PrecisionBioLogic

CRYO*check*™ IVD

HEMOSTASIS CONTROL PLASMAS

POOLED NORMAL PLASMA

Intended Use

CRYO*check* Pooled Normal Plasma is recommended as a normal control for the one-stage prothrombin time (PT) and activated partial thromboplastin time (APTT) assays. It may also be used as an alternative to laboratory collected pools of normal patient plasma. **CRYO*check* Pooled Normal Plasma is not intended for use as a calibrator.**

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 therapy[1]. 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* Pooled Normal Plasma consists of a pool of normal citrated human plasma from a minimum of 20 healthy individuals. The plasma pool is then buffered using HEPES buffer, aliquoted, and rapidly frozen. Each lot of CRYO*check* Pooled Normal Plasma has been tested and confirmed to contain normal levels of coagulation factors II through XII, and 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 FDA required tests. 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* Pooled Normal Plasma 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
1.5 mL	5 minutes
4.0 mL	5 minutes

CRYO*check* Pooled Normal Plasma 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
Pooled Normal Plasma	CCN10-10	10 vials x 1.0 mL
	CCN-10	80 vials x 1.0 mL
	CCN-15	80 vials x 1.5 mL
	CCN-40	81 vials x 4.0 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* Pooled Normal Plasma, use in accordance with established laboratory procedures for the quality control of PT and APTT assays.

Materials Provided

- CRYO*check* Pooled Normal Plasma

Materials Required but not Provided

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

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 three lots of CRYO*check* Pooled Normal Plasma 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**
Lot A	9.1 – 10.9	26.3 – 29.2
Lot B	9.2 – 10.9	28.2 – 33.8
Lot C	9.3 – 10.8	28.5 – 31.2

Actual clotting times recovered with CRYO*check* Pooled Normal Plasma for PT and 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 coefficients of variation (%CV) were observed with three lots of CRYO*check* Pooled Normal Plasma 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**
Lot A	4.48	2.62
Lot B	4.16	4.51
Lot C	3.87	2.29

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 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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