

Cascade® POC PT-C Controls

REF 5841, 5871



Contents

Cat. No. 5841 Level 1 - 25 x 1mL vials

Cat. No. 5871 Level 2 - 25 x 1mL vials

Intended Use

The Cascade POC PT-C controls are intended for use with the Cascade POC analyzer and PT-C test cards to provide a method for quality control of the system. The 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 PT-C test card results. These controls can also be used to determine system (analyzer and PT-C test cards) precision.

SUMMARY

Two levels of control plasma are recommended to ensure the accuracy of the PT-C 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 with a deficiency in extrinsic coagulation factors and will exhibit a prolonged clotting time.

REAGENTS

For *in vitro* diagnostic use only.

Level	Volume	Ingredients	Storage	Stability
1	1 mL	Lyophilized preparation of human plasma and an inert bulking agent. Diluent prepared with deionized water, an antimicrobial agent, and an antifoam reagent.	2–8°C (36–46°F) 20–25°C (68–77°F)	Unreconstituted – until the expiration date on the vial label or Unreconstituted – 2 weeks or Reconstituted – 5 minutes
2	1 mL	Lyophilized preparation of human plasma, treated to decrease clotting factor levels, and an inert bulking agent. Diluent prepared with deionized water, an antimicrobial agent, and an antifoam reagent.	2–8°C (36–46°F) 20–25°C (68–77°F)	Unreconstituted – until the expiration date on the vial label or Unreconstituted – 2 weeks or Reconstituted – 5 minutes

CAUTION: The reconstituted control is stable for 5 minutes at room temperature.

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^{1,4}.

PRODUCT INTEGRITY: Broken or cracked glass ampules in nonreconstituted vials of controls may cause unexpected 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 Required But Not Provided:

- Cascade POC analyzer
- Cascade POC PT-C Test Cards

STEP-BY-STEP

Equilibrate PT-C controls and test cards at room temperature (20 to 25°C, or 68 to 77°F) before use. For PT-C test card instructions, refer to the PT-C 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 is stable for 5 minutes at room temperature.

1. Place the test card in the analyzer and allow to warm.
2. Select **CONTROL PLASMA** when prompted for the sample type.
3. Reconstitute the control plasma as follows:
 - a. Place the control vial in the protective sleeve.

- b. 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.
 - c. Remove the vial from the sleeve and shake it vigorously 20 times or until no clumps of lyophilized plasma are visible.
 - d. Remove the shrink wrap and colored cap exposing the dropper tip.
 - e. Replace the vial in the protective sleeve prior to dispensing the control material.
4. Immediately dispense **five (5) waste drops** of reconstituted control into a container approved for biohazardous material to clear the vial filter.
 5. Add one drop of reconstituted control onto the sample well (colored circle) on the test card.
 6. Sample placement automatically initiates testing. Results should be within the ranges given in the Quality Control section below.
 7. Dispose of 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

At least two levels of EQC quality control for each type of test card must be performed every 8 hours of operation when patient samples are tested.

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

Each facility should establish its own expected ranges for each level of control. The mean of the facility's established range should fall within the PT-C ranges listed below:

PT-C Ranges	
Level 1	7 – 14 seconds
Level 2	40 – 70 seconds

Establishing Expected Ranges for Quality Control Plasmas: An expected range for each level of control plasmas should be established for each lot number of either control plasmas or test cards. This may be accomplished by performing one PT-C test on each level of plasma once a day for 20 days. Determine the mean and standard deviation of the 20 tests performed on each control. The lower value for the range is equal to the mean minus two standard deviations. The upper value is equal to the mean plus two standard deviations.

Preliminary ranges may be more rapidly determined by performing four PT-C tests per day for 5 days and determining a range based on the statistical evaluation of these values; however, ranges established in this manner should be used only temporarily while collecting data for a more valid determination.

Interpretation of Quality Control Results: If the results fail to fall within a facility's established 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 established range, do not report any patient test results before contacting a supervisor qualified to resolve the problem.

LIMITATIONS

The expected ranges are only for PT-C controls with the PT-C test cards, and only when tested on the Cascade POC analyzer within 5 minutes of reconstitution. These ranges are for illustration purposes only. Operators should establish their own expected values.

PERFORMANCE CHARACTERISTICS

Lot-to-lot precision: Precision studies of the PT-C controls with the PT-C test cards show an interlaboratory variation resulting in a coefficient of variation (CV) of approximately 3 to 6% for the Level 1 and 5 to 10% for Level 2.

	Lot	Mean (sec)	SD (sec)	CV (%)
Level 1	1	9.9	0.8	8.1
	2	11.0	0.7	6.4
	3	11.0	0.6	5.5
Level 2	1	53.5	3.1	5.8
	2	57.3	3.7	6.5
	3	53.6	3.3	6.2

REFERENCES

RÉFÉRENCES/LITERATUR/RIFERIMENTI/REFERENCIAS

- 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.
- Clinical and Laboratory Standards Institute. Protection of laboratory workers from instrument biohazards and infectious disease transmitted by blood, body fluids, and tissue; approved guideline. NCCLS Document M29-A3. Wayne (PA): NCCLS; 1997 Dec. 90p.
- Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910.1030.
- Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington [HHS Publication No. (CDC) 93-8395] 1993.
- Clinical and Laboratory Standards Institute. Point-of-Care in vitro diagnostic (IVD) testing; approved guideline. NCCLS Document AST2-A. Wayne (PA): NCCLS; 1999 June, 45-50.

Patented 4,849,340; 5,110,727; 5,350,676

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

Helena Laboratories warrants its products to meet our published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be buyer's exclusive remedies.

In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

EC REP European authorized representative
Helena Laboratories UK, Ltd.
Colima Avenue
Sunderland Enterprise Park
Sunderland SR5 3XB
England



Manufacturer

Helena Laboratories
Point of Care
Beaumont, Texas

Form 399-014
1/09(2)