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| Department: | Laboratory and Blood Bank (Hormone) | | |
| Document: | Internal Policy and Procedure | | |
| Title: | Handling and Operational Technique for COBAS e411 | | |
| Applies To: | All Laboratory Staff | | |
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1. PURPOSE:

- 1.1 This policy provides all the information about the handling and operational technique for COBAS e411.

2. DEFINITONS:

- 2.1 ECL (electrochemiluminescence): ECL is a process in which highly reactive species are generated from stable precursors at the surface of an electrode. These highly reactive species react with one another, producing light. The development of ECL immunoassays is based on the use of a ruthenium (II)-tris (bipyridyl) [Ru (bpy)] complex and tripropylamine (TPA).

3. POLICY:

- 3.1 The Roche Diagnostic cobas e411 Immunoassay System is a fully automated, random access, software-controlled system for immunoassay analysis. Three test principles are available on the system: competitive principle for extremely small analytics, sandwich principle (one or two steps) for larger analytics and a bridging principle to detect antibodies in the sample.
- 3.2 The cobas e411 automates the immunoassay reactions utilizing electrochemiluminescence (ECL).
- 3.3 The final chemiluminescent product is formed during the detection step. The chemiluminescent reactions that lead to the emission of light are initiated electrically by applying voltage to the immunological complexes that are attached to the streptavidin-coated micro particles.

4. PROCEDURE:

- 4.1 Turn front switch on analyser to OFF position before doing maintenance procedures in the morning.
- 4.2 Remove reagent compartment lid and reagent wheel to check for condensation inside.
- 4.3 Wipe out any moisture.
- 4.4 Replace wheel, replace lid.
- 4.5 Clean S/R probe with distilled H₂O on gauze, and then dry gauze. Use 70% Isopropanol when probe is visibly dirty.
- 4.6 Turn front switch to ON position. When analyser has returned to standby, proceed with the following:
 - 4.6.1 Each test reagent cartridge is displayed with # of tests and position #. Additional cartridges to be added should warm >45 minutes prior to loading.
 - 4.6.2 Check for sample tips and cups. Do not add to partial racks.
 - 4.6.3 Replace Pro Cell/Clean Cell if less than 20%. Move full bottles from left side to right and load new bottles on left.
 - 4.6.4 Empty waste containers.
 - 4.6.5 Check volume of System Water.
 - 4.6.6 Do a 'clear sample data' from the Overview screen. Note: Perform data backup weekly.
- 4.7 **Calibration:** Refer to "Celest calibration Instructions" for handling of calibrator.
 - 4.7.1 Confirm lot number by checking Calibration, Calibrator, and Test.
 - 4.7.2 If lot number is not on this screen, go to Install tab, insert card in slot and select BC Card Scan.
 - 4.7.3 Allow calibrator vials to warm ~15 minutes before loading.

- 4.7.4 Load on ring aligning the slight extension on the rim of the calibrator vial with the notch in the hole on the ring. Open caps to 90° angle.
- 4.7.5 Press START on keyboard. e411 will read barcodes on vials and perform calibration for that test.
- 4.8 **To Run QC:**
 - 4.8.1 (If running behind calibrators, leave a space open before inserting controls.) Allow calibrator vials to warm to room temperature before loading.
 - 4.8.2 Allow control cups to warm 15 minutes before loading. Replace ring with sample disk.
 - 4.8.3 Load control cups on ring. Manually program by selecting QC from Overview screen, then Control, Position Assignment, and select control and position, then assign (if we directly use the QC vial no need for assignment it will be identified by barcode).
 - 4.8.4 Controls are identified by letter and are poured into large Hitachi cups.
 - 4.8.5 Press START on right side of screen and START on the START screen.
 - 4.8.6 Be sure to unassigned positions for QC after running QC, so other samples may be run in those same positions. From Overview screen, select QC, Control, and Position Assignment; then, select control, position, and remove.
- 4.9 **Sample running:**
 - 4.9.1 Place cup(s) in sample disk, enter the position number and patient ID then choose required tests. Press START, and then START.
 - 4.9.2 To run a STAT sample, if e411 disk is currently sampling other specimens, touch Work Place, Test Selection, Stat (E), type in position #, and test(s). Place cup in proper position touch Save. Touch Stat mode on right side of screen, START and START. Return to home screen and Sample Tracking to make sure sample was programmed in as STAT.
 - 4.9.3 If disk is in S. Stop, samples can be added by starting at the STOP cup. Place new ones in sample disk, enter the position number and patient ID then choose required tests. Touch START and START.
- 4.10 **Printing results:** results are automatically printed (be sure that there is paper in the printer and ink is ok)

5. MATERIALS AND EQUIPMENT:

- 5.1 **Non-consumable materials:**
 - 5.1.1 COBAS e411 machine
 - 5.1.2 Computer terminal
- 5.2 **Consumable materials:**
 - 5.2.1 Calibrators.
 - 5.2.2 Controls.
 - 5.2.3 Serum / Plasma / Body fluids
 - 5.2.4 Distilled water
 - 5.2.5 Reagents
- 5.3 **Maintenance:**
 - 5.3.1 Refer to Cobas e411 for maintenance details and fulfil it and do marks on maintenance paper.

6. RESPONSIBILITIES:

- 6.1 Hormone shift on charge is responsible for maintenance, running calibration and control and routine samples.
- 6.2 All staff are responsible for running urgent cases (B.HCG and Troponin T).

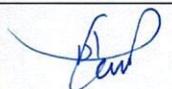
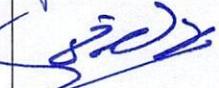
7. APPENDICES:

- 7.1 N/A

8. REFERENCES:

- 8.1 Roche Diagnostics cobas e411 System Operator's Manual

9. APPROVALS:

| | Name | Title | Signature | Date |
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