Prothrombin Time Reagent Kit (Clotting)

Catalog No.: W480

INTENDED USE

The Prothrombin Time Reagent Kit (Clotting) is intended to be used along with Optical Coagulation Analyzer (Model No.: OCG-102) to provide quantitative measurement of Prothrombin Time (PT) and International Normalized Ratio (INR) in citrated venous whole blood.

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

SUMMARY

Prothrombin Time Test is a coagulation test which is sensitive to abnormalities of the extrinsic and common coagulation pathway. Use of Prothrombin Time Test is also essential for monitoring and management of oral anticoagulation therapy warfarin.
While PT test results (in seconds) may vary with use of different test systems, the INR was devised to standardize the results. The INR is the ratio of a patient's prothrombin time to a normal control sample, raised to the power of the ISI value for the test system:

$$INR=\left(\frac{PT_{test}}{PT_{normal}}\right)^{ISI}$$

Where the International Sensitivity Index (ISI) value indicates how a particular batch of tissue factor compares to an international reference tissue factor.

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. 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. The Prothrombin Time Reagent Kit (Clotting) can only be usedwith the Optical Coagulation Analyzer (Model No.: OCG-102).
5. 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.
6. The phlebotomy and the test must be operated by certified medical personnel.
7. Non-siliconized tube is inappropriate for blood sample collection.
8. 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.
9. One pipette tip or capillary tube should be used for one specimen only. Discard after single use.
10. Do not smoke, eat, or drink in areas where specimens orkit reagents are handled.
11. 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.
12. 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. 24 capillary tubes (20 μL)
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. 0.109 mol/L trisodium citrate anticoagulant

STORAGE AND STABILITY

1. Store Prothrombin Time 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°C-8°C 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 throughfoaming 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. Remove a test strip from its foil pouch. Insert it into the instrument as instructed on the display screen.
3. The instrument will warm the test strip to the required temperature. Wait till the preheating is done and the instrument reminds of adding sample.
4. Load 20 μL of specimen into the sample well. Vigorous agitation and foaming should be avoided.
5. Results are displayed on the main screen. Test results can be printed if the instrument is connected to a printer.
6. Remove the used test strip from the instrument. Discard it with used pipette tip or capillary tube according to local regulations and procedures.

INTERPRETATION OF RESULTS

The reference range for normal volunteers on venous blood is 10~ 14 seconds, and the reference range for INR is 0.7~1.3.
Before initiating the Prothrombin Time Reagent Kit to the laboratory, users must establish the normal reference range using blood obtained from apparently healthy male and female subjects selected

from reference population.

A prolonged PT means that the blood is taking too long to form a clot. Prolonged PT may be caused by liver disease, decreased vitamin K, decreased or defective factor I, II, V, VII or X, disseminated intravascular coagulation (DIC), anticoagulation drug therapy, primary fibrinolysis, hypofibrinogenemia or afibrinogenemia.

QUALITY CONTROL

To validate the accuracy and repeatability of Prothrombin Time Reagent Kit (Clotting), 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 Prothrombin Time 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 Test 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. Existence of thrombin inhibitor, for example, hirudin or Argatroban, in whole blood sample may increase PT.
4. Lupus anticoagulant may skew PT tests.
5. Barbiturates, oral contraceptives and hormone-replacement therapy (HRT) may decrease PT.

PERFORMANCE CHARACTERISTICS

Reportable Range

The PT is measured in seconds. The reportable range of PT is 7~ 90 seconds.
The reportable range of INR is 0.5~ 9.

Precision

Intra-lot Precision: CV≤5% Inter-lot Precision: CV≤10%
Precision study was conducted over three lots. The precision was determined using normal and abnormal control materials.

Accuracy

When evaluating Prothrombin Time Reagent Kit (Clotting) using normal and abnormal controls with given concentration levels, the relative bias shall be 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 10% and 60% has no significant effect on the results.

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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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	尺寸(长*宽*高)：285*210mm	颜色：C100M40 K35	材质：双胶	工艺：/
	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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