

BioMed-Fibrinogen



Reagent for Quantitative Estimation Of Fibrinogen

REF: FIB203020 (20 test)

INTENDED FOR USE:

For quantitative determination of Fibrinogen in plasma

PRINCIPLE:

The addition of thrombin coagulates fresh citrated plasma. The coagulation time is proportional to the fibrinogen concentration. This allows the estimation of plasma fibrinogen by functional clotting assay.

SPECIMEN COLLECTION:

At present there are known to be at least eleven factors in circulating blood, are required for normal haemostasis. Deficiency in any of these., Factors **I,II,V,VII,VIII,IX,X,XI** and **XIII**, results in a notable hemorrhagic condition, and the severity of the bleeding is proportional to the degree of deficiency. In order to treat the hemorrhagic condition, it is important to identify and quantify the deficient factor.

Fibrinogen (Factor) is a high molecular weight glycoprotein synthesized in the liver, which plays an important role in haemostasis. For normal haemostasis to occur in response to injury or tissue damage, A sufficient concentration of fibrinogen must be present in plasma. Fibrinogen is converted into fibrin by the action of thrombin and is a key component of clot formation.

FIBRINOGEN kit contains lyophilized thrombin and fibrinogen calibrator to determine the quantitative reactivity of fibrinogen calibrator to determine the quantitative reactivity of fibrinogen. Since the reagent system contains heparin-neutralizing substances, heparin levels upto **0.4 IU/ml** does not interfere with test results. When used as a front line test with **PT, APTT**, platelet count and thrombin time, fibrinogen assay helps in investigating acute haemostatic failure.

REAGENT COMPOSITIONS :

FIBRINOGEN kit contains:

1. Thrombin reagent, which is alyophilized preparation from bovine source ~ **50 NIH** units per vial.
2. Fibrinogen calibrator, which is a lyophilized preparation of human plasma equivalent to stated amount of fibrinogen on a mg basis (refer **FIBRINOGEN** graph paper supplied with each kit for the value of each lot).
3. Owren's buffer, ready to use (**pH 7.35**).

PACKAGE: Collection and storage.

1. Store the unopened reagent vials at **2-8°C**. **DO NOT FREEZE**.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.
3. Once reconstituted the **FIBRINOGEN** thrombin reagent is stable for **6** days when stored at **2-8°C** and for **4** hours at room temperature (**20-25°C**), provided it is not contaminated. Extreme care has to be taken to maintain aseptic precautions while reconstituting, retrieving and handling reagents to prevent contamination. The reagent vial must be replaced to **2-8°C** immediately upon retrieving the reagent for the day's work.
4. The reconstituted **FIBRINOGEN** calibrator is stable for **6** hours at **2-8°C** and for **2** hours at room temperature (**20-25°C**).

PRECAUTIONS & WARNING :

Avoid pipetting with mouth.

The preparation, according to current regulation, is classified as not dangerous.

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.

Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes.

The samples must be handle as potentially infected from HIV or Hepatitis

REAGENT PREPARATION & STABILITY :

No special preparation of the patient is required prior to sample collection by approved techniques. Withdraw blood without undue venous stasis and without frothing into a plastic syringe fitted with a short needle of **19** to **20 SWG**. The venepuncture must be a "clean" one and, if there is any difficulty, take a new syringe and needle and try another vein. Transfer the blood into tubes, after detaching the needle from the syringe.

Mix nine parts of freshly collected blood with one part of sodium citrate (**0.109mol/l, 3.2%**). Centrifuge immediately for fifteen minutes at **3000rpm (approximately 2000 g)** and transfer the plasma into a clean test tube. Plasma must be tested within **3** hours of collection.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Bring all the reagents and sample to room temperature before testing.

A) Procedure for fibrinogen Calibration Curve Preparation

- The **FIBRINOGEN** thrombin reagent vial must be reconstituted exactly with one ml of distilled water; wait for **5** minutes, do not shake but gently swirl the vial till the solution attains homogeneity. Further keep the vial aside for **10** minutes to attain equilibrium. Once reconstituted it is ready to use for the fibrinogen test.
- The **FIBRINOGEN** calibrator vial must be reconstituted exactly with one ml of distilled water; wait for **5** minutes, do not shake, gently swirl the vial till the solution attains homogeneity. Further keep the vial aside for **10** minutes to attain equilibrium. This is the fibrinogen calibrator stock solution
- Dilute fibrinogen calibrator stock solution with Owren's buffer as follows:

Test tube no.	I	II	III	III
Owren's buffer	NIL	0.4 ml	0.6 ml	0.8ml
Fibrinogen calibrator	0.2 ml	0.2 ml	0.2 ml	0.2ml
Dilution(Calibrator)	NIL	1 : 2	1 : 4	1:5

1. Pipette **0.2** ml of each fibrinogen calibrator dilution into clean test tubes and prewarm for **3** minutes at **37°C**.
2. Add **0.1** ml of reconstituted thrombin reagent (prewarmed at **37°C** for one minute) and simultaneously start stopwatch.
3. Stop the stopwatch at the first appearance of the fibrin web, as the gel clot begins to form and record the time in seconds.
4. Repeat steps **1-3** for a duplicate test on each calibrator dilution.
5. Plot average of the duplicate test values on **FIBRINOGEN** graph paper.
6. Connect the points, which should produce a straight line.
7. The calibration curve may be extended beyond the lowest and highest point.
8. The calibration curve is valid only for the same lot of **FIBRINOGEN** thrombin reagent.

B) Test Procedure for sample

1. Prepare **1:10** dilution of plasma specimen with Owren's buffer solution.
2. To a **10 x 75** mm test tube at **37°C** add **0.2** ml of **1:10** dilution of plasma sample to be tested.
3. Incubate at **37°C** for one minute.
4. To the test tube add **0.1** ml of **FIBRINOGEN** thrombin reagent (prewarmed at **37°C** for one minutes) and start the stopwatch simultaneously.
5. Stop the stopwatch at the first appearance of the fibrin web, as the gel clot begins to form and record the time in seconds.
6. Repeat steps **1-5** for a duplicate test.
7. If at the sample dilution of **1:10** the observed clotting time is usually between **8-25** seconds, the fibrinogen content is normal (Fibrinogen content between **150** and **400** mg/dl). Assay results can be read off directly from the graph paper provided with the **FIBRINOGEN** kit for the fibrinogen concentration.
8. If the fibrinogen content is high the clotting time will be less than **8** seconds. In such cases repeat the test at **1:20** dilution of the sample or **1:30** dilution of the sample. The results read off the graph will be multiplied by a factor **2** or **3** for the respective dilution.
9. Conversely, if fibrinogen content is low, the clotting time will be over **25** seconds. Repeat the assay at **1:5** dilution, or if necessary at **1:2** dilution. In this case the results read off the graph will be divided by a factor of **2** or **5** for the respective dilution.

EXPECTED VALUE:

150 mg/dl - 400 mg/dl

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

A known normal control should be run in parallel with each batch of tests. This control may be plasma coagulation control (**PLASMATROL**) or freshly drawn normal plasma.

REFERENCES:

1. Significant levels of heparin and elevated levels of fibrinogen degradation products (**FDP**) in the patient plasma can cause falsely low fibrinogen results.
2. Insufficient prewarming of plasma and reagent or contaminated glassware may cause erroneous results.
3. **EDTA** should not be used as an anticoagulant.
4. Use reagents of the same lot for performing the test.
5. Do not interchange reagents from different lots.






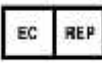



PERFORMANCE:

1. Biggs R. and R.G. McFarlane: Human Blood Coagulation and its disorders, Blackwell Scientific Publications, Oxford 1962.
2. Quick A.J.: Hemorrhagic diseases and thrombosis, 2nd Edition, Philadelphia, Lea and Febiger 1966.
3. CRC handbook Series in Clinical Laboratory Science, Section 1: Haematology, Volume III, 1980.
4. Dacie J.V. and Lewis S.M.: Practical Haematology, 8th Edition, Churchill Livingstone Publications, 1995.
5. Provan D. et al. Oxford Handbook of Clinical Haematology, 8th Edition, 1998.

LIMITATIONS :

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.

2. The individual reagents contain **0.1%** sodium azide as preservative.
3. **FIBRINOGEN** thrombin reagent is not from a human source hence contamination due to **HBsAg, HIV** and **HCV** is practically excluded.
4. Fibrinogen calibrator provided in the fibrinogen kit is from a human source, which was tested and found to be non-reactive for **HBsAg, HCV** and **HIV**. However no known test methods can assure that infectious agents are absent. Handle all human products as potentially infectious.
5. It is very important that absolutely clean and dry micropipettes be used to aspirate and dispense the reagent.
6. Avoid exposure of the reagent to elevated temperatures, direct light and contamination. Immediately replace the cap after use and store at recommended temperature.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

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