

Prepared by: C.Guertin, CLS. Updated by S.DeMarinis, MT. (ASCP)

Revised and Adopted on 12/5/22 by Lab Director: J. Mills Barbeau MBal MD

Annual Review:				
Reviewed by Medical Director	Date	Reviewed	by Medical Director	Date
-				
	4 2000			
		L		
Name of the control o		Harris and the second		
Revisions:				
		-		
	11	-		
		-		
		-		
		-		
		-		
Bristol – MARI		E:	East Greenwich CC	
1180 Hope Street			1454 S. County Trail	
Bristol, RI		E	ast Greenwich, RI	
Miriam Hospital	Newport Hospital		Rhode Island Hospital	
164 Summit Avenue	11 Friendship Street		593 Eddy Street	
Providence, RI	Newport, RI		Providence, RI	

Purpose

To ensure proper operation of the ACL TOP Analyzers, the following daily, weekly and monthly maintenance procedures will be performed by the laboratory staff.

Annual and Semi-Annual Maintenance is performed by authorized Service personnel every 6 months (including syringe tip replacement at 6 month intervals). Documentation of these maintenance procedures is stored in database of each analyzer.

Principle

- The following maintenance procedures will be performed on the ACL TOP 300, 500 and 700 instruments. Procedures must be performed daily, weekly and monthly for optimal performance of instruments. Documentation of maintenance is stored in analyzer database.
- Technologists have a unique log on for analyzer operation and all testing of specimens and quality control. Operator Identification is maintained throughout analyzer use. Technologists update their operator identification at the start and end of their working shift.
- Review of maintenance procedures is performed monthly and recorded by tech specialist(s) on documentation of review form (included in this procedure) and stored in Maintenance Review log book located in Coagulation lab stat area along with instrument service reports.

Reagents

HemosIL Cleaning Solution (Clean A Solution: Acid:), 0.1N HCL, Instrumentation Laboratory

Ready to use, in original container. This solution cleans analyzer probes. Stable until manufacturer's expiration when stored or is use at room temperature in original container. Cleaning Solution (Clean A) must remain on instrument at all times;

Replace Cleaning Solution as needed, when analyzer sends alarm signal (red exclamation point), indicating level has reached 25 ml. Analyzer will self prime after replacement

HemosIL Critical Care Cleaning Agent (Clean B Solution: Base), Sodium Hypochlorite, Instrumentation Laboratory

Caution: Corrosive material. This concentrated solution is used to perform enhanced cleaning of probes and must be removed from instrument immediately after daily cleaning procedure. Store with cap in glass vial. Stable until manufacturer's expiration date.

HemosIL Rinse Solution, Instrumentation Laboratory

Ready to use in original container. Stable until manufacturer's expiration when stored or is use at room temperature in original container.

Replace daily and as needed, when instrument sends alarm signal (red exclamation point) indicating level has reached 600ml. Analyzer will self prime after replacement.

Daily Maintenance Procedure: ACP TOP: Day shift

Daily Maintenance includes the following procedures:

- Enhanced Cleaning of Probes
- Prepare and load new vial of "Dilute Clean B' Solution
- Change Factor Diluent
- Empty Liquid waste and cuvette waste

A. Perform "Enhanced Clean for All Probes"

1. Purpose; Daily deep cleaning of sample and reagent probes:

Load one full <u>10ml vial</u> of **Critical Care Cleaning Agent** (Clean B) into each instrument location as follows:

ACL TOP 300		
Load 2 vials:		
One vial in D1 +		
One vial in R1 (or R2 or R3 or R4)		

2. Select: Menu Bar > System> Maintenance

Select: Enhanced Clean for all Probes> Perform (running man with wrench icon)

When task is complete, comment window will appear: Enter your initials in comment Window >select OK

3. Immediately remove all vials of Critical Care Cleaning Agent (Clean B) from instrument. Cap tightly and store at room temperature. Failure to remove this concentrated cleaning solution will cause corrosion of instrument.

B. Prepare 1:8 "Dilute Clean B Solution" for continual use on the instrument

1. To prepare 1:8 Dilute Clean B Solution:

Add 2.0 ml HemosIL Critical Care Cleaning Agent (B) + 14.0 ml distilled water into 20 ml glass vial with "Dilute Clean B' barcode label.

- 2. Remove expired Dilute Clean B solutions from instrument and discard.
- 3. Load two vials freshly prepared Dilute Clean B Solution onto each instrument as follows: To prevent carryover of dilute clean B solution into other reagents during instrument initializing process:

USE ONLY DESINATED VIAL POSITION OF THE APPROPRIATE RACK.

ACL TOP 300		
One vial in position 6 of row R4		
·		

4. Update Maintenance records as follows:

From Screen

Select >Daily Maintenance

Select> "Make Fresh Clean B Diluted"> Perform (running man with wrench icon) Enter your initials in comment Window > select OK.

5. Diluted Clean B Solution must remain on instrument at all times for reagent probe cleaning to occur during test procedures. Instrument will not run in absence of "Dilute Clean B solution".

C. Change Factor Diluent:

- 1. Remove the white plastic barcoded vial that contains Factor Diluent solution.
- 2. Discard remaining diluent, rinse vial with distilled water, and allow to thoroughly dry.
- 3. Fill a clean/dry white plastic barcoded vial with at least 10 ml Factor Diluent solution.
- 4. Load into Diluent Rack as follows:

	_
ACL TOP 300	
One vial in Row D1*	
*Additional vials of factor diluent may be ad	ded for special coagulation tests as needed.

5. Update Maintenance record as follows:

From Screen > Daily Maintenance; Select > Change Factor Diluent > Perform (running man with wrench icon) Enter your initials in comment Window > select OK.

D. Liquid Waste Container; Day Shift and as needed

- 1. The 10 liter water container holds the fluid waste that is pumped from the accumulator.
- 2. Empty this container each day, and as needed during the day, when alarm warning sounds. If allowed to fill completely during testing, analyzer will perform emergency stop, testing will suspend and operator must empty waste container to allow testing to resume.
- 3. Discard liquid waste in sink, **rinsing with copious amounts of water to prevent build up of Sodium Azide;** Allow tap water to run 2 minutes or more, to completely flush rinse liquid through the drain.
- 4. Replace container and cap; check tubing for large air bubbles, blockages or kinks and remove if necessary.
- 5. Empty waste while instrument is idle.
- 6. If liquid waste is emptied while analyzer is running, the container must be replaced within 3 miuntes of removal or analyzer will initiate "emergency stop" and "Recovery" must be performed to resume operation.

E. Empty Cuvette Waste: Midnight shift and as needed

- 1. Cuvette drawer may be emptied any time; even while instrument is running.
- 2. Remove the cuvette waste drawer and discard used cuvettes in biohazard waste bin as needed.
- 3. Instrument will signal with alarm when waste drawer is nearly full.
- 4. Instrument will place itself into "Controlled stop" and operation will pause if drawer is completely full;
- 5. Change while instrument is idle or running.
- 6. If instrument is running, replace cuvette drawer within 3 minutes of removal, or analyzer will "emergency stop" and a"Recovery" must be performed to resume operation.

Maintenance As Needed: Replace Clean A and Rinse Solution

1. Important: Replace Clean A and Rinse Solution ONLY when a Material Error alarm has occurred.

- 2. Change these solutions ONLY when status of fluids is indicated as an alarm "red exclamation point". Automatic priming of solutions to remove air bubbles from the rinse lines occurs only after container is changed when status light is "red".
 - Amber warning alarm indicates that Clean A has reached <75 ml; Rinse has reached 1000 ml.
 - Red warning alarm indicates that Clean A has reached 25 ml; Rinse 600 ml.

Weekly Maintenance Procedures

A. Clean Cuvette Waste Drawer

- 1. Select Menu Bar> System> Maintenance
 - Select Clean Cuvette Waste Drawer> Perform (running man with wrench icon)
- 2. Remove the used cuvette waste drawer liner and replace with a clean liner. Select >OK.
- 3. Enter your initials in Comment window; Select>OK.
- 4. Discard the used cuvettes into the biohazard waste bin. Use a scoopful of powdered Buell laboratory cleaner to wash the waste drawer liner. Allow to dry at room temperature. Replace with clean liner and resume operation.

B. Clean Deep Wash and Cup Area

- 1. From Menu Bar Select> System> Maintenance
- 2. Select> "Clean Deep Wash and Clean Cup Area" > Perform (running man with wrench icon)
- 3. Open the Sample area cover.
- 4. Using a LINT free cotton swab, clean the deep wash and clean cup as follows:
- 5. Rinse both areas with a maximum of 10ml distilled water to remove debris. Use a transfer pipet or small 10 cc syringe with tubing to rinse areas.
- 6. Using LINT free cotton swab, thoroughly dry the cover and the metal ring of the wash deck around the deep wash well clean cup.

- 7. Select OK at the prompt to indicate that these maintenance procedures have been performed. Open the cover(s), perform the maintenance work, close the covers(s) once again and press OK.
- 8. Enter your initials in the Comment window> select OK.
- 9. Wait: The instrument will initialize by checking volumes of reagents, setting probes and equilibrating temperatures, before it can be used for testing.

Monthly Maintenance Procedures

The following maintenance procedures will be performed on the ACL TOP instruments.

- Database Back up Procedure
- Computer Shutdown Procedure

Refer to procedures for Database Backup, create a backup CD in this manual.

Annual and Semi-Annual Maintenance

Preventive maintenance is to be performed by authorized Service personnel every 6 months (including syringe tip replacement at 6 month intervals).

References:

ACL TOP Instrument Training Manual (2010).