

5-PROTEIN Antithrombin (Human)

REF 5D-60104

**For Research Use Only.
Not for Use in Diagnostic Procedures.
For *in vitro* use only.**

**Store at 2-8°C
1 vial of about 10 IU**

English, last revision: 03-2023

INTENDED USE:

All research studies and protocols where a source of highly purified human Antithrombin (AT) is necessary.

This kit is for research use only and should not be used for patient diagnosis or treatment.

REAGENTS:

Highly purified from human plasma using a combination of affinity and ion-exchange chromatographies.
Vial containing about 10 IU of AT (when determined and standardized against the WHO/NIBSC International standard for Antithrombin, Concentrate, human).
1 vial of 1 mL.

WARNING AND PRECAUTIONS:

- The plasma used for AT purification was tested with registered methods and found negative for HIV antibodies, HBs Ag and HCV antibodies. However, no assay may warrant the total absence of infectious agents. Any product of human origin must then be handled with all the required cautions, as being potentially infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface.
- Ageing studies show that the reagents can be shipped at room temperature without degradation.
- To preserve reagent stability, seal the vials after use with their respective caps.
- This device is intended for professional use in the laboratory.
- For *in vitro* use.

REAGENT PREPARATION AND STABILITY:

Reconstitute the contents of each vial with exactly **1 mL distilled water**, in order to get a concentration of at least 9 IU/mL. Dilute in the adequate buffer, if necessary. Shake vigorously until fully dissolved. Allow to stabilize for 15 minutes at room temperature (18-25°C), shaking occasionally.

Homogenize the reagent prior to use.

STORAGE CONDITIONS:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

Reagent stability after reconstitution, excluding any contamination or evaporation, and stored in the original vial, is of:

- 1 month at 2-8°C.
- 72 hours at room temperature (18-25°C).
- 6 months frozen at -20°C or less*

*Thaw only once, as rapidly as possible at 37°C, adapting the incubation period to the volume of reagent. The stability of the thawed reagent should be checked under laboratory work conditions. (tested for anti-Xa chromogenic activity in presence of heparin: > 9 IU/mg).

LIMITATIONS:

- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.
- Excipients: Content per vial: Glycine (20 mg), Hepes (6 mg), Sodium Chloride (9 mg).
- Purity: One major band at about 58,000 daltons on SDS-PAGE.
- Activity: In a clotting assay for the thrombin inhibition capacity in presence of an excess of unfractionated heparin: 9 IU AT neutralize at least 2,000 NIH units of thrombin. Tested for anti-Xa activity in presence of heparin, with a chromogenic assay (> 9 IU/mg). Factor Xa neutralisation capacity is > 500 µg of Xa/mg AT.

The absence of heparin is verified after purification, using a toluidine blue assay (refer to: F.C MacIntosh, "A colorimetric method for the standardization of heparin preparations", Biochem, 1941, 35:776-782), and an anti-Xa specific chromogenic assay.

The exact activity is reported on the analysis certificate for each substrate.

The results obtained should be for research purposes only and not used for patient diagnosis or treatment.

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see symbol definitions below.

| | |
|---|-------------------------|
|  | Catalog number |
|  | Batch code |
|  | Expiration date |
|  | Reconstitution volume |
|  | YYYY-MM-DD Use by |
|  | See instruction for use |
|  | Temperature limitation |

Certificate of Analysis

5-PROTEIN Antithrombin (Human)

Vial of 1 ml

REF 5D-60104

LOT XXX

EXP XXX

Store at 2-8°C

Analytical Data | Specifications

Protein Content:

1.37 mg/vial | For information only

SDS-PAGE (4-12 % acrylamide):

58,000 daltons | 1 major band of about 58,000 daltons

Anti-Xa activity (chromogenic assay in presence of heparin):

AT activity: 13 IU | > 9 IU

Absence of heparin (Toluidine blue assay):

Absence | Absence

Batch homogeneity

N = 15 – CV : 1.9% | CV(OD) ≤ 2%

Conclusions:

Date: XXX

Passed
 Refused