

## *Dia-AT III*



LIQUID REAGENT FOR ANTITHROMBIN (AT III) DETERMINATION

**Ref. No.: 01036**

- Bovine FXa **6 x 6 ml**
- Chromogenic substrate for FXa **3 x 3 ml**

**PRODUCT NAME**

Dia-AT III

**INTENDED USE**

The Antithrombin Liquid kit is intended for the quantitative determination of Antithrombin activity in human citrated plasma.

 **PRECAUTIONS**

The reagents of the kit are only for *in vitro* diagnostic use and required to have directions from a professional.

**BACKGROUND A PRINCIPLE OF METHOD**

Antithrombin (AT) is the primary physiological inhibitor of thrombin and factor Xa (FXa) in plasma and thereby effectively regulates blood coagulation. Unfractionated (UF) and low molecular weight (LMW) heparin greatly enhances AT activity. Hereditary or acquired AT deficiency is an important risk factor for venous thromboembolic disorders. Antithrombin activity is determined in a two-stage chromogenic assay as follows:

- An excess of FXa is added to citrated plasma in the presence of heparin.
- The residual FXa activity is determined from the hydrolysis of a chromogenic FXa-substrate, which results in the release of free p-nitroaniline, pNA. The AT activity is inversely related to the amount of released pNA and is expressed as % AT activity derived from a standard curve.

**PRODUCT DESCRIPTION**

- Factor Xa reagent: 6 x 6 mL of bovine FXa, 10 nkat/mL, in Tris buffer pH 8.2, containing heparin, stabilizers and preservatives.
- Chromogenic substrate for FXa: 3 x 3 mL of chromogenic FXa substrate in water medium containing detergent and preservatives.

For sample and calibrator dilutions, the following material should be used (not included in the kit):

- Dia-Imidazol Ref. No.: 21180

 **PRECAUTIONS**

Suitable protection clothing is recommended. Avoid contact with skin and eyes.

All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.

Do not use the reagent beyond the expiration date printed on the label!

 **STORAGE CONDITIONS AND STABILITY**

Unopened reagents are stable until the expiration date shown on the label when stored at 2-8°C.

Opened reagent of bovine FXa is stable for 1 month at 2-8°C and for 48 hours at 12- 15°C.

Opened reagent of chromogenic FXa-substrate is stable for 1 month at 2-8°C and for 48 hours at 12-15°C

Note: Keep FXa-substrate in dark.

Avoid contamination of opened reagents.

**SPECIMEN COLLECTION AND STORAGE**

It is recommended that specimen collection and storage be carried out in accordance with CLSI guideline H21-A5.

Venous blood is collected in 3.2% sodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio). The ratio is critical. If using commercial vacuum tubes, a full draw must be assured. Trauma or stasis during drawing should be avoided. Blood should not be collected through a heparin lock or other heparinized line. The presence of a clot in a specimen is cause for rejection. Centrifuge at 1500 x g for 15 minutes or at a speed and time required to produce platelet poor plasma (platelet count < 10,000/ $\mu$ l). Unless samples are to be processed immediately, transfer plasma to a plastic tube as soon as centrifugation is completed. Plasma samples can be stored at room temperature (18-26°C) for up to 4 hours; refrigerated (2-8°C) for up to 4 hours; frozen at -20°C for up to 2 weeks or at -70°C for up to 6 months. Quick thaw frozen samples and test immediately. If testing cannot be performed immediately, the sample may be held for a maximum of 2 hours refrigerated (2-8°C) prior to testing.

No contact with glass should occur.


**PARAMETER SET UP**

Be sure that the final volume is within instrument specification.

Typical settings for an automated analyzer:

- Dispense 4 µl sample + 40µL saline
- Add 140 µl Factor Xa
- Incubate 120 sec
- Start reaction by adding 40µl FXa Substrate
- First reading after 5 sec
- Final reading after 60 sec
- Wave length 405 nm
- Temperature 37 °C

**CALIBRATION**

Recommended calibrator (not included in the kit):  
 Dia-Cal AT III (Ref. No.: 90512) human normal plasma, which is calibrated in IU/mL vs the SSC/ISTH Secondary Coagulation Standard Plasma. 1% AT activity is defined as 0.01 IU of AT activity in 1 mL plasma.

**QUALITY CONTROL**

Recommended normal and pathological controls (not included in the kit):

Dia-MULTI N Ref. No.: 90112

Dia-MULTI P Ref. No.: 90212

in accordance with good laboratory practice.

**MATERIALS REQUIRED BUT NOT PROVIDED**

Dia-Cal AT III Ref. No.: 90512

Dia-MULTI N Ref. No.: 90112

Dia-MULTI P Ref. No.: 90212

Dia-Imidazol Ref. No.: 21180

**SPECIFICITY AND INTERFERENCE**

Antithrombin Liquid, which is based upon the use of FXa, is not affected by Heparin Cofactor II activity. Furthermore, no affect is caused by UF and LMW heparin up to 4.0 U/mL, by bilirubin up to 40 mg/dL, by triglycerides up to 500 mg/dL and by hemoglobin up to 150 mg/dL.

**EXPECTED VALUES**

Each laboratory should establish its own normal range on the specific instrument used.

**TYPICAL PERFORMANCE (ACL 9000)**

Precision within run:

Level 0.90 CV = 2.1 %


Level 0.45 CV = 2.6 %

Precision between runs:











Level 0.90 CV = 4.4 %

Level 0.45 CV = 3.3 %

Linearity: 0.15 – 1.2 IU/mL

**MANUFACTURER**


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SYMBOLS			
	<i>In vitro</i> diagnostic medical device		Consult Instruction for Use
	Biological risks		Temperature limit range
	Do not re-use		Used-by date (Expiration date)
	Manufacturer		CE European conformity mark
	Batch code (LOT number)		Catalogue number (Reference number)