

CRYOcheck™ **IVD**

HEMOSTASIS CONTROL PLASMAS

ABNORMAL 1 CONTROL ABNORMAL 2 CONTROL

Intended Use

CRYOcheck Abnormal 1 Control and CRYOcheck Abnormal 2 Control are recommended for use as abnormal controls for the one-stage prothrombin time (PT) and activated partial thromboplastin time (APTT) assays.

Summary and Principle

The PT and APTT are routinely used to identify abnormalities in quantitative levels of plasma clotting proteins (factors) resulting from inherited or acquired factor deficiencies including anticoagulant therapy¹. The use of controls to confirm the integrity of reagents, instrumentation, operator technique and all other test system variables is an essential component of the coagulation laboratory's quality assurance program.

Reagents

CRYOcheck Abnormal 1 Control and CRYOcheck Abnormal 2 Control consist of normal citrated human plasma, which has been buffered using HEPES buffer. The plasma is then treated to contain reduced levels of clotting factors II, VII, IX, and X, aliquoted and rapidly frozen.



All blood products should be treated as potentially infectious. Source material from which this product was derived was found to be negative when tested in accordance with current required tests for transfusion-transmitted diseases. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. Accordingly, these human blood-based products should be handled and discarded as recommended for any potentially infectious human specimen².

Storage, Preparation and Handling

When stored at -40 to -80°C, CRYOcheck Abnormal 1 Control and CRYOcheck Abnormal 2 Control are stable to the end of the month indicated on the product packaging.

Thaw each vial at 37°C (± 1°C) in a waterbath. **The use of a dry bath or heating block for thawing is not recommended.** Thawing times are important and should be strictly adhered to. The use of a timer is

recommended. Refer to the Thawing Table for recommended thawing times based on aliquot size. Allow thawed plasma to acclimate to room temperature (18 to 25°C) and invert gently prior to use.

Thawing Table	
Aliquot Size	37 °C (± 1 °C) Waterbath
1.0 mL	4 minutes

CRYOcheck Abnormal 1 Control and CRYOcheck Abnormal 2 Control may be used for up to 24 hours after thawing, if capped in the original vial and maintained at 2 to 8 °C. Allow refrigerated plasma to acclimate to room temperature (18 to 25°C) and invert gently prior to use. **Thawed material should be discarded after 24 hours and should not be refrozen.**

Availability

Product	Catalog #	Format
Abnormal 1 Control	CCA1-10	80 vials x 1.0 mL
Abnormal 2 Control	CCA2-10	80 vials x 1.0 mL

Instruments

Each lab should prepare the local instrument in accordance with the manufacturer's instructions for use.

Procedure

After thawing and preparing CRYOcheck Abnormal 1 Control or CRYOcheck Abnormal 2 Control, use in accordance with established laboratory procedures for the quality control of PT and APTT assays.

Materials Provided

- CRYOcheck Abnormal 1 Control or
- CRYOcheck Abnormal 2 Control

Materials Required but not Provided

- Waterbath capable of maintaining 37 °C (± 1 °C)
- Timer
- Assay reagents
- Coagulation instrument or assay system
- Plastic disposable pipettes
- Volumetric pipette

Results and Interpretation

Control results should fall within the laboratory's established QC ranges provided the integrity of the test system has not been compromised.

Quality Control

Each laboratory should establish its own quality control (QC) ranges using acceptable statistical methods. These QC ranges may then be used to monitor and validate the integrity of the test system³. For all coagulation tests, the laboratory must include at least two levels of control for every eight hours of operation and any time a change in reagents occurs⁴.

Limitations of the Procedure

When proper control values are not obtained, assessment of each component of the test system including reagents, control plasmas, instrumentation and operator technique must be undertaken in order to ascertain that all other components are functioning properly.

Expected Values

The following clotting times were observed with *CRYOcheck* Abnormal 1 Control and *CRYOcheck* Abnormal 2 Control using Hemoliance RecombiPlasTin® (ISI=1.01) and Organon Teknika Automated APTT reagent on an ACL 100 over a 24-hour period (tested at 0 hours and 24 hours):

Clotting Times (sec.)		
	PT	APTT
Abnormal 1 Control	22.6 – 27.1	55.55 – 65.9
Abnormal 2 Control	40.0 – 48.0	70.3 – 77.7

Actual clotting times recovered with *CRYOcheck* Abnormal 1 Control and *CRYOcheck* Abnormal 2 Control for PT and APTT assays may vary according to technique, instrument and reagent system used. Each laboratory should establish its own mean values and tolerance limits for quality control purposes.

Performance Characteristics

The following percent coefficients of variation (%CV) were observed with *CRYOcheck* Abnormal 1 Control and *CRYOcheck* Abnormal 2 Control using Hemoliance RecombiPlasTin® (ISI=1.01) and Organon Teknika Automated APTT reagent on an ACL 100 over a 24-hour period (tested at 0 hours and 24 hours):










Coefficient of Variation (%)		
n=36	PT	APTT
Abnormal 1 Control	4.57	4.26
Abnormal 2 Control	4.55	2.49

Each laboratory should establish its own acceptable limits of performance for quality control samples.

Bibliography

1. Triplett DA, Smith C. Routine testing in the coagulation laboratory. In: Triplett DA, editor. Laboratory evaluation of coagulation. Illinois: ASCP Press; 1982. p. 28-51.
2. Biosafety in Microbiological and Biomedical Laboratories 6th ed. Centers for Disease Control and Prevention / National Institutes of Health, 2020.
3. Cembrowski GS, Carey RN. Laboratory Quality Management. Chicago: ASCP Press; 1989. p. 166-171.
4. CLIA 2004 – Code of Federal Regulations, 42CFR493.1269, 2004.

Symbols Used

	In vitro diagnostic medical device		Biological risks
	Batch code		Manufacturer
	Catalogue number		Authorized representative in the European Community / European Union
	Use by date	Rx ONLY	For prescription use only
	Temperature limit		Consult electronic instructions for use



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