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PLASMATROL - R

REFERENCE PLASMA FOR USE WITH COAGULATION ASSAYS

SUMMARY

In the diagnostic control of state of coagulation it is necessary to correlate the values obtained in the individual blood coagulation tests to certain normal values. Several procedures performed in the Haemostasis laboratory therefore require the use of characterized reference plasma to evaluate levels of clotting factors, inhibitors, and fibrinolytic proteins in specimens. The use of pooled plasma of normal healthy blood donors is generally used as a suitable reference plasma. The pool plasma has to be obtained from several healthy donors . It is practically difficult to carry out such procedures in routine diagnostic laboratories. The use of lyophilized plasma that has assayed values of the coagulation factors is therefore suggested for use as a suitable reference system. Plasmatrol-R is a Freeze dried human plasma with assayed values for specific coagulation factors.

PRESENTATION

REF	11043061
PLASMATROL-R	6 x 1 ml
Pack insert	1
Assay value sheet	1

REAGENT

Plasmatrol-R is a stabilized freeze dried preparation of selected human pool plasma with assayed values of parameters listed on the Assay value sheet. The values are assigned using Tulip's coagulation reagents and/or by independent, recognized reference laboratory. The value assignment for PT, APTT, Fibrinogen, Factors II, V, VII, VIII, IX, X, XI, and XII is done by methods described in the Assay Value Sheet.

The assigned values for Plasmatrol-R has been determined by using standard reference methods and commercial reference materials which is traceable to World Health Organization standards to ensure utmost credibility in values stated.

REAGENT STORAGE AND STABILITY

Unopened vials should be stored at 2-8^{0}C and are stable upto expiry date mentioned on the vial labels. After reconstitution the shelf life of Plasmatrol-R is 3 hours at 25-30^{0}C and 7 hours at 2-8^{0}C.

PRINCIPLE

The properties of Plasmatrol-R are similar to those of fresh pooled plasmas. Since Plasmatrol-R has assigned values for PT, APTT, Fibrinogen, Factor II, V, VII, VIII, IX, X, XI, XII, Protein C, Protein S and Antithrombin III. It can be used as a suitable calibrator for measurement of above mentioned factors. Plasmatrol-R can also be substituted in place of a normal pool plasma while performing clot based coagulation assays and for quality control of reagents , method and instrument relevant to the factors with assigned values.

NOTE

1. Invitro diagnostic reagent for laboratory and professional use only. NOT FOR MEDICINAL USE.
2. The source material used for preparation of the reagent is screened by third generation assays for HBsAg, HCV and HIV antibodies and are found to be non-reactive. However handle the material as if infectious, as no test method can assure that infectious agents are absent.

PREPARATION OF REAGENT

1. Reconstitute Plasmatrol-R with exactly 1 ml of bi-distilled water. Avoid use of water containing preservatives.
2. Recap the Plasmatrol-R vial and allow to stand still until hydration is complete (usually 5-7 minutes).
3. Mix by gentle swirling , avoiding froth formation. Do not shake.
4. Allow to stand and equilibrate for further 20 minutes before use.

TEST PROCEDURE

Plasmatrol-R is to be used as specimen/ calibrator/control by the recommended procedures with the relevant assays strictly adhering to manufacturers recommendations.

REMARKS

1. When used appropriately, Plasmatrol-R is subject to limitations of the assay system deployed.
2. If proper values are not obtained it may indicate problems with one or more variables of the assay system.
3. Stability of the reagent is dependant on storage and handling conditions. Since these can vary between laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.

4. In correct mixing of Plasmatrol-R and reagent, insufficient preparation of Plasma/reagent, contaminated reagents and glassware etc. are potential sources of error.
5. Due to inter laboratory variations in techniques, standardization of test procedures and calibration of equipments, some variations from assigned values may be expected.

PERFORMANCE CHARACTERISTICS

Plasmatrol - R should give values within the range described in the accompanying assay value sheet under the described assay conditions with the respective reagents. An internal evaluation demonstrated a within run precision of less than 5 % when Plasmatrol - R were tested with the reagents described in the assay value sheet. The tests were performed on Hemostar-XF (coagulomter).

WARRANTY

The product is designed to perform as described in the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Dacie & Lewis, Practical Haematology, Ninth Edition, Pg. 351.
2. Data on file: Tulip Diagnostics, India.

SYMBOL KEYS

 Temperature limitation	 Manufacturer	 This side up	PS Production Site
 Use by	 Consult Instructions for use	EC REP	Authorised Representative in the European Community
 Date of Manufacture	REF Catalogue Number	REC Xml	Reconstitute with stated amount of distilled water
LOT Batch Number/ Lot Number	IVD *In vitro* Diagnostic Medical Device	REAGENT	Description of reagent

TULIP DIAGNOSTICS (P) LTD.

PS

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EC REP

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