PrecisionBioLogic

CRYO*check*™ IVD

HEMOSTASIS CONTROL PLASMAS

ABNORMAL 1 REFERENCE CONTROL
ABNORMAL 2 REFERENCE CONTROL

Intended Use

CRYO*check* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control are recommended for use in controlling the accuracy of quantitative assays used to assess hemostasis. CRYO*check* Abnormal 1 Reference Control controls accuracy in the borderline pathological range while CRYO*check* Abnormal 2 Reference Control controls accuracy in the pathological range.

Summary and Principle

The use of reference plasma is widely recommended for the quantification of hemostatic parameters in human plasma[1-4]. These procedures are performed as part of the laboratory evaluation of patients with coagulation disorders and require the construction of reference 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 reference curves, quality control materials should be used to confirm the integrity of the assay system.

Reagents

CRYO*check* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control consist of normal citrated human plasma collected from a minimum of 20 carefully screened donors. The plasma pool is buffered using HEPES buffer. The pool is then adjusted to defined concentrations of hemostatic parameters, 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* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference 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.** Thaw 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* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference 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
Abnormal 1 Reference Control	ARP1-05	25 vials x 0.5 mL
Abnormal 1 Reference Control	ARP1-10	25 vials x 1.0 mL
Abnormal 2 Reference Control	ARP2-10	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* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control, use in accordance with established laboratory quality control procedures.

Materials Provided

- CRYO*check* Abnormal 1 Reference Control *or*
- CRYO*check* Abnormal 2 Reference Control

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 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[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* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control.

Performance Characteristics

Ranges that have been assigned to CRYO*check* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control 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* Abnormal 1 Reference Control and CRYO*check* Abnormal 2 Reference Control are subject to the limitations of the assay system in use.

Bibliography

1. Dombrose FA, Barnes CC Jr, Gaynor JJ, Elston rC. A lyophilized human reference plasma for coagulation factors. Evidence for stability of factors I, II, V, and VII through XII. Am J Clin Pathol. 1982; 77(1):32-45.
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.
3. Thelin GM. Preparation and standardization of a stable AHF plasma. Thromb Diath Haemorrh 1968; 19(3):423-429.
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 and Biomedical Laboratories 6th ed. Centers for Disease Control and Prevention / National Institutes of Health, 2020.
6. Cembrowski GS, Carey RN. Laboratory quality management. Chicago: ASCP Press; 1989. p. 166-171.
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 Date	**Rx ONLY**	For prescription use only
	Temperature limit		Consult instructions for use

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

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