LEPU MEDICAL

CE

Coagulation Analysis Solution

PT-M1-11 Coagulation Analyzer& PT-S1-01 Prothrombin TimeDetection Card
(Electrochemical Method)

Features

Micro blood sampling

Long standby (Test more than 200 times)

Light and convenient, easy to carry

Large screen display result clearly

Intended Use:

PT-M1-11 coagulation Analyzer and PT-S1-01 Prothrombin Time Detection Card need to be used together, and its purpose is to determine theprothrombin time (PT) of human capillary blood

- Please read IFU carefully or purchase and use under the guidance of medical staff
- Please refer to IFU for details of contraindications or precautions
- The product is only used as coagulation function dynamic monitoring tool, the results can't be used as a basis for clinical diagnosis

Bluetooth Connection

Clinical significance of Prothrombin Time

Prothrombin Time (PT) refers to the time required for the conversion of prothrombin to thrombin when excess tissue thromboplastin and calcium ions are added to platelet-deficient plasma, resulting in plasma coagulation. Prothrombin time is an index reflecting the activity of coagulation factors I, II, V, VII and X in plasma. Determination of prothrombin time is a screening test to check the function of the exogenous coagulation system, and it is also an important monitoring index for clinical anticoagulation therapy.

PT-M1-11& PT-S1-01 Specifications

Test Sample: Peripheral whole blood

Blood Collection Method: Blood collection needle

Detection Range: INR: 0.7-6.0

Preheat Time: ≤3 min

Test Time: 90 seconds

Result Storage: 200 latest results

Bluetooth Connection: Yes

Battery: 4 AA/1.5V batteries

Battery Life: About 200 tests

Accessories: Disposable blood sampling needle (optional)

Test Temperature: 10℃~35℃

Test Humidity: ≤80%

PT-M1-11 Dimensions: 145mm x 69mm x 33mm (length x width x thickness)

PT-S1-01 adapted Equipment: PT-M1-11 Coagulation Analyzer

PT-S1-01 Packaging Specifications: 10/ 25/ 50 per box

PT-S1-01 Store Condition: 2℃-30℃: 12 months (Unopened)

(Note: Dear customer, PT-M1-11 Coagulation Analyzer doesn't include PT-S1-01 Prothrombin Time Detection Card. If PT-S1-01 is necessary, you need to purchase it separately)

Applicable People

People with abnormal coagulation or long-term oral anticoagulants requiring regular monitoring of coagulation function
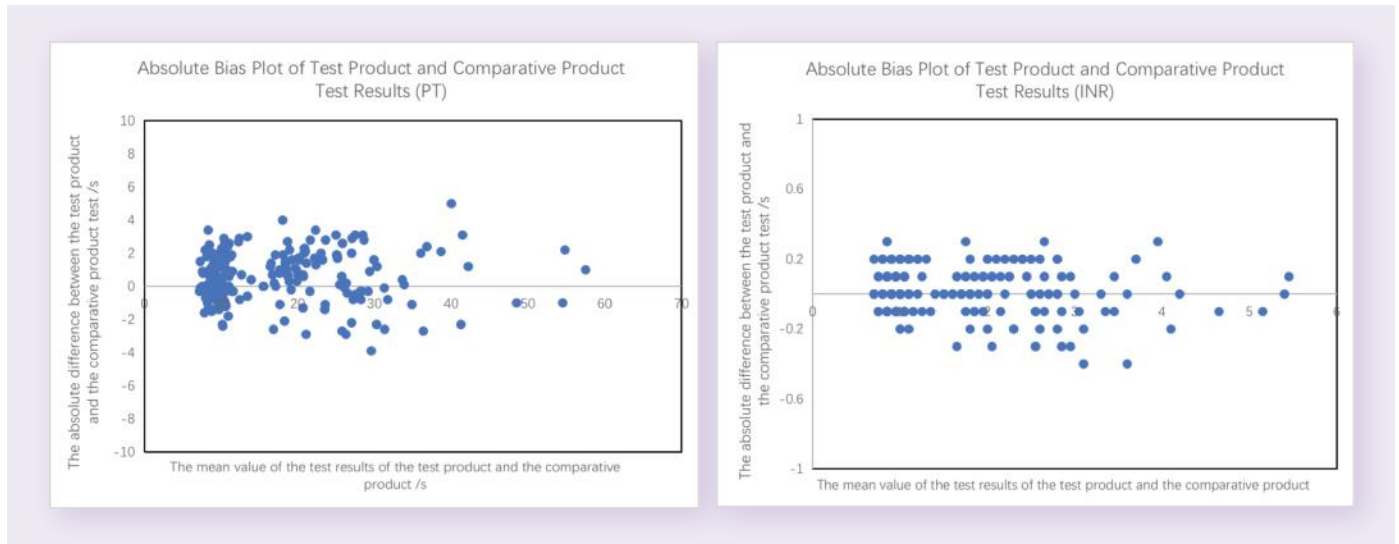
Detection Principle

The whole blood sample is dripped into the test card, the blood sample is gradually coagulated, and its conductivity will change accordingly, and the current value will change. The analyzer tests this process and calculates the change time of the sample, meanwhile display the result on the screen.

This coagulation analyzer reports the prothrombin time (PT) and the international normalized ratio (INR) at the same time when the prothrombin time is detected.
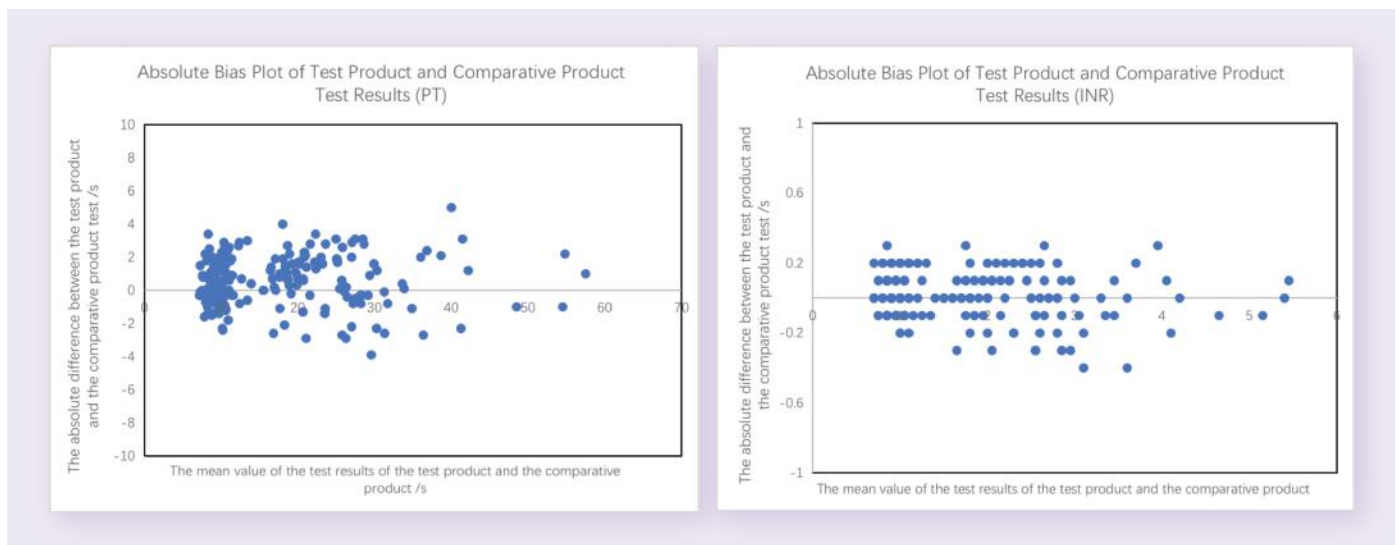
Experimental data of Lepu PT-M1-11& PT-S1-01

Lepu IVD team conducted clinical tests of PT-M1-11& PT-S1-01 with the control products in relevant hospitals, the results are as follows:

Figure 1. Absolute bias plot of the test product and the comparative product

Conclusion: It can be seen from Figure 1 that the difference between the prothrombin time (PT) and the international normalized ratio (INR) of the test product and the comparative product is evenly distributed on the upper and lower sides of the center line 0, indicating that the data meets the requirements compared with the comparative product.

Figure 2. Relative Bias Plot of the Test Product and the Comparative Product

Conclusion: It can be seen from Figure 2 that the ratio of prothrombin time (PT) and international normalized ratio (INR) between the test product and the comparative product is evenly distributed on the upper and lower sides of the center line 1, indicating that the data meets the requirements compared with the comparative product.

- **PT-M1-11 Coagulation Analyzer&**
- **PT-S1-01 Prothrombin TimeDetection Card**

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