Special Coagulation Control Abnormal

REF C.BMD.SCCA180-01ML-A 10 x 1.0 mL

CE IVD For *In Vitro* Diagnostic Use

INTENDED USE

The Special Coagulation Control Abnormal is intended to be used as an unassayed abnormal control for monitoring the performance of special and routine coagulation assays on analyzers in a clinical setting[1-3].

REAGENT

The Special Coagulation Control Abnormal 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.

REAGENT PREPARATION

1. Reconstitute the Special Coagulation Control Abnormal 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 product will be stable until the expiration date when stored unopened at 2°C to 8°C. The reconstituted plasma control is stable for 8 hours when stored at room temperature in the original container, however stability of FVIII and Protein S may be reduced after 4 hours.

PROCEDURE

The reconstituted Special Coagulation Control Abnormal is tested in the same manner as freshly drawn citrated patient plasma in routine and special coagulation tests. Refer to the appropriate product inserts for test specific instructions.

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

Influences such as reagent type, methodology, instrumentation and technique contribute to variation in test results. Each laboratory should establish its own acceptance ranges with each new lot of plasma control. The Special Coagulation Control Abnormal will typically yield results within the range specified in the following table:

Coagulation Test	Target Range
Prothrombin Time	18.0 – 26.0 seconds
Activated Partial Thrombin Time	50.0 – 70.0 seconds
Thrombin Time	22.0 – 35.0 seconds
Fibrinogen Concentration	< 200 mg/dL
Factor II Activity	≤ 60%
Factor V Activity	≤ 60%
Factor VII Activity	≤ 60%
Factor VIII Activity	≤ 60%
Factor IX Activity	≤ 60%
Factor X Activity	≤ 60%
Factor XI Activity	≤ 60%
Factor XII Activity	≤ 60%
Factor XIII Activity	≤ 60%
Protein S Activity	≤ 50%
Protein C Activity	≤ 60%
Antithrombin III Activity	≤ 60%
Plasminogen Activity	≤ 60%
Alpha2-Antiplasmin Activity	≤ 60%

REFERENCES

1. Plebani, M., *et al*. *Semin Thromb Hemost* 2008, 34(7): 642.
2. Bonar, R., *et al*. *Biochemia Medica* 2010, 20(2): 184.
3. McFarlane, A., *et al*. *Int Jrnl Lab Hem* 2015, 37: 729.

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's 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

BioMedica Diagnostics Inc.
P.O. Box 1030, 94 Wentworth Road
Windsor, NS, Canada B0N 2T0
Tel: 1-902-798-5105 | Fax: 1-902-798-1025
info@biomedicadiagnostics.com | www.biomedicadiagnostics.com

EC REP
Obelis s.a.
53 Boulevard General Wahis
1030 Brussels – Belgium
Tel: +(32) 2 732-59-54 | Fax: +(32) 2 732-60-03
email: mail@obelis.net