Fibrinogen Reagent Kit (Clotting)

Catalog No.: W482

INTENDED USE

The Fibrinogen Reagent Kit (Clotting) is used along with Optical Coagulation Analyzer (Model No.: OCG-102) for quantitative measurement of fibrinogen in citrated venous whole blood.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

Fibrinogen, also known as coagulation factor I, is a glycoprotein that helps in the formation of blood clots. When injury and bleeding occurs, a coagulation cascade activates the prothrombin by converting it into thrombin. Thrombin then converts the soluble fibrinogen into insoluble fibrin strands.

The Fibrinogen testing is often prescribed as part of an investigation of a possible bleeding disorder or inappropriate blood clot formation. It is also used to help diagnose disseminated intravascular coagulation, abnormal fibrinolysis, or to monitor the status of end- stage liver disease. The testing is occasionally used with other tests to help determine a person's overall risk of developing cardiovascular disease.

TEST PRINCIPLE

The test is performed by inserting a test strip into the Optical Coagulation Analyzer (Model No.: OCG-102). The instrument contains a test chamber which warms the test strip to the required temperature.

The test strip contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The spokes rotate across the path of a light beam and mix the liquid sample with the reagent which is dried in the reaction well. The thrombin contained in the test strip acts on the clotting factor fibrinogen to form insoluble fibrin that crosslink together to fibrin net. When the sample clots, the clot is picked up by the spokes, interrupting the path of the light beam that is detected by the instrument. An internal timer measures the elapsed time between the start of the test and the clot formation.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only.
2. This reagent kit is for single use only. Do not reuse.
3. Do not ingest the desiccant.
4. Inspect the packaging and labeling before use. Make sure that the lot No. on the packaging and on the ID chip are the same.
5. The Fibrinogen Reagent Kit (Clotting) can only be used with the Optical Coagulation Analyzer (Model No.: OCG-102).
6. Do not use the test strip beyond its expiration date printed on the package. The test strip must remain in its original sealed pouchuntil ready to use. Do not use if the pouch or the test strip is damaged, tore or not fully sealed.
7. The phlebotomy and the test must be operated by certified medical personnel.
8. Non-siliconized tube is inappropriate for blood sample collection.
9. The operation shall be conducted away from vibration and magnetic field. The test may generate minute vibration during use, which should be regarded as normal.
10. One pipette tip or capillary tube should be used for one specimen only. Discard after single use.
11. Do not smoke, eat, or drink in areas where specimens orkit reagents are handled.
12. All specimens and used test materials are considered as potentially infectious. Proper laboratory safety procedures should be followed at all times when working with patient specimens.
13. Discard the test strip after single use. The disposal of all used test materials and specimens must be in accordance with local regulations and procedures.

MATERIAL

Material Provided

Each box contains:

1. 24 individual sealed pouches, each containing:
   - 1 test strip
   - 1 desiccant pouch
2. 1 ID chip
3. 1 Leaflet with Instructions for Use

Material Required But Not Provided

1. Optical Coagulation Analyzer (Model No.: OCG-102)
2. Venous blood collection system with single use plastic tubes or siliconized glass tubes
3. Transfer pipette or capillary tube
4. 0.109 mol/L trisodium citrate anticoagulant

STORAGE AND STABILITY

1. Optical Coagulation Analyzer (Model No.: OCG-102)
2. Venous blood collection system with single use plastic tubes or siliconized glass tubes
3. Transfer pipette or capillary tube
4. 0.109 mol/L trisodium citrate anticoagulant

STORAGE ANDSTABILITY

1. Store Fibrinogen Reagent Kit (Clotting) at 2~30 ℃.
2. The shelf life of the test kit is 18 months. Refer to the expiration date printed on the package.
3. Once opened, use the test strip within 15 minutes.
4. Keep the test strip away from sunlight and moisture.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with citrated venous whole blood.

1. Fresh venous whole blood (9 vol) is collected in 0.109 mol/L trisodium citrate anticoagulant (1 vol). Mix gently by inverting it for several times.
2. EDTA, heparin or oxalate anticoagulants are unacceptable.
3. Specimens must be collected and stored in single-use plastic tubes or siliconized glass tubes that have nonactivating surfaces.
4. Avoid hemolysis or tissue contamination.
5. Citrated samples are generally stable for up to six hours at room temperature, stored at 2 ℃-8 ℃ for eight hours. Samples which contain heparin must be tested within four hours after collection.
6. pH value of the specimen may rise if the specimen is exposed to air, thus the specimen shall be stored and transported capped. Specimen tubes should be protected from vibrations and shock to avoid protein denaturation and platelet activation through foaming of the specimens.

TEST PROCEDURE

Refer to the Operation Manual of Optical Coagulation Analyzer (Model No.: OCG-102) for complete instructions of the test.

1. Power on the instrument.
2. Take ID chip from the kit and insert it into the ID chip slot.
3. Remove a test strip from its foil pouch. Insert it into the instrument as instructed on the display screen.
4. The instrument will warm the test strip to the required temperature. Wait till the preheating is done and the instrument reminds of adding sample.
5. Load 20 μL of specimen into the sample well. Vigorous agitation and foaming should be avoided.
6. Results are displayed on the main screen. Test results can be printed if the instrument is connected to a printer.

7. Remove the used test strip from the instrument. Discard it with used pipette tip or capillary tube according to local regulations and procedures.

Traceability: The Fibrinogen Reagent Kit (Clotting) is traceable to the international standard NISBC 09/264.

INTERPRETATION OF RESULTS

The concentration of fibrinogen in blood sample is measured in g/L. The reference range established using apparently healthy individual of the Fibrinogen Reagent Kit (Clotting) is 2.0~4.0 g/L.
Before instituting using the Fibrinogen Reagent Kit (Clotting), users must establish the normal reference range using blood obtained from apparently healthy male and female subjects selected from reference population.
Elevated level of fibrinogen may be seen with:

- acute infections
- cancer
- stroke
- acute inflammatory disorders such as glomeruloenphritis
- coronary heart disease, myocardial infarction
- trauma
- connective tissue disease
- pregnancy hypertensive syndrome

Chronically low level of fibrinogen is often related to inherited condition such and afibrinogenemia or hypofibrinogenemia or to an acquired condition such as end-stage liver disease or severe malnutrition.
Acutely low level of fibrinogen is often related to consumption of fibrinogen such as disseminated intravascular coagulation (DIC) and abnormal fibrinolysis.

QUALITY CONTROL

To validate the accuracy and repeatability of Fibrinogen Reagent Kit (Clot), quality control (QC) should be conducted according to the laboratory's standard quality control procedures.
Wondfo quality control (Catalog No. W863) is recommended and can be used in the following cases:

- When a new lot is tested;
- In case the Optical Coagulation Analyzer (Model No.: OCG-102) or Fibrinogen Reagent Kit (Clotting) are not working properly;
- In case if there are doubts about their accuracy on the test results.

Note: Please refer to the Instructions For Use of Wondfo quality control (Catalog No. W863) for detailed operation.
If a QC test fails for any reason, no patient results shall be reported. Inspect every component of the test system to identify source(s) of error. Repeat the test on a new test strip if patient sample is still available. If problems still exist, contact Guangzhou Wondfo Biotech Co., Ltd. or your local distributor.

LIMITATIONS OF PROCEDURE

1. The results of Fibrinogen Reagent Kit (Clotting) should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. This test is developed for testing citrated venous whole blood samples. Do not use plasma samples.
3. Blood transfusions within the past month may affect fibrinogen test results.
4. Certain medications, including anabolic steroids, phenobarbital, streptokin, may decrease fibrinogen level.

PERFORMANCE CHARACTERISTICS

Precision

Intra-lot Precision: CV≤5%
Inter-lot Precision: CV≤10%

Reportable Range

The reportable range of Fibrinogen Reagent Kit (Clotting) is 1.5~6.0 g/L.

Linearity

The linear range of Fibrinogen Reagent Kit (Clotting) is 1.5~6.0 g/L, with a correlation coefficient ≥0.98.

Accuracy

When evaluating Fibrinogen Reagent Kit (Clotting) using normal and abnormal controls with given concentration levels, the bias was within 15%.

Analysis Specificity

1. In vitro studies showed that the sample contained hemoglobin no more than 500 mg/dL or bilirubin no more than 20 mg/dL, or triglycerides no more than 3000 mg/dL, had no significant effect on the test results.
2. Hematocrit in samples between 15% and 55% has no significant effect on the results.

BIBLIOGRAPHY OF SUGGESTED READING

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2. Quick A J, Stanley-Brown M, Bancroft F W. A Study of the Coagulation Defect in Hemophilia and in Jaundice.*[J]. The American Journal of the Medical Sciences, 1935, 190(4): 501-510.
3. G.D.O. Lowe. Anabolic steroids and fibrinolysis. 10.1136/bmj.2.5401.122-c
4. Yuming Huang, Zhimei Li, Yongqing Zhao, Chengyun Ding, Effects of antiepileptic drugs on plasma fibrinogen levels.1006-351X（2007）03-0189-02
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INDEX OF SYMBOLS

Consult instructions for use		Contains sufficient for <n> tests		Date of manufacture	
IVD	*In vitro* diagnostic medical device		Use-by date		Do not re-use
	Temperature limit	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
CE	CE marking	EC REP	Authorized representative in the European Community/ European Union		

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	工艺：风琴二折3页 再上下对折	修改内容：□文字 □颜色 □尺寸 □工艺 □材质 □其他 □无		
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