Deviation From SOP

Date: 08/30/2021

Affected SOPs: Neo Weekly Maintenance; Neo Monthly Maintenance: Echo Monthly Maintenance

Description:

Immucor notification sent stating that the "recommended cleaning solution" used for Neo and Echo/Lumena maintenance tasks will be changing from Rely On tabs to a 0.25% dilution of bleach (Sodium Hypochlorite NaClO). The SOP change and software updates should occur no later than Sept 1, 2021.

New Maintenance Bottles, Graduated Cylinders and 8.25% Sodium Hypochlorite has been purchased and placed at all three blood bank locations (MH, UH and Riley) and instruction sent to primary maintenance users in advance via email.

Currently during the Policy STAT online SOP freeze, no permanent changes to these SOPs and applicable Forms can be made. Deviation SOP/Draft Forms for Neo Weekly Maintenance (BBGN-F 002.02), Neo Monthly Maintenance (BBGN-F 003.01) and Echo Maintenance Record (BBGE- F 001.04) will be effective as a DRAFT on 09.01.21 until permanent edits can be made in new online SOP system.

Summary of Changes:

1) Removing any and all references to Rely On cleaning tabs and replacing with "recommended cleaning solution" throughout SOP and on Maintenance Forms

2) Changing List of Materials in SOP to "Sodium Hypochlorite" (diluted to 0.25%)

3) Add Instruction for making 0.25% Sodium Hypochlorite solution for the recommended cleaning solution for the Immucor Neo and Echo/Lumena.

    a. Make Dilution with DI H2O
        i. V1C1= V2C2

    b. Neo Weekly requires 500ml (V2)of solution at a 0.25% (C2)
        i. How much 8.25% Bleach (C1) do you need?
            1. V1= 500 x 0.25 / 8.25
            2. V1 = 15 ml of 8.25% Sodium Hypochlorite (NaClO)
            3. 500ml – 15 ml = 485ml of DI H20

c. Monthly Maintenance (Neo and Echo/Lumena). End Volume(V2) = 2000ml (2Liters)
   i. V1= 2000 x 0.25 / 8.25
   ii. V1 = 60 ml of 8.25% NaClO
   iii. 2000 – 60 ml = 1940ml of DI H2O

4) Make 0.25% Dilution of Sodium Hypochlorite on **DAY OF USE** only. Do not store extra solution in the maintenance bottle after tasks are complete.

5) V1C1=V2C2 calculation can be used to make various volumes of 0.25% NaClO that might be needed other than the above two examples.

   a. Likewise, if the initial concentration of Sodium Hypochlorite being used should change (not 8.25%), then use this calculation to determine appropriate volumes of solute (NaClO) and solvent (DI H2O) to make a 0.25% solution.

***Attached are DRAFT Maintenance Forms that will be placed in appropriate locations for use on 09/01/2021.**

Tracie Ingle
BB Supervisor

Approved By: BB Medical Director
Verbal approval 08/30/21 by Dr. Amy Gabbard

Galileo Echo Maintenance Record

Instructions for Use: Operator(s) must perform the maintenance requirement at the specified time. the date of each activity must be entered in the table. Ink the initials of the operator in the designated box(es) to signify successful completion of the task(s). Refer to **Chapter 11 – Maintaining the Galileo Echo** for written information about maintenance requirements.

FACILITY		INSTRUMENT serial number		MONTH/YEAR	

DAILY MAINTENANCE

DATE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1. Refill PBS supply container																															
2. Empty waste container																															
3. Clean and Initialize ECHO																															
4. Check probe alignment: **Maintenance action**																															
5. Check probe vertical position: **Maintenance action**																															
6. Washer residual volume test (visual): **Maintenance action**																															
7. Check and document incubator 1 sensor: 38.1-38.9C																															
8. Reagent QC																															
9. **Daily Quality Control Peer Review**																															

Weekly MAINTENANCE	Week 1		Week 2		Week 3		Week 4		Week 5	
Operator notation:	Operator	Date	Operator	Date	Operator	Date	Operator	Date	Operator	Date
1. Instrument and computer shutdown										
2. Archive results (at least weekly) and delete from database										

Monthly MAINTENANCE	Operator notation:	Operator	Date
1. Wipe down probe block with recommended cleaning solution and replace Priming Strips			
2. Remove Wash Manifold (Stylus and Flush) Repeat Washer Basic Test after Initialization			
3. Decontamination (Decontaminate / Flush / Purge / Prime)			
4. Washer residual volume test (refer to Washer residual volume test and Washer dispense accuracy test Maintenance Record for results).			
5. Washer dispense accuracy test (refer to Washer residual volume test and Washer dispense accuracy test Maintenance Record for results).			

Monthly BB Management Review _____

NEO WEEKLY Maintenance Record

Instructions for Use: Operator(s) must perform the maintenance requirement at the specified time. The date of each weekly activity must be entered in the table. Ink initials of the operator in the designated box(es) signify successful completion of the task(s). Refer to **Chapter 10 – Maintaining the NEO** for written information about weekly maintenance requirements.

FACILITY	IU Health Pathology Lab: Blood Bank	**INSTRUMENT #**	5030090385

MONTH/YEAR:
MAINTENANCE REQUIREMENT

Perform the actions below in the numbered sequence.	***Operator notation:***	**Operator**	**Date**	**Result**
1. Verify Washer with Flow Verification Tool: Check dispensed volume per channel (required to be between 2.0 and 3.0 ml per channel with channel to channel variation not greater than 0.5 ml)	Flow 350			_____ml
Record the **Flow350** and **Flow200** estimated average volume results in this table:	Flow 200			_____ml
2. Check Reader Performance:				
3. Power off the NEO module (**only** the module and not the PC)				
4. Fill probe rinse cup and waste cup of both pipettor wash towers with Recommended cleaning solution; and expose for 10 minutes.				
5. Common Waste Container: (a) Empty and rinse with Recommended cleaning solution. **(b)** Clean inside of lid with isopropanol wipes. **(c)** Empty and rinse with deionized water. **(d)** Empty and reconnect the container.				
6. Inspect syringes for leakage and check tightness of barrels.				
7. Power on the NEO module and allow initialization to occur. Note: the instrument must be powered back on for a minimum of thirty (30) minutes to allow the reader lamp to warm up before using the reader module to read plates.				
8. Archive. Use DVD+R disks. Label disk with "NEO Archive" and date range included on disk (yyyymmdd_yyyymmdd) oldest date—current date				

NEO MONTHLY Maintenance Record

Instructions for Use: Operator(s) must perform the maintenance requirement at the specified time. The date of each MONTHLY activity must be entered in the table. Ink initials of the operator in the designated box(es) signify successful completion of the task(s). Refer to **Chapter 10 – Maintaining the NEO** for written information about monthly maintenance requirements.

FACILITY IU Health Pathology Lab: Blood Bank	**INSTRUMENT #** 5030090385		**MONTH/YEAR**
MAINTENANCE REQUIREMENT	**Operator**	**Date**	**Calibration Date**
Software: Clear Test Data			
Software: Check the RVP Calibration Date. Note: Immediately notify Technical Support if the subsequent calculated date, by adding three (3) years to the calibration date, is within one (1) month of the expiration date, or is after the expiration date.			
Run **ALL DECONTAMINATION** Procedures and Follow all on-screen instructions: (Decontaminate tubings: **Maintenance** action): • Decontaminate tubings: (De-bubbler Check) Note: After the **DB_CK** assay is finished, verify that liquid has collected into the collection container from the blue tubing. • Decontaminate tubings: (Decontaminate System Lines & Containers) Note: Make 2L of Recommended cleaning solution (Soak 20 minutes) Note: Empty and rinse both system liquid containers with the Recommended cleaning solution followed by two (2) rinses with saline (both rinses using approximately 400 mL of saline). • Decontaminate tubings: (Air) • Decontaminate tubings: (Flush with PBS) Note: Before refilling clean containers with new PBS and reconnecting, Wipe system liquid sensors and lids with isopropanol before returning them to clean containers. • Decontaminate tubings: (Hemolysis check) Note: After the **HemCheck** assay is finished, verify that there is no visible hemolysis in the wells of the plate.			