

Special Coagulation Calibrator PC/PS/AT

REF C.BMD.SCC030-01ML-A 6 x 1.0 mL
CE **IVD** For *In Vitro* Diagnostic Use

INTENDED USE

The Special Coagulation Calibrator is intended for use as a calibrator for the creation of a reference curve for assays that measure Protein C activity, Protein S activity and Antithrombin activity via a manual method, or via semi-automated or automated coagulation analysers in a clinical setting.

REAGENT

The Special Coagulation Calibrator is a lyophilized preparation of buffered human plasma.

PRECAUTIONS

1. Do not ingest.
2. Avoid contact with skin, eyes or clothing.
3. **WARNING: POTENTIAL BIOHAZARDOUS MATERIAL**
 The source material for this product has been tested and found negative for the presence of HIV and HCV antibodies as well as Hepatitis B Surface Antigen by approved test methods. However, no known test method can offer assurance that products derived from human blood are free of infectious agents. Therefore, handle this material observing the same safety precautions employed when handling any potentially infectious material.

Dispose of discarded material and packing in accordance with all applicable local regulations.

REAGENT PREPARATION

1. Reconstitute the Special Coagulation Calibrator with 1.0 mL of purified water.
2. Replace the stopper and gently invert the vial to thoroughly disperse the contents. Let stand at room temperature for no less than 30 minutes before use to assure complete rehydration of the contents.

STORAGE AND STABILITY

This lyophilized calibrator is stable until the expiration date stated on the vial when stored unopened at 2°C to 8°C. Reconstituted calibrator is stable for 4 hours when stored at room temperature in the original container.

PROCEDURE

The reconstituted Special Coagulation Calibrator is diluted and assayed to generate a reference curve for Protein C, Protein S, and Antithrombin assays. Refer to the appropriate Instructions For Use or Instrument Application for the instructions specific to the protein assay of choice.

LIMITATIONS






The Special Coagulation Calibrator, when properly used, is subject to the limitations of the assay system employed. Results outside of the performance range may indicate product deterioration or problems with one or more components of the test system.

VALUE ASSIGNMENT

The Special Coagulation Calibrator has been assigned values for Protein S, Protein C, and Antithrombin by direct comparison with World Health Organization International Standards. The assigned values are lot specific, therefore refer to the Certificate of Analysis accompanying each lot to obtain the lot specific values.

WARRANTY

This product is warranted to perform in accordance with its labeling and literature. BioMedica Diagnostics Inc. disclaims any implied warranty of merchantability or fitness for any other purpose. Purchaser must calibrate and determine the suitability of BioMedica Diagnostics products for their specific applications. In no event will BioMedica Diagnostics Inc. be liable for any consequential damages arising out of aforesaid express warranty.

Symbols Key	
	Manufacturer
	Consult Instructions For Use
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
	Expiration Date (YYYY.MM)
	Temperature Limitations
REF	Catalogue Number
CON	Contents
REC	Reconstitution Volume
	Biological Risks

