SPECTRUM

The Creative Approach to Bioscience

Lyoplastin ISI 1.0
PT Reagent

REF: 623 000 40 Test
REF: 623 001 400 Test
REF: 623 002 100 Test

Intended Use

Spectrum Diagnostics Lyoplastin reagent is intended for prothrombin time (PT) determination on manual or automated systems.

Background

Spectrum Diagnostics Lyoplastin reagent has three major applications based upon the PT
1. As a rapid screening test to detect single or combined deficiencie of the extrinsic coagulation system indicative of hereditary and acquired coagulation disorders, liver disease or vitamin K deficiency.
2. As a sensitive monitoring test for oral anticoagulant therapy.
3. As an assay for specific coagulation factors.
Additionally, various photo-optical coagulation analyzers are able to derive the fibrinogen value from the determination of the prothrombin time.
Spectrum Diagnostics Lyoplastin reagent is highly sensitive to factor deficiencies and oral anticoagulant-treated patient plasma samples. The sensitivity of Spectrum Diagnostics Lyoplastin reagent is very similar to the WHO human brain reference thromboplastin. Spectrum Diagnostics Lyoplastin reagent is insensitive to therapeutic levels of heparin. The high sensitivity of spectrum. Reagent to coagulation factors and its insensitivity to therapeutic heparin make it beneficial in monitoring oral anticoagulant therapy. In addition, its high sensitivity (i.e. the responsiveness of the reagent to moderately depleted factor activity) allows differentiation of abnormal plasmas, even in the mildly pathological range.

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

Lyophilized Rabbit Brain Thromboplastin.

Reagent Preparation

Reconstitute the vial with diluent supplied with the kit as mentioned on vial label;Mix powder and diluent gently and wait 30 minutes.

Stability

After reconstitution the stability of reconstitute is :
10 days at 2 – 8 ^{O}C
5 days at 20 – 25 ^{O}C
1 day at 37 ^{O}C

Warnings and Precautions

For in-vitro diagnostic use.

Materials required but not provided

- Normal Plasma Control
- Abnormal Plasma Control
- Standard Human Plasma or fresh normal plasma 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
- De-ionized water without preservatives
- Plastic tubes
- Plastic transfer pipettes
- Pipettes for precise measurement of 20.0 uL, 10.0 uL,1.0 mL, 0.50 mL, 0.20 mL and 0.10 mL
- Coagulation analyzer

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 of PPP

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. An evacuated tube system or syringe may be used.
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 anticoagulant therapy, the results may vary with time of storage.

Procedure

Reagent at +37 °C.

Pipet into coagulation tubes as follows:

	Test Sample	Control
Plasma	50 µl	---
Control	---	50 µl

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

Add pre-warmed lyoplastin Reagent

	100 µl	100 µl

Start stopwatch simultaneously with addition of spectrum lyoplastin 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 enables 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 9.7 - 12.3 seconds.

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 anticoagu-lant 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 lyoplastin 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 Lyoplastin Reagent is insensitive to concentrations of unfractionated 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 % reference interval in a study around : 10.4 to 12.8 seconds

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

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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: 623 000	40 Test
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