



COAG.1500.2.0 SYSMEX CA-1500 LED CAL S

PRINCIPLE

The CA-1500 system is capable of a semi-automated calibration of the LED based detection unit. THE CA-CAL S reagent is used for the semi-automated adjustment of the scattered light detector. Calibrations are performed at predefined 90 day intervals.

OWNERS

Manager, Regional Hematology Laboratory

SPECIMEN

CA-CAL S

REAGENTS

- A. Dade 1500 Clean I Solution
 - 1. 5 ml clean I solution in a push vial placed in position E3.
 - 2. Stable until expiration date on bottle when stored at 2-8°C, or 30 days at room temperature.
 - 3. 24 hour expiration when on board analyzer.

- B. Clinical Laboratory Reagent Water (CLRW)
 - 1. Stable at room temperature until expiration date labeled on box.

- C. CA-CAL S
 - 1. Once opened CA-CAL S must be used within one day.
 - 2. Unopened CA-CAL S is stable at 2-8°C until expiration date on box and bottle label.
 - 3. Contains active ingredients.
 - a. Polystyrene Latex 0.01%
 - b. Sodium azide 0.05%

NOTE: Sodium azide can form explosive azides when contacting heavy metals. Dilute the product with plenty of water for disposal.

EQUIPMENT

- A. Sysmex CA-1500 Coagulation Analyzer and peripheral equipment.
 - 1. 4 ml sample cup
 - 2. Reaction tubes
 - 3. Sample plates
 - 4. Waste and rinse containers

QUALITY CONTROL

None



PROCEDURE

The calibration confirmation window appears 90 days after the previous LED calibration. The window will appear when the analyzer is turned off and on during daily maintenance if the calibration is due.

It's time to calibrate detector channels. Please execute LED Calibration.

NOTE: The CA-CAL S does not need to be done immediately when calibration window appears. The analyzer will continue to run. The LED calibration should be performed as soon as possible. This calibration will NOT interrupt analysis of specimens or quality control when the 90 day CA-CAL S is due. Normal analyzer operation should still be observed. However, the calibration may only be bypassed one time. The procedure must then be performed or the analyzer will not be available for use.

A. To perform LED Calibration:

1. From the Main Menu screen, press the [Special Menu] key.
2. Press the [Maintain] key
3. Press the [Calib. Lamp & LED] key.
4. Press the [Calib. LED] key.

NOTE: The last calibration date and a present channel status can be checked by pressing the [Detector Status] key.

5. Enter the Target Value of the CA-CAL S calibrator.
 - a. This value is found on the Table of Target Value sheet which is included the CA-CAL S box.
 - b. Enter the indicated value with the alphanumeric key, and press [Enter].
6. Set vial type for a 4 ml cup.
 - a. To change cup type press [Vial Type] key.
 - b. Move the cursor by pressing the arrow keys to the correct container to be selected, and press the [OK] key.
7. Check that CA Clean I is set and place CA-CAL S vial in the reagent rack position D1.

CAUTION: Use the adapter suitable for the container (4 ml cup) or the calibrator may not be correctly aspirated by the pipette and correct calibration may not be obtained.

8. Press the [Execute] key. Do not press QUIT in the numeric keypad otherwise the instrument will exit the CAL function.
9. Press the [OK] key.
 - a. A window showing detector numbers and status of the detectors appears once the LED calibration is started.



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- b. When the calibration is complete, the LED Calibration Updated Confirmation screen will appear.
 - c. Verify all channels have a status of ok.
 - d. If a channel has an error, proceed to step 10.
 - e. If all are ok press [SET]. The new adjustment value is saved and returns to LED Calibration screen.
 - f. Press [QUIT] key. The message window will appear asking to remove the calibrator from the reagent rack D1 and set former reagent.
 - g. Press [OK].
 - h. Press [RETURN] until the main menu appears.
10. When there is a channel with a calibration error, a window is displayed which shows channels that will NOT be available for specimen analysis if ok is selected. The analyzer will still perform testing, with slower turnaround time, as long as at least one channel has a status of ok.

PRESS [CANCEL]

If all the channels have errors and set is selected, the analyzer will not run any clotting assays. Press [QUIT].

Repeat the entire calibration process with fresh CA-CAL S.

CALIBRATIONS

None

REPORTING RESULTS

None

LIMITATIONS

- A. Never freeze the calibration product.
- B. Do not use an outdated product.
- C. Ensure that dust, refuse, or fungi do not get mixed into the product after opening.

INTERPRETATION

None

REFERENCES

- A. Sysmex Operators Manual, CA-1500 Automated Coagulation Analyzer. NO.461-2662-6. Revised October, 2003.
- B. Product Insert, Sysmex America, INC., Mundelein, IL, Revised June, 2003.
- C. Released Notes for Sysmex CA-1500 Sysmex Software Version 00-18, December, 2003, Manual Order NO:1 000 668.1103.



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