

IN VITRO DIAGNOSTIC USE

IVD

REF 34014	10 x 2 ml (100-200 T)	R1: 10 x 2 ml (Lyoph)	R2: 1 x 100 ml
REF 34021	10 x 4 ml (200-400 T)	R1: 10 x 4 ml (Lyoph)	R2: 1 x 150 ml
REF 34038	5 x 2 ml (50-100 T)	R1: 5 x 2 ml (Lyoph)	R2: 1 x 100 ml

CLINICAL SIGNIFICANCE

Fibrinogen (factor I), protein synthesized by the liver, is the substance used in blood to form a clot. Its determination is used to evaluate abnormal blood clotting. Elevated fibrinogen levels are observed in acute inflammation and pregnancy; low values are observed in thrombotic therapy, in hepatic disease, in the congenital non fibrinogen in DIC.

PRINCIPLE

In the presence of an excess of thrombin, the clotting time of previously diluted plasma is inversely proportional to the quantity of plasma fibrinogen.

REAGENT COMPOSITION

Reagent 1	Thrombin	Bovin Thrombin
Reagent 2	Diluent	Buffer Hepes pH = 7,35

REAGENT PREPARATION

- Reconstitute vial R1 by the volume of preferably sterile distilled water indicated on the label.
- Allow the solution to stabilize for 20 minutes at room temperature (20-25°C).

SAFETY CAUTIONS

Biomaghreb reagents are intended for qualified personnel, for in vitro use (do not pipette with the mouth).

- Consult the current MSDS available on request or on www.biomaghreb.com;
- Check the integrity of the reagents before use; and
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious. Respect the regulation in force

SAMPLE PREPARATION

- Blood is collected by clean venipuncture on liquid trisodium citrate 0.11 M (1 volume of citrate for 9 volumes of blood).
- Centrifuge for 10 minutes at 4000 rpm (2500g) or allow to settle.
- Perform the determination within 6 hours of specimen collection.

PRESERVATION AND STABILITY

- Before opening:** (lyophilisate) between 2-8°C, until the deadline indicated on the box.
- After opening (Reconstituted) :**
8 h at 20 - 25°C;
48 h at 2 - 8°C;
1 month at - 20°C (freeze by small fraction in plastic tube).

PROCEDURE

- Dilute the plasma 1:10 in R2 buffer. This dilution usually results in a coagulation time of 8-25 seconds. (fibrinemia between 1.5 and 4 g/l).

- If the coagulation time is less than 8 seconds, repeat the test with a dilution of 1/20 or possibly 1/30. In the latter cases, the result obtained will be multiplied by 2 or 3 respectively.

- If the time is longer than 25 seconds, repeat the test on a 1/5 or possibly 1/2 dilution. In the latter cases, the results obtained are divided by 2 or 5 respectively.

1) MANUAL TECHNIQUE

In a disposable cup of fibrometer at 37°C: Add

Dilute Plasma	200 µl
Maintain 2 min at 37°C	
R1 pre incubate at 37°	200 µl

- Simultaneously start the stopwatch;

- Dip the hook regularly in the middle of the tube until a thin fibrin filament appears and note the coagulation time.

2) TECHNIQUE USING FIBROMETER:

ARM 0,4 ml

In a disposable cup of fibrometer at 37°C: Add

Diluted plasma or capillary blood	200 µl
Incubate 2 min at 37°C	
Reagent 1, not incubated, well-mixed	200 µl
Read the clotting time	

3) AUTOMATED TECHNIQUE:

Electro magnetic detection

At time of test dilute the plasma in Reagent 2:

Fibrinemia	Dilutions	Plasma (ml)	Reagent R2
Low	1: 5	0.1	0.4
Normal	1:10	0.1	0.9
High	1: 20	0.1	1.9

In a disposable cup. Add:

Diluted plasma or capillary blood	100 µl
Incubate 1 min at 37°C	
Reagent 1, not incubated, well-mixed	50 µl
Read the clotting time	
Make a double determination by dosage	

4) AUTOMATED TECHNIQUE:

Optic detection

At time of test dilute the plasma in Reagent 2.

Fibrinemia	Dilutions	Plasma (ml)	Reagent R2
Low	1:10	0.1	0.9
Normal	1:20	0.05	0.95
High	1:40	0.05	1.95

In a disposable cup. Add:

Diluted plasma or capillary blood	100 µl
Incubate 1 min at 37°C	
Reagent 1, not incubated, well-mixed	50 µl
Read the clotting time	
Make a double determination by dosage	

N.B : To improve the optical detection of the coagulation, it's necessary to use Kaolin in 10% (reconstitute the lyophilisate by 2 ml of distilled water for the (REF) 34014 and (REF) 34038) and add 10µl of kaolin 10% in this vial : it is the working reagent)

*The Kaolin is supplied on demand

RESULTS

- For each clotting time, read off the value of fibrinogen by referring to the correspondence table specific to each lot or provided in the kit.
- Correction for liquid anticoagulant:

- If the hematocrit is normal, add 20 % to the result obtained from the table (i. e., multiply the result read on the table by 1.20).

- If the hematocrit is abnormal, multiply the result obtained from the table by the correction factor (C) :

$$C = \frac{(10 - (9 \text{ Hte}^*))}{(9 - (9 \text{ Hte}))} \quad * \text{Hte} = \text{Hematocrite}$$

ADDITIONAL EQUIPMENT

- Basic equipment of the medical analysis laboratory;
- Automatic or semi-automatic coagulation analyzer.

USUAL VALUES

- Between 2,5 and 4 g/l

REFERENCES

- Claussa : Acta Haematol 17,137 (1957) ;
- Caenj. Larrieu M.j. Sammama M. L'expansion scientifique Paris 1975 ;
- Andrew M.et al. Blood 70, 165 (1987).



Manufacturer



Use by



In Vitro Diagnostic



Temperature
Limitation



Catalogue number



See insert



Store away from light



Sufficient
for < n > essais



Batch number