

Cascade® POC EQC Test Card

Helena Laboratories



REF 5818

RESULTS

The clotting time results for periodic testing of the EQC test card should fall within the reference ranges shown below. The analyzer will automatically report an error message if either the clotting time or the signal strength values are out of range. Acceptable ranges are encoded on the card.

EQC Test	Maximum error (sec)	% Error	Acceptable clotting time range (sec)
1	0.9	3.0	29.1 -30.9
2	2.7	3.0	87.3 -92.7
3	8.1	3.0	261.9 -278.1

The EQC test card checks three clotting time levels, and reports clotting time and signal strength values that correspond to 30-, 90-, and 270-second clotting times. The Signal Value fluctuates over time and with use of the card. A Signal Value equal to or greater than the Target Signal value indicates that the analyzer is operating properly. Target Signal values, by test level, can be viewed by following the steps listed above in Viewing Test Result Records.

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Leave the power switch in the OFF position while storing the analyzer.

- The Operator Identification Code and the Quality Control Lockout are optional features. Refer to the operator's manual if either of these features has been enabled.
- Operate the analyzer only at room temperatures between 18 and 32°C (64 and 90°F).
- Ensure that the analyzer is either plugged into an appropriate AC wall outlet or has a sufficiently charged battery.

VIEWING TEST RESULT RECORDS

The View Patient Records user function displays (and prints) EQC test records stored in the analyzer. Test records can be printed if the analyzer printer option is enabled (see Printing Test Records in Section 7.1.6.2 of the Operator's Manual.)

To view stored EQC test results:

1. From the Ready screen, press ENTER. The Select Function menu is displayed, showing available user functions.
2. From the Select Function menu, choose the View Patient Recs option. The VIEW PATIENT RECS option appears in uppercase characters when selected.
3. Press ENTER. The View By menu is displayed.
4. Choose the Test Name option. The TEST NAME option is displayed in uppercase characters when selected.
5. Press ENTER. The Select Test menu is displayed. This menu lists in alphabetical order all of the test types currently stored in analyzer memory.
6. Scroll up or down through the selections, using the up and down arrow keys, until EQC is displayed in uppercase characters. Press ENTER
7. The Target CT (clotting time) and Target Signal (S) for Level 3, the last test run, are displayed. Press ENTER to view actual test results.
8. Press EXIT to return to the Level 3 Target Results screen. Use the down arrow to view Level 2 Target Results, then press ENTER to view Level 2 Actual Results.
9. Press EXIT to return to the Level 2 Target Results screen. Use the down arrow to view Level 1 Target Results, then press ENTER to view Level 1 Actual Results.
10. Press EXIT two times to return to the Ready screen.

QUALITY CONTROL

Calibration: Operator calibration is not required. Calibration of both the analyzer and EQC card was performed at the time of manufacture.

Routine Quality Control: Each day of use, verify that the date and time displayed on the analyzer are correct. Reset if necessary. Refer to the operator's manual for detailed instructions.

The microprocessor in the analyzer automatically monitors the parameters necessary for accurate testing. If the analyzer detects an error during the performance of a test, it will display an error message. Refer to Section 10 of the operator's manual for details and an explanation of error messages.

REFERENCE VALUES

Samples of 10 different EQC test cards were tested on the analyzer for six days. The range of clotting times values is shown in the table below. These ranges are given for illustrative purposes only.

EQC Test	1	2	3
Mean (sec)	29.6	89.4	269.4
SD (sec)		0.24	0.33
CV(%)			0.81
0.23			0.37

Contents

1 EQC Test Card.

INTENDED USE

The Electronic Quality Control (EQC) Test Card is used with the Cascade POC analyzer to help ensure that the electronic components of the analyzer are working properly. It is intended for use as part of a daily quality control regimen. The EQC Test Card is intended for use as a supplement to commercially available quality control plasma, but not as its replacement.

The EQC Test Card is a reusable quality control test card intended for repeated use. It can be used for up to six months after first use.

NOTE: The EQC Card is designed for use with only Cascade POC analyzer, Version 4.58 or higher.

SUMMARY

The Joint Commission on Accreditation of Healthcare Organizations recommends that medical and laboratory instrumentation be enrolled in a quality assurance program that adequately maintains the equipment at an accurate and reliable level of performance. This program should include keeping accurate records of instrument quality maintenance.

Routine quality control testing and tracking are part of a comprehensive quality assurance program. Cascade POC products make routine quality control convenient and affordable. It is recommended that once during each shift the analyzer is used, three levels of quality control checks be performed on the analyzer, using the EQC Test Card, to assure optimum analyzer performance. To supplement the EQC, two levels of control plasma should be run periodically as a method of assuring the accuracy of specific thrombosis test results.

PRINCIPLE

The EQC test card is similar in appearance to the Cascade POC reagent test cards. The reaction area of the EQC card is composed of a magnetic material. No sample is added to the card. A magnetically encoded stripe on the back of the EQC card contains lot-specific information, such as test type, lot number, and calibration parameters. The analyzer reads this information upon initiation of a test.

The analyzer produces an oscillation magnetic field, using an electromagnet with an alternating field and a thin permanent magnet mounted at a right angle above it. As soon as the EQC Test Card is inserted into the analyzer, the test begins. The reaction chamber of the card is illuminated with light from a light emitting diode mounted adjacent to a light detector. This light reflects off the test card surface and is measured. The electromagnet cycles off and on once every second. Particles in the magnetic film stand up when the magnet is on, causing more light to reflect off the card, and fall down when it is off, causing less light to reflect off the card. This particle movement produces the signal.

Information encoded on the EQC test card turns the electromagnet off at 30-, 90-, and 270-seconds. The analyzer then reports clotting time and signal strengths at these time intervals.

CARD COMPONENTS

For in vitro diagnostic use only.

The EQC Test Card contains a magnetic film placed in the reaction chamber area.

CAUTION: Exposure of the test card at any time to magnetic objects or fields may corrupt the encoded information on the card and prevent the analyzer from starting the test.

CAUTION! POTENTIAL BIOHAZARD: Once used in the analyzer, the EQC Test Card has been exposed to biohazardous materials. Handle according to normal procedures for biohazards. When necessary to wipe off the EQC Test Card, use a soft disposable wipe and warm water. Do not use chlorine or solvents to clean the card.

Storage: Store the EQC Test Card at a temperature of 15 to 30°C (59–86°F). It is recommended that the card be stored in the case provided. Store away from strong sunlight and magnetic fields. The EQC Test Card may be used up to six months after the date of first use. Using a permanent marker pen, record the expiration date in the space provided on the case label and the back of the card.

SPECIMEN COLLECTION AND PREPARATION

No specimen is used with the EQC Test Card.

PROCEDURE

Materials Required But Not Provided:

- Cascade POC analyzer (software version 4.58 or higher)
- Cascade POC Operator's Manual

STEP-BY-STEP

1. At the Ready screen, pass the EQC Test Card from left to right through the card reader as described in Section 5 of the Operator's Manual.
2. Insert the EQC Test Card into the analyzer card holder when instructed to do so. The analyzer warms the card prior to performing the EQC tests.
3. When the card is properly warmed, the EQC test automatically begins. Test in Progress is displayed on the screen.
4. At the end of the test, Level 1 clotting time (CT) and signal strength (Signal) are displayed on the screen. The CT results represent the clotting time returned by the algorithm analyzing the AC signal collected from the EQC card.
5. Press ENTER to obtain Level 2. At the end of the second test, the clotting time and signal strength are displayed on the screen.
6. Press ENTER to continue testing and obtain Level 3 clotting time and signal strength.
7. Press ENTER. If the tests pass, message is displayed: "EQC TEST, TEST PASSED, please remove card".
8. If the "EQC TEST FAIL" message appears during any of the three levels, press any key as instructed. Remove the EQC Test Card when instructed to do so.
 - a. Repeat the test.
 - b. If results continue to fall out of range, contact a supervisor qualified to resolve the problem or contact your analyzer distributor.

Procedural Notes

- The analyzer is preset to provide a constant temperature of 37 ± 0.3°C (98.6 ± 0.5°F) and will automatically prewarm the test card. All other calibrations necessary are magnetically encoded on each test card. Refer to the operator's manual for details.
- To maintain a fully charged battery, leave the unit plugged into its power supply which is, in turn, plugged into an AC outlet.