LIAPHEN AT technical file (#A120002)

Intended use and applications

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

Principle

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

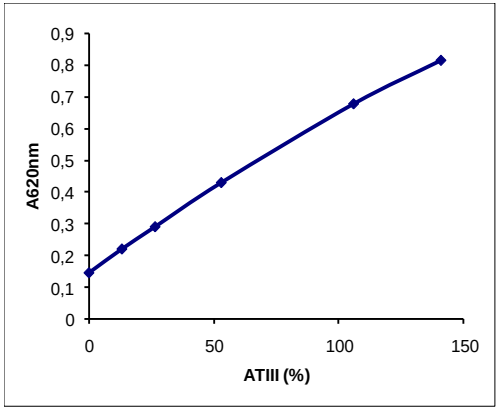
R1: Latex reagent, liquid form.

R2:: Reaction buffer, ready to use.

Characteristics and advantages

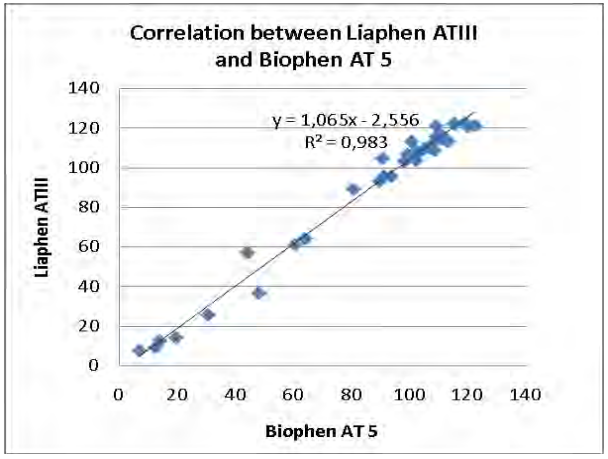
- **Simple and rapid:** « ready to use »; total assay time <20 min.
- Easy to use on major **coagulation analyzers or with basic equipment (** ~80 (STAR) or 50 (manual method) tests per kit).
- **Associated calibrators and controls** validated against the International Standard for AT (NIBSC).
- Dynamic range ~ **0 - 130% in human citrated plasma (or serum or purified milieu)** (dilution **1:40** with physiological saline)
- Detection threshold: ≤**5%**
- Highly **specific, sensitive, reproducible** (AT deficient plasma 2-4%; Intra assay CV 2.5-3.1% ; Inter assay CV 4.5-5.2 %)
- **Highly stable (** ≥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 r2>0.97.
- **No interference of** heparin (UFH or LMWH) < 2IU/ml; Presence of rheumatoid factor may lead to overestimation of AT concentration.
- **No hook effect** for AT concentrations ≤ 200% (7.5µg/ml of purified AT).

Calibration curve (eg: manual method)



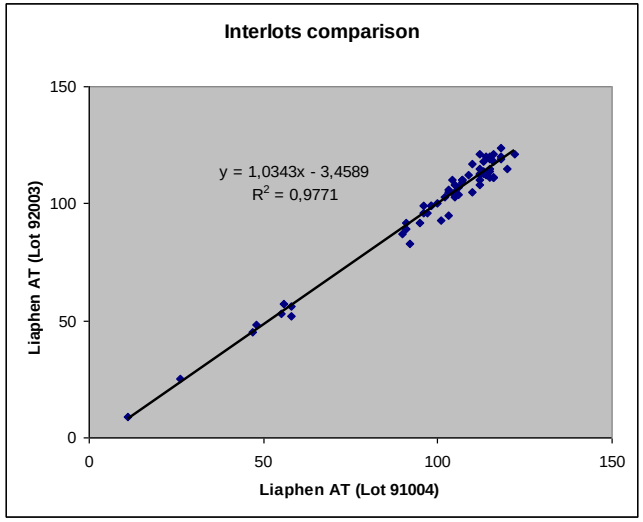
Performance comparison with Biophen AT

Tested using the STAR on normal plasmas (from French Blood bank), hospital samples and deficient plasma (N=30) samples.



Excellent correlation between Liaphen AT and Biophen AT (chromogenic assay).

Inter lots comparison (tested on STAR)



Excellent correlation from lot to lot in the range 10-130%. Normals are measured in the range 80-130%.

Related products

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

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