PT HS Liquid ISI 0.99/1.0

Liquid Prothrombin Time Reagent. High Sensitivity.
Recombinant Human Tissue Factor (RTF)

CE

Code 01116IL **Packaging 10x5 ml.**

INTENDED USE

is used for the determination of the prothrombin time (PT) and assays for factors II, V, VII and X.I
FOR *IN-VITRO* DIAGNOSTIC USE ONLY

SUMMARY AND PRINCIPLE

The PT is used as a screening tool and as a quantitative test for coagulation factors in the extrinsic and common pathways. It is especially well suited for the induction and monitoring of oral anticoagulant therapy. The PT is also widely used for checking the synthesis performance of the liver in hepatic diseases. When a mixture of recombinant human tissue factor and calcium ions is added to test plasma, the clotting mechanism is initiated. The time to formation of a fibrin clot is then measured.

REAGENTS

Materials provided
PT Reagent
Pack for 10×4ml
Composition
PT Reagent: <1µg/ml recombinant human tissue factor, phospholipids, calcium chloride, buffers, salts and stabilizers.
Reagent Preparation
PT reagent is ready for use.
Storage and Stability
Store unopened vials at + 2 to + 8℃.
Stability after use: 1 month at + 2 to +8℃. **Do not freeze**.
Before use, mix by inverting.

SPECIMEN COLLECTION AND PREPARATION

Mix nine parts of freshly collected patient blood with one part of 0.11 or 0.13 mol/l (3.2 or 3.8%)sodium citrate. Avoid hemolysis and contamination by tissue fluids.
Samples that have less than 90%of the expected fill volume should be rejected. Centrifuge the blood specimen for a minimum of 10 minutes at 1000 rcf as soon as possible after collection. If immediate testing is to be done, the plasma may remain on the packed cells or separated. To separate the plasma, use a plastic transfer pipet, remove plasma to a plastic tube and keep refrigerated until ready to test. Do not store on ice. Patient plasma should be tested within two hours of blood collection. Samples should not stand at 37℃ for more than five minutes.

TEST PROCEDURE

Manual:

- Prewarm PT reagent to +37℃.
- Add 0.1ml test plasma to the test tube and prewarm at + 37℃ for 3 minute.
- Add 0.2ml prewarmed PT reagent to test plasma. Mix.
- Simultaneously with addition of PT reagent start stopwatch, and determine the coagulation time.

Automatic:

- Refer to the appropriate Instrument's Operator's Manual for the complete assay procedure instructions.

QUALITY CONTROL

Normal and abnormal plasmas should be tested in conjunction with patient plasmas. Controls should be also tested with each change of reagent, and at least once during an 8-horu shift. Each laboratory should establish its own QC ranges based on the assigned values and ranges provided by the control manufacturer or based on values determined by the laboratory.

RESULTS

Report clotting times for each plasma to the nearest 0.1 second. It also may be reported in % of the norm, in prothrombin ratio (PR) or in International Normalized Ratio (INR).

$$PR: \frac{\text{Reaction time of sample(s)}}{\text{Reaction time of normal plasma(s)}}$$

The ISI value for PT reagent is stated in the lot -dependent table of values.
The table of values should be checked in each laboratory using control plasma samples. If the results obtained are within the confidence interval, it is not necessary for the laboratory to establish its own reference curve. If the values are outside, the laboratory must establish its own reference curve.

LIMITATIONS

PT results may be affected by many commonly administered drugs and further studies should be made to determine the source of unexpected abnormal results.

EXPECTED VALUES

Normal Range: 70 - 120 % (10.7—14.3 (s))
Therapeutic Range: 20 - 35 %
These results were obtained using a specific lot of reagent. Due to many variables which affect clotting times, each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

The precision of the PT determination is highly dependent on the method used. Precision studies were performed on the CA500 System by assaying normal and pathological control plasmas. The within-run precision ranged from 0.5 to 5%, and the between-run precision ranged from 1.5 to 8%.

INTERNATIONAL SENSITIVITY INDEX(ISI)

The ISI values of this reagent are: 0.99/1.0

QC:
Control Plasma N ref. K29005301
Control Plasma P ref. K29005302

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