

priecloTM ...Coagulation Reagents

PROTHROMBIN TIME HS

(Liquid Stable) Reagent For Prothrombin Time Test

In vitro diagnostic test kit, for professional use only

INTENDED USE : Prothrombin Time is the one stage screening test for extrinsic clotting system.

ORDERING INFORMATION :	Pack Size	Cat No.
	1 X 5 ml	PT HS 01 05
	6 X 5 ml	PT HS 06 05

CLINICAL SIGNIFICANCE :

Deficiencies of Prothrombin and factors V, VII and X as well as hypofibrinogenemia will give rise to prolonged clotting time.

The common causes of prolonged Prothrombin Time are :

1. Therapy with coumarin or indanedione drugs.
2. Obstructive Jaundice.
3. Haemorrhagic disease of the new born.
4. Liver disease.
5. Heparin therapy.
6. Nephrotic syndromes.
7. Congenital deficiency of one or more factors II, V, VII or X.
8. Fibrinogen deficiency.
9. Malabsorption state (Vitamin K deficiency)

PRINCIPLE :

Tissue thromboplastin in the presence of Ca⁺⁺ activates extrinsic pathway of human blood coagulation mechanism. Activation time is proportional to the concentration of individual clotting factors taking part in the coagulation mechanism.

This assists in estimating cause and extent of haemorrhagic disorder.

When thromboplastin reagent is added to citrated anticoagulated plasma, clotting mechanism is initiated, forming gel clot. The time required for clot formation would be prolonged if there is deficiency of factors / factor activity in the extrinsic pathway of the coagulation cycle.

REAGENT COMPOSITION :

1. Rabbit Brain Thromboplastin
2. Ca⁺⁺
3. Antimicrobials
4. Stabilizers

REAGENT STORAGE :

Strictly at 2 to 8°C.

REAGENT STABILITY :

Till expiry date Stated on the vial label when stored at 2 to 8°C.

PRECAUTION :

Venous blood should be directly transferred into the tube containing the anticoagulant. The absence of micro clots should be checked. Separate plasma immediately by centrifugation after collection of blood. Plasma must be stored in siliconized glass tubes or plastic containers. Avoid turbid, lipemic or hemolyzed samples. Use clean, dry micropipette tips and glassware to dispense the reagent. Close reagent vial and transfer immediately at 2 to 8°C after dispensing.

WASTE MANAGEMENT :

To follow the procedure and comply with the rules and regulations of local authorities.

MATERIAL REQUIRED BUT NOT PROVIDED :

Centrifuge, Pipettes, Stop Clock / Timer or Coagulometer

SAMPLE COLLECTION & PREPARATION :

Mix gently, 9 parts of blood in a plastic tube or siliconized glass tube containing 1 part of 3.2 % trisodium citrate solution (0.109M). Centrifuge immediately for 15 min at 3000 RPM (2000 to 2500 G) to obtain platelet poor plasma. Transfer supernatant plasma in a silicon glass tube or plastic tube immediately, do not disturb buffy coat while collecting supernatant plasma. The test should be performed within a time limit not exceeding 2 hours after blood collection.

I) TEST PROCEDURE FOR PT :

The Prothrombin Time for each sample should be determined at least twice.

REAGENT PREPARATION FOR MANUAL AS WELL AS INSTRUMENT METHOD :

1. Bring contents of the vial to room temperature and gently swirl the vial before use. Do not shake.
2. Dispense from the vial enough PT Reagent for immediate use, in a thoroughly clean and dry test cuvette.
3. Prewarm the dispensed PT Reagent to 37°C for 10 min.

A) MANUAL METHOD :

1. Pipette 100 µl of patient or control plasma into a test cuvette and prewarm at 37°C for 2 minutes.
2. Add forcibly 200 µl pre-warmed PT Reagent into the test cuvette.
3. Start a timer simultaneously and record the clotting time in seconds.

CALCULATION :

As the International Sensitivity Index (ISI) as well as nature of preparation varies world wide, it is recommended to express results of the Prothrombin Time in terms of International Normalization Ratio (INR) and this can be derived from the accompanying INR Conversion Table or calculated as follows.

$$INR = R^{ISI}$$

$$R \text{ (Prothrombin Ratio)} = \frac{\text{Mean Prothrombin time of the patients plasma in sec}}{\text{Mean Normal Prothrombin Time in sec.}}$$

B) INSTRUMENT METHOD (for *easy CLOT & FOURCLOT*) :

1. For setting up the instrument, please refer to the instrument user manual.
2. Place the magnetic bead into cuvette as shown.
3. Pipette 50µl of plasma in cuvette.
4. Prewarm the plasma at 37°C for exactly 2 minutes. (Set the timer provided in instrument)
5. Select INR program in instrument. Follow the steps as prompted on display. * Note : While programing test parameters of INR mode please provide the input ISI and MNPT
6. After 2 minutes incubation place the cuvette in the measurement chamber of the instrument.
7. Instrument will sense the insertion of cuvette in the measurement chamber and the display will prompt "Dispense Reagent".
8. Dispense 100 µl of reagent.
9. Instrument will automatically sense the dispensed reagents and start the timer and mixing of reaction mixture. Instrument will display the time taken for the clot formation. It will also display the ratio & INR value.

PRECAUTION :

Reagent left over in the cuvette after the test procedure should not be put back into the reagent bottle. Doing so can lead to contamination.

EXPECTED VALUE :

Mean Normal Prothrombin Time (MNPT) 10 to 15 sec.

Reference value on optical system 11.5 to 14 seconds.

MNPT should be established in the users laboratory as this is equipment and procedure related.

CALIBRATION OF THE THROMBOPLASTIN REAGENT :

The sensitivity of the thromboplastin reagent to the depression of factors II, VII and X during oral anticoagulant treatment is qualified numerically as an International Sensitivity Index (ISI) according to the WHO international system of prothrombin time standardization.

Determination of ISI is achieved by calibration of the reagent against secondary international calibrator and also against the known INR calibrators using optical system.

ISI indicated on label is equipment, reagent lot specific (*easy clot* - optical equipment). Assigned ISI also Confirmed using AK calibrant plasma and results conform to the prescribed limits as per CLSI guidelines.

THERAPEUTIC RANGES :

Therapeutic ranges for INR may vary depending on the indication of oral anticoagulant therapy.

WARRANTY :

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIOGRAPHY :

1. J. V. Dacie and S.M. Lewis : Practical Hematology. 1984 R Biggs and R G McFarlane: Human blood coagulation and its disorders 1962
2. B. F. Rodak, Hematology, clinical principles and applications- II Edition.
3. John Bernard Henry: Clinical Diagnosis and Management by Laboratory Methods XX Edition.
4. Tomenson J A and Thomson J M Standardization of Prothrombin Time. Blood coagulation and Hemostasis : a practical guide, Edinburgh Churchill Livingstone : 1985 page 370-409.
5. Williams : Hematology VII edition.
6. WHO expert committee on biological standardization 1984. 34th report.
7. Data on file.

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easy CLOT & FOURCLOT are the Trade Marks of ROBONIK (INDIA) PVT. LTD., for Clot Time Analyser.



An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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INR Conversion Table

ISI								
→	1.00	1.05	1.10	1.15	1.20	1.25	1.29	
1.0	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
1.1	1.10	1.11	1.11	1.12	1.12	1.13	1.13	
1.2	1.20	1.21	1.22	1.23	1.24	1.26	1.27	
1.3	1.30	1.32	1.33	1.35	1.37	1.39	1.40	
1.4	1.40	1.42	1.45	1.47	1.50	1.52	1.54	
1.5	1.50	1.53	1.56	1.59	1.63	1.66	1.69	
1.6	1.60	1.64	1.68	1.72	1.76	1.80	1.83	
1.7	1.70	1.75	1.79	1.84	1.89	1.94	1.98	
1.8	1.80	1.85	1.91	1.97	2.02	2.08	2.13	
1.9	1.90	1.96	2.03	2.09	2.16	2.23	2.29	
2.0	2.00	2.07	2.14	2.22	2.30	2.38	2.45	
2.1	2.10	2.18	2.26	2.35	2.44	2.53	2.60	
2.2	2.20	2.29	2.38	2.48	2.58	2.68	2.77	
2.3	2.30	2.40	2.50	2.61	2.72	2.83	2.93	
2.4	2.40	2.51	2.62	2.74	2.86	2.99	3.09	
2.5	2.50	2.62	2.74	2.87	3.00	3.14	3.26	
2.6	2.60	2.73	2.86	3.00	3.15	3.30	3.43	
2.7	2.70	2.84	2.98	3.13	3.29	3.46	3.60	
2.8	2.80	2.95	3.10	3.27	3.44	3.62	3.77	
2.9	2.90	3.06	3.23	3.40	3.59	3.78	3.95	
3.0	3.00	3.17	3.35	3.54	3.74	3.95	4.13	
3.1	3.10	3.28	3.47	3.67	3.89	4.11	4.30	
3.2	3.20	3.39	3.59	3.81	4.04	4.28	4.48	
3.3	3.30	3.50	3.72	3.95	4.19	4.45	4.67	
3.4	3.40	3.61	3.84	4.09	4.34	4.62	4.85	
3.5	3.50	3.73	3.97	4.22	4.50	4.79	5.03	
3.6	3.60	3.84	4.09	4.36	4.65	4.96	5.22	
3.7	3.70	3.95	4.22	4.50	4.81	5.13	5.41	
3.8	3.80	4.06	4.34	4.64	4.96	5.31	5.60	
3.9	3.90	4.17	4.47	4.78	5.12	5.48	5.79	
4.0	4.00	4.29	4.59	4.92	5.28	5.66	5.98	
4.1	4.10	4.40	4.72	5.07	5.44	5.83	6.17	
4.2	4.20	4.51	4.85	5.21	5.60	6.01	6.37	
4.3	4.30	4.63	4.98	5.35	5.76	6.19	6.56	
4.4	4.40	4.74	5.10	5.50	5.92	6.37	6.76	
4.5	4.50	4.85	5.23	5.64	6.08	6.55	6.96	
4.6	4.60	4.96	5.36	5.78	6.24	6.74	7.16	
4.7	4.70	5.08	5.49	5.93	6.40	6.92	7.36	
4.8	4.80	5.19	5.62	6.07	6.57	7.10	7.56	
4.9	4.90	5.31	5.74	6.22	6.73	7.29	7.77	
5.0	5.00	5.42	5.87	6.37	6.90	7.48	7.97	
5.1	5.10	5.53	6.00	6.51	7.06	7.66	8.18	
5.2	5.20	5.65	6.13	6.66	7.23	7.85	8.39	
5.3	5.30	5.76	6.26	6.81	7.40	8.04	8.60	
5.4	5.40	5.88	6.39	6.95	7.57	8.23	8.81	
5.5	5.50	5.99	6.52	7.10	7.73	8.42	9.02	
5.6	5.60	6.10	6.65	7.25	7.90	8.61	9.23	
5.7	5.70	6.22	6.78	7.40	8.07	8.81	9.44	
5.8	5.80	6.33	6.91	7.55	8.24	9.00	9.66	
5.9	5.90	6.45	7.05	7.70	8.41	9.20	9.87	
6.0	6.00	6.56	7.18	7.85	8.59	9.39	10.09	

RATIO

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