ANIARA DIAGNOSTICA LLC

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.**

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ANIARA
Manufactured by Hyphen BioMed.

CE

LIAPHEN Fibrinogen technical file (#A120102)

Intended use and applications

IVD : Diagnosis of quantitative deficiencies of Fibrinogen (Fbg) (low Fbg levels observed in acute liver failure, congenital afibrinogemia or hypofibrinogemia, DIC, primary and secondary fibrinolysis, treatment with thrombolytic drugs …). Measurement of Fbg on plasma (elevated concentrations, eg associated with inflammation).

Principle

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

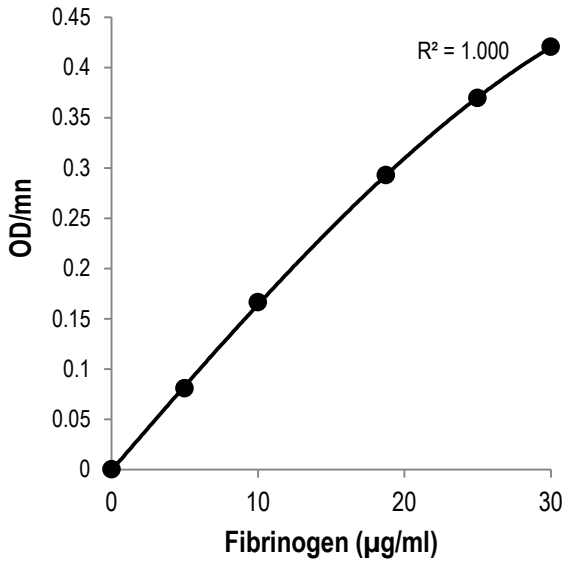
R1: Latex reagent, liquid form.

(Necessary but not provided in the kit: TBSA Buffer (#AAR005A)

Characteristics and advantages

- Simple and rapid: « ready to use »; total assay time <20 min, single reagent, one-step assay.
- Easy to use on major coagulation analyzers or with basic equipment (~100 (STA-R) or 50 (manual method) tests per kit).
- Associated calibrators and controls validated against the International Standard for Fibrinogen (SSC/ISTH).
- Dynamic range: ~ 1 – 30 µg/ml in the test dilution (i.e. 0,2 to 6 g/L in the test sample), using STA-R method.
- Detection threshold: ≤1 µg/ml (i.e. 0.2 g/L in test plasma on STA-R)
- Repeatability (within-run): CV = 3.1 to 3.8 %; Reproducibility (Total): CV = 7.7 to 9.8 %
- 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: Heparins (UFH or LMWH) up to 2 IU/ml; Haemoglobin up to 2 mg/ml; Bilirubin up to 0.2 mg/ml; Intralipid® up to 0.75% (equivalent to 30 mg/ml Triglycerides). Presence of rheumatoid factor may lead to overestimation of Fng concentration.
- No hook effect for Fibrinogen concentrations up to 90 µg/ml in the test dilution (i.e. 18g/L on STA-R).
- Cross reactivity: Fng fragment D, DDimer, Fibrin Degradation Products (FDPs); no reactivity with Fragment E

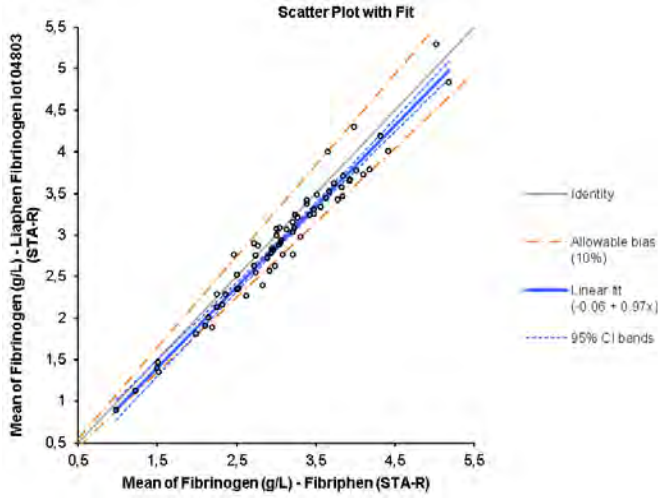
Calibration curve (eg: STA-R method)



Method comparison

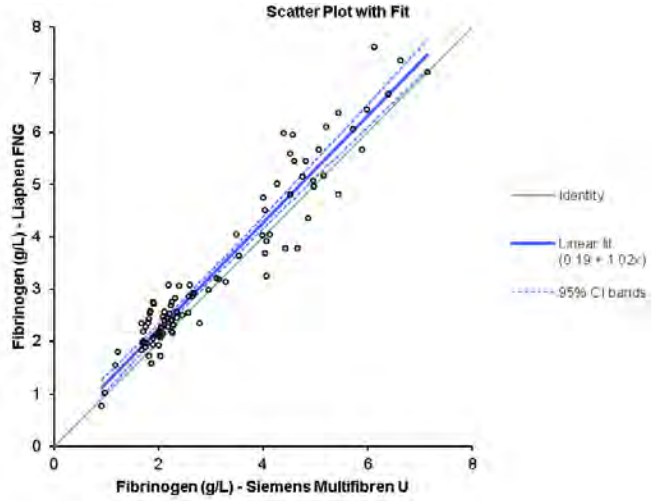
Liaphen Fibrinogen vs Fibriphen (Hyphen-Biomed) on STA-R (Stago):

N= 70 plasmas; Y = 0.97X - 0.06; R = 0.977.



Liaphen Fibrinogen vs Multifibren U® (Siemens) on BCS XP (Siemens):

N= 96 plasmas; Y = 1.02X + 0.19 ; R = 0.958.



Related products

1. Biophen Plasma Calibrator, Normal and Fibrinogen Low Control Plasmas: (# A222101 / A223201/ A223101 / ASC070K) (CE)
2. TBSA Buffer (#AAR005A)
3. Fibriphen (Clauss 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.

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