English

Cascade® Abrazo® c-ACT Controls

REF 5737, 5738

CE

Contents

Cat. No. 5737 Level 1 - 10 x 0.5 mL vials

Cat. No. 5738 Level 2 - 10 x 0.5 mL vials

Intended Use

The Cascade Abrazo c-ACT assayed controls are intended for use with the Cascade Abrazo analyzer and c-ACT test cards to provide a method for quality control of the system. The assayed controls produce clotting times that must be within accepted, standard ranges to indicate that the analyzer and test cards are functioning accurately, and thereby ensure accuracy of the c-ACT test card results. These controls can also be used to determine system (analyzer and c-ACT test cards) precision.

SUMMARY

Two levels of control plasma are recommended to ensure the accuracy of the c-ACT test results. Level 1 provides a sample that will clot within the time range expected for a normal human sample. Level 2 mimics a sample from an individual receiving heparin in concentrations greater than 1 U/mL and will exhibit a prolonged clotting time.

REAGENTS

For *in vitro* diagnostic use only.

Level	Volume	Ingredients	Storage	Stability
1	0.5 mL	Lyophilized preparation of human plasma and an inert bulking agent. Diluent prepared with deionized water and an antifoam reagent.	2–8°C (36–46°F)	Unreconstituted – until the expiration date on the vial label
2	0.5 mL	Lyophilized preparation of human plasma, heparin, and an inert bulking agent. Diluent prepared with deionized water and an antifoam reagent.	2–8°C (36–46°F)	Unreconstituted – until the expiration date on the vial label

CAUTION: The reconstituted control is not stable. This preparation must be used within one minute after crushing the glass ampule, since the clotting reaction begins *immediately* upon mixing the diluent with the plasma. Clotting times increase with successive drops of the control suspension; therefore, use only one ampule per test card.

POTENTIAL BIOHAZARD: The controls are of human source material and should be treated as potentially infectious. Each donor unit used in the preparation of this product has been tested and found to be non-reactive for antibodies to HIV 1/2, HCV, and has tested negative for HBsAg. Because no known test method can offer complete assurance that infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices, using appropriate precautions.[1-4]

PRODUCT INTEGRITY: Broken or cracked glass ampules in nonreconstituted vials of controls may cause erroneous results. Diluent should be clear and colorless.

NOTE: Protective sleeve must be used to reconstitute and dispense the control material to avoid contact with biohazardous material.

PROCEDURE

Materials provided: The following materials are contained in the Abrazo c-ACT Control Kits.

Item	Cat. No.
Cascade Abrazo c-ACT Level 1 Control (10 vials)	5737
Cascade Abrazo c-ACT Level 2 Control (10 vials)	5738

Materials provided but not contained in the kit:

Item	Cat. No.
Cascade Abrazo Analyzer	5710
Cascade Abrazo c-ACT Test Cards	5724
Cascade Abrazo Electronic QC (EQC) Test Card	5848

STEP-BY-STEP

Equilibrate c-ACT controls and test cards at room temperature (20 to 25°C, or 68 to 77°F) for 15 minutes before use. For c-ACT test card instructions, refer to the c-ACT package insert.

WARNING: Do not reconstitute the control plasma until the test card has been warmed in the analyzer. Reconstituting the control plasma before warming the test card can cause erroneous results. The reconstituted control should be used immediately (within one minute).

1. From the **MAIN MENU**, select **QC TEST** option.
2. Then select **LIQUID QC**. The unit will prompt the user to scan the test card barcode.
3. Place the test card in the analyzer and allow to warm.
4. The Abrazo prompts the user for the plasma control barcode.
5. Reconstitute the control plasma as follows:
   a. Remove the shrink wrap from the plasma control.
   b. Place the control vial in the protective sleeve.
   c. Hold the vial in the protective sleeve and firmly bend the vial over the edge of a table top one or two times until the inner glass ampule is completely crushed.
   d. Remove the vial from the sleeve and shake it vigorously 20 times or until no clumps of lyophilized plasma are visible. **WARNING:** Not following manufacturer's reconstitution procedures may lead to skin punctures and exposure to biohazards.
   e. Remove the colored cap exposing the dropper tip.
   f. Replace the vial in the protective sleeve prior to dispensing the control material.
6. Immediately dispense **three (3) waste drops** of reconstituted control into a container approved for biohazardous material to clear the vial filter.
7. Holding the control vial at least one inch above the sample well on the test card, add one free falling drop of control. NOTE: Do not allow the control vial nor the hanging control drop to contact the test card when applying the control.
8. Sample placement automatically initiates testing. Results should be within the assay ranges given for each lot of control.
9. Dispose of the control vial and the test card in a manner approved for biohazardous material.

QUALITY CONTROL

Daily quality control (QC) is a 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 the QC programs meet established standards.[5]

There are two types of quality control available for use 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. EQC quality control must be performed every 8 hours of operation when patient samples are tested.

It is imperative that, at a minimum, Level 1 and 2 plasma controls are tested:

- 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 or controls
- Whenever improper storage or handling of test cards is suspected
- Whenever patient results appear abnormally high or low

Each facility should verify the assay ranges for each level of control. When changing the lot number of cards or controls, the user should be able to obtain mean values within the manufacturer's assay range.

Interpretation of Quality Control Results: If the results fail to fall within assayed ranges, verify that the sample type chosen was "CONTROL PLASMA" and repeat with a new control vial. If the results continue to fall outside the assayed range, do not report any patient test results before contacting a supervisor qualified to resolve the problem.

LIMITATIONS

Variations in technique and ambient temperature may alter performance characteristics. It is important to follow the STEP BY STEP instructions in this package insert. The assayed ranges are only for c-ACT controls with the c-ACT test cards, and only when tested on the Cascade Abrazo analyzer within 1 minute of reconstitution.

PERFORMANCE CHARACTERISTICS

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

Within-run Precision*

N= 80

c-ACT	Grand mean	within run		between run		between day		total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	148	10.5	7.1	0.0	0.0	2.1	1.4	10.7	7.2
Level 2	478	14.2	3.0	0.0	0.0	0.0	0.0	14.2	3.0

Lot to Lot Precision*

N= 80

Lot Number	1			2			3		
Sample	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
Level 1 Control	138	14.0	10.2	125	12.0	9.5	148	10.7	7.2
Level 2 Control	492	13.2	2.7	498	13.1	2.6	478	14.2	3.0

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	138	13.7	9.9	136	14.5	10.7	135	12.2	9.0
Level 2 Control	488	13.2	2.7	490	13.5	2.8	490	16.0	3.3

*Precision studies were performed according to EP05-A2.[6]

References

RÉFÉRENCES/LITERATUR/RIFERIMENTI/REFERENCIAS

1. Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR, 1988; 37: 377–82, 387–8.
2. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline. CLSI Document M29-A3: Vol. 25 No. 10, 2005.
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910.1030.
4. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington [HHS Publication No. (CDC) 93-8395] 1993.
5. Clinical and Laboratory Standards Institute. Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline. CLSI Document POCT4-A2, Vol. 26 No. 30, 2006.
6. Clinical and Laboratory and Standards Institute: Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline. CLSI Document EP05-A2, 2004.

For Sales, Technical and Order Information and Service Assistance, call 800-231-5663 toll free.

Helena Laboratories
1530 Lindbergh Drive
Beaumont, TX 77707 USA

HELENA LABORATORIES
Beaumont, Texas USA 77707

Form 399-032
5/22(4)

Shaded areas indicate that text has been modified, added or deleted.