DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-CONT LA P

CE

LA positive control

Cat. No.: 09501 Dia-CONT LA P (1x1 ml)

Intended Use

Dia-CONT LA P is prepared with plasma from human donors positive for Lupus anticoagulants. The plasma gives results typical of a Lupus Anticoagulant patient in DRVVT Screen, DRVVT Confirm and APTT-based tests.

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!**

Plasma products have been screened and found negative 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. During the use of deficient plasmas please keep the precautions for infectious materials treatment.

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 LA P	1 x 1 ml	Each kit contains lyophilised, citrated human plasma.	Reconstitute each vial with 1 ml of distilled/deionised water. Swirl gently and allow to stand for 15 minutes. Mix well before use. Do not shake.
Each kit contains Instructions for use.			
Each kit contains lot specific reference values insert.			

Materials required but not provided

Cat. No.: 07310 Dia-DRVVT Screen

Cat. No.: 07405 Dia-DRVVT Confirm

Storage and stability

Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Reconstituted vials of plasma should be kept on ice and are stable for 4 hours at $^{+}2 - ^{+}8$°C.

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

Dia-CONT LA P should show abnormal results when tested with Dia-DRVVT Screen reagent which are more normal when tested with the Dia-DRVVT Confirm reagent. Refer to the reference values insert for lot specific reference ranges.

Limitations

The results obtained with Dia-CONT LA P depends on several factors strongly associated with instrumentation, types of reagents, and laboratory to laboratory variations[1,2,3]. Each laboratory should establish an expected range for the particular instrument-reagent system.

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 range.

Performance characteristics

The following performance characteristics have been determined by Diagon Ltd. or their representatives as a guideline. Each laboratory should establish its own performance data.

Reproducibility			
PI-LI		**APTI Si**	
Clot formation (seconds)	***CV (%)***	***Clot formation (seconds)***	***CV (%)***
12,3	0,72	34,20	1,0

DRVVT screen		**DRVVT confirm**		
Clot formation (seconds)	***CV (%)***	***Clot formation (seconds)***	***CV (%)***	***Ratio***
47,3	4,96	33,8	2,52	1,40

References

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology*, **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP*, **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP*,**59:**231-235.

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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		