PrecisionBioLogic

CRYO*check*™ IVD

HEMOSTASIS CONTROL PLASMAS

LOW FIBRINOGEN CONTROL

Intended Use

CRYO*check* Low Fibrinogen Control is recommended for use as an abnormal control in quantitative fibrinogen assays.

Summary and Principle

Fibrinogen is a plasma protein that is converted to fibrin by the action of thrombin. The most common quantitative assay for fibrinogen is based on the method described by Clauss, which measures the functional ability of fibrinogen to form a thrombin induced clot in plasma[1]. The time required for clot generation is inversely proportional to the fibrinogen concentration.

Reagents

CRYO*check* Low Fibrinogen Control is normal citrated human plasma, which has been buffered using HEPES buffer. The plasma is then adjusted to exhibit hypofibrinogenemic characteristics, aliquoted and rapidly frozen. CRYO*check* Low Fibrinogen Control contains known, abnormally low concentrations of fibrinogen.

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, Preparation and Handling

When stored at -40 to -80°C, CRYO*check* Low Fibrinogen 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* Low Fibrinogen Control may be used for up to 72 hours after thawing, if capped in the original vial and maintained at 2 to 8°C. Allow thawed plasma to acclimate to room temperature (18 to 25°C) and invert gently prior to use. **Thawed material should be discarded after 72 hours and should not be refrozen.**

Availability

Product	Catalog #	Format
Low Fibrinogen Control	CCLF-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* Low Fibrinogen Control, use in accordance with established laboratory procedures for the quality control of fibrinogen assays.

Materials Provided

- CRYO*check* Low Fibrinogen 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 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 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 fibrinogen values were observed with two lots of CRYO*check* Low Fibrinogen Control using Diagnostica Stago FIBRIPREST® 2 reagent on a Diagnostica Stago STA Compact over a 72-hour period (tested at 0 hours and 72 hours):

Clauss Fibrinogen (g/L)	
Lot A	0.62 – 0.69
Lot B	0.57 – 0.66

Actual fibrinogen values recovered with CRYO*check* Low Fibrinogen Control 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 CRYO*check* Low Fibrinogen Control using Diagnostica Stago FIBRI-PREST® 2 reagent on a Diagnostica Stago STA Compact over a 72-hour period (tested at 0 hours and 72 hours):

Coefficient of Variation (%) n= 36	
Lot A	2.8
Lot B	3.7

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

Bibliography

1. Clauss A. Rapid physiological coagulation method for the determination of fibrinogen. Acta Haemat 1957; 17(4):237-246.
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 date	**Rx ONLY**	For prescription use only
	Temperature limit		Consult electronic instructions for use

EC REP European Authorized Representative (Regulatory affairs only)
Emergo Europe— Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

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