

**Intended use and applications**

IVD:  CE  510(k)  RUO

Diagnosis of congenital or acquired AT deficiencies (eg in pregnancy, oral contraceptive therapy, spontaneous thromboembolic diseases contexts).

**Principle**

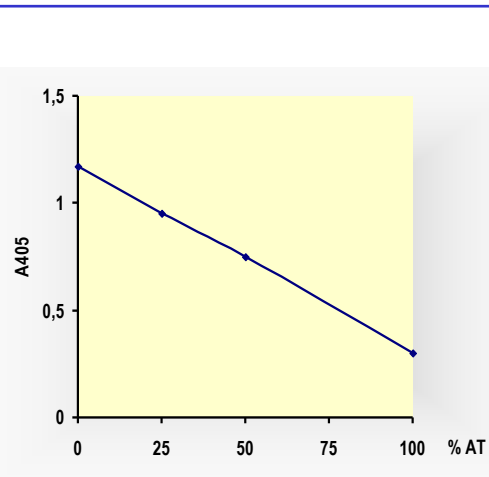
Quantitative determination of the heparin cofactor activity of AT in human citrated plasma, using a chromogenic anti-Xa method, manual or automated.

- R1: Bovine Factor Xa, lyophilised.
- R2: FXa chromogenic substrate (Sxa-11), lyophilised.
- R3: Tris-Heparin buffer, ready to use.

**Characteristics and advantages**

- **Simple and rapid:** lyophilised and ready to use; total assay time < 5 min.
- Easy to use on major **coagulation analyzers, microplate or basic equipment** (~50 or 200 tests per kit (on STAR or microplate)).
- **Associated calibrators and controls** validated against the International Standard for AT (NIBSC 93/768).
- Dynamic range ~ **0 - 120% AT in human citrated plasma** (dilution **1:20** with physiological saline)
- Detection threshold < 5%
- Highly **specific, sensitive, reproducible** (AT poor plasma <10%; Intra assay CV< 2% ; Inter assay CV <4 %)
- **Variant protocol available for abnormal AT with decreased heparin binding activity.**
- **Highly stable** ( 3 months at 2-8 C , 7 days at RT(18-25 C)).
- **Safe, optimized, standardized:** highly purified bovine FXa; inter lots correlation r2>0.97
- **No significant interference** of heparin<2IU/ml, bilirubin<0.1mg/ml, haemoglobin<5mg/ml, triglycerides<1.25mg/ml added to plasma.

**Calibration curve (Manual method)**



**Performance comparison with commercial devices**

Eg compared with Coamatic AT (Chromogenix) or Berichrom AT (Dade Behring) for AT measurement on patients' plasma samples

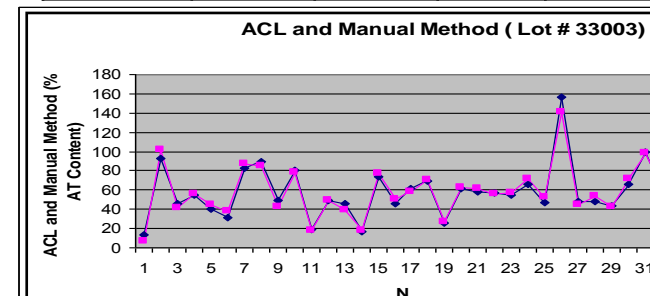
On BCS	Coamatic	Biophen	On STA	Coamatic	Biophen
N	21	21	N	14	14
Mean %AT	88.6	89.5	Mean %AT	99.9	105.2
Median	83.0	83.0	Median	111.5	124.0
SD	23.8	26.3	SD	44.1	41.2
Min-Max	41-139	39-143	Min-Max	26-140	35-142

	Coamatic	Berichrom	Biophen
N	26	26	26
Mean %AT	87.5	84.5	85.1
Median	100.5	95.0	96.5
SD	27.3	26.5	29.1
Min-Max	39-120	34-124	31-128

Excellent consistency, on various instruments.

**Inter lots and inter-instruments**

N=65	STA		Manual method	
	33003	31403	33003	31403
Lot	33003	31403	33003	31403
Mean %AT	86.9	85.1	83.4	81.6
Median	98	97	94	92
SD	30.5	28.8	33.3	31.7
Min-Max	14-142	9-129	7-144	13-144



Excellent correlation on the dynamic range from lot to lot, on multiple instruments.

**Related products**

- 1 Biophen Plasma Calibrator, Normal and Abnormal Control Plasmas (#A222101/A223201/A223301)
- 2 Liaphen AT (#A120002)