DIAGON
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INSTRUCTION FOR USE

Dia-CONT Spec

Speciality Assayed Controls

CE

Cat. No.: 09305 Dia-CONT Spec N 5x1 ml
Cat. No.: 09405 Dia-CONT Spec P 5x1 ml

Instructions for use

Speciality Assayed Control N (SAC - N) may be used as a normal control, and Speciality Assayed Control A (SAC - A) may be used as an abnormal control when assaying for Factors II, V, VII, VIII, IX, X1, XI, XII[2], and Protein S (total and free), as well as the chromogenic assays including, Protein C and Plasminogen. Speciality Assayed Controls are used in factor assays and other testing in the same manner as a fresh plasma pool. Factor II, VII, VIII, IX and X values and the chromogenic Protein C values are traceable to World Health Organisation standards to ensure the utmost credibility in values stated[3]. The control plasma should be used to gauge internal factors in each laboratory's system.

Warnings

The reagents contained in this kit are for *in vitro* diagnostic use only under professional's leadership.

Precaution

Potentially dangerous material. - **DO NOT INGEST!** Wear gloves when handling all kit components. Plasma products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of Hepatitis B Antigen (HbsAg) HIV 1 and 2 antibody and HCV antibody; however they should be handled with the same precautions as a human plasma sample. All immunodepleted plasmas are HCV negative

Waste Material Treatment

Refer to the product safety data sheets for risk and safety phrases and disposal.

Materials provided

Component	Content	Description	Preparation
Dia-Cont Spec N	5 x 1 mL	Prepared from a frozen pool of citrated plasma and is buffered and lyophilised to ensure stability of all plasma constituents[5].	Reconstitute with 1 mL of distilled or deionised water. Swirl gently. Allow product 20 minutes for complete dissolution.
Dia-Cont Spec P	5 x 1 mL	Prepared from a frozen pool of citrated plasma and is buffered and lyophilised to ensure stability of all plasma constituents[5].	Reconstitute with 1 mL of distilled or deionised water. Swirl gently. Allow product 20 minutes for complete dissolution.
Each kit contains Instructions For Use.			
Each kit contains lot specific reference values insert.			

Materials required but not provided

Speciality Assayed Controls may be used when performing tests on any mechanical or photo-optical coagulation instrument in conjunction with all suitable, commercial reagents.

Storage and stability

Unopened vials are stable until the given expiry date when stored under the related conditions.

Component	Stability	Signs of Deterioration
DiaCont Spec N and DiaCont Spec P	Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at $^{+}2$ –$^{+}8$°C. All other factors are stable for 4 hours at $^{+}2$ –$^{+}8$°C.	Unreconstituted Speciality Assayed Controls must appear as a light yellow, dry plug. If any unusual conditions are noted, the customer should notify Diagon Ltd. before using.

Procedure

Each control should be treated in the same manner as the unknown specimen in accordance with the instructions outlined in each particular test protocol.

Interpretation of results

The assayed percent activities of the various coagulation factors should be used as a guideline. If the product does not perform as expected, the measurement of the patient specimens should not be started. Ensure the lot number printed on this assay sheet is the same as that on the vial of Dia-ContSpec N and P to be used.

Limitations

The results obtained with Speciality Assayed Controls depend on several factors strongly associated with instrumentation, types of reagents, deficient substrates and laboratory to laboratory variations[5,6,7]. Each laboratory should establish an expected range for the particular instrument-reagent system used.

Quality control

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient specimen measurements should not be started.

Reference values

Refer to the reference values insert for lot specific reference ranges. Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges.

Performance characteristics

The following performance characteristics have been determined by Diagon Ltd or their representatives using an opto-mechanical coagulation instrument. Each laboratory should establish its own performance data.

Inter-assay precision					
		DiaCont Spec - N		**DiaCont Spec - P**	
Parameter	***n***	***Mean***	***CV (%)***	***Mean***	***CV (%)***
Fibrinogen (g/L)	3	lot specific data		lot specific data	
Factor IX (%)	3	lot specific data		lot specific data	
Protein S (%)	3	lot specific data		lot specific data	

References

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Faktors V and X, *AJCP*,**64:**817-819
2. Hardisty RM, *et al.* (1962) A One Stage Faktor VIII Assay and Its Use on Venous and Capillary Plasma, *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229
3. Elodi S, Katalin V, Hollan S (1978) Some Sources of Error in the One-Stage Assay of Faktor VIII, *Haemostasis*, **7:**1-9
4. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasm, *Thrombosis et Diathesis Haemorrhagica*, **19:**423
5. Kirkwood TBL et al. (1977) Identification of Sources of Variationin Faktor VIII Assay, *British Journal of Haematology*,**37:**559-568
6. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, **55:**561-564
7. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Faktor Assay Techniques, *AJCP*, **59:**231-235

DIAGON LTD.
Baross u. 48-52, 1047 Budapest, Hungary
Tel.: +36 1 3696500
Fax.: +36 1 3696301
Web: www.diagon.com
E-mail: diagon@diagon.com

Symbols			
IVD	In vitro diagnostics devices		Check in user manual
	Biohazard		Temperature range
	Manufacturer		Expiry date
LOT	LOT number	CE	CE conformity sign
REF	Catalogue number		