# Cascade<sup>®</sup> Abrazo<sup>®</sup> Electronic QC (EQC) Test Card

#### REF Cat. No. 5848



## 1 EQC Test Card

## INTENDED USE

The Electronic Quality Control (EQC) Test Card is used with the Cascade Abrazo 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 by trained medical professionals. The EQC Test Card is intended to supplement the quality control plasma but not as its replacement.

The EQC Test Card is a reusable quality control test card intended for repeated use on one instrument. It can be used for up to 600 tests or six months after first use. Place the EQC Card into the EQC Renew Sleeve for storage after each test run. If one card is used on multiple instruments, the total usage must be limited to 600 EQC runs of all 3 levels.

#### SUMMARY

Routine quality control testing and tracking are part of a comprehensive quality assurance program. Abrazo 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. Two levels of control plasma should be run periodically as a method of assuring the accuracy of specific thrombosis test results.

#### PRINCIPI F

The EQC test card is similar in appearance to the Abrazo reagent test cards. The reaction area on the front of the EQC card is composed of a magnetic material. No sample is added to the card.

A 2D barcode 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.

The EQC Test Card must be stored in a protective sleeve designed to evenly disperse the magnetic particles in the EQC card. This helps prevent signal strength failures and allows for an accurate assessment of the electromagnet and optics in the instrument. The EQC Renew Sleeve is not disposable and can be used with each new lot of EQC cards. CARD COMPONENTS

## For in vitro diagnostic use only.

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

CAUTION! POTENTIAL BIOHAZARD: Once used in the analyzer, the EQC Test Card has been exposed Ø to biohazardous materials. Handle the EQC card and the Renew Sleeve 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 EQC Renew Sleeve or the Docking Station after each test cycle. 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 date of first use and 6 months from that date as the expiration date in the space provided on 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 Abrazo analyzer- Cat. No. 5710
- Cascade Abrazo Operator's Manual
- Cascade EQC Renew Sleeve Cat. No. 5849

#### STEP-BY-STEP

- 1. At the MAIN MENU screen, press the QC TEST button. The QC TYPE screen appears with the two types of QC tests available
- 2 Press the EQC button. The ABRAZO prompts the user to scan the barcode on the back of the EQC card. When prompted, insert the EQC test card. The analyzer warms the card before performing the EQC test.
- 3.
- An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed. At the end of this test, Result 1 clotting time count (CT) and the signal strength are displayed on the screen. The 5.
- CT results represent the clotting time returned by the algorithm analyzing the AC signal collected from the EQC test card. After the RESULT SCREEN is displayed, the analyzer will automatically proceed to the next test level.
- The EQC TEST IN PROGRESS screen displays. At the end of this test, Result 2 EQC clotting time and signal strength are displayed. The analyzer will continue to the next test level. At the end of this test, Result 3 EQC clotting time and signal strength are displayed. If the test was valid, it will display EQC PASSED on the screen. Click the ACCEPT RESULTS button to accept the results. 7
- The unit prompts the user to remove the EQC card and returns to the Main Menu 9
- If any of the three tests fails, place the card into the EQC Renew Sleeve or Docking Station and then repeat the EQC test. If the test results continue to fall out of range, contact a supervisor qualified to resolve the problem, or contact your analyzer distributor.
- 10. Return the EQC to the sleeve for storage after each test cycle

#### 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 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.
- The Operator Identification 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 15 to 32°C (59 to 90°F).

#### VIEWING EQC RESULT RECORDS

- From the MAIN MENU screen, press DATA REVIEW. From the DATA REVIEW screen, press EQC DATA. 2
- The EQC HISTORY screen appears listing all results starting with the most recent test. If this is the first time use, the screen will be empty. If not, the data will be listed by the date and time of the test.
- 4. Each time the EQC card is run, 3 levels of values are generated along with the date/time stamp.

- 5. Using the up and down arrows, find the desired QC test and select it. The EQC level number, lot number and date and time are shown full screen
- 6. Pressing either the back arrow or the additional data button returns the unit to the EQC history 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.

#### PERFORMANCE CHARACTERISTICS

Four EQC cards were tested on 4 Abrazo units 1 time a day for 20 days following the CLSI Guideline EP05-A2.<sup>2</sup> The range of clotting times values is shown in the table below. These ranges are given for illustrative purposes only.

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Level	1	2	3	
Mean (sec)	30.3	90.4	270.4	
SD (sec)	0.3	0.3	0.3	
CV(%)	1.0	0.3	0.1	

#### 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	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 card checks three clotting time levels, 30, 90, and 270 seconds and reports clotting time. An internal signal is generated by the EQC test card during testing. An EQC signal greater than or equal to the Target Signal Value encoded in the EQC test barcode indicates the Cascade Abrazo is operating properly. At the completion of the EQC test, a Pass or Fail condition is reported and the clotting time for the last completed level is displayed.

#### BIBLIOGRAPHY

- Clinical And Laboratory Standards Institute. Point-Of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline. CLSI Document POCT4-A2, Vol. 26, No. 30, 2006.
- Clinical and Laboratory and Standards Institute: Evaluation of Precision Performance of Quantitative Measurement 2. Methods: Approved Guideline. CLSI Document EP05-A2, 2004.

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Pro 211 7/22(3)

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