PROTHROMBIN TIME – HIGH SENSITIVITY

TARGET ISI: 1.00 (Actual ISI value on vial)

CAT NO	DESCRIPTION	PACK SIZE
COAPTH1	PROTHROMBIN TIME – HIGH SENSTIVITY	5x5ml
COAPTH2	PROTHROMBIN TIME – HIGH SENSITIVITY	10x5ml
COAPTH3	PROTHROMBIN TIME – HIGH SENSITIVITY	10x10ml

Intended Use:

PT Reagent is an in vitro diagnostics assay for the determination of prothrombin time (PT) and assay for factors II, V, VII and X. This reagent is for In vitro diagnostic use by trained professionals only.

Summary and Principle:

The PT reagent is used as a screening tool and as a quantitative test for coagulation factors in the extrinsic pathway and common pathways. The reagent is used as an indicator for prognosis and monitoring of oral anticoagulant therapy. The Prestige Diagnostics PT reagent is a recombinant human tissue factor based reagent. Recombinant human tissue factor reagent and calcium ions when added to test plasma, initiates the clotting process. The time required to form the fibrin clot is measured. INR values are calculated based on the MNPT and the ISI value.

Reagent Composition:

PT REAGENT – HIGH SENSITIVITY	Recombinant Human Tissue Factor (<1 ug/ml)
	Calcium Chloride
	Buffer
	NaCl
	Preservatives

Materials required but not provided:

Control material, pipettes, Coagulation Analyser, plastic tubes

Reagent Preparation and Stability:

The PT Reagent is supplied ready to use. Shake the reagent gently before use.

Unopened reagents are stable up to expiry when stored at 2 - 8°C.

Once opened the reagents are stable for a period of 30 days when stored tightly capped and stored at 2 - 8°C.

Specimen Collection:

Mix nine parts of freshly collected patient blood with 1 part of 3.2% sodium citrate. Avoid haemolysis. Centrifuge anti-coagulated blood for 15 minutes at 3000 rpm. Test immediately.

If tests cannot be conducted immediately, store at 2 - 8°C and test within 3 hours. Clotting time prolongs with storage time.

Procedure:

Manual Method:

1. Remove the required volume of PT reagent from the vial and incubate for at least 10 minutes at 37°C.
2. To a test tube, 100 µl of test plasma and incubate at 37°C for 3 minutes.
3. Add 200 µl of the pre-incubated PT reagent rapidly and start the timer.
4. Record the clotting time.

For automated assays, refer to the instrument operator manual and follow instructions.

Calculations:

ISI VALUE: ***International Sensitivity Index.*** This value is provided on the reagent component label.

INR: ***International Normalized Ratio:*** The WHO introduced the concept of INR as a means of standardizing Prothrombin results. Prestige Diagnostics determines the ISI value on each batch prepared using the reference material rTF/95. This ISI value is a correction factor to correlate the sensitivity of the reagent to the First International Preparation (IRP) and is used to calculate the INR values. This ensures commutability of prothrombin values.

INR = (Patient PT / Mean Normal PT)^{ISI}

Or

INR = (Prothrombin Ratio)^{ISI}

Calculation of Mean Normal PT:

Mean Normal PT values are provided with the kit.

Contact Prestige Diagnostics technical department for more details on calculation of Mean Normal Prothrombin Time.

Clotting times are reported to the nearest 0.1 second. Values are also reported in %, Ratio or INR.

INR values are calculated using the formula:

INR = PTR^{ISI}

Performance Characteristics:

Sensitivity: 3 seconds with 99.7% confidence limit.

Linearity: 3 seconds to 255 seconds.

Interferences: Criterion: +/- 10% of initial value.

Lipaemia: No significant interference up to a level of 2000 mg/dl

Icteremia: No significant interference up to a bilirubin level of 40 mg/dl

Haemolysis: No significant interference up to a haemoglobin concentration of 500 mg/dl.

Intra Assay Precision

LEVEL	MEAN (SEC)	CV%
Plasma Control L1	12.6	1.2%
Plasma Control L 2	37.1	0.74%

Inter Assay Precision

LEVEL	MEAN (SEC)	CV%
Plasma Control L1	12.6	2.03%
Plasma Control L 2	37.1	2.42%

Reproducibility of the control plasma of CV </= 5%

Repeatability of the reagent: within 5%

Expected Values:

Expected Values: 10.7 – 14.3 seconds

Each laboratory must determine the reference ranges for their population.

Quality Controls:

We recommend the use of Prestige Diagnostics Quality controls with this kit.

QCCPCL1 – Plasma Control Level 1 – 5x1ml

QCCPCL2 – Plasma Control Level 2 – 5x1ml

Limitations:

Prothrombin time results are affected by the commonly administered drugs and further studies must be made to determine the source of unexpected abnormal results.

Ratio of anticoagulants to the patient blood, while collecting specimen, is a crucial factor in the determination of Prothrombin Time. Follow the recommended technique.

Warning and Precautions:

- All precautions necessary for laboratory reagents must be taken with this reagent.
- Contains preservatives. Do not swallow. Avoid contact with skin and mucous membranes.
- The result from this test should not be used as the sole criteria for the diagnosis of clotting disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated
- Disposal of all waste material should be in accordance with the local guidelines. MSDS available upon request.

References:

1. Biggs, Rosemary Ed., Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Ed, Blackwell Scientific Publications, London.
2. Young D.S.et al., Effect of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press Washington DC 1990.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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