

### Intended use and applications

**RUO** : Diagnosis of quantitative deficiencies of Fibrinogen (Fng) (low Fbg levels observed in acute liver failure, congenital afibrinogenemia or hypofibrinogenemia, DIC, primary and secondary fibrinolysis, treatment with thrombolytic drugs ...). Immunoassay of Fng on plasma (elevated concentrations, eg associated with inflammation).

### Principle

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

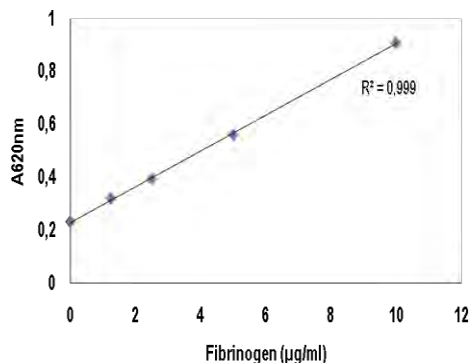
**R1:** Latex reagent, liquid form.

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

### Characteristics and advantages

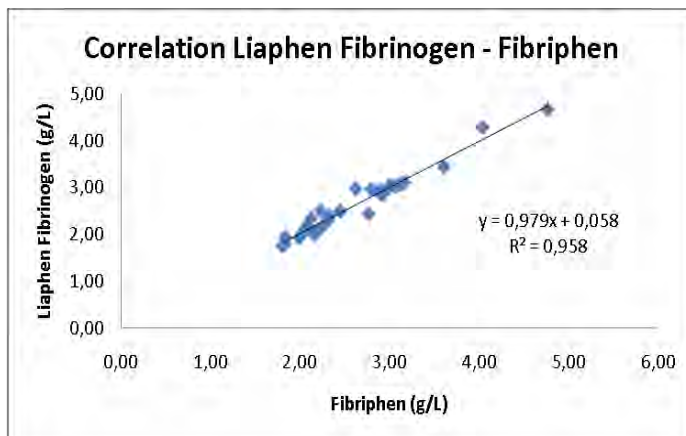
- **Simple and rapid:** « ready to use »; total assay time <20 min.
- Easy to use on major **coagulation analyzers or with basic equipment** (~80 (STAR) or 50 (manual method) tests per kit).
- **Associated calibrators and controls** validated against the International Standard for Fibrinogen (SSC/ISTH).
- Dynamic range ~ **0 – 10µg/ml** (ie for human citrated plasma dilution **1:500** with Tris-NaCl-BSA buffer)
- Detection threshold: **≤1 µg/ml** (eg 0.3 µg/ml on STAR)
- Highly **specific, sensitive, reproducible** (no reactivity with serum; Intra assay CV 3.2-3.8% ; Inter assay CV 7.1-7.5 %)
- **Highly stable** (≥6 months at 2-8 C , 7 days at RT(18-25 C)).
- **Safe, optimized, standardized:** raw materials tested for viral safety.
- **No interference** of heparin (UFH or LMWH) < 2IU/ml; Presence of rheumatoid factor may lead to overestimation of Fibrinogen concentration.
- **No hook effect** for Fibrinogen concentrations ≤30µg/ml.
- **Cross reactivity:** Fng fragment D, DDimer, Fibrin Degradation Products (FDPs) prepared from plasma or from purified Fng; reactivity with Fragment E is weak or nil

### Calibration curve (eg: manual method)

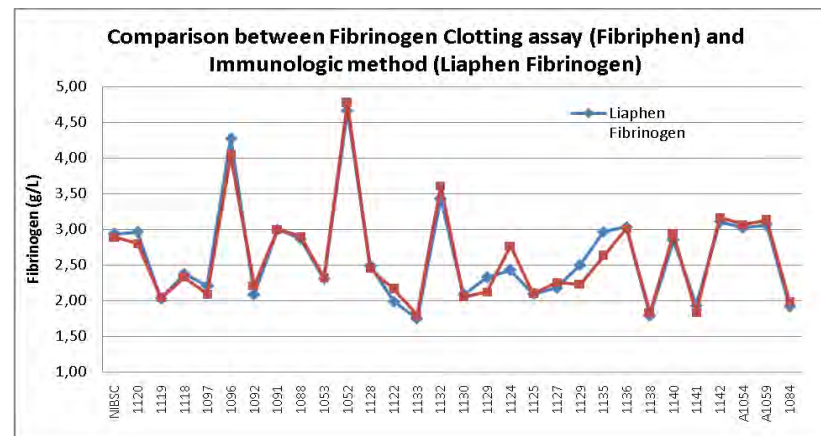


### Performance comparison with Fibriphen (clotting assay)

Tested using the STAR on N=31 plasma samples.



Excellent correlation between Liaphen Fibrinogen and Fibriphen (clotting assay, Claus method).



### Related products

1. Biophen Plasma Calibrator, Normal and Fibrinogen Low Control Plasmas (# A222101 / A223201 / ASC070K) (CE)
2. Fibriphen (Claus method) (# ACK571K / ACK572K / ACK575K) (CE)
3. Zymutest Fibrinogen (# ARK024A)

### References

1. Lord ST. Fibrinogen. In: Molecular basis of thrombosis and haemostasis. High KA and Roberts HR. ed. Marcel Dekker Inc, 1995: 51-74.
2. Mosesson MW. Fibrinogen structure and fibrin clot assembly. Sem Thromb Hemost 1998; 24 (2): 169-174.
3. Henschen-Edman AH. On the identification of beneficial and detrimental molecular forms of; 29: 179 fibrinogen. Haemostasis 1999-186.