Cat. No 7-419

BS-400
Chemistry Analyzer

CE CORMAY

A-400 FIBRINOGEN

DIAGNOSTIC KIT FOR DETERMINATION OF FIBRINOGEN CONCENTRATION

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	1 x 31 ml
2-Reagent	1 x 8.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Store closed. Protect from light and avoid contamination!

Concentrations in the test

TRIS (pH 8.0); PEG; sodium chloride; anti human fibrinogen antiserum; HEPES buffer (pH 7.4); 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 HBsAg and antibodies to HIV 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 (< 0.1%) 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 analyser BS-400.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

BASIC

Test information		Reagent volume	
No.	37	R1	250
Test	FIBR	R2	50
Full Name	Fibrinogen	R3	
Std. No.	37	R4	

Sample volume

Standard	3	15	10
Increased	6	15	10
Decreased			

Reaction Parameters

Reac. Type	Endpoint	Direction	Increase
Pri. Wave	340	Rgt. Blank	41 42
Sec. Wave	700	Reac. Time	76 77

Result Setup

Decimal	1	Slope	1
Unit	mg/dl	Inter	0

Judgment Criteria

Absorbance	0	0	Lin. Range
Incre. Test	0		Lin. Limit
Decre. Test	0		Subs. Limit

□ Prozone ○ Rate ○ Antigen

Q1	0	Q2	0	Q3	0	Q4	0
PC	0			ABS	0		

CALIBRATION

Calibration

Rule	Two Point Linear
Replicate	1
K	

Judgment Criteria

Sensitivity	Blank Abs.
Factor Diff.	Error Limit
SD	Corr. Coeff.

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 4-292) is recommended. Calibrator and 0.9% NaCl should be used for calibration.
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 Cobas Mira. 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 [mg/dl]	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 [mg/dl]	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 CORMAY reagent (y) and ФТІЩЕРУК commercially available assay (x) using 17 samples gave following results:
y = 0.86 x + 86.9 mg/dl;
R = 0.9566 (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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