

## Intended use and applications

**RUO** (US/Canada): For Research Use Only. Not For Use in Diagnostic Procedures.

## Principle

Turbidimetric latex immunoassay for measuring AT in human citrated plasma, using a manual or automated method, in vitro exclusively.

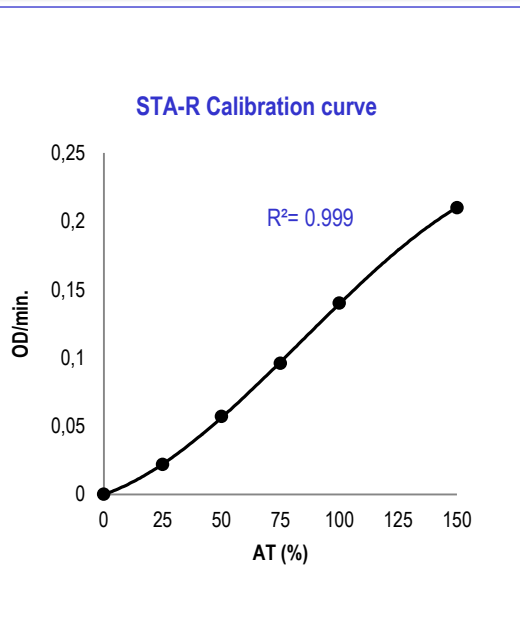
**R1:** Latex reagent, liquid form.

**R2::** Reaction buffer, ready to use.

## Characteristics and advantages

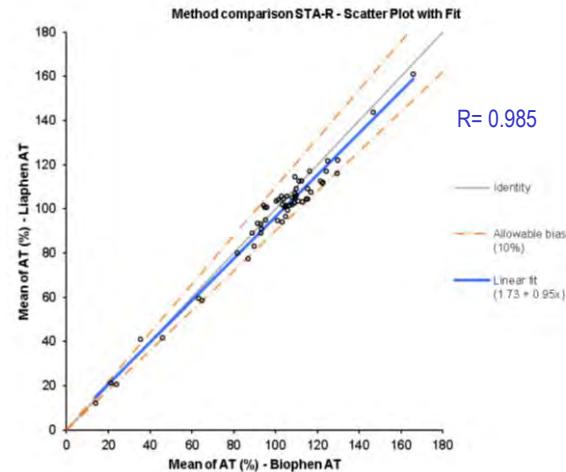
- Simple and rapid: « ready to use» **liquid reagent** ; Total assay time : < 10 min.
- Easy to use on major coagulation analyzers or with basic equipment ( ~80 (STAR) or 50 (manual method) tests per kit).
- Associated calibrators and controls validated against the International Standard for AT (NIBSC).
- Dynamic range: **0 – 150 %** in human citrated plasma
- Limit of Blank:  $\leq 5 \%$  ; Limit of Quantification:  $\leq 11.4 \%$
- Highly **specific**: AT deficient plasma assayed < 5%;
- Highly reproducible: **Repeatability = 1.9 - 3.0 %** ; **Total reproducibility = 4.4 - 7.4 %**
- Highly stable after opening:  $\geq 6$  months at 2-8°C , 7 days at RT (18-25°C).
- **Safe, optimized, standardized**: raw materials tested for viral safety, inter-lots correlation R=0.992.
- No interference of Heparin (UFH or LMWH)  $\leq 2$  IU/ml, Bilirubin  $\leq 0.2$  g/L, Haemoglobin  $\leq 2$  g/L, Triglycerides  $\leq 20$  g/L.
- No hook effect for AT concentrations  $\leq 200\%$  (on STA-R instrument).

## Calibration curve



## Method comparison with Biophen AT

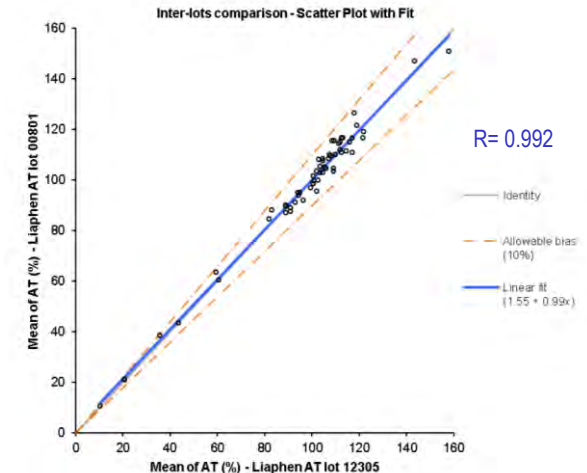
**Predicate device:** Biophen AT (AT chromogenic assay), Hyphen-Biomed.  
**Instrument:** STA-R **Number of samples :** N=59



Excellent correlation between Liaphen AT and Biophen AT.

## Inter-lots comparison

Liaphen AT Lot 1: 00801; Liaphen AT Lot 2: 12305.  
**Instrument:** STA-R **Number of samples :** N=58



Excellent correlation from lot to lot .

## Related products

1. Biophen Plasma Calibrator (# A222101) (CE, 510(k))
2. Normal and Abnormal Control Plasmas (#A223201/A223301) (CE, 510(k))
3. Biophen AT (LRT) (# A221111) (CE)
4. Biophen AT (# A221102/A221105) (CE, 510(k))

## References

1. Tsiang M et al. Functional requirements for inhibition of Thrombin by Antithrombin III in the presence and absence of heparin. J. Biol Chem vol. 272, N°18 12024-12029 (1997)
2. Mann K.G. Biochemistry and Physiology of blood coagulation. Thromb Haemost vol 82 N° 2 165-174 (1999).
3. Mortensen J.Z. Inherited ATIII deficiency. Fast and slow inactivation of thrombin and Factor Xa Thromb. Res., 33, 511-515 51984).
4. Tollefsen D.M. Laboratory Diagnosis of Antithrombin and Heparin Cofactor II deficiency. Seminars in Thromb haemost 16, 162-168 (1990).