



Please note that the uses described in the following page(s) have not been approved or cleared by FDA, with respect to the described assay or test.

In the US, the product is intended **For Research Use Only.**
Not for Use in Diagnostic Procedures.

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.

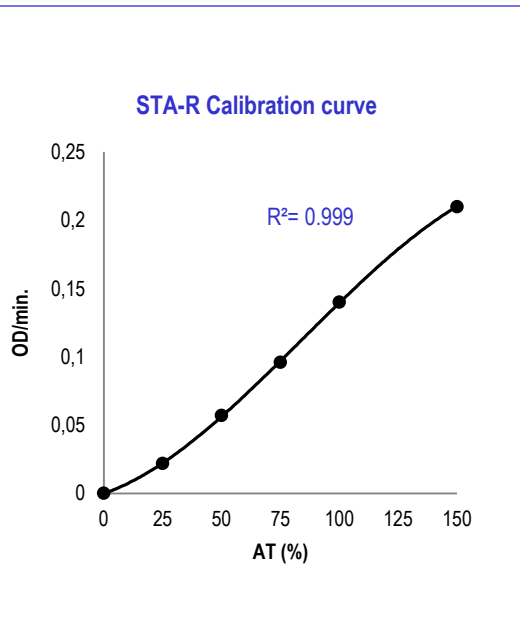
R1: Latex reagent, liquid form.

R2:: Reaction buffer, ready to use.

Characteristics and advantages

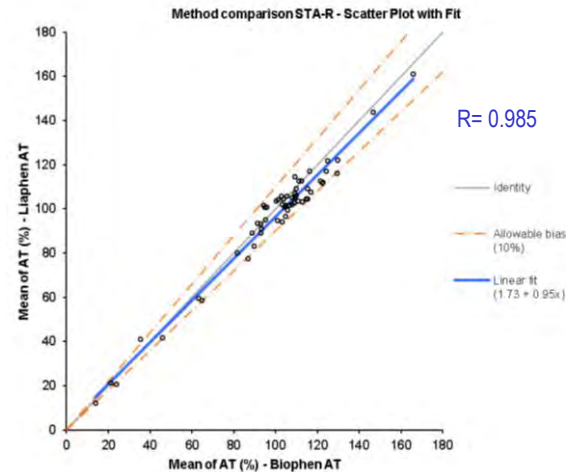
- Simple and rapid: « ready to use» **liquid reagent** ; Total assay time : < 10 min.
- Easy to use on major coagulation analyzers or with basic equipment (~80 (STAR) or 50 (manual method) tests per kit).
- Associated calibrators and controls validated against the International Standard for AT (NIBSC).
- 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: ≥ 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) ≤ 2 IU/ml, Bilirubin ≤ 0.2 g/L, Haemoglobin ≤ 2 g/L, Triglycerides ≤ 20 g/L.
- No hook effect for AT concentrations $\leq 200\%$ (on STA-R instrument).

Calibration curve



Method comparison with Biophen AT

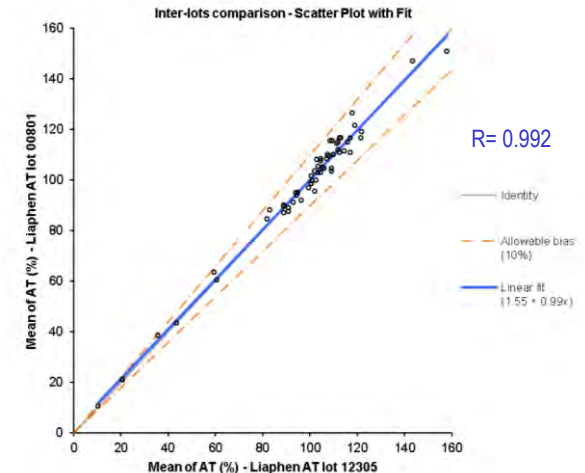
Predicate device: Biophen AT (AT chromogenic assay), Hyphen-Biomed.
Instrument: STA-R **Number of samples :** N=59



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).