

Native Human Antithrombin Reference Standard

Cat. No. Antithrombin-15HRS **Lot. No.** (See product label)

SPECIFICATION

Product Overview

Species	Human
Source	Human Plasma
Tag	Non
Form	white freeze-dried powder
Stability	Accelerated degradation study, involving the potency estimation of ampoules stored at elevated temperatures relative to ampoules stored at -150°C was carried out in one laboratory, using the heparin cofactor chromogenic thrombin based assay. Estimated loss of functional and antigen activity after 6 years storage is less than 0.02% per year when stored at -20°C, the storage temperature of the proposed IS. These data indicate that the preparation is exceedingly stable and suitable for long term use as an International Standard. The predicted loss at +20°C is less than 0.4% per year which supports the shipment at ambient temperature. The accelerated degradation study and real time monitoring will continue for the lifetime of the standard.
Storage	Unopened ampoules should be stored in the dark at or below -20°C.
contents	Thirty-four vials (1500 IU/vial) of plasma derived human antithrombin concentrate were each reconstituted with 30 ml of sterile distilled water. Following the dilution of

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the pooled material with approximately 9 litres of 0.05M Tris, 0.15M NaCl, pH 7.4 containing 2 mg/ml trehalose and 10 mg/ml human albumin. the solution was distributed at 4°C into 10,000 ampoules.

Shipping

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

UNITAGE

The assigned potencies are as follows:

Functional : 4.4 IU/ampoule

Antigenic: 4.5 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 used as soon as possible.

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