PrecisionBioLogic

CRYO*check*™ IVD

HEMOSTASIS CONTROL PLASMAS

HEPARIN CONTROL

Intended Use

CRYO*check* Heparin control is recommended for use as an abnormal control for activated partial thromboplastin time (APTT) assays.

Summary and Principle

The APTT is routinely used to identify abnormalities in quantitative levels of plasma clotting proteins (factors) resulting from inherited or acquired factor deficiencies including anticoagulant therapies such as unfractionated heparin (UFH)[1]. The elevation of the APTT is proportional to the quantity of UFH present in the patient sample. 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

CRYO*check* Heparin control consists of normal citrated human plasma, which has been buffered using HEPES buffer. The plasma is then treated with a sodium heparin salt, 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 specimen[2].

Storage and Handling

When stored at -40 to -80°C, CRYO*check* Heparin Control is 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

CRYO*check* Heparin Control may be used for up to eight 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 eight hours and should not be refrozen.**

Availability

Product	Catalog #	Format
Heparin Control	CCH-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 CRYO*check* Heparin Control, use in accordance with established laboratory procedures for the quality control of APTT assays.

Materials Provided

- CRYO*check* Heparin Control

Materials Required but not Provided

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

Results

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 system[3]. 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 occurs[4].

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 CRYO*check* Heparin control using organon Teknika Automated APTT reagent on an IL ACL 100 over an eight-hour period (tested at zero hours and eight hours):

APTT Clotting Times (sec.)
58.2 – 71.9

Actual clotting times recovered with CRYO*check* Heparin control for APTT assays may vary according to technique, instrument and reagent system used. It is recommended each laboratory establish its own mean values and tolerance limits for quality control purposes.

Performance Characteristics

The following percent coefficient of variation (%CV) was observed with CRYO*check* Heparin control using organon Teknika Automated APTT reagent on an IL ACL 100 over an eight-hour period (tested at zero hours and eight hours):

APTT Coefficient of Variation (%) n=36
5.27

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

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

EC REP European Authorized Representative (Regulatory affairs only)
Emergo Europe—Prinsessegracht 20, 2514 AP The Hague, The Netherlands

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