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Abbott Alinity I-Series Analyzer Maintenance

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to provide maintenance to the Alinity I-Series Analyzers

II. PRINCIPLE

The ALINITY -i is a high-performance, immunoassay diagnostic systems capable of quantifying selected analytes in biological fluids. Daily, weekly, Semiyearly, and as-needed maintenance are performed to assure that the instrument is functioning optimally. The system stores data for a maximum of 2 years.

III. REAGENTS:

A. Wash buffer: The wash buffer is phosphate-buffered saline with an antimicrobial ingredient. Concentrated wash buffer is supplied in a 2 L bottle. You can add wash buffer while the system is in Ready or Running mode. Has a 30-day stability on the instrument.

B. Trigger: Made of sodium hydroxide. Has 28-day stability on the instrument.

C. Pre-trigger solution: Made of hydrogen peroxide and kept refrigerated. It is sensitive to light. Has a 16-day stability on the analyzer.

IV. EQUIPMENT:

This maintenance procedure is intended for the ALINITY i-system

V. SUPPLIES

A. Cotton swabs

B. Gloves

C. DI water

D. Maintenance Cleaning Cartridge (LN 02R5250) for daily maintenance (use the supplied maintenance cleaning cartridge).

E. Probe Conditioning Solution (LN 01R5840) loaded in the reagent carousel.

F. 25 mL measuring device

VI. QUALITY CONTROL

The ALINITY-i uses various quality control materials. Refer to the ALINITY-i Procedure for details on quality control types, frequency, and acceptability criteria.

VII. DAILY MAINTENANCE PROCEDURE

A. **Daily Maintenance completes the following tasks:**

1. Cleans and conditions sample pipettor probe
2. Cleans wash zone 1 and 2 probes with 0.5% sodium hypochlorite solution
3. Flush and prime the Pre-Trigger and Trigger solutions.
4. Flush the Pre-Trigger Solution reservoir. If the Pre-Trigger solution on-board stability is less than 24 hours and the remaining volume in the reservoir is less than 350 mL, the system software flushes the Pre-Trigger Solution reservoir until the level sensor indicates the reservoir is empty.
5. Estimated time to complete 23 minutes. If a bulk transfer is needed, additional time of 5 minutes to 25 minutes may be required.
   Note: The Alinity Reagent Sample Module (RSM) must be in **Idle or Running status and the Processing module must be in **Warming, Idle or Running** in order to complete daily maintenance. The Procedure key setting is positioned **OFF.**

B. From the menu bar, select **Procedures**. The default is the **Maintenance** tab.

1. The **Maintenance** Tab displays To Do procedures.
2. On the right side of the Procedures screen, select the **Daily maintenance (2500)** tab or the **To Do** tab.
3. Select **Perform** to view the Maintenance procedure.
4. Select **Proceed** to perform the maintenance, and follow the instructions in the instruction box.
5. Add 25 mL of 0.5% Sodium Hypochlorite solution to the empty Maintenance cartridge. Note: Select **Help** for assistance calculating amounts to prepare the 0.5% Sodium Hypochlorite solution.

6. Place the Maintenance Cleaning cartridge in any available position on the RSM.
7. Click OK to perform procedure.
8. Remove the maintenance cartridge once it is unloaded on the RSM.
9. Select **Done** on the Screen to complete the procedure.

VIII. WEEKLY MAINTENANCE PROCEDURE

A. The following procedures are the required weekly maintenance for the ALINITY-i system:
    1. Manual Pipettor Probe Cleaning
    2. Manual Wash Zone Probe Cleaning
    3. Manual Wash Cup Cleaning

B. From the menu bar, select **Procedures**. The default is the **Maintenance** tab.
    1. The procedure key must be turned to the **ON** position to complete Weekly Maintenance. Open the front electronics door of the processing module to access the key.
    2. On the right side of the Procedures screen, select the **Weekly maintenance** tab. Select the weekly maintenance procedure that you wish to perform from the weekly Maintenance tab. The weekly maintenance procedures are listed above.
    3. Select **Perform**.
    4. Click **OK** to perform procedure.
    5. Select **Proceed**, and then follow the instructions in the instruction box.
    6. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
    7. Select **Done** on the Screen display to complete the procedure.
       Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete

IX. SEMIYEARLY MAINTENANCE PROCEDURE: CLEANING AIR FILTERS

A. From the menu bar, select **Procedures**. The default is the **Maintenance** tab.
    1. Select **Semiyearly Maintenance Tab**.
    2. Select the procedure, clean the filters.
    3. Select **Perform**.
    4. Tap **Proceed**, and then follow the instructions in the instruction box.
    5. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.

6. Select **Done** on the Screen display to complete the procedure.
   Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete.

X. AS NEEDED MAINTENANCE

A. As needed maintenance is usually performed as part of troubleshooting and should only be performed when the need arises. Abbott technical support personnel or the On-line System Operations Manual may instruct medical technologists and technicians to perform as needed maintenance as part of troubleshooting. The following procedure categories are found under diagnostics:
   1. **Optics**
   2. **Pipettors**
   3. **Fluidics**
   4. **Temperature**
   5. **RV Loader**
   6. **Process Path**
   7. **Sample Manager**
   8. **Reagent Manager**
   9. **Modules**

B. From the menu bar, select **Procedures**. Select the **Diagnostics** tab
C. Select the as diagnostic procedure that you wish to perform from the procedure list.
D. Select **Perform**.
E. Click **OK** to perform procedure.
F. Select **Proceed**, and then follow the instructions in the instruction box.
G. If applicable, view the videos that are embedded in the individual maintenance procedures for instructions.
H. Select **Done** to return to maintenance screen.
   Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead at the end of each procedure. The System Status returns to ready when a maintenance procedure is complete.

XI. REFERENCES

A. Alinity c-i-series Operations Manual
B. Alinity ci series System Quick Reference Guide

Approval Signatures

Step Description	Approver	Date
CLIA Directors	Ann Marie Blenc: System Med Dir, Hematopath	7/19/2024
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Applicability

Royal Oak