PrecisionBioLogic

CRYO*check*™ IVD

HEMOSTASIS CONTROL PLASMAS

REFERENCE CONTROL NORMAL

Intended Use

CRYO*check* Reference Control Normal is recommended for use in controlling the accuracy of quantitative hemostasis assays in the normal range.

Summary and Principle

The use of assayed reference plasma is widely recommended for the quantitative assessment of hemostatic parameters in human plasma[1-4]. These laboratory procedures are commonly performed to evaluate patients with coagulation disorders and require the construction of calibration or dose response curves from which quantitative measures of individual analytes can then be determined. The World Health organization (WHO) has established a series of international standards for this purpose in an attempt to standardize these procedures. Upon the establishment of calibration curves, normal and pathological quality control materials should be evaluated to confirm the integrity of the assay system.

Reagents

CRYO*check* Reference Control Normal consists of normal citrated human plasma collected from a minimum of 20 carefully screened normal donors. The plasma pool is buffered using HEPES buffer, aliquoted and rapidly frozen. Each lot number is assayed using international reference standards (where available) and ranges for hemostatic parameters are assigned. **Refer to the ASSAY CERTIFICATE for the assigned ranges specific to each lot number.**

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[5].

Storage, Preparation and Handling

When stored at -40 to -80 °C, CRYO*check* Reference Control Normal 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**
0.5 mL	3 minutes
1.0 mL	4 minutes

CRYO*check* Reference Control Normal 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
Reference Control Normal	RCN-05	25 vials x 0.5 mL
	RCN-10	25 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* Reference Control Normal, use in accordance with established laboratory quality control procedures

Materials Provided

- CRYO*check* Reference Control Normal

Materials Required but not Provided

- Waterbath capable of maintaining 37 °C (± 1 °C)
- Timer
- Assay reagents
- Coagulation instrument or assay system
- Calibration plasma (e.g. CRYO*check* Normal reference Plasma)
- Sample cups
- Volumetric pipettes
- Plastic disposable pipettes

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[6]. 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[7].

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

Refer to the **ASSAY CERTIFICATE** for the expected ranges specific to each lot number of CRYO*check* reference control Normal.

Performance Characteristics

Ranges that have been assigned to CRYO*check* Reference Control Normal have been determined in accordance with accepted clinical laboratory procedures. All components in each individual system should be assessed to determine their effect on the reproducibility and accuracy of expected values. When used properly, CRYO*check* Reference Control Normal is subject to the limitations of the assay system in use.

Bibliography

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2. Burgi W, Schnell, E. Artificial control materials: coagulation. In: Rosalki, SB, editor. New approaches to laboratory medicine. Darmstadt: G-I-T Verlag Ernst Giebeler; 1981.p. 57-65.
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4. Dombrose FA, Barnes cc. A standard reference plasma for coagulation assays. In: Triplett DA, editor: Standardization of coagulation assays: An overview. Illinois: ASCP Press; 1982. p. 223-234.
5. Biosafety in Microbiological Laboratories 6th ed. Centers for Disease control and Prevention / National Institutes of Health, 2020.
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7. 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— Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

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