

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

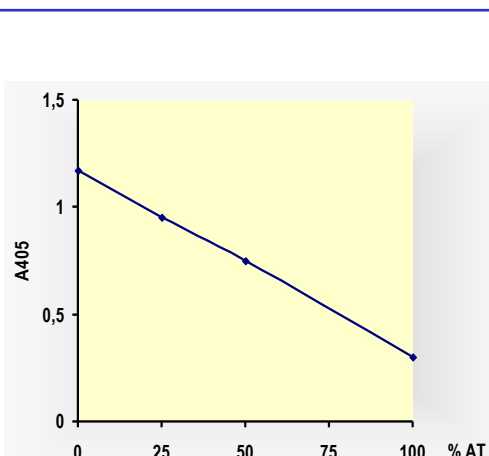
Quantitative determination of the heparin cofactor activity of AT in human citrated plasma, using a chromogenic anti-Xa method, manual or automated.

- 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

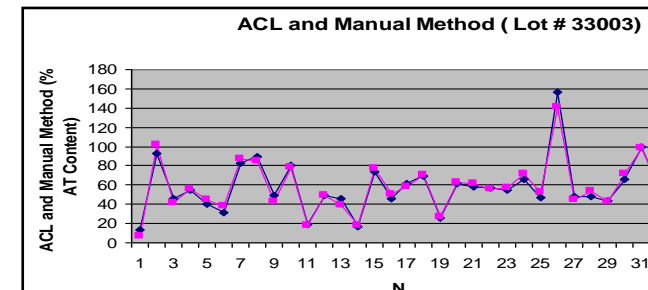
On BCS	Coamatic	Biophen	On STA	Coamatic	Biophen
N	21	21	N	14	14
Mean %AT	88.6	89.5	Mean %AT	99.9	105.2
Median	83.0	83.0	Median	111.5	124.0
SD	23.8	26.3	SD	44.1	41.2
Min-Max	41-139	39-143	Min-Max	26-140	35-142

	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. Biophen AT (LRT) (#A221111)
3. Liaphen AT (#A120002)