English

Cascade® Abrazo® c-ACT-LR Test Cards

REF **Cat. No. 5701**

CE

Contents
50 c-ACT-LR test cards, individually sealed in foil pouches

INTENDED USE
The Cascade Abrazo c-ACT-LR test cards are activated clotting time tests to be used with the Cascade Abrazo analyzer and are intended to monitor the effect of low to moderate heparin on coagulation in fresh whole blood.
The Abrazo c-ACT-LR test cards, together with the Abrazo analyzer, are especially suited for use by trained medical personnel in decentralized areas of testing near the site of patient care such as surgical suites, intensive care units, and other areas where patients are treated with low to moderate levels of heparin.

SUMMARY
Heparin is currently the major intravenous drug used to control blood coagulation. It is used to control or prevent clotting in patients with thromboembolic diseases such as deep venous thrombosis and acute myocardial infarction. It is also used to maintain an anticoagulated state in patients undergoing percutaneous transluminal coronary angioplasty, coronary bypass surgery, and other invasive surgical procedures. Heparin is composed of a mixture of glycosaminoglycan molecules of various sizes, and it exists naturally in various body tissues. Heparin acts as an anticlotting agent by combining with Antithrombin (AT, previously Antithrombin III) in the blood to accelerate the rate of neutralization of various serine proteases (clotting factors), especially thrombin and Xa, that participate in the coagulation cascade. Although it is widely used, heparin is responsible for more iatrogenic complications than any other drug. The major side effect is bleeding.[1] For this reason and because of the variability of patient response to the dose of heparin,[2,3] many attempts have been made to develop and improve the monitoring of heparin therapy.
The c-ACT-LR test cards together with the Abrazo analyzer are intended for rapid monitoring of the effect of heparin levels up to 3.0 U/mL on coagulation. Precise pipetting of reagent or sample and manual timing skills are not a factor with the c-ACT-LR test card. Many of the variables encountered with sample transport and handling are avoided although testing of fresh whole blood must be done immediately to obtain accurate results.

PRINCIPLE
The Cascade Abrazo c-ACT-LR test consists of the contact activation of whole blood with the subsequent measurement of the time for clot formation.
The c-ACT-LR test may be used as a sensitive means of monitoring the effect of heparin on clotting in whole blood samples. Generally, in the presence of adequate levels of Antithrombin and clotting factors, increasing heparin concentration results in progressive prolongation of the c-ACT-LR result.

REAGENT
For in vitro diagnostic use only.

Components	Storage	Stability
Calcium chloride, celite, ellagic acid activator, modifiers, stabilizers, and paramagnetic iron oxide particles	2–8°C (36–46°F)	Unopened – until expiration date on the pouch label
	20–25°C (68–77°F)	or Unopened – 2 weeks

Any pouches not kept refrigerated should be dated and used within 2 weeks.

CAUTION: Exposure of the test cards at any time to magnetic objects or fields (for example, an MRI instrument) can potentially prevent the analyzer from performing the test properly.

SPECIMEN COLLECTION AND PREPARATION
The c-ACT-LR test cards may be used with fresh whole blood collected according to CLSI Guidelines H03-A6[4] and H11-A4[5]. For indwelling catheters, the line should be flushed with 5 mL saline; separate, single-use syringes should be used to collect at least 5 mL or 6 dead space volumes of blood (to be discarded) prior to collection of blood specimens for testing, to minimize effects of hemodilution (e.g., crystalloid fluid in line) or heparin in solutions used for flushing indwelling lines. Institutional polices and procedures should be followed.[6] Fresh whole blood collected into a plastic syringe should be used immediately.[6]

CAUTION: Heparinized syringes are not appropriate vehicles for the c-ACT-LR Test.

CAUTION: When handling blood specimens, all samples should be treated as biohazards.[8,9]

PROCEDURE
Materials provided: The following materials are contained in the Abrazo c-ACT-LR Test Kit (Cat. No. 5701).

50 Cascade Abrazo c-ACT-LR Test Cards

Materials provided but not contained in the kit:

Item	Cat. No.
Cascade Abrazo Analyzer	5710
Cascade Abrazo Electronic QC (EQC) Test Card	5848
Cascade Abrazo c-ACT-LR Level 1 Control	5727
Cascade Abrazo c-ACT-LR Level 2 Control	5728

Materials Required but not provided:
- Blood sampling materials such as venipuncture needles, syringes, alcohol swabs
- Sample transfer devices (pipettes or droppers) capable of delivering approximately 30 to 35 µL

STEP BY STEP
1. Refer to the Abrazo Operator's manual for appropriate analyte set up procedures.
2. Equilibrate test cards at room temperature (15 to 25°C, or 59 to 77°F) for a minimum of 15 minutes before removing from the foil pouch.
   CAUTION: The test card must be used within 15 minutes after the pouch is opened. Pouches of cards should not be repeatedly warmed and returned to the refrigerator.
3. Select patient test from main menu on Abrazo. Remove the test card from its foil pouch and hold it backwards with the barcode facing the Abrazo, approximately 6 to 8 inches from the Abrazo.
4. Tilt the card backwards slightly (approx. 15 degrees) and scan the encoded 2D barcode in the middle of the card. The analyzer interprets the encoded information on the test card and display prompts for each step of the procedure.
5. When prompted, place the test card in the analyzer, and allow to warm. Once the card is warmed, the Abrazo starts a countdown for the sample addition.
   CAUTION: The Abrazo will only perform tests on test cards and sample types that have been entered into the instrument's setup menu.
6. Holding the sample transfer device at least one inch above the sample well (colored circle) on the test card, add 30 to 35 µL of free-falling sample. **NOTE:** Do not allow the transfer device nor the hanging sample drop to contact the test card when applying the sample. Sample placement automatically initiates testing.
7. At the end of the test, confirm that the test was performed with the analyzer set to the appropriate sample type. The sample type is displayed along with the result at the end of the test.
8. When the card is removed from the analyzer at the end of each test, ensure that the entire reaction chamber was filled with sample. If an inadequate amount of sample was added to the card, repeat the test, using a fresh card.
9. After testing is complete, inspect the test card. Refer to the Operator Manual for images of the test card for comparison.
10. Dispose of the test card and other contaminated items in a manner approved for biohazardous material.[7-9]

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 before prompting the user to apply the sample drop. 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 ambient temperatures between 15 to 32°C (59 to 89.6°F).
- Ensure that the sealed pouch containing a test card has reached room temperature and that the analyzer is either plugged into an appropriate AC wall outlet or has a sufficiently charged battery.
- Collect the sample as described in Specimen Collection and Preparation.
- After the test card is inserted into the Abrazo, the card should not be touched until the test has been completed.

QUALITY CONTROL
Calibration: Operator calibration is not required. Calibration of both the analyzer and test cards was performed at the time of manufacture.
Daily quality control (QC) is good laboratory practice and is required by most states in the U.S. and the Clinical Laboratory Improvement Amendment, 1988 (CLIA '88). Quality control procedures are part of an overall quality assurance program to ensure the accuracy and reliability of patient results and reports. Monitoring the results of QC analyses can alert you to possible system performance problems. Healthcare professionals should follow proper local and national guidelines for quality control and check with appropriate licensing/accrediting bodies to ensure that QC programs meet established standards. Participation in Proficiency Survey programs allows for the comparison with systems in other laboratories and may help identify possible errors not detected by intra-laboratory QC testing alone.
There are two types of quality control that may be used on the Cascade Abrazo: Electronic Quality Control (EQC Test Card) and plasma controls.
The EQC Test Card ensures that the electronic components of the Cascade Abrazo analyzer are working properly. The purpose of the EQC Test Card is to offer a simple and economic alternative to the daily use of Cascade Abrazo test cards and plasma controls. However, the EQC test card is **not** intended to permanently replace plasma controls.
At least two levels of EQC quality control must be performed every 8 hours of operation when patient samples are tested. It is imperative that, at a minimum, plasma controls are tested in the following situations:
- With each new box of test cards or at least once per week
- With each new shipment of test cards
- With each new lot number of test cards
- Whenever improper storage or handling of test cards is suspected
- Whenever patient results appear abnormally high or low

This testing is in addition to the daily EQC testing. For more detailed information about quality control for the Cascade Abrazo, refer to the Cascade Abrazo Operator's Manual, the EQC test card package inserts, or contact your local authorized distributor.

REFERENCE VALUES
A total of 105 fresh whole blood samples were collected from 105 patients including males and females, ranging from 23 to 87 years, undergoing interventional cardiac procedures, ECMO (Extracorporeal Membrane Oxygenation), and hemodialysis. Preheparinized samples were tested and resulted in a reference range of 111 to 164 seconds. These ranges should be used as a guideline only. Operators should establish their own normal ranges, based on their own population of normal individuals.[6,11]
Individual c-ACT-LR clotting responses to heparin depend on several factors and can vary considerably. In general, as heparin concentration is increased in the presence of Antithrombin, c-ACT-LR clotting times will be progressively long.

RESULTS
The Abrazo c-ACT-LR test reporting units are in seconds. The results are displayed upon test completion. The Abrazo c-ACT-LR test card limits are 70 and 500 seconds. Verify results <70 seconds and > 500 seconds by repeat testing.
If a test result appears inconsistent with the patient's clinical presentation, the result should be verified by testing a fresh sample or evaluated using an alternative diagnostic method.

LIMITATIONS
The c-ACT-LR has not been evaluated with low molecular weight heparin (LMWH). Test sensitivity to factor deficiencies has not been verified. *In vitro* studies indicate c-ACT-LR results are affected by hemodilution. Blood dilution produced prolonged c-ACT-LR results. The use of c-ACT-LR during cardiac bypass should be limited to before bypass and after heparin reversal.

Recommended specimen handling procedures should be strictly followed.
Whole blood samples that are not tested immediately may produce erratic results. When performing a c-ACT-LR test to monitor patients for heparin, avoid handling samples in a manner that could induce the release of PF4 from platelets.[6] This includes traumatic collection, refrigeration, or delay in testing or processing.

INTERFERENCES

The presence of oxalate, EDTA or any additive other than sodium citrate can interfere with the test. Hemolysis should not affect the results; however, it is often an indication of poor specimen quality. The Cascade Abrazo c-ACT-LR card uses Celite as an activator, therefore, the presence of aprotinin may result in prolonged clotting times in patients receiving heparin.[13] The following table lists those factors that do not normally interfere with the c-ACT-LR test:

Factors	Concentration	Factors	Concentration
Hespan	≤ 30%		
Fibrinogen	< 30 mg/dL		
Hematocrit	10–60%	Nitroglycerin	≤ 1000 ng/mL
Bilirubin	0-20 mg/dL		

PERFORMANCE CHARACTERISTICS

SPECIFICITY: Studies show that in the presence of adequate levels of Antithrombin, the c-ACT-LR test is sensitive to the presence of unfractionated heparin. The c-ACT-LR test is sensitive to heparin with concentrations of up to 3.0 U/mL.

PRECISION: The precision studies were performed using three lots of Cascade Abrazo c-ACT-LR cards and one lot each of Cascade Abrazo c-ACT-LR controls Level 1 and Level 2. The studies were performed by three non-laboratorian (POC) operators at a single site across 6 Cascade Abrazo analyzers over a period of 20 days. Each operator performed 2 runs per day, 2 tests per run on each lot of Abrazo c-ACT-LR test cards.

Within-run, between run, and between day Precision*
N=240

	Grand	within run		between run		between day		total	
c-ACT-LR	mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	121.3	7.8	6.4	3.9	3.2	0.0	0.0	8.7	7.2
Level 2	275.3	13.2	4.8	6.5	2.4	4.9	1.8	15.5	5.6

Lot to Lot Precision*
N=80

Lot Number	1			2			3		
Sample	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Level 1 Control	119	8.3	7.0	129	6.8	5.3	127	7.7	6.0
Level 2 Control	275	15.3	5.6	281	12.3	4.4	270	13.8	5.1

Operator to Operator Precision*
N=80

	Operator 1			Operator 2			Operator 3		
Sample	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Level 1 Control	119	8.3	7.0	120	7.5	6.3	125	8.2	6.6
Level 2 Control	275	15.3	5.6	279	15.7	5.6	272	14.9	5.5

*Precision studies were performed according to EP5-A2.[12]

COMPARISON: Clinical studies were conducted using fresh whole blood samples collected from patients undergoing interventional cardiac procedures before, following heparinization, and post-procedure prior to sheath pull. The Abrazo c-ACT-LR test was compared to a commercially available activated clotting time (ACT). Comparisons of 309 whole blood samples gave correlation coefficients of 0.88 for the c-ACT-LR compared to predicate ACT.

Clinical studies were conducted using fresh whole blood samples collected from 18 patients, ranging in age from 5 days to 72 years old, undergoing Extracorporeal Membrane Oxygenation (ECMO). Comparisons of 314 samples with a significance level set to $p = 0.05$ yielded a p value of 0.585 demonstrating no statistical difference between the Abrazo c-ACT-LR and the predicate.

Comparison
N=309
R=0.83

Extracorporeal Membrane Oxygenation

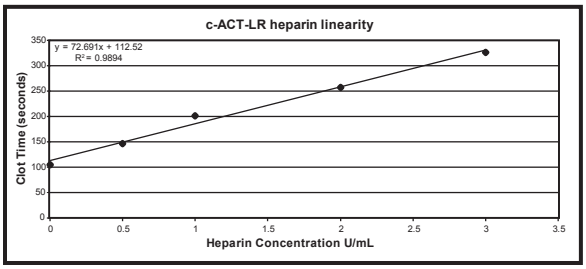
Patients	18
Samples	314
p significance level	0.05
p value	0.585
age ranges	5 days to 72 years

HEPARIN RESPONSE AND LINEARITY

The Abrazo c-ACT-LR cards were tested for heparin response with fresh whole blood to which porcine unfractionated heparin had been added. The linearity of the heparin response was evaluated by CLSI Guideline EP6-A. The data support the claim of linear response from 0.5 to 3 units/mL heparin. Testing was performed on three instruments by a single operator on a single day.

Heparin Linearity with the Abrazo c-ACT-LR Test

Heparin					
U/mL	0	0.5	1.0	2.0	3.0
	96	145	193	274	326
	114	140	190	248	344
	103	155	219	248	309
Mean	104	147	201	257	326
Mean SE	4.6	3.7	8.0	7.5	8.8
SD	9.3	7.4	16.0	14.9	17.5
CV	8.9	5.1	8.0	5.8	5.4



Fresh Whole Blood

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