PT-s

Prothrombin Time

Product information

24PT01	**Coax PT-s**	**10 x 4 mL**
24PT01	**Coax PT-s**	**10 x 2 mL**

Purpose

Coax PT-s is a stable, liquid and ready-to-use Thromboplastin derived from rabbit brain for the determination of Prothrombin Time according to Quick. Tissue Factor contains lipids and calcium ions and is used for the study of the extrinsic pathway of coagulation. PT LIQUID is a Thromboplastin highly sensitive to Vitamin K antagonists, low levels of extrinsic pathway factors (Factor II, V, VII and X), hereditary or acquired coagulation disorders, hepatic failure.

Summary

Prothrombin Time (also known as PT) and derived measurements (Ratio, INR, and Percent Prothrombin Activity) are measurements of the extrinsic and common pathway of coagulation. It is used to determine the tendency to blood clotting (preoperative screening), to adjust the dosage of anticoagulant therapy with warfarin, or to better determine the severity of a liver disease and to check the status of vitamin K. The PT is useful for assessing five of the twelve clotting factors. (I - Fibrinogen, II - Prothrombin, V - Proaccelerin, VII - Proconvertine and X - Prothrombinase). All these factors are synthesized by the liver, and three of them (II, VII and X) are activated by enzymes linked to vitamin K.
Coumadin - Oral anticoagulants such as warfarin are vitamin K antagonists and therefore inhibit the activation of the above clotting factors. By acting in this way, these drugs "fluidize the blood" and prevent the formation of clots in the circulating stream. PT is used in combination.
The PT reagent can also be used to determine fibrinogen concentrations within the normal range using the prothrombin time-derived fibrinogen application (PT Der Fib).

Basic tests

The test contains thromboplastin and calcium, which, when added to citrated human plasma, initiate the activation of the extrinsic coagulation cascade. The time elapsed between the addition of the reagent to the plasma and the formation of the fibrin clot is measured and reported in seconds, INR (International Normalizing Ratio) or percentage of normal. Furthermore, the absorbance change during PT determination can be used to obtain a fibrinogen concentration in mg/dL (Prothrombin Time Obtained Fibrinogen).

Reagents - working solutions

Reagent, ISI 1.0 (Liquid saline extract of rabbit brain, BSA 0.5%, Calcium chloride CaCl2 0.015M, Sodium azide 0.2%)

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).
If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Prothrombin time testing can be performed by accepted manual methods or **by using mechanical or photo-optical** coagulation devices **such as** the Coax FT40.

Storage and stability

Reagent

Storage: 2~8 °C, Unopened Vial Expiry Date: Refer to labels for expiration date.
Opened Vial Expiry Date: If opened, the reagent is stable at 2~8°C for 30 days.

Sample

PT tests must be completed within 24 hours of sample collection. If the test is not completed within 24 hours, the plasma should be removed from the cells and frozen for up to 2 weeks at -20°C or for up to 6 months at -70°C.

Sample collection and preparation

After the first whole blood draw with 3.2% sodium citrate, all test tubes, syringes, and pipettes used during testing must be plastic.
Sample: Plasma from whole blood anti-coagulated with 0.1 M (3.2%) sodium citrate.
Specimen Collection: Nine pieces of freshly collected whole blood should be immediately added to one piece of anticoagulant.
Sample Preparation: Samples can be stored at 18 to 24°C in an unopened tube without centrifugation or by centrifugation with plasma remaining on the cells (CLSI H21-4, 2003). To obtain a plasma sample, the sample tube with a cap should be centrifuged at 1500 x g for 15 minutes, and the plasma should be taken with a plastic pipette, placed in a plastic tube, and sealed.

Required Materials (not included in the kit)

1. Cat# 24PC01 Coax Plasma Control L1
2. Cat# 24PC02 Coax Plasma Control L2
3. Cat# 24RC01 Cuvette of Coax Reaction Cuvette or related device
4. Cat# 24FT4001 Coax FT40 or related device
5. 100 µL adjustable automatic pipette
6. General laboratory equipment
7. Distilled or deionized water

Working Procedure

If you are using a device to perform this test, refer to the User's Manual for the relevant device for detailed instructions.

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Prothrombin Time

For use in manual or semi-automatic systems, proceed as follows.

1. Have a sufficient amount of Reagent to perform the planned tests at 37°C.
2. Add 50 µL of control plasma, calibration plasma (complete or diluted), or the patient's plasma to each reaction cuvette.
3. Incubate the reaction cuvettes at 37°C for at least 2 minutes.
4. Bring a reaction cuvette to the reading cell, reset the stopwatch, add 100 µL of Reagent, and start the stopwatch at the same time, measuring coagulation.

Each laboratory should establish a quality control program that includes normal and abnormal controls to evaluate instrument and reagent performance. Normal and abnormal controls should be tested daily before tests are performed on patient plasmas. Monthly quality control charts (Levy Jennings) are recommended to determine the mean and standard deviation of each of the daily control plasmas. Coax L1 normal control and Coax L2 abnormal level checks are recommended. If controls do not perform within the reference ranges, patient results should be considered invalid and should not be reported.

Expected values

The reference interval study was carried out using three copies of samples from 120 normal healthy adults. Approximately an equal number of men and women were used. The PT results are as follows:

	Average Seconds	Range + 2 SD
Optics	13.5	12.1 - 16.9 sec
Mechanic	14.0	12.6 - 17.1 sec

These values should only be used as a guide. Because there may be differences between instruments, laboratories, and local populations, it is recommended that each laboratory establish its own reference range for expected prothrombin time results.

International Normalized Ratio (INR)

It is a standardization index recommended by the WHO (World Health Organization). It takes into account the sensitivity of the Thromboplastin used, expressed in the ISI (International Sensitivity Index) value, which in turn takes into account both the Reagent and the instrument used for the reading. HEAT represents the sensitivity of the system used (instrument + reagent) to coagulation factors. The lower the HEAT value, the higher the sensitivity of the system. The HEAT values of the reagent vary from lot to lot and are shown on the page attached to the kit. They are different depending on the type of instrumentation.

To calculate INR, add the ratio (base) to the ISI (exponent).

$INR = Ratio^{ISI}$

For example, if the patient's PT is 36 seconds, and the PT of plasma 100% is 12 seconds, then:

Ratio = Patient Duration / Plasma Time 100% = 36/12 = 3

If the thromboplastin ISI value for the system used is 1.05:

$INR = Ratio^{ISI} = 31.05 = 3.17$

Limitations

The expected values for the prothrombin time test will vary from one laboratory to another, depending on several variables. These include clot detection method, temperature, pH, sample collection technique, type of anticoagulant, and plasma storage time and method. Therefore, laboratories must establish their own expected values for patients and well-defined performance standards for control plasmas. Especially when using optical devices, the use of icteric, lipemic or hemolyzed samples should be avoided due to possible interference. In addition to oral anticoagulant therapy, the action of other therapeutic drugs may affect the interpretation of PT test results. Taking an accurate patient history and noting specific drug treatments can help accurately understand the potential impact on laboratory test results. The presence of heparin as a contaminant in the patient specimen should always be considered when an abnormal result is obtained.

Performance characteristics

A- Precision

		Reproducibility	Intermediate sensitivity
Coax L1	n	20	60
	Mean	13.7	13.7
	SD	0.2	0.2
	CV%	1.7	1.3
Coax L2	n		60
	Mean	31.3	31.1
	SD	0.5	0.6
	CV%	1.6	1.8

B- Comparison

Optics			
N = 105		r2 = 0.98	Y = 1.065X – 0.1245
Mechanic			
N = 105		r2 = 0.92	Y = 1.059X – 0.114

Y = Coax PT-s Reagent

X = Reference thromboplastin reagent

References

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