

Human Antithrombin Reference standard

Cat. No. Antithrombin-21H **Lot. No.** (See product label)

SPECIFICATION

Product Overview	The reference standard containing aliquots of a freeze-dried concentrate prepared from human plasma.
Species	Human
Enzyme Unit	The assigned potencies are as follows: Functional : 4.4 IU/ampoule Antigenic: 4.5 IU/ampoule Uncertainty: the assigned unitage does not carry an uncertainty associated with its calibration. The uncertainty may therefore be considered to be the variance of the ampoule content and was determined to be +/- 0.21 %.
Usage	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.
Notes	This preparation is not for administration to humans. The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratorys safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

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Care should be exercised in opening ampoules or vials, to avoid cuts.

Stability

Reference materials are held at Creative Biomart within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use. 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 (Creative Biomart), using the heparin co- factor chromogenic thrombin based assay. These data indicate that the preparation is exceedingly stable and suitable for long term use as an International Standard. The predicted loss at $+20^{\circ}\text{C}$ 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 . Please note: because of the inherent stability of lyophilized material, Creative Biomart may ship these materials at ambient temperature.

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