# CHEM.COBAS.2.0 Cobas e411 Operating Procedure

## STATEMENT OF PURPOSE

The Cobas e411 analyzer is an automated, random-access, multichannel analyzer for immunological analysis. It is designed for both quantitative and qualitative in vitro determination of a wide range of analytes by use of electrochemiliminescence (ECL) technology.

## SCOPE

The Cobas e411 and all of its components is the scope of this procedure.

## OWNERS

Technical Supervisor, St. Vincent Evansville

## RELATED DOCUMENTS

| | |
|---|---|
| CHEM.COBAS.2.1 | Cobas e411 Daily Maintenance |
| CHEM.COBAS.2.2 | Cobas e411 Maintenance Log |

## SPECIMEN

Refer to individual Cobas e411 assay procedures.

## REAGENTS

A. System reagents
   1. ProCell
      a. Used for conditioning of the electrodes, transport of assay reactant mixture, washing of the streptavidin-coated microparticles and signal generation.
      b. Storage and handling: Store at 15-25°C. **Avoid foam formation.**
      c. Stability
         i. Until the expiration date unopened at 15-25°C
         ii. Total of 72 hours open on the analyzers
         iii. 4 weeks on the analyzer alternating between open and closed (do not exceed 72 hours open in total)

d. Place bottles in the appropriate position on the analyzer at least 1 hour before use. Open cap. If the analyzer stands idle for more than 3 hours, the bottles should be closed (to avoid evaporation effect).

2. CleanCell
    a. Used for cleansing of the tubing system and measuring cell after every measurement and conditioning of the electrodes.
    b. Storage and handling: Store at 15-25°C. **Avoid foam formation.**
    c. Stability
        i. Until the expiration date unopened at 15-25°C
        ii. Total of 72 hours open on the analyzers
        iii. 4 weeks on the analyzer alternating between open and closed (do not exceed 72 hours open in total)

B. Assay reagents – Refer to individual Cobas e411 assay procedures.

**EQUIPMENT**

Cobas e411

**CALIBRATION**

A. Types of calibration
    1. Lot Calibration
        a. Performed on a new or expired lot.
        b. For a new lot, perform within 24hours of loading the reagent onto the instrument.
        c. If the lot calibration has expired, perform a lot calibration for the current lot on a new pack within the first 24 hours of loading on the instrument.
        d. Valid for all reagent packs of the same lot.
    2. Reagent pack calibration
        a. Performed when a reagent pack that has been on-board the analyzer more than 24 hours is calibrated.
        b. Calibration adjusts for changes in reagent activity over time.
        c. Calibration is used for only the single reagent pack.
        d. Valid until the expiration date.

B. Calibration procedure
    1. Determine if calibration is requested or calibration renewal is due
        a. Lot Calibration
            i. When instrument is in standby, observe the reagent rotor graphic on **System Overview.**
            ii. If the Cal (middle) portion of the segment is the new segment is yellow, a new lot of reagent was loaded. Calibration is automatically ordered on a

reagent pack of a new lot. The reagent pack must be calibrated before any results can be generated with that reagent pack.

iii. If the Cal (middle) portion of the segment is not yellow, touch the position segment for the new reagent pack(s) on the rotor graphic to display the reagent detail.
   1. Observe the **(L-Calib) recommended at** date.
   2. If the displayed date is the current date or a past date, the calibration should be performed.
   3. If the displayed date is in the future, determine if the reagent pack should be calibrated now or when a future reagent pack is loaded.

b. Reagent Pack Calibration
   i. Touch each position segment for existing reagent packs on the reagent rotor to display the reagent detail pop-up window
   ii. Observe the **(R-Calib) recommended at** date to determine if that reagent pack needs to be calibrated.
   iii. If the **(R-Calib) recommended at** date is blank, observe the **First Registration Date and Time**. If the current date is 7 or more days past the **First Registration Date and Time**, it is recommended that a calibration be performed on this reagent pack.
   iv. If the Reagent Calibration is due and there is an additional pack(s) of the same assay on board the analyzer, you must choose the specific reagent pack for calibration.

2. Select the reagent pack(s) to be calibrated as follows:
   a. Touch the **Calibration** button at the bottom of the System Overview screen.
   b. Touch the **Status** sub-tab.
   c. Touch (highlight) the line that lists the pack to be calibrated.
   d. Touch the **Full** button in the Method box.
   e. Touch the **Save** button.
3. Load calibrators in assigned positions in BLACK racks.
4. Load QC in assigned positions in GRAY racks.
5. Touch the global Start button to display the Start Conditions screen.
6. Touch the Start button to begin the run.
7. Review calibration and control reports for acceptability.

## QUALITY CONTROL

A. A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure LAB.GEN.QC.2.0 for specific details.
B. Request QC on current/standby reagent packs

1. Touch the **QC** button/tab
2. Touch the **Status** sub-tab
3. Touch (highlight) desired assay pack(s)
4. Touch the **Select** button
5. After all desired reagent packs are selected, touch the **Save** button

C. Load QC into assigned positions on gray rack
D. Select Run, Run
E. Review QC for acceptability

**PROCEDURE**

A. Power on analyzer and log on.
B. Verify analyzer is in stand-by.
C. Perform and document any maintenance needed. (See CHEM.COBAS.2.1 and CHEM.COBAS.2.2)
D. Print Reagent Load/Unload list
   1. Touch the **Reagent Load List** button the System Overview screen and press **OK**.
   2. Assemble reagents and allow to equilibrate to room temperature for a minimum of 45 minutes prior to loading on the analyzer.
   3. Reagent must maintain an upright position for best accuracy. If reagent has not been upright, allow to stand in upright position for a minimum of 24 hours to settle microbeads.
E. Load necessary reagent/dilution packs.
   1. Ensure that all reagent or dilution packs have been allowed to come to room temperature for a minimum of 45 minutes prior to loading on the analyzer.
      **NOTE: Do not mix reagent or diluent packs. No mixing prior to placing on the instrument is required.**
   2. Open the reagent rotor cover by turning the handle to the left until it reaches the open position and lift it clear.
   3. Open the reagent/diluent pack(s) lids fully and inspect contents for bubbles: remove any that are present. Inspect the lid of the microbead bottle (reagent packs only) for dried microbeads. Discard the reagent pack if dried microbeads are present.
   4. Close the lids to the first "stop" so they are closed to the atmosphere but not tightly closed.
   5. Load the reagent/diluent pack into any empty reagent rotor position. Ensure that the barcode on the white-capped bottle is facing outward and note the position(s) in which the new reagent pack was placed.
   6. Replace the reagent rotor cover and turn the handle to the right until it reaches the lock position.
   7. Touch the **Reagent Scan** button on the System Overview screen.
F. Sample Processing
   1. If running non-interfaced test(s), manually program patient samples in **Workplace>Test Selection** screen.
   2. Load sample racks

a. If running bar-coded samples, place barcode-labeled tubes into appropriate racks. The bar-codes should face toward the slotted side of the rack. If running non-barcode labeled tubes, place tubes in the rack with the barcode facing inward so that it will not be read.
b. Place racks on the input tray.

3. Initiate the run
    a. Touch the global **Start** button to display the start conditions screen
    b. Touch **Start** button to begin the run.
4. Monitor run and review results
    a. Touch the **Sample Tracking** button on the System Overview screen to monitor the run.
    b. Touch **Workplace>Data Review** to review patient results.
5. Print reports if necessary.
    a. Select (highlight) samples to be printed on **Workplace>Data Review**.
    b. Touch global **Print** button.
    c. Select (highlight) **Result Report** in the Workplace Items list.
    d. Choose desired print format, **Monitor or Report**.
    e. Touch **Print**.

## CALCULATIONS

See individual Cobas e411 Test Method Procedures

## REPORTING RESULTS

A. See normal and critical range limits in individual Cobas e411 Test Method Procedures.
B. Verify results in DI (if applicable and result does not auto-verify) or enter results manually in OEM.

## PROCEDURE NOTES

A. For telephone Technical Assistance: 1-800-428-2336.

## LIMITATIONS

A. See individual test method procedures for limitations.

**REFERENCES**

A. Cobas e411 analyzer Procedure Manual
B. Cobas e411 analyzer – rack, Best Practices – Detailed Daily Checklist for non-24hour operation, Document # 6154-01-0216, Version 1