CHEM.COBAS.2.1 Cobas e411 Routine Maintenance

STATEMENT OF PURPOSE

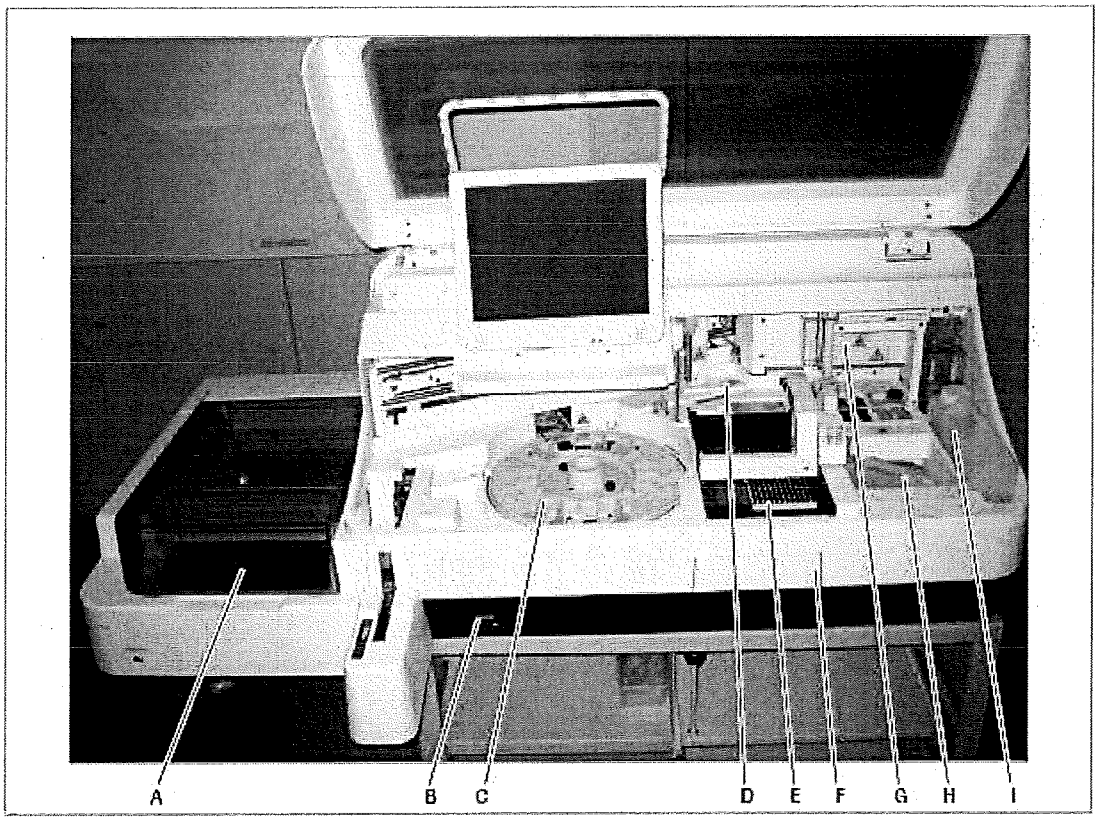
Maintenance is performed to ensure optimal operating efficiency of the analyzer.

SCOPE

The Roche Cobas e411 analyzer is an automated system for immunological analysis. The analyzer uses electrochemiluminescence (ECL) technology to provide a wide variety of tests. The analyzer consists of two units:

- Analyzer unit
- Control unit (computer and software)

The analyzer unit consists of the sections below:



A Sample area
B Operation switch
C Reagent area
D Measuring area (1 of 2)
E Consumables area
F Solid waste area
G Measuring area (2 of 2)
H Liquid waste container
I System water container

Analyzer unit (rack system)

OWNERS

Technical Supervisor, St. Vincent Evansville

RELATED DOCUMENTS

CHEM.COBAS.2.0 Operation of the Cobas e411

CHEM.COBAS.2.2 Cobas E411 Maintenance Log

SPECIMEN

Refer to individual Cobas e411 assay procedures.

MATERIALS

A. Lint-free cloths
B. Isopropyl alcohol or ethanol
C. DI water
D. Syringe with attached flexible tubing
E. Cotton swabs

REAGENTS

Refer to individual Cobas e411 assay procedures.

CALIBRATION

See CHEM.COBAS.2.0 Operation of the Cobas e411.

QUALITY CONTROL

Refer to laboratory quality control policy and procedures.

PROCEDURE

To perform maintenance procedures, from the System Overview window, choose Utility>Maintenance. From the Type column, choose Maintenance. Then choose the desired maintenance action>Start.

A. Daily Maintenance (when analyzer in use)

1. Clean sample/reagent probe
   a. Ensure power switch is in "OFF" position.
   b. Lift the top cover of the instrument.
   c. Gently move the S/R probe into accessible position.
   d. Wipe the probe gently from top to bottom with a lint-free cloth moistened with DI water. If the probe is visibly dirty, wipe first with isopropyl alcohol or methanol and then with DI water.
   e. Close the top cover of the analyzer.
2. Check condensation inside reagent rotor and system reagent compartments
   a. Ensure power switch is in "OFF" position and lift the top cover of the analyzer.
   b. Rotate the handle of the reagent cover counterclockwise to unlock and remove it.
   c. Close the lids of the reagent packs and remove them.
   d. Remove the black thumbscrews from the center of the reagent rotor and remove it.
   e. Inspect the reagent rotor and system reagents compartments. If there is condensation, wipe it dry with a lint-free cloth.
   f. To replace the rotor, align the pin on the compartment center plate with the hole in the rotor.
   g. Replace and tighten the black thumbscrews, replace the reagents, open the lids and replace the cover.
   h. Close the top cover of the analyzer and power on.
3. Empty liquid waste container, if necessary.
   a. Cap and remove the liquid waste container.
   b. Empty the container and rinse with water
   c. Replace the empty liquid waste container on the analyzer ensuring that the cap is removed and the opening is placed directly under the liquid waste outlet.

   NOTE: Do not mix bleach with the liquid waste.
4. Empty the solid waste tray.
   a. Open the solid waste door and lift and pull out the solid waste tray.
   b. Dispose of the solid waste in a biohazard bag.
   c. NOTE: If you remove the solid waste tray for any reason, always discard the solid waste. When the analyzer senses that the tray has been removed, the counter resets to zero and starts counting as if the tray has been emptied.
   d. Replace the Clean-Liner if visibly soiled.
5. Fill system water container, if necessary.
   a. Raise and remove the system water container
   b. Remove cap and discard any water remaining inside the container.
   c. Fill with distilled or deionized water up to the 3.0L (top) mark.
   d. Add 35mL of SysWash to the water.
   e. Replace the cap and replace container on the analyzer.
   f. Close the solid waste door.

6. Replace any empty assay cups or tip trays with full ones.
7. Open the sipper shield, open the lids on the ProCell and CleanCell bottles and close sipper shield. Reagents may be replaced at this time if necessary. Note that these reagents are always replaced as a pair. These reagents have a 72 hour open vial stability. Keep lids closed when instrument not in use.
8. Clear Sample Data (at end of day)
    a. Touch the Sample Clear Data button on the System Overview Screen.
    b. Ensure the Clear button is selected (light blue).
    c. Touch OK.
9. Perform finalization (at end of day)
    a. From the System Overview menu, choose **Utility>Maintenance**. From the Maintenance items list, choose **Finalization Maintenance**. Select and then press **Start**.
10. Put in "sleep" mode (at end of day)
    a. Turn power switch off to place instrument in "sleep" mode.

B. Weekly Maintenance
1. Clean incubator and aspiration station
    a. Turn off the instrument and lift the top cover of the analyzer
    b. Move the sample/reagent arm to the far left, over the sampling position.
    c. Move the gripper to the front.
    d. Open the sipper shield and move the sipper arm to the far right, over the CleanCell bottle.
    e. Use a lint-free cloth moistened with DI water to clean the incubator and aspiration station.
    f. Use cotton swabs moistened with DI water to clean each position in the incubator and aspiration station.
    g. Dry the incubator with a lint-free cloth.
    h. Close the top cover and turn the power switch on.
2. Clean the sipper probe
    a. Turn off the instrument and lift the top cover of the analyzer.
    b. Open the sipper shield and gently move the sipper probe into an accessible position.
    c. Wipe the sipper probe with a lint-free cloth moistened with alcohol using a downward motion.
    d. Repeat step c. using DI water.
    e. Close the sipper shield, close the top cover and turn the power switch on.
3. Clean the flow path for the direct drain
    a. Turn the power switch off and lift the top cover of the analyzer.
    b. Using a syringe with flexible tubing attached, push approximately 100mL of DI water into the inlet of the reserve tank.
    c. Check to ensure the water flows freely through the drain tube. If it does not, inspect the drain tube for pinches and incorrect placement.

d. Close the top cover of the analyzer and turn power switch on.

C. Every 2 weeks

1. Clean rinse station
   a. Turn the power switch off and lift the top cover of the analyzer.
   b. Move the arm of the S/R probe to the far left, over the sampling area.
   c. Move the microbead mixer to a safe position.
   d. Open the sipper shield and move the sipper arm to the far right.
   e. Use a syringe with flexible tubing attached to remove water from both compartments of the rinse station for the microbead mixer.
   f. Use a cotton swab moistened first with alcohol then DI water to clean the rinse station of the microbead mixer.
   g. Using the syringe, refill the rinse station of the microbead mixer with DI water.
   h. Use a syringe filled with DI water to rinse the S/R probe.
   i. Use the syringe to remove the water from the rinse station for the microbead mixer.
   j. Refill the rinse station of the microbead mixer with DI water.
   k. Use a cotton swab moistened first with alcohol then DI water to clean the rinse station. for the sipper probe.
   l. Use a syringe filled with DI water to rinse the rinse station.
   m. Close the top cover and turn the power switch on.

D. Monthly

1. Perform liquid flow cleaning
   a. Turn the power switch off and lift the top cover of the analyzer.
   b. Empty the liquid waste container and rinse with DI water.
   c. Open the sipper shield and move the sipper arm to the far left.
   d. Remove the ProCell bottle.
   e. Place the SysClean adapter, with the USER label facing the back of the instrument into the system reagent compartment.
   f. Pour SysClean into the USER compartment of the adapter up to the ledge (approximately 9mL).
   g. Close the sipper shield and the top cover of the analyzer. Turn the power switch on.
   h. From the System Overview window, choose **Utility>Maintenance**.
   i. From the **Type** column, choose **Maintenance**.
   j. From the Maintenance Items, choose **Liquid Flow Cleaning>Select**.
   k. In the Liquid Flow Cleaning count field, enter "1" and press Start.
   l. When the procedure is complete, the system will return to Standby.
   m. When complete, turn the power switch off and lift the top cover.
   n. Remove the liquid waste container, rinse it with DI water, empty and return to instrument.
   o. Open the sipper shield and remove SysClean adapter. Rinse adapter with DI water.

p. Return ProCell bottle on instrument, close sipper shield, close top cover and turn power switch on.

E. As needed maintenance

Refer to the operator's manual for instructions to perform any as-needed maintenance.

PROCEDURE NOTES

Document all maintenance performed on CHEM.COBAS.2.2 Cobas e411 Maintenance Log.

REFERENCES

Roche Cobas E411 Operator's Manual, Version 3.0