



Intended Use

Diagen Normal Reference Control is a multi-purpose reference plasma with clotting factor concentrations set in the normal range.

Summary and Principle

Diagen Normal Reference Control Plasma is prepared from a pool of citrated human plasma, which is buffered and freeze-dried. All analytes are found to be in the **Normal Range** and have been assayed against international standards (where available). The product may be used as reference plasma in the quantitative determination of individual coagulation factor concentrations, as well as a being a control for Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Thrombin Time (TT).

Reagent

Normal Reference Control Plasma **10 vials**

Lyophilised, buffered human plasma. For reconstitution, remove the cap and rubber stopper and add 1.0 mL of distilled water. Swirl gently and allow 5 - 10 minutes for complete solution.

Warnings and precautions

POTENTIAL BIOHAZARD MATERIAL.

Diagen Normal Reference Control Plasma is of human origin. All donor units used in production of this product have been found negative for anti HIV, anti HCV, HBsAg and Syphilis by approved methods. However, all plasma of human origin should be considered as potentially infectious and handled appropriately. Please refer to the relevant SDS Sheet (provided on request) for handling and safety procedures. Dispose of all waste materials according to the national and local regulations.

Procedure

Materials Provided

Cat. No.

RSCN070 - Normal Reference Control Plasma (10 x 1.0 mL).

Materials and equipment required, but **not** provided:

1. General routine laboratory coagulation equipment.
2. Reaction cups or test tubes (12 x 75 mm).
3. Pipette delivering between 1.0 mL.
4. Distilled water.

Expected Results

The table on page 2 shows the defined value for each specific coagulation factor and the Standard Deviation (SD) of the between laboratory assayed values. All assays are performed using the manual clotting technique. Diagen Reference Plasma should be used in accordance with the instructions for use accompanying the reagents and can be used with all coagulation instrument and reagent combinations.

Note: For photo-optical and mechanical instruments, always follow the manufacturer's instructions.

Limitations

Values for the PT, APTT and Thrombin Time of Diagen Reference Control Plasma will vary from one laboratory to another. This depends on several variables including reagent used, method of clot detection, pH and temperature. However, the assigned mean clotting factor values will be the same regardless of reagents used.

Table of Defined Values

Clotting Factor	Mean Value	S.D	Units
Fibrinogen (claus)	-	-	g/L
Factor II	-	-	iu/dL
Factor V	-	-	iu/dL
Factor VII	-	-	iu/dL
Factor VIIIc	-	-	iu/dL
Factor IX	-	-	iu/dL
Factor X	-	-	iu/dL
Factor XI	-	-	iu/dL
Factor XII	-	-	iu/dL
Protein C amidolytic	-	-	iu/dL
Protein C clotting assay	-	-	iu/dL
Protein S Total ELISA	-	-	iu/dL
Protein S Free	-	-	iu/dL
Antithrombin amidolytic	-	-	iu/dL

One-stage PT - Diagen	LOT	Secs	Range
Freeze - Dried Thromboplastin	DT141	15.0	14.0 – 16.0
Calcium Thromboplastin	T83	14.0	13.0 – 15.0

APTT - Diagen

	LOT	Secs	Range
Bell & Alton Platelet substitute (2 minute activation time)	Not		Tested
Kaolin/Platelet substitute mixture (2 minute activation time)	KC335	46.5	43.5 – 49.5
Mic.Silica/Platelet Substitute (5 minute activation)	SP68	36.5	34.0 – 39.0

Thrombin Time - Diagen

	LOT	Secs	Range
(Thrombin @ 7.0 u/mL)		13.0	12.0 – 14.0

Storage and stability

The unopened freeze-dried vials are **best stored deep frozen**, but may be stored for up to 3 years at 2 - 8°C without deterioration. Once reconstituted the contents of the vial are then stable for up to 4 hours when held at 2 - 8°C.

Packaging

10 x 1.0 mL.

Key guide to symbols

REF	Manufacturers catalogue number.	i	Consult instructions for use.
LOT	Manufacturers batch number.	Recon.	Requires reconstitution.
IVD	For <i>in vitro</i> diagnostic use only.	Hourglass	Product expiry date.
Biohazard	Biological risks.	Thermometer	Store at 4°C or below. Best stored deep frozen.

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Diagnostic Reagents Limited is a BS EN ISO13485:2016 certified company