SPECTRUM

The Creative Approach to Bioscience

NORMAL AND ABNORMAL PLASMA CONTROLS FOR COAGULATION ASSAYS

REF: 618 001 (HI) 1 x 1 ml
REF: 618 002 (HII) 1 x 1 ml
REF: 618 003 (HI) 2 x 1 ml
REF: 618 004 (HI+HII) 2 x 1 ml

Summary

Spectrum Diagnostics PLASMATROL H-I and PLASMATROL H-II are two level human plasma controls that are suitable for use as normal and abnormal control plasma for PT, APTT and Fibrinogen testing using clot based methods. Coagulation controls provide a means of day quality control in the laboratory for control of accuracy and precision.

Reagent

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 spectrum Coagulation reagents.

Reagent Storage and Stability

Unopened vials should be stored at 2 – 8 ^{o}C and are stable upon the expiry date mentioned on vial labels. After reconstitution the shelf life of the control plasma is 3 hours at 25 – 30 ^{o}C, 8 hours when stored at 2 – 8 ^{o}C and one week at - 20 ^{o}C. For storage at - 20 ^{o}C avoid repeated freezing and thawing.

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.

Note

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

Preparation Of The Reagent

1. Reconstitute the control plasma with exactly 1 ml of bidistilled 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 15 minutes before use.
5. Use the reconstituted plasma within 3 hours of reconstitution.

The 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 ULTRAPLASTIN, NORMOPLASTIN, and UNICELIN package inserts.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Expected Values

1. The expected value of specific assays are provided on the assay value sheet accompanying each kit, and are lot specific.
2. The expected values are obtained using replicate assay of each manufactured lot of PLASMATROL.
3. The individual laboratory values should fall within the expected values.
4. It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

Remarks

1. When used appropriately, PLASMATROL controls are subjected to the limitation 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 dependent on storage and handling conditions. Since these can vary among laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.
4. Incorrect mixing of control plasma and reagent, insufficient preparation of plasma/reagent, contaminated reagent, and glassware etc. are a potential source of error.
5. Due to inter laboratory variations in techniques, standardization of test procedures and calibration of equipments, some variation from assigned mean values may be expected.

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