SPECTRUM

The Creative Approach to Bioscience

Recoplastin ISI 1.0 PT Reagent

REF: 624 000	1 x 8 ml	80 Test
REF: 624 001	6 x 4 ml	240 Test
REF: 624 002	6 x 5 ml	300 Test
REF: 624 003	6 x 8 ml	480 Test

Intended Use

Spectrum Recoplastin reagent is intended for Prothrombin time (PT) determination.

Background

Spectrum Diagnostics Recoplastin reagent as prothrombin time (PT) test, utilize this series of enzymatic events in vitro under controlled conditions to diagnose deficiencies in the blood coagulation systems of patients, and to monitor patients on anticoagulant therapy. In the PT test, a reagent which induces coagulation is added to a sample of the patient's plasma. All PT reagents contain tissue factor as a coagulation inducing ingredient. The time it takes for clot formation to occur in the plasma sample is the prothrombin time or PT value. Most commercially available PT reagents contain crude tissue factor extracted from natural sources, e.g., rabbit brain, rabbit brain/lung mixtures, human placenta or bovine brain. The crude extracts, because they are natural products, often lack lot to lot uniformity. For example, rabbit brain thromboplastins show seasonal variability. Another problem with natural extracts is the presence of contaminants. For example, human tissue factor may be a source of HIV or other human viral diseases and many natural-sourced thromboplastins also contain other extraneous coagulation factors which can detrimentally affect the PT value.
In an attempt to overcome some of these problems, recombinant tissue factors have been used to formulate Recoplastin PT reagents.

Assay Principle

The coagulation cascade is activated by incubating plasma with the optimal amount of Thromboplastin and calcium; the clotting time is then measured

Reagent

Recombinant tissue factor thromboplastin ISI 1.0 clear liquid ready to use calcium thromboplastin reagent.
Each batch of reagent undergoes vigorous quality control at various stages of manufacture for its sensitivity and performance.

Reagent Storage and Stability

Store the reagent at 2 – 8ºC (Do not freeze) .The reagent is stable up to the expiry date stated on vial label when stored at 2–8ºC.Once opened , the reagent is stable for 2 months at the specified temperature if contamination is avoided.

Warnings and Precautions

For in-vitro diagnostic use.

Materials required but not provided

- Normal Plasma Control
- Abnormal Plasma Control
- Human pooled normal Plasma PNP for determining the mean normal PT
- Sodium citrate solution(0.11 mol/L or 0.13 mol/L / 3.2 % or 3.8 %) for blood collection
- Plastic tubes
- Plastic transfer pipettes
- Pipettes for precise measurement
- Coagulation analyzer

Equipment

Reagent can be used manually and with automated or semi automated coagulation analyzers.
Please refer to the instruction manual of the instrument .

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

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 solution.Centrifuge the blood specimen at 1500 -3000 g for no less than 15 minutes at room temperature. Store in an unopened tube at room temperature. Do not store on ice or at +2 to +8 °C as cold activation of F VII may alter results. Plasma should be tested within 24 hours of blood collection. Samples should not stand at +37 °C for more than 5 minutes. If the patient is on both heparin and coumarin-based anti-coagulant therapy, the results may vary with time of storage.

Procedure

Reagent at +37 °C.

Pipet into coagulation tubes as follows:

	Test Sample	Control
Sample	50 ul	---
Control	---	50 ul

Incubate tubes and samples for 1 - 2 minutes at +37 °C

Add pre-warmed Recoplastin Reagent		
	100 ul	100 ul

Start stopwatch simultaneously with addition of spectrum Recoplastin reagent. Observe time of clot formation.

Internal Quality Control

Two levels of quality control material (normal plasma control,and Abnormal plasma control) must be measured at start of the test run, with each calibration, upon reagent vial changes and at least every eight hours on each day of testing.The control material should be processed in the same manner as the samples.

Results

Currently, various methods are used for reporting PT results. ISI (International Sensitivity Index) values for Spectrum .Reagent are provided for the particular reagent/instrument combination; these enable the results to be reported in INR (International Normalized Ratio). Computation and use of the INR are described below. The INR system is the preferred method for reporting results for oral anti-coagulated patient specimens. Alternatively, the patient's PT (in seconds) together with the reference range (in seconds) can be used to report results.
Example: patient result of 18 seconds; reference range 10.2 -13.5 seconds.

*Please refer to the table included in the kit for % and INR calculation.

Determination of INR (International Normalized Ratio)

According to the joint recommendations of the World Health Organization (WHO) and the International Committee on Thrombosis and Haemostasis, the PT results for patients on oral anticoagulants should be reported as INR values. Reported INR results are independent of the reagents and methods used, and are specifically intended for assessing patients stabilized on long-term oral anticoagulant therapy.
The INR is determined according to the following equation:
INR = (R) ^{ISI}
where R = Patient PT / Mean normal PT in seconds

ISI is the International Sensitivity Index of the reagent/instrument combination.The ISI values for Recoplastin reagents are determined in accordance with WHO recommendations.

Limitations of the Procedure

It is the responsibility of the user to validate modifications to these instructions or use of the reagents on different analyzers Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Interfering Substances

Many commonly administered drugs may affect the results obtained in prothrombin time testing. This should be kept in mind especially when unusual or unexpected abnormal results are obtained. Unexpected abnormal results should be followed by additional coagulation studies to determine the source of the abnormality.
Spectrum Recoplastin Reagent is insensitive to concentrations of un-fractionated heparin up to approximately 2.0 units per mL. The heparin sensitivity study was conducted using spiked normal pooled plasma and the sensitivity to heparin was defined by the concentration of heparin in the specimen that prolonged the PT results exceeding the upper limit of the reference range.
Inhibitors such as lupus anticoagulant may interfere with the prothrombin time and result for example in INRs that do not reflect the exact degree of anticoagulation. Hirudin or other direct thrombin inhibitors in therapeutic dose result in prolonged prothrombin times

Expected Values

Values for healthy individuals vary from laboratory to laboratory depending on the technique used. Therefore, each laboratory should establish its own reference intervals based on the procedure and coagulation analyzers used.
90 % of normal individuals reveal PT Value of 10.2 - 13.5 sec. using Recoplastin reagent

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

Specific Performance Characteristics

Precision
Precision of prothrombin time results is generally limited by the method used. Therefore, within a single lot, the reagent should yield results which are reproducible within the quality control of the laboratory.
All the performance characteristics are found in the corresponding Technical Report and available on request

References

1. Spicer EK, Horton R, Bloem L, et al. Isolation of cDNA clones coding for human tissue factor: Primary structure of the protein and cDNA. Proc Natl Acad Sci USA. 1987; 84:5148-52.
2. Quick AJ. Hemorrhagic diseases and thrombosis. Philadelphia: Lea and Febiger; 1966.
3. Bader R, Mannucci PM, Tripodi A, et al. Multicentric evaluation of a new PT reagent based on recombinant human tissue factor and synthetic phospholipids. Thromb Haemost. 1994;71:292-9.
4. Poller L. The Prothrombin Time. WHO/LAB/98.3. 1998.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
REF: 624 000	80 Test
REF: 624 001	240 Test
REF: 624 002	300 Test
REF: 624 003	480 Test

Egyptian Co for Biotechnology - Spectrum Diagnostics (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

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