Fibrinogen

VonClauss method

Code: HC00300 8 x 2 ml

Store at 2 - 8°C

CYPRESS DIAGNOSTICS

CE

Fibrinogen dosage in plasma

Clinical meaning:

Fibrinogen (Factor I) is the substance in blood that forms a clot. Its determination is used to evaluate abnormal blood clotting.
Fibrinogen concentration values out of the referring elapse have been observed in acute inflammations and in pregnancy (high values); in the thrombolitic therapy, in the hepatic disease, in the congenital non fibrinogen, in DIC and in pancreatitis (low values).
For in vitro use and professional use only.

Principle:

At the presence of an excess of Thrombin, the Fibrinogen changes into Fibrin. The logarithm of the time of clot formation in diluted plasma is proportional to the logarithm of the concentration of fibrinogen in the plasma sample.

Reagent Composition:

Reagent 1	Human alpha Thrombin
Reagent 2	Imidazol Buffer Stabilizer
Optional	Calibrator (HC00600)

Preparation:

Reagent 1: Reconstitute a vial of lyophilized thrombin with 2 ml of distilled water. Keep the thromboplastin at 18-25°C for 30 minutes. Swirl the vial gently before use and do not shake. Avoid contact of the fluid with the stopper.
Reagent 2: Ready-to-use.

Storage and stability

All the components of the kit are stable at 2 - 8°C up to the date of expiration as specified.
Stability of reagent 1 after reconstitution: 3 days at 22°C, 5 days at 15°C and 7 days at 2-8°C in the original vial. Do not freeze!
Stability of reagent 2 after opening: up to the date of expiration as specified, when stored at 2-8°C, tightly closed, protected from light and contaminations prevented during their use.

Sample preparation:

SAMPLE: Plasma obtained from whole blood anti-coagulated with 3.2% sodium citrate.
SAMPLE COLLECTION: Nine parts freshly collected whole blood should be immediately added to one part anticoagulant.
SAMPLE PREPARATION: Centrifuge the whole blood specimen at 1500 x g for 15 minutes (NCCLS H21-A4). Immediately separate the plasma from the red blood cells using a plastic pipette and place it in a plastic test tube at 2 to 8°C until assayed. Perform the time test within 4 hours.
NOTE: After initial whole blood collection, during testing all test tubes, syringes and pipettes should be plastic.

Procedure:

1. Dilute the patient plasma 1/10 in buffer (reagent 2).
2. Bring the thrombin reagent at room temperature.
3. Transfer in a test tube:

Diluted sample	200µl
Incubate for 2 minutes at 37°C Add Thrombin (reagent 1).	
R.1. Thrombin	100 µl
Start the chronometer or apparatus immediately. Measure time of clot formation.	

If using an instrument to perform this test, refer to the appropriate Instrument Operator's Manual for detailed instructions.

Calibration

Prepare the dilutions of the calibrator in buffer (reagent 2) as described in the table below. Separately prepare dilution 1/7. Thereafter, dilutions 1/10, and the 1/20 and 1/30 have to be generated by serial dilution. The diluted calibrator must be processed within 2 hours.

Dilution	1/7	1/10	1/20	1/30
Calibrator (ml)	0,1 (-)**	0,2 (-)**	1,0 (1/10)**	1,0 (1/20)**
Imidazol (ml)	0,6	1,8	1,0	0,5
Factor (F)	10/7	10/10	10/20	10/30
Concentration (g/l)	C* x F	C* x F	C* x F	C* x F

* Calibrator concentration;

** Dilution of calibrator solution that has to be used

Calculate the mean of the duplicate clothing times. Construct a log-log curve that plots the fibrinogen concentrations (g/l) of the different dilutions versus the clothing time (sec). Draw the straight line of best fit.

Results

- The fibrinogen value can be obtained by simple reading of the table that is included in the kit.
- The fibrinogen value can also be calculated from the calibration curve, obtained as described above.

In case the obtained patient values are lower than 1 g/l it is recommended to retest the plasma at a 1/5 dilution.

Expected values:

Normal values are between 2,0 and 4,0 g/l.

Quality control

Normal and pathological controls (HC00500) are recommended for verified measurement. Each laboratory should establish its own quality control program.

Precautions

1. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as patient samples and used material should be properly disposed of.
2. Reagent 2 contains sodium azide which may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagent by flushing with large amounts of water to prevent azide buildup
3. Do not use the reagent beyond the expiration date printed on the label.
4. Avoid microbial contamination of the reagent or erroneous results may occur.
5. Each donor unit used in the preparation of this reagent is tested and found to be negative for the following tests: antibodies to HIV, hepatitis C and hepatitis B surface antigen. However, the product must be handled with care, observing the precautions recommended for biohazardous material.

Bibliography

1. Clauss A. Acta Haematol; 17: 237; 1957
2. Koepke JA et al. Am. J. Clin. Pathol; 63: 984; 1975.

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CYPRESS DIAGNOSTICS

Calibration Curve Values Valeurs Courbe d'étalonnage	
Lot 920627	
CYANCOAG	
Sample dilution Dilution échantillon	1/10
Concentration (g/l)	Sec
4.43	8.6
2.95	11.1
1.48	21.1
0.98	30.0
OPTICAL READERS & MANUAL METHOD LECTEURS OPTIQUES & MÉTHODE MANUEL	
Sample dilution Dilution échantillon	1/10
Concentration (g/l)	Sec
4	7.4
3	9.2
2	12.7
1	21.7
MECHANICAL READERS LECTEURS MECANIQUES	
Sample dilution Dilution échantillon	1/20
Concentration (g/l)	Sec
4	15.2
3	20.1
2	29.7
1	58.4

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CYANCOAG	
Lot 920627	
Sample dilution Dilution échantillon	1/10
Sec	Concentration (g/l)
6.0	6.5
6.5	5.9
7.0	5.4
7.5	5.0
8.0	4.6
8.5	4.3
9.0	4.0
9.5	3.8
10.0	3.5
10.5	3.3
11.0	3.2
11.5	3.0
12.0	2.9
12.5	2.7
13.0	2.6
13.5	2.5
14.0	2.4
14.5	2.3
15.0	2.2
15.5	2.1
16.0	2.0
16.5	2.0
17.0	1.9
17.5	1.8
18.0	1.8
18.5	1.7
19.0	1.7
19.5	1.6
20.0	1.6
20.5	1.5
21.0	1.5
21.5	1.4
22.0	1.4
22.5	1.4
23.0	1.3
23.5	1.3
24.0	1.3
24.5	1.2
25.0	1.2
25.5	1.2
26.0	1.2
27.0	1.1
28.0	1.1
29.0	1.0
30.0	1.0
31.0	0.9
32.0	0.9
33.0	0.9
34.0	0.8

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OPTICAL READERS & MANUAL METHOD LECTEURS OPTIQUES & MÉTHODE MANUEL	
Lot 920627	
Sample dilution Dilution échantillon	1/10
Sec	Concentration (g/l)
5.0	6.6
5.5	5.8
6.0	5.2
6.5	4.7
7.0	4.3
7.5	3.9
8.0	3.6
8.5	3.3
9.0	3.1
9.5	2.9
10.0	2.7
10.5	2.5
11.0	2.4
11.5	2.3
12.0	2.1
12.5	2.0
13.0	1.9
13.5	1.8
14.0	1.8
14.5	1.7
15.0	1.6
15.5	1.5
16.0	1.5
16.5	1.4
17.0	1.4
17.5	1.3
18.0	1.3
18.5	1.2
19.0	1.2
19.5	1.1
20.0	1.1
20.5	1.1
21.0	1.0
21.5	1.0
22.0	1.0
22.5	1.0
23.0	0.9
23.5	0.9
24.0	0.9
24.5	0.9
25.0	0.8
25.5	0.8
26.0	0.8
26.5	0.8
27.0	0.8
27.5	0.7
28.0	0.7
28.5	0.7
29.0	0.7
29.5	0.7
30.0	0.7

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MECHANICAL READERS LECTEURS MECANIQUES	
Lot 920627	
Sample dilution Dilution échantillon	1/20
Sec	Concentration (g/l)
12.0	5.1
13.0	4.7
14.0	4.4
15.0	4.1
16.0	3.8
17.0	3.6
18.0	3.4
19.0	3.2
20.0	3.0
21.0	2.9
22.0	2.7
23.0	2.6
24.0	2.5
25.0	2.4
26.0	2.3
27.0	2.2
28.0	2.1
29.0	2.1
30.0	2.0
31.0	1.9
32.0	1.9
33.0	1.8
34.0	1.7
35.0	1.7
36.0	1.6
37.0	1.6
38.0	1.6
39.0	1.5
40.0	1.5
42.0	1.4
44.0	1.3
46.0	1.3
48.0	1.2
50.0	1.2
52.0	1.1
54.0	1.1
56.0	1.0
58.0	1.0
60.0	1.0
62.0	0.9
64.0	0.9
66.0	0.9
68.0	0.9
70.0	0.8
72.0	0.8
74.0	0.8
76.0	0.8
78.0	0.7
80.0	0.7
82.0	0.7
84.0	0.7

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