MediRox

CE

Revision: 2016-11-04
Changes: Information about saline updated and changed place in IFU. MRX184 included as material needed but not included, MRX1202 and 1203 included calibrator material
Supersedes: 2016-01-01

# MRX Antithrombin Liquid Art. No: MRX1200

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

**FOR IN VITRO DIAGNOSTIC USE**

## BACKGROUND AND 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.

Material needed but not included in the kit:

Saline (0,9% NaCl)
MediRox recommend the use of MRX184 Sample diluent (0,9% Saline)
For sample and calibrator dilutions

## PRECAUTIONS
Wear suitable clothing for protection. Avoid contact with skin and eyes.

## 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 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/µl). 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

Procedure (Be sure final volume is within instrument specification)
Typical settings for an automated analyser

- 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 MATERIAL (Not included in kit)
MediRox recommends the use of Calibrator Plasma MRX1201, MRX1202 or MRX1203, 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 (Not included in kit)
MediRox recommends the use of normal control plasma (GHI162, GHI163, GHI164, MRX171 or MRX181) and abnormal control plasma (GHI167B, GHI169, GHI170, MRX172 or MRX182) for reliable quality control of the performance and at a frequency in accordance with good laboratory practise.

## SPECIFICITY AND INTERFERENCES
Antithrombin Liquid, which is based upon the use of FXa, are 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
A normal range study was performed using the Antithrombin Liquid kit

| **System** | **n** | **range** |
|---|---|---|
| ACL Top | 50 | 0,80-1,20 IU/mL |

These results were obtained using a specific lot of reagent. Due to many variables which may affect results, each laboratory should establish its own normal range.

## 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 | |

Correlation: Medirox AT LR / IL HemosIL AT

| **System** | **n** | **slope** | **intercept** | **r** |
|---|---|---|---|---|
| ACLTop | 78 | 1,018 | -0,7 | 0,98 |

## REFERENCES


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