DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-FIB

QUANTITATIVE FIBRINOGEN REAGENT

Cat. No.: 61060 **12 x 5 ml**
Cat. No.: 61024 **12 x 2 ml**

PRODUCT NAME

Dia-FIB fibrinogen reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-FIB is a fibrinogen reagent used for quantitative determination of fibrinogen levels in plasma.

SUMMARY AND EXPLANATION

Fibrinogen is the final plasma protein of coagulation cascade. Its presence and intact function has a vital importance for normal blood coagulation.

Fibrinogen, produced in the liver, contains three pairs of protein chains. This soluble fibrinogen molecule is cleaved by thrombin to fibrin monomers. The formed fibrin monomers compose the fibrin fibers and then the insoluble fibrin net, which is stabilized by factor XIIIa.

PRINCIPLE

The method of Clauss measures the clotting time after adding a high concentration of thrombin to diluted plasma. The fibrinogen concentration of the plasma is inversely proportional to the clotting time.

ACTIVE INGREDIENTS

Dia-FIB is a freeze-dried, highly purified human alpha thrombin in buffered medium with calcium and preservative.

PRECAUTIONS

- Person installing the Dia-FIB reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-FIB reagent, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagent coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- Each donor unit used in the preparation of this reagent tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the reagent beyond the expiration date printed on the label!

PREPARATION

Dia-FIB reagent is dissolved with the required amount of distilled water, which is indicated on the label. Keep the reagent at room temperature (20-25°C) for at least 30 minutes for proper reconstitution. Swirl the vial gently, horizontally more times (5-10) before using it, but do not shake. Wait until the reagent reaches the working temperature!

SPECIMENS

Dia-FIB test requires freshly decalcified plasma. To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3,2%; 109mmol/L). The use of higher concentration of trisodium citrate (3,8%; 129mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 4 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

TEST PROCEDURE

Dia-FIB test is a fibrinogen test, which can be used with semi-automated coagulation analysers (Coag 4D) according to the protocol detailed below. The duplicated measurement is recommended.

1.	**Sample dilution with buffer**	**1:10**
2.	**Adding diluted sample into cuvette**	**100µl**
3.	**Sample incubation**	**2min**
4.	**Adding FIB reagent into cuvette**	**50µl**
5.	**Simultaneously start the timer**	**~1min**

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program. In case of determination by any other coagulometer, please follow the instructions of the manual. Use only Dia-IMIDAZOL buffer in order to achieve correct result!

STORAGE AND STABILITY

Dia-FIB reagent in intact vial is stable until the expiration date given on the vial, when stored at

2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	20-25	15-19	2-8
Day	3	7	7

EXPECTED RESULTS

Dia-FIB test results can be reported in g/l. This dimension is calculated from a log-log calibration curve. A method specific master calibration curve in the value sheet can be used for the calculation. The conversion table on the Diagon website helps the usage of reagent with manual method (www.diagon.com/ /Customer support).

The normal range of plasma fibrinogen by clotting assays is between 2,0-4,0 g/l. Every laboratory should determine its own normal or reference range.

The linearity range of Dia-FIB without extra dilution on Diagon analysers (Coag Line) is 1,0-5,0 g/l. In case of lower fibrinogen value (<1,0 g/l) it is recommended to retest the sample at 1:5 dilution. In case of higher fibrinogen value (>5,0 g/l) it is recommended to retest the sample at 1:20 dilution.

LIMITATIONS

The result of FIB test with Dia-FIB reagent may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on Diagon analysers (Coag Line) with the following result:

Heparin	Hemoglobin	Triglicerid	Bilirubin
2,0 IU/mL	6,8 g/L	10 mmol/L	340 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Dia-FIB reagent on Diagon analysers (Coag Line) gives the following results:

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
n	10	10	10	10
Mean (G/L)	2,54	1,26	2,60	1,37
CV (%)	2,106	1,292	3,008	3,845

MATERIALS REQUIRED BUT NOT PROVIDED

- Dilution buffer for sample dilution (Dia-IMIDAZOL; Cat. No.: 21180)
- Different levels of control for quality control (Dia-CONT I-II; Cat. No.: 91020, 91010).
- Optical or mechanical coagulation analyser for measuring, Diagon analysers (Coag Line) are recommended.

BIBLIOGRAPHY

1. CLSI: Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline- Fifth Edition. CLSI document: H21-A5; 28:5; 2008.
2. CLSI: Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline-Second Edition. CLSI document: H30-A2; 21:18; 2001.
3. Clauss A: Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens. Acta Haematol; 17:237-46; 1957.

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SYMBOLS			
	Manufacturer		Use-by date
LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged		Fragile, handle with care
	Keep dry		Temperature limit
	Biological risks		Consult instruction for use
	Caution	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <*n*> tests		This side up
CE	CE mark		