

Native Human Protein C Concentrate Reference Standard

Cat. No. Protein C-12HRS **Lot. No.** (See product label)

SPECIFICATION

Product Overview

Species	Human
Source	Human Plasma
Tag	Non
Form	white freeze-dred powder
Stability	Stability of this standard has been assessed in an accelerated degradation study which involves the potency estimation of ampoules stored at elevated temperatures relative to ampoules stored at -150°C. Potency assessment after 7 years of storage at elevated temperatures showed that at -20°C there was no loss of activity. The predicted loss at +20°C is less than 0.6% for all measured parameters which supports shipping of the Standard at ambient temperatures. The accelerated degradation study and real time monitoring will continue for the lifetime of the standard.
Usage	This standard is intended for use in the estimation of functional chromogenic activity and antigenic content of protein C concentrates.
Storage	Unopened ampoules should be stored in the dark at or below -20°C.
contents	One aliquot (50,000 U, ~100 ml) of plasma derived human protein C concentrate was thawed at 37°C and was further diluted with approximately 3.5 litres of 0.05M Tris,

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0.15M NaCl, pH 7.4 containing 2mg/ml trehalose and 5 mg/ml human albumin. The solution was distributed at 4°C into 3500 ampoules.

Shipping

Because of the inherent stability of lyophilized material, may ship these materials at ambient temperature.

UNITAGE

The following potency was assigned based on the geometric mean of all the valid assay results:

Functional (chromogenic assay only) : 15.0 IU/ampoule

Antigenic: 14.5 IU/ampoule

USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

Allow ampoules to warm to room temperature. Open ampoule, taking care to ensure that all material is in the lower part, and reconstitute with 1.0 ml distilled water. Stand for 10 minutes at room temperature to allow complete dissolution of the material before use. The reconstituted standard should be transferred to a plastic tube and stored on melting ice. The reconstituted Standard should be used as soon as possible, preferably within 4 hours of reconstitution.