



Table of Defined Values

Clotting Factor	Mean Value	S.D	Units
Fibrinogen (claus)	125	4.0	g/L
Factor II	22	1.4	iu/dL
Factor V	35	2.5	iu/dL
Factor VII	27	1.3	iu/dL
Factor VIIIc	30	3.2	iu/dL
Factor IX	20	1.4	iu/dL
Factor X	23	1.1	iu/dL
Factor XI	28	2.4	iu/dL
Factor XII	39	5.0	u/dL
Protein C amidolytic	17	0.7	iu/dL
Protein C clotting assay	17	3.2	iu/dL
Protein S Total ELISA	24	0.6	iu/dL
Protein S Free	21	4.4	iu/dL
Antithrombin amidolytic	46	5.0	iu/dL

Intended Use

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

Summary and Principle

Diagen Abnormal 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 **Abnormal 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 or, **as control plasma to validate patient values obtained by using the Normal Reference control plasma as the assay calibrant.** They may also be used as a control for the PT, APTT and TT tests.

Reagent

Abnormal 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 Abnormal 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.

RSCA080 - Abnormal 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.

One-stage PT - Diagen	LOT	Secs	Range	INR
Freeze - Dried Thromboplastin	DT141	32.8	29.5 – 36.1	2.75
Calcium Thromboplastin	T82	31.5	28.3 – 34.7	2.82

APTT - Diagen

Bell & Alton Platelet substitute (2 minute activation time)	N/A	-	-	
Kaolin/Platelet substitute mixture (2 minute activation time)	KC334	83.0	73.0 – 93.0	
Mic.Silica/Platelet Substitute (5 minute activation)	SP68	79.2	69.2 – 89.2	

Thrombin Time - Diagen

(Thrombin @ 7.0 u/mL)	N/D	14.5	13.5 – 16.5	
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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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