

## SBio Control Plasma H-I/H-II

Assayed human control plasma for  
PT/APTT/TT/FIBRINOGEN

	H-I	H-II
REF	90370061	90380061
Pack size	6 x 1 ml	6 x 1 ml



Temperature limitation	Manufacturer	This side up
Use by	Consult Instructions for use	Authorised Representative in the European Community
Date of Manufacture	Catalogue Number	Reconstitute with stated amount of distilled water
Batch Number/ Lot Number	In vitro Diagnostic Medical Device	Description of reagent

### SUMMARY

**SBio Control Plasma H-I/H-II** are two level human plasma controls that are suitable for use as control plasma 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.

### REAGENT

**SBio Control Plasma** 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 Tulip Coagulation reagents.

### REAGENT STORAGE AND STABILITY

Unopened vials should be stored at 2-8°C and are stable upto the expiry date mentioned on the vial labels. 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.

### 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

- In vitro diagnostic reagent for laboratory and professional use only. NOT FOR MEDICINAL USE.
- The source material used for preparation of the reagent 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

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

### TEST PROCEDURE

- Use the reconstituted **SBio Control Plasma** controls in the same manner as freshly prepared citrated Platelet Poor Plasma from a patient.
- Use the procedure as laid out in the PT, APTT, TT and FIBRINOGEN pack inserts.

### EXPECTED VALUES

- The expected value of specific assays is provided on the assay value sheet accompanying the kit, and are lot specific, instrument specific.
- The expected values are obtained using replicate assay of each manufactured lot of **SBio Control Plasma**, manually and using mechanical coagulometers such as HEMOSTAR, HEMOSTAR XF, CoaLAB 6000, CoaSTAT, HEMOSTAR AUTO.
- The individual laboratory values should fall within the expected values.
- It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

### REMARKS

- When used appropriately, **SBio Control Plasma** 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 equipments, some variation from assigned mean values may be expected.

### PERFORMANCE CHARACTERISTICS

**SBio Control Plasma H-I/H-II** 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 **SBio Control Plasma H-I/H-II** were tested with the reagents described in the assay value sheet. The tests were performed on Hemostar-XF (coagulometer).

### WARRANTY

This 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

- W.H.O. Technical Series, 687, 1983.
- Human Blood Coagulation, Hemostasis and Thrombosis; Edited by Rosemary Biggs, Blackwell Scientific Publications 1972.

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