

The test should be used in conjunction with clinical observations and results of other laboratory tests.

Catalogue # 40112 (ROW)

## PROTEIN C NORMAL CONTROL PLASMA

10 x 0.5ml. For *in vitro* diagnostic use only.

### FOR INFORMATION USE ONLY

**Not to be used for performing the assay.  
Refer to the insert accompanying kit**

#### I. INTENDED USE

Protein C Normal Control Plasma is used for day-to-day control of Protein C assays.

#### II. PRINCIPLE

Protein C is a Vitamin K-dependent anticoagulant protein that normally circulates in plasma as the inactive zymogen <sup>(1,2)</sup>. After activation, Protein C proteolytically degrades factors V and VIII, thus prolonging the clotting time <sup>(3,4)</sup>.

Protein C Normal Control Plasma is a freeze-dried preparation of normal human plasma for which the Protein C activity has been determined. The antigen level is assayed by ELISA. The Protein C activity is assayed using both a clottable assay and a chromogenic assay. The clottable Protein C activity is measured using Biopool Bioclot<sup>®</sup> Protein C Kit (Catalogue #40133). The chromogenic Protein C activity is measured using Biopool Spectrolyse<sup>®</sup> Protein C Kit (Catalogue #40131). Both the clotting and chromogenic assay systems employ a Protein G-specific snake venom fraction to activate Protein C <sup>(5)</sup>.

#### III. REAGENT

##### A. Reagent Description

###### Protein C Normal Control Plasma:

10 vials of 0.5ml, freeze-dried. Each vial contains normal human plasma prepared from a pool of normal donor plasmas that were anticoagulated with sodium citrate, buffered, and rapidly processed to preserve the plasma Protein C.

##### B. Reagent Preparation

**Protein C Normal Control Plasma:** Reconstitute each vial with 0.5ml reagent grade water. Allow to stand at room temperature with occasional swirling for 20 minutes to allow complete dissolution. Transfer plasma to a plastic test tube immediately after reconstitution and store at 2-8°C. Reconstituted material is stable for four hours when stored at 2-8°C.

#### IV. STORAGE AND STABILITY

All unreconstituted reagents are stable until the expiration date stated on the box and vial labels when stored at 2-8°C.

#### V. WARNINGS AND PRECAUTIONS

Each unit of source plasma used in the preparation of this product has been tested by an FDA approved method for the presence of antibody to Human Immunodeficiency Virus (HIV) Type I and Type II, Hepatitis B surface antigen (HB<sub>s</sub>Ag) as well as for Hepatitis C (HCV) and found negative (not repeatedly reactive). Donors have been screened for Creutzfeldt-Jakob Disease (CJD) and new variant Creutzfeldt-Jakob Disease (nvCJD) and found acceptable. However, no test can offer complete assurance that products derived from human blood will not transmit infectious diseases. As with all materials of human origin, this product should be handled as a potentially infectious material. All wastes containing biological material should be properly labelled and stored separately from other wastes. Dispose of all waste materials according to prescribed international, national and local regulations.

#### VI. PROCEDURE

##### A. Material Provided

Protein C Normal Control Plasma

##### B. Additional Material Required (but not provided)

Reagent grade water  
100-1000 µl variable volume pipette  
Test tubes (plastic)

##### C. Assay Procedure

Use Biopool Protein C Normal Control Plasma as a reference plasma or as a control plasma in a manner similar to plasmas being tested and in accordance with instructions for test procedures being used.

#### VII. QUALITY CONTROL

Biopool Protein C Normal Control Plasma is intended for use as a reference plasma or quality control check in Protein C assays. An inability to achieve test results as listed in EXPECTED VALUES, Section VIII. could indicate product deterioration. Contact Trinity Biotech Technical services.

#### VIII. EXPECTED VALUES

Each lot of Biopool Protein C Normal Control Plasma is tested by procedures listed in the lot specific data sheet part number 646-377.

#### IX. REFERENCES

1. Stenflo, J. A., New vitamin K-dependent protein. *J. Biol. Chem.* **251**: 355,1976.
2. Esmon, C.T., Stenflo, J., Suttie, J.W., and Jackson, C.M., A new vitamin K-dependent protein. A phospholipid-binding zymogen of a serine esterase. *J. Biol. Chem.* **251**: 3052,1976.
3. Walker, F.J., Sexton, P.W., and Esmon, C.T., The inhibition of blood coagulation by activated protein C through the selective inactivation of activated factor V. *Biochim. Biophys. Acta.* **571**: 333, 1979.
4. Fay, P.J. Smudzin, T.M., and Walker, F.J., Activated protein C catalyzed inactivation of human Factor VIII and Factor VIIIa. Identification of cleavage sites and correlation of proteolysis with cofactor activity. *J. Biol. Chem.* **266**: 20139,1991.
5. Martinoli, J.L., and Stocker, K., Fast functional protein C assay using Protac<sup>®</sup>, a novel protein C activator. *Thromb. Res.* **43**: 25364,1986.

## X. KEY GUIDE TO SYMBOLS



Use by



Lot



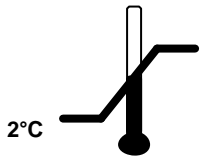
Catalogue number



Manufacturer



For *in vitro* diagnostic use



Store at 2-8°C



Consult accompanying documents



Biological risks

**Recon.**

Reconstitute with

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**Fax: (353) 1 276 9888,**  
**Web: [www.trinitybiotech.com](http://www.trinitybiotech.com)**

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