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PLASMATROL H-I/II/III

ASSAYED HUMAN CONTROL PLASMA FOR PT/APTT/TT/FIBRINOGEN

REF: BS.1/PLA01.001.0001
REF: BS.1/PLB01.001.0001
REF: BS.1/PLC01.001.0001

CLINICAL SIGNIFICANCE

BioScien PLASMATROL H-I/II/III are three level human plasma controls that are suitable for PT, APTT, TT and Fibrinogen testing using clot-based methods. Coagulation controls provide a means of day-to-day quality control in the hemostasis laboratory for control of accuracy and precision.

METHOD PRINCIPLE

The properties of the control plasma are Similar to those of pooled fresh plasmas. Since the plasma controls have assigned values, when substituted in place of a sample, in clot-based coagulation assays, they can be used for Laboratory Quality Assurance.

REAGENT COMPOSITION

PLASMATROL is a stabilized and freeze-dried preparation of selected human plasma with values determined and assigned for specific clot-based tests, which are lot specific. The plasma controls are assayed using ***BioScien*** Coagulation reagents.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the PLASMATROL material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Reagent Preparation:

1. Reconstitute the control plasma with stated amount of deionized water. Avoid using water containing preservatives.
2. Re-stopper the vial and allow to stand until the hydration is complete (usually 5-7 minutes).
3. Mix by gently swirling and inversion, avoiding froth formation. Do not shake.
4. Allow to stand and equilibrate for a further 20 minutes before use.
5. Use the reconstituted plasma within 3 hours of reconstitution.

BioScien PLASMATROL is stable until expiration date stated on label when properly stored refrigerated at 2-8°C (do not freeze). After reconstitution the shelf life of the control plasma is 3 hours at 25-30°C and 8 hours when stored at 2-8°C.

ASSAY PROCEDURE

1. Use the reconstituted PLASMATROL controls in the same manner as freshly prepared citrated platelet poor plasma from a patient.
2. Use the procedure as laid out in the UNIPLASTIN, LIQUIPLASTIN, LYOPLASTIN, LIQUICELIN-E, CELIN-SE, FIBROSCREEN, and FIBROQUAN package inserts.

EXPECTED VALUES

1. The expected value of specific assays are provided on the assay value sheet accompanying the kit, and are lot specific, instrument specific.
2. The expected values are obtained using replicate assay of each manufactured lot of PLASMATROL, manually and using mechanical coagulometers such as HEMOSTAR, HEMOSTAR XF, CoalAB 6000, CoaSTAT, HEMOSTARAUTO.
3. It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

PERFORMANCE CHARACTERISTICS

Plasmatrol H-I/H-II/H-III 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 H-I/H-II/H-III were tested with the reagents described in the assay value sheet. The tests were performed on HEMOSTAR-XF (coagulometer).

Remarks

- When used appropriately, PLASMATROL controls are subjected to the limitations of the assay system deployed.
- If proper values are not obtained it may indicate problems with one or more variables of the assay system.
- Stability of the reagent is dependent on storage and handling conditions. Since these can vary between laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.
- Incorrect mixing of control plasma and reagent, insufficient preparation of plasma/ reagent, contaminated reagents and glassware etc. are a potential source of error.
- Due to inter laboratory variations in techniques, standardization of test procedures and calibration of equipment, some variation from assigned mean values may be expected.

REFERENCES

1. W.H. O. Technica1Series,687, 1983.
2. Human Blood Coagulation, Hemostasis and Thrombosis; Edited by Rosemary Biggs, Blackwell Scientific Publications 1972.

PLASMATROL H-II

ASSAY VALUE SHEET

A) Value on Hemostar/Hemostar-XF

Prothrombin Time Test				
Sr.No.	**Reagent**	**Unit**	**Mean**	**Range**
a)	**Uniplastin**	**Sec.**	**21.0**	**16.8-25.2**
b)	**Liquiplastin**	**Sec.**	**19.0**	**15.0-23.0**

Activated Partial Thromboplastin Time Test				
Sr.No.	**Reagent**	**Unit**	**Mean**	**Range**
a)	**Liquicelin-E**	**Sec.**	**50.0**	**40.0-60.0**
b)	**Celin-SE**	**Sec.**	**54.0**	**43.0-65.0**

Fibrinogen Assay

Thrombin Time Test				
Sr.No.	**Reagent**	**Unit**	**Mean**	**Range**
a)	**Fibroscreen**	**Sec.**	**10.0**	**7.5-12.5**
Fibrinogen Qualification Assay				
b)	**Fibroquant**	**Mg/dl**	**175**	**132-218**

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use	Number of <n> test in the pack
LOT Batch Code/Lot number	Caution
REF Catalogue Number	Do not use if package is damaged
Temperature Limitation	Consult Instruction for use
Expiration Date	
Manufactured by	

EC REP **Medical Device Safety Service**
MDSS GmbH
Schiffgr aben 41
30175 Hannover, Germany

CE