Fibrinogen (Fg) (Latex Immunoturbidimetric)

R1：60ml×2 + R2：20ml×2　Calibrator: 1ml×1

R1: 500mlx3　R2: 500mlx1

R1: 1LX3　R2: 1LX1

R1: 5LX3　R2: 5LX1

R1: 10LX3 R2: 10LX1

【Intended Use】

In vitro test for the quantitative determination of Fibrinogen Kit in human serum on automated clinical chemistry analyzers for clinical laboratories.

【Summary and Explanation】

Fibrinogen (Fg), or coagulation factor I, is the most abundant coagulation factor in the blood, and it is also an acute reactive protein. Fibrinogen has dual biological activities. It is not only the substrate of thrombin, but also the target substance of high-concentration plasmin. Therefore, fibrinogen plays an important role in both the coagulation system and the fibrinolytic system. Elevated plasma fibrinogen content is an independent risk factor for coronary thrombosis, and is positively correlated with myocardial infarction and stroke. Elevated fibrinogen can be seen in some acute or chronic infections, burns, shock, severe tissue damage and surgical operations. When severe liver injury or cirrhosis and diffuse intravascular coagulation (DIC) occur, the fibrinogen content decreases.

【Principle】

The fibrinogen in human plasma binds with the appropriate amount of specific antibody in the reagent to form an insoluble immune complex, which changes the absorbance of the reaction solution. Under the condition of a certain amount of antibody, the magnitude of the change in absorbance is the same as the Fg concentration in the human plasma sample Into a positive correlation.

【Components】

Materials Required（but not provided）

Contents	components	Concentration
R1	Tris buffer, PH8.0	10mmol/L
R2	Goat anti-human fibrinogen antibody	titer
Calibrator	Sodium Citrate Buffer Solution，Human fibrinogen	-

【Storage and Stability】

1.Unopened reagent: stable for 12 months at 2～8℃, protect from light.

2.Opened reagent: stable up to 30 days at 2～8℃, protect from light.

【Specimen Collection and Handling】

Only the specimens listed below were tested and found acceptable.

For specimen collection and preparation, only use suitable tubes or collection containers.

Specimen: Serum samples on an empty stomach are the recommended specimens.

Serum: Collect fresh serum using standard sampling tubes. When processing samples in primary tubes, follow the instructions of the tube manufacturer.

For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended.

Stability：Store serum less than 7 days at 2～8℃, 1 month at -20℃～-15℃. Protected from light and avoid repeated freeze thaw cycles.

Centrifuge samples containing precipitate before performing the assay.

【Procedure】

Reagent preparation:

R1: Ready for use; R2: Ready for use.

Wavelength：340nm

Temperature：37℃

Cuvette: 1cm

	Blank Tube	Calibration Tube	Sample Tube
Sample	—	—	2ul
Calibrator	—	0.02ml	—
Deionized water	0.02ml	—	—
R1	2.1ml	2.1ml	2.1ml
Mix, incubate at 37℃ for 5 minutes.			
R2	0.70ml	0.70ml	0.70ml
Mix, incubate at 37℃ for 5 minutes, zero setting for blank tube, read the absorbance $\triangle A_{\text{calibrator}}$ and $\triangle A_{\text{sample}}$			

Calibration

It is recommended to use the Fg Calibrators for calibration.

Calibration frequency

Recalibration is recommended:

- as a blank calibration after 24 hours
- as a blank calibration after reagent bottle change
- as a two point calibration every 30 days if the reagent always on-board
- as a two point calibration after reagent lot change
- as a two point calibration if required following quality control procedures

Calibration verification: Not necessary

Quality control

It is recommended to use the Fg Quality Control for daily quality control.

Two levels of controls should be assayed at least once a day.

Values obtained should fall within a specified range.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Calculation：

The analyzer automatically calculate the analyte concentration of each sample.

【Expected Value】

2.2g/L～3.8g/L

The reference range should be determined by each hospital to confirm with the characteristics of the region being tested.

【Limitations and Interference】

1.Lipemia (Intralipid): no interference up to 500mg/dl of intralipid.

2. Hemolysis: no interference up to 1000mg/ dl.
3. Bilirubin: no interference up to 40mg/ dl.
The result may vary with different analyzers or calibrations.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

2.2g/L～3.8g/L
Determine the samples with higher concentrations via the rerun function. In the event of a rerun the upper limit of the assay ranges is increased to approximately .
These values are dependent on the lot specific values of the calibrators in use.

【Performance characteristics】

The following performance data was obtained using

analyzer at 37℃. Results obtained in individual laboratories may differ.

Blank Absorbance： A≤0.200

Analytical sensitivity

0.100～0.450 at 5mg/L
The lower detection limit represents the lowest measurable total uric acid concentration that can be distinguished from zero. It is calculated as three standard deviations of 20 replicates of the lowest standard.

Accuracy

≤±10%

Precision

≤8%

Batch Error

R≤10%

【Precautions and warnings】

1. For in vitro diagnostic use.
2. Avoid skin and eye contact. Avoid ingestion.
3. Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.
4. Do not use the product if interior package is damaged during shipment.
5. The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth, calibration results do not meet the appropriate standard specification, or control values out of range.
6. Exercise the normal precautions required for handling all laboratory reagents.
7. Wear protective clothing and disposable gloves while handling the kit reagents.
8. Wash hands thoroughly after performing the test.
9. Use in ventilated area.
10. For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician".
11. For biological spills, indicate appropriate disinfectants and disinfection procedure.
12. Dispose of all specimens and components of the kit as potentially infectious agents.
13. Do not use the kit or any kit component past the indicated expiry date.
14. Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
15. Avoid microbial contamination of reagents.
16. The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

【Definition of Symbols】

USE BY (LAST DAY OF THE MONTH)	
BATCH CODE	
DATE OF MANUFACTURE	
TEMPERATURE LIMITS	
CONSULT INSTRUCTIONS FOR USE	
HANDLE WITH CARE	
UPWARDS LAY	
KEEP DRY	
KEEP AWAY FROM SUNLIGHT	
IN VITRO DIAGNOSTIC MEDICAL DEVICE	
CATALOGUE NUMBER	
SUFFICIENT FOR	
MANUFACTURER	

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