ball in the vial.
    ii. Storage: 1-8C when not in use
    iii. Expiration: Use until date listed by manufacturer

G. Safety

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

H. Procedure

a. Shutdown and restart instrument
   i. Touch or click the *Shutdown* button on the main menu bar.
   ii. Touch or click the *Shutdown* button on the Shutdown dialog.
   iii. Following the shut off of the monitor, power off the instrument with the power switch on the bottom right side of the machine.
   iv. After the instrument is off and the software has closed down, immediately press the power switch on the front panel of the PC to turn on the computer.
   v. Switch on the Neo instrument using the on/off switch on the right side of the machine that you used to turn it off.
   vi. Verify that the Neo instrument is switched on by checking that the camera reader lamp and the instrument overhead lights are both illuminated.

b. Check and refill system liquid containers
   i. Open the lower cabinet doors and pull out the drawer to access the container.
   ii. Ensure that the liquid in the system container is at the minimum acceptable level.
   iii. Ensure that the volume of saline in the original container is sufficient for sample processing.
   NOTE: Although this step is only documented once daily, each shift is responsible for verifying liquid level is sufficient for sample processing.
   iv. Replace the saline cube if the saline is so low that the tubing leading to the system liquid container is not full of saline, or if it seems too low to run for the next 8 hours.
   v. If necessary, remove the lid and fill the container with saline.
   vi. Press the *Washer* button the Machine Monitor to display the *Wash Buffers* dialog. Buffer name should be PBS, phosphate buffered saline, or 0.9% buffered saline.

c. Check waste container
   i. Ensure that waste is emptying into floor drain.

d. Clean instrument
   i. Touch or click the *Maintenance* button on the main menu bar.
   ii. Touch or click *Clean Instrument* from the action list.
   iii. Touch or click *Start* and follow the on-screen instructions for cleaning.
   iv. Touch or click *Continue* after function is complete.

e. Check pipettor Reference
   i. Verify pipettors are idle and no assays are scheduled to run.

ii. Touch or click the *Maintenance* button on the main menu bar if needed.
iii. Touch or click *Check Pipettor Reference* from the action list.
iv. Touch or click *Start* and follow the on-screen instructions.
v. Touch or click the *Check Reference* button.
vi. Select the *Left* pipettor arm and touch or click *Reference Position.* The left pipettor moves to the reference position target and the probe moves to the previous Z-position.
vii. After the probe is aligned correctly, touch or click *Position OK* button.
viii. Select the *Right* pipettor arm and touch or click *Reference Position.*
ix. After touching or clicking either the *Position OK* or the *Position Wrong* button, touch or click the *Close* button. The pipettors will then initialize and return to the maintenance action screen.
x. After initialization is complete, return to the maintenance screen and then touch or click the *Done* button.

f. Perform the Pipettor Self Check
i. Touch or click the *Maintenance* button on the main menu bar if needed.
ii. Touch or click the *Pipettor Self check* from the *Maintenance and Verification Action Status* list.
iii. Make sure the pipettor self check tool is clean and insert it into a plate carrier.
iv. Load the Pipettor Self Check tool into the plate loading tower. The red tower of the tool should be orientated to the left side of the plate carrier when inserted onto the plate loading tower.
1. Note: The pipettor self check tool occupies two (2) tower slots.
v. Close the door to initiate an automatic reading of the tool barcode.
vi. Start the *PCheck* assay via the the *Pipettor Self Check* task on the *Maintenance* screen.
Note: No liquid/Not enough liquid flags are generated and appear in the Log List during processing. This is expected and necessary.
vii. After completion of the *PCheck* assay, remove the Pipettor Self Check tool from the plate loading tower and then also from the plate carrier.
viii. Rinse the cavities only of the Pipettor Self Check tool with tap water and then immediately dry all of its surfaces carefully with a paper towel.
Note: Make sure not to damage the barcode affixed to the tool
ix. Store the pipettor self check tool in a dry secure place.

g. Verify the reader
i. Touch or click the *Maintenance* button on the main menu bar if needed.
ii. Touch or click *Verify Reader* from the action list.

iii. Touch or click *Start* and review the on-screen instructions.
iv. Touch or click *Continue* to display the *Resource Overview Window*.
v. Touch or click *Plates* to display the *Plate Loading Tower.*
vi. Load the Reader Verification Plate into a transport frame with the text up and to the left side. Load the transport frame into any position of the loading tower. **DO NOT** close the tower door.
vii. Touch or click *Assay Selection* tab and *Plate ID* field next to the orange LED.
viii. Type a unique plate ID using the date and your initials.
ix. Touch or click *RVerify* assay from the list.
x. The system displays the selected assay next to the plate ID under *Assay Code*.
xi. Touch or click *Done*. The system displays the *Resource Overview* window indicating that all resources are sufficient to run the assay.
xii. Touch or click *Start*. The transport system takes the plate to the reader module and performs the analysis. The plate returns to the tower for removal.
xiii. Return the plate to its protective case.
xiv. Verify that the state of the action is *OK* on the main maintenance screen.

h. ABO Reagent QC
i. Load an unused ABO plate into the loading tower. Initiate a barcode scan.
ii. Press the *Maintenance* button on the Main Menu Bar.
iii. Select the *ABO Reagent QC* and press *START*.
iv. After reviewing the on-screen instructions, press *Continue* to access the *Resource Overview* window.
v. Select the *QCTEST* on the *Resource Overview* and add any additional resources that are needed.
vi. Press *Start* to begin the assay.
NOTE: Reagent QC must be successfully completed a minimum of every 24 hours or if a new reagent lot number is loaded. Scheduling patient or donor tests will not be permitted until QC has been successfully completed

i. 3 Cell QC
i. Load an unused Capture-R Ready-screen strip at strip position one (1) into the loading tower. Initiate a barcode scan.
ii. Press the *Maintenance* button on the Main Menu Bar
iii. Select the *3_Cell Plate QC* and press *Start.*
iv. After reviewing the on-screen instructions, press *Continue* to access the *Resource Overview* window.
v. Select the QC3_Cell line and select the Plate tower.
vi. *** Using the Strip selection dialog, indicate that all 12 strips are available for testing***

vii. Add any additional resources that are needed.
viii. Press *Start* to begin the assay.

j. Delete historic plate entry
The instrument automatically deletes historic plates from the plate list that are > 24 hours old. This occurs after a complete initialization of the instrument.

I. **Reporting Results**

a. Document successful performance of tasks by placing initials of operator in appropriate date box.
    i. If unacceptable results are obtained, indicate corrective action in the appropriate section of the form.

b. Check pipettor reference
    i. Acceptable – The probe tip is within the reference target.
    ii. Unacceptable – The probe tip is not within the reference target.
        1. Gently bend the tip to the target and repeat test.
        2. If problem persists, the pipettor may need to be replaced.

c. Pipettor Self Check
    i. The software analyzes the results and sets a pass or fail status.
    ii. Refer to Chapter 11 Troubleshooting in the NEO manual to investigate a failed status.

d. Reagent QC
    i. Acceptable – All reagents results are as expected.
    ii. Unacceptable – Unexpected or missing results obtained.
        1. Investigate possible causes and repeat tests.
        2. If problem persists, discard current vials and load new vials onto the instrument. Repeat tests.
        3. If problem persists, contact supervisor and technical support.

e. Refer to SOP Troubleshooting the Neo or the Neo Operator Manual for additional information regarding unacceptable results.

J. References

a. Neo Operator Manual, 2010, Chapter 10, ImmucorGamma, Norcross, GA.
b. Standards for Blood Banks and Transfusion Services, AABB, 26th Edition, 2009, Std. 3.5 & 5.1.3, Bethesda, MD.

PROCEDURE AND FORM CHANGE CONTROL

Title: Daily Quality Control and Preventive Maintenance of the Neo										
Written		Validated		Path Review		Review		Effective		Reason for Revision
Date	By	Date	By	Date	By	Date	By	Date	By	
10/9/11	GJM									
Revised										
9/2/15	JLH									Changed the order of items down and changed the shutdown procedure to match manufacturer's recommedations.

Location of any copy(s) of the procedure:

Out of use:

Date:_____By:_____Reason:_____