DIAGNOSTIC KIT FOR DETERMINATION OF FIBRINOGEN CONCENTRATION

Cat. No. GLAU964

AU Series – FIBRINOGEN

INTRODUCTION
Fibrinogen is the plasma protein precursor of fibrin, which when cross-linked becomes the principal component of fibrin clot.
Fibrinogen is a sensitive acute phase protein whose concentration rises several fold during inflammation. It can be increased as a response to inflammatory states, with infections, during pregnancy and after trauma.
Evidence has shown that plasma levels above the reference range constitute a significant independent risk factor for both coronary artery and cerebrovascular diseases.
Fibrinogen can be deficient in congenital afibrinogenemia. Levels may also fall significantly as the result of sequestration in extravascular spaces such as the body cavities and sites of recent trauma.

METHOD PRINCIPLE
Fibrinogen presents in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at λ=340 nm is proportional to fibrinogen concentration in the sample.

REAGENTS
Package

1-Reagent	2 x 20.0 ml
2-Reagent	2 x 5.0 ml

Buffer (1-Reagent) stored at 2-8°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Store closed and avoid contamination.

Concentrations in the test
TRIS (pH 8.0); PEG; sodium chloride; anti human fibrinogen antiserum; HEPES buffer (pH 7.4); sodium azide (< 1 g/l); stabilizers.

Warnings and notes
- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for the HIV antibody, HbsAg and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 1 g/l) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Plasma (sodium citrate).
Before analysis calibrator and samples should be diluted 20-fold with 0.9% NaCl and mixed gently.
It is recommended to perform the assay with freshly collected samples!

PROCEDURE
These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION
Reagent ID: **505**

Specific Test Parameters
General | LIH | ISE | Range

Test name: FIBR Type: Serum Operation: Yes

Sample:	Volume	5	µL	Dilution	0	µL	Pre-Dilution Rate:	1
Reagents:	R1 Volume	250	µL	Dilution	0	µL	Min OD	Max OD
	R2 Volume	50	µL	Dilution	0	µL	L -2.0000	H 2.5000

Reagent OD Limit:

Wavelength:	Pri. 340	Sec. 700	First L -2.0000	First H 2.5000
Method:	END		Last L -2.0000	Last H 2.5000
Reaction Slope:	+		Dynamic Range:	
Measuring Point 1: First 0		Last 27	L	H
Measuring Point 2: First 0		Last 10	Correlation Factor:	
Linearity:	%		A 1.000	B 0.000
No-Lag-Time:			On-board Stability Period:	

Specific Test Parameters
General | LIH | ISE | Range

Test name: FIBR Type: Serum

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: mg/dl Decimal Places: 1

Calibration Specific
General | ISE

Test name: FIBR Type: Serum

Calibration Type: 2AB Formula: Polygonal Counts: 3 Process: CONC

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:					
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: None Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES [4]

adults	200 – 400 mg/dl
children	125 – 300 mg/dl

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
For internal quality control it is recommended to use the control plasma with each batch of samples.
For the calibration of automatic analysers systems the FIBRINOGEN CALIBRATOR (Cat. No GL9964) is recommended.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser AU640. Results may vary if a different instrument is used.

- **Analytical range:** 20 mg/dl to 1000 mg/dl.

- **Interferences:**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 2000 mg/dl, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD	CV [%]
level 1	274.4	3.9	1.4
level 2	146.3	3.1	2.1
level 3	104.4	5.2	5.0

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD	CV [%]
level 1	269.7	7.5	2.8
level 2	141.9	5.8	4.1
level 3	98.1	5.0	5.1

- **Method comparison**

A comparison between the Glenbio reagent (y) and commercially available assay (x) using 17 samples gave following results:
y = 0.86 x + 86.9 mg/dl;
R = 0.9556 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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3. Roitt, I., Essential Immunology, Blackwell, Oxford, (1991).
4. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: Moss D. W., Henderson A. R., 1813, (1999).

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