Coagulation 4 Test Panel

For professional and in vitro diagnostic use only.

1 Specification

-1 test/pouch, 20 tests/kit (Cat.no: VE60008)

2 Intended Use

The Coagulation 4 Test Panel is intended for in vitro quantitative determination of thrombin time (TT), prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB) concentration in animal plasma or whole.

3 Summary and Explanation of Test

TT is mainly used to reflect the abnormal content or structure of plasma fibrinogen, and can also be used to reflect the function of the fibrinolytic system. TT prolonged: found in increased heparin or presence of heparinoid substances, increased fibrin (proto) degradation products (FDP)/D-D, low (no) fibrinogenemia, abnormal fibrinogenemia. TT shortened: It is common in the presence of small coagulation or calcium ions in blood samples.

PT is mainly used clinically for screening of dysfunction of exogenous coagulation system and monitoring of oral anticoagulant therapy. PT prolonged: found in congenital factor II, V, VII, IX deficiency and low (no) fibrinogenemia; Acquired seen in DIC, primary fibrinolysis, vitamin K deficiency, and the presence of anticoagulants in the blood circulation such as oral anticoagulants, heparin and FDP. PT shortened: found in congenital factor V hyperplasia, oral contraceptives, hypercoagulable state and thrombosis.

APTT is mainly used clinically for screening of deficiencies in the endogenous coagulation system and monitoring of heparin anticoagulation therapy. APTT prolonged: seen in plasma coagulation factor VIII, factor IX, factor XI and factor XII levels decreased; severe deficiency of prothrombin, factor V, factor X and fibrinogen; increased fibrinolytic activity; anticoagulant substances in blood circulation; monitoring the treatment of common heparin. APTT shortened: found in hypercoagulable state and thrombotic diseases (such as pregnancy hypertension syndrome, nephrotic syndrome, myocardial infarction, unstable angina).

FIB is clinically mainly used for the auxiliary diagnosis of diffuse intravascular coagulation, primary fibrinolysis and the monitoring of thrombolytic efficacy. Increased FIB content: found in diabetes and diabetic acidosis, arterial thrombo-embolism, acute infectious diseases, connective tissue diseases, acute nephritis, uremia, shock, post-surgical and mild hepatitis. Decreased FIB content: found in diffuse intravascular coagulation, primary fibrinolysis, severe hepatitis, liver cirrhosis, antifibrotic therapy and thrombolytic therapy.

4 Test Principle

The principles of each item test in the Coagulation 4 Test Panel are as follows:

TT：thrombin is added into plasma to be tested to convert fibrinogen into insoluble fibrin. The time required for plasma coagulation, is thrombin time of the plasma to be tested.

PT：excess calcium-containing tissue thromboplastin is added into plasma to be tested to convert prothrombin into thrombin. Thrombin converts fibrinogen into insoluble fibrin. The time required for plasma coagulation, is prothrombin time for plasma to be tested.

APTT: APTT (Allagic acid) reagent is added into plasma to be tested. after pre-warming at 37°C, fibrinogen is converted into insoluble fibrin under the action of calcium ion. The time required for plasma coagulation, is activated partial thromboplastin time for plasma to be tested.

FIB: excess thrombin is added into plasma to be tested to converted fibrinogen into insoluble fibrin. The coagulation time of plasma is inversely proportional to the fibrinogen content.

5 Composition

- Reagent panel: each reagent panel is individually packaged in the sealed pouch with reagent information printed on the package. There is a reagent panel and a desiccant in the pouch. The reagent panel is pre-packaged with lyophilized reagents corresponding to the test items.

Item	Composition	
TT	TT reagent	TT stock solution, 0.05g/mL polyvinylpyrrolidone
PT	PT reagent	PT stock solution, 0.05g/mL bovine serum albumin
APTT	APTT reagent	APTT stock solution, 0.05g/mL dextran
	Calcium chloride reagent	Calcium chloride stock solution, 0.05g/mL polyvinylpyrrolidone
FIB	FIB reagent	FIB stock solution, 0.02g/mL polyvinylpyrrolidone

- QR Code contains the reagent name can be scanned.
- Instruction for use

6 Storage and Stability

Store the reagent panel as packaged in the sealed pouch at 2-8°C. The reagent panel is stable within the expiration date printed on the labeling. Once open the pouch, the reagent panel should be used immediately.

See the label for LOT and expiry date.

7 Applicable Instrument

Pushkang Chemistry Analyzer: MSC100V and MS200V.

8 Materials Required but Not Provided

- Pushkang Chemistry Analyzer

  MSC100V (Cat.no: VE20001)

  MS200V (Cat.no: VE20002)
- Sample transfer tips (type:200μL and 1mL)
- Quality control
- Normal
- Abnormal
- Diluent

9 Warnings and Precautions

For in vitro diagnostic use only.

1. Reagent panels can only be used once.
2. Used reagent discs contain animal body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Pushkang Chemistry Analyzer User's Manual for instructions on cleaning biohazardous spills.
3. The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as it may spray biohazardous material throughout the interior of the analyzer.
4. A torn or otherwise damaged pouch may allow moisture to reach the unused disc and adversely affect reagent performance. Do not use a disc from a damaged pouch.
5. Using reagents from different manufacturers to test the same sample, the test results may be different, and should not be directly compared with each other to avoid false medical interpretations.
6. Avoid accidental ingestion or contact with skin and mucous membranes. If accidentally spill this product into your eyes, mouth or stick to your skin, please rinse it with plenty of water, please seek medical advice if necessary.
7. Take protective measures and follow all the precautions for laboratory reagent operation. All specimens and waste liquid should be considered sources of infection and should be handled in according to local regulations.

10 Specimen Collection and Preparation

This kit could use both plasma and whole blood directly.

1. Plasma: fresh venous blood should be mixed with 0.109mol/L sodium citrate in a ratio of 9:1, centrifuge at 3000rpm for 15 minutes and collect plasma.

   Whole blood: fresh venous blood should be mixed with 0.109mol/L sodium citrate in a ratio of 9:1, then can be used directly.
2. Sample collection, storage and determination should use plastic or silicified glass products.
3. EDTA salt, heparin and oxalate as anticoagulants should not be used.
4. Samples should avoid hemolysis and contamination by tissue fluid.
5. Both plasma and whole blood sample should be detected within 4 hours.
6. Plasma storage: 4 hours at 20 ± 5 °C,14 days at -20°C, 6 months at -80°C. Do not store at 2-8 °C.

   If on heparin therapy, plasmas remain stable for 2 hours at 20 ± 5 °C.
7. Whole blood storage: 4 hours at 20 ± 5 °C. If wants to be stored for long time, it needs to be stored as plasma.
8. The sample can only be used once after thawing, repeated freezing and thawing will affect the measured value. The samples stored at low temperature should be restored to room temperature for 15-20 minutes before each test, so that the test results can be accurate.
9. When the bilirubin is not more than 200 mg/L, the hemoglobin is not more than 36 mg/mL, and the triglyceride is not more than 7.5 mg/mL, there will be no significant impact on the test results.

11 Test Procedure

- **Reagent preparation**
  The reagent panel is lyophilized reagent, and the diluent should be manually added before use.
- **Test condition**
  The information about the reagent panel can be obtained by scanning the QR code on the package of the reagent panel.
- **Operation steps**

1. The instrument scans the QR code on the reagent panel to read the reagent information.
2. Take the reagent panel out of the sealed bag and place it horizontally. Add 180μL of the sample to be tested (plasma or anticoagulant whole blood) into the sample hole and 180μL of diluent into the diluent hole.
3. Place the reagent panel in the middle of the reagent panel tray of the analyzer.
4. Operate in accordance with the operating instructions of the instrument. The instrument automatically distributes the sample and diluent in the reagent panel to each reaction well, the lyophilized reagent is dissolved, the reaction starts, and the instrument automatically reads the test result.

Note:

1. The QR code contains the information required for the test, and each batch of products is different. It must be used with the reagent panel of the same batch number, and cannot be mixed, otherwise you will get wrong test results.
2. If the product's individual package has been damaged before use, or the reagent panel is found to be broken after opening the sealed pouch, it cannot be used for

testing, otherwise it may cause abnormal testing process and even damage the instrument. When the reagent panel falls from a high place, it should not be used for testing, regardless of whether the panel produces visible broken or not, in order to avoid more serious accidents.

3. Foreign objects and stains on the surface of the reagent panel may affect the accuracy of the test results. Be especially careful during operation to avoid touching the upper and lower surfaces of the reagent panel. It is recommended to wear powder-free gloves for operation.
4. When adding samples, the pipette tip should be inserted into the corresponding liquid filling hole, and then press the pipettor button to ensure that the liquid completely enters the inside of the panel.
5. The reagent panel should be tested immediately after adding the sample and diluent. After sample adding, excessive tilt and deliberate shaking should be avoided.
6. In order to avoid cross-contamination, the same pipette tip should not be reused for absorbing multiple samples, nor can it be mixed for absorbing samples and diluents.
7. You should prepare your own diluent to use this reagent panel. The diluent is purified water. The diluent should avoid prolonged exposure to the air to prevent contamination. It is suggested to use a single package of small dose of sterilization water for injection, ready to use.

- **Test result calculation**

The built-in calculation function of the instrument can automatically calculate the test results of each item according to the change value of the optical signal, and display and/or print them.

- **Calibration procedure**

1. There is a QR code on each reagent tray, which contains calibration information. The user scans the QR code, and the instrument automatically reads the calibration curve information. The FIB calibrator can be traced to the NIBSC international reference material (WHO International Standard NIBSC code: 09/264).
2. When changing the batch number of the kit, you should scan the QR code again to read the calibration information. Each laboratory can formulate its own calibration cycle according to the specific situation.
3. When the following situations occur, it is recommended to rescan the calibration information: the batch number of the kit has changed, the quality control value has a remarkable deviation, and the analyzer has undergone major maintenance.

- **Quality control procedure**

1. Quality control must be performed when the batch number of the kit is changed and the instrument undergoes major maintenance.
2. Select appropriate control for quality control, and the preparation method is operated in accordance with its instruction.
3. Each laboratory can set appropriate control limits and quality control cycles according to their own conditions. The quality control value must be within the specified control limits.
4. If the quality control results are not in line with expectations, it indicates that the test results are unreliable, and a test report should not be issued.

12 Reference Interval

Item	Unit	Group	Reference interval
TT	s	Cat	8～20
	s	Dog	8～20
PT	s	Cat	5～15
	s	Dog	5～15
APTT	s	Cat	15～45
	s	Dog	15～45
FIB	mg/dL	Cat	1～4
	mg/dL	Dog	1～4

Due to differences in geography, race, gender, and age, it is recommended that each laboratory establish its own reference interval.

13 Limitations

1. The coagulation process includes a series of reactions, which are affected by many factors, including sample collection and storage, the proficiency of technicians, interfering substances, etc. These factors must be strictly controlled.
2. Hemolysis, lipemia, jaundice and contaminated samples may affect test results and the use of such samples should be avoided.

14 Index of Symbols

	Store between 2-8°C
	Consult instructions for use
	Batch code
	Use-by date
	Contains sufficient for <n> tests
	Do not use if package is damaged
	Do not reuse
	Keep away from sunlight
	Caution

15 Basic Information

Manufacturer: Zhejiang PushKang Biotechnology Co., Ltd.

Address: C408, science and technology Innovation Park, No.398, Mahuan Road, Binhai New Area, 312366 Shaoxing,Zhejiang, P.R.China

Tel: +86-575-82002091