FIBRINOGEN

DETERMINAZIONE QUANTITATIVA IMMUNOTURBI-DIMETRICA DEL FIBRINOGENO SU PLASMA

REF		IVD
SHD4FIB		

PRINCIPLE OF TEST

Minimizing the loss of blood depends on three factors. One is the pooling of blood platelets on the wounded part. Another is the vasoconstriction of the injured blood vessel to reduce the flow through the interruption. The third factor is the aggregation of a protein, "fibrin", into a clot - a three dimensional stable latex - that is strong enough to close the damaged vessel while it is repaired. Coagulation occurs because a soluble fibrinogenic blood protein is partially hydrolyzed to form "fibrin". High levels of fibrinogen in plasma are expected in inflammatory processes after major traumas or surgical operations and even in tumor metastases. Decreasing levels of fibrinogen may occur in coagulopathy, intravascular coagulation (DIC), primary hyperfibrinolysis, hepatic insufficiency, and genetic deficiencies. Epidemiological studies have shown that high levels of fibrinogen in the plasma are associated with an increasing risk of arteriosclerosis.

SAMPLES

• Fresh, non-haemolytic and non-lipemic plasma. Citrate is suggested. Collection of samples in accordance with CLSI (NCCLS) (see Bibliography 3).

Samples can be stored for up to 8 hours at 2 ° C-8 ° C. DO NOT FREEZE.

REAGENTS

Composition of kit:

R1 - Anti-FIB : Buffer Ph 7.43, Policlonali anti-fibrinogeno, Sodio Azide 0.95 g/l

R2 – Buffer : Buffer Ph 7.43, Sodio Azide 0.95 g/l

STABILITY: Closed Reagents are stable until the expiration date indicated on the labels, if stored in their primary container intact, at 2-8 ° C unless exposed to thermal sources and / or pressure variations. Dispose of in the event of damage to the primary container.

PREPARATION OF REAGENTS

Liquid reagents, ready to use

PRECAUTIONS FOR USE

1. **This product has been formulated for in vitro diagnostic use.**
2. **DO NOT mix Reagents from different production batches.**
3. **In addition to any indications of risk, the Reagent contains preservatives (sodium azide or others) whose total concentration is below the limits given in Directives 67/548 / EEC and 88/379 / EEC and the relevant amendments to the Classification, Labeling and Packaging of hazardous preparations (Reagents). However, it is recommended to manipulate reagents with caution, avoid ingestion and contact with eyes, skin and mucous membranes; To follow the rules of good laboratory practice in the use of these materials.**

ANALITICAL PROCEDURE

Wavelenght	340 nm
Optical path	1 cm
Temperature	37°C
Method	Fixed-Time

PROCEDURE HYDRA 09

LEAK THE AMBIENT TEMPERATURE REAGENTS AT LEAST 30 MIN BEFORE USE

0) **Pre-dilute the Sample by dispensing 900UL of Diluent and 100µL of Sample in the appropriate dilution cuvettes.**

1) **Dispense 325 µl of Reagent R1 in the appropriate test tube.**

2) **Preheat the cuvette containing reagent R1.**

3) **Add 20 µl of sample and shake gently for a few seconds.**

4) **Add 75 µl of Reagent R2 and shake gently for a few seconds.**

5) **Insert the cuvette into the reading cell and wait for the end of the incubation period for the result.**

CALCULATION

The Hydra 09 automatically performs the calculation of the results at the end Of incubation.

REFERENCE VALUES

Normal values Fibrignogen: infants 125-300 mg / dL
Adults 200-400 mg / dL.
Since normal values depend on age, gender, diet, geography, and other factors, each laboratory must establish its normal values for this procedure.

PERFORMANCE OF TEST

Limitations of method: unknown limitations.
Linearity of method: test is linear up to 600 mg/dL.
However, for Fibrinogen concentrations greater than the maximum calibrator value, it is recommended to dilute the 1: 5 sample with physiological, retest and multiply result x 5.
Limit of sensibility : 4.5 mg/dL.
Interferences:
No interference with specimens was observed with:
- Emoglobin up to 1000 mg/dl
- Bilirubin up to 30 mg/dL
- Triglicerides up to 2500 mg/dl
- Sodium citrate up to 1000 mg/dl
- EDTA up to 10 mg/ml

PRECISION CV%:

determinated on 20 replicates. The risults obtained are as followings:

	LOW	MEDIUM	HIGH
IN THE SERIES	2.20	3.76	3.69
BETWEEN THE SERIE	3.15	2.56	3.69

Accuracy:

A group of 20 sera was tested with this procedure and using a similar commercially available reagent. The comparison gave the following results:
Linear regression y = 0.9904x
Correlation coefficient r = 0.9842

CONSIDERATIONS ON DISPOSAL

The product is intended for use within professional analysis laboratories. For proper waste disposal refer to current regulations and safety data sheets.

BIBLIOGRAPHY

1.Textbook of Clinical Chemistry, Ed. by N.W. Tietz, W.B. Saunders Co., Philadelphia (1999).
2.Young D.S., Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).
3.CLSI(NCCLS) C49-A/H56-A: Collection, Handling, Transport and Storage for Body Fluids. Quick Guide

SIMBOLS– 98/79/EC DIRECTIVE

Attenzione! Leggere le istruzioni	Size – No. Of determination	Manufacturer	
IVD For in vitro diagnostic use only	Expiry	Do not reuse	
30°C 2°C Store at --°C	LOT Lot. #	REF Code #	

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