DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-CAL Spec

Calibration Plasma

Cat. No.: 09605 Dia-CAL Spec 5 x 1 ml

Intended Use

Calibration Plasma may be used as a reference plasma when assaying for Factors II, V, VII, VIII, IX, X[1], XI, XII[2], and protein S (total and free) as well as the chromogenic assays, including, Protein C, and Plasminogen. Calibration plasma is 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 most credibility in values stated. The reference plasma should be used to gaure internal factors in each laboratory system. The reference plasma should not be used to determine normal ranges since normals vary from population to population.

Warnings

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

Precautions

DO NOT INGEST! Wear gloves when handling all kit components. Refer to the product safety data sheets for risk and safety phrases and disposal information. The D-Dimer Calibrator is of human origin. 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.

Waste Material Treatment

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

Preparation

Components	Content	Description	Preparation
Calibration Plasma	1 x 1 mL	Calibration Plasma is prepared from a frozen pool of citrated Plasma from healthy donors and it is buffered and lyophilised to ensure stability of all plasma.	Reconstitute with 1 ml_ of distilled or deionised water. Swirl gently. Allow product 20 minutes for completed its solution.

Items required but not provided

Calibration Plasma 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 conditions indicated on the vial or kit label. Values for Factor VIII are stable for 2 hours at +2 -+8°C. All other factors are stable for 4 hours at+2 -+8°C. The unreconstituted Calibration Plasma must appear as a light yellow, dry plug. If any unusual conditions are noted, the customer should notify Diagon, before using.

Procedure

For detailed instructions and specific application please contact Diagon Ltd.

Interpretation of results

Ensure the lot number printed on this assay sheet is the same that on the vial of Calibration Plasma to be used. The assayed percent activities of the various coagulation factors should be taken from the "Reference Value" column when Calibration Plasma is used to determine the laboratory's standard curves.

Limitations

The results obtained with Calibration Plasma 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.

Quality Control

Each laboratory should establish a quality control program. Normal and abnormal control Plasma 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 results should be considered invalid. Diagon Ltd supplies the following controls available for use with this product:

Cat. No.: 09305 Dia-CONT Spec N

Cat. No.: 09405 Dia-CONT Spec P

Reference values

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own normal range.

Performance Characteristics

The following performance characteristics have been determined by Diagon Ltd, using a photo-optical coagulation instrument. The user should establish product performance characteristics for the specific instrumentation used.

Reproducibility

Interbatch precision

Parameter	n	mean	CV(%)
Fibrinogen (g/L)	5	3,0	3,6
factor IX. (%)	5	124,7	1,9
Protein S (%)	5	98,5	2,9

References

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, AJCP, 64: 817-819.
2. Hardisty RM et al. (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. Thrombosis et Diathesis Haemorrhagica, 7:215-229.

3. Elodi S et al (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, Haemostasis, 7:1-9.
4. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, Thrombosis et Diathesis Haemorrhagica, 19:423.
5. Kirkwood TBL et al. (1977) Identification of Sources of Variation in Factor 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 Factor 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		