

HemosIL[®]

Complete PT Testing Solutions

HemosIL™
RecombiPlasTin 2G
 0020002950

5 x 8 mL RecombiPlasTin 2G (RTF)
 5 x 8 mL RecombiPlasTin 2G Diluent (RTF Diluent)

For the determination of Prothrombin Time and Fibrinogen.
 Composition: Recombinant human tissue factor, synthetic phospholipids, calcium ions and 0.17% of sodium azide.
 For In Vitro Diagnostic Use. 体外診断用医薬品

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 Made in USA

Prothrombin Time

Sensitivities for
Oral Anticoagulant Therapy
and Extrinsic Factors
to Meet Your Lab's Requirements



Complete PT Testing Solutions

Background

Prothrombin Time (PT) is the screening test for the extrinsic coagulation pathway. The assay is based on the activation of the coagulation cascade by the addition of thromboplastin to citrated plasma at optimized calcium concentrations. PT is sensitive to the vitamin K-dependent clotting factors (Factor II, VII and X) and to Factor V. It is performed for pre-surgical screening, to detect congenital or acquired factors deficiencies, for oral anticoagulant therapy monitoring or to assess liver disease.^{1,2}

Since its first application in 1935 by Quick using rabbit brain extract, different sources of thromboplastin have been developed. Thromboplastin, a combination of the apoprotein Tissue Factor (TF) and phospholipids, has now been fully characterized and production processes have been standardized to allow consistency and reproducibility of PT results.

IL brings the most advanced technology for standardized PT testing, by either human or rabbit recombinant Tissue Factor (TF), together with the classic rabbit-brain-extract-based reagents.

Standardization

Oral anticoagulants, such as warfarin, are used to prevent unwanted blood clotting by inhibiting the formation of vitamin K, necessary for the liver to form Factor II, VII, and X. They are used to maintain the coagulative status of patients within a defined therapeutic range; PT testing is necessary to monitor the coagulative status of patients and eventually define therapeutic dosage adjustments.

The sensitivity of the PT test toward vitamin K-dependent clotting factors depends upon the source and type of TF, and varies according to the coagulation instrument and to the calibrator used.

In 1976, the World Health Organization (WHO) set up the first International Reference Preparation (IRP) of thromboplastin and defined the International Sensitivity Index (ISI) to establish a standardized protocol for the expression of the PT sensitivity.³ The ISI of the first IRP was assigned a value of 1.0 by definition. From that preparation, rabbit, bovine and human IRP thromboplastins were developed to allow proper ISI value assignment. The ISI value demonstrates the responsiveness of the thromboplastin to the effects of oral anticoagulants. The lower the ISI of a thromboplastin, the more sensitive or responsive the preparation.

PT test results can be expressed in different ways: seconds, % activity or International Normalized Ratio (INR). With oral anticoagulant therapy, the use of the INR is recommended.

International Normalized Ratio (INR)

INR is a widely accepted expression of the PT results which compares the results obtained with different thromboplastins, instruments and methods.

$$INR = \left(\frac{\text{Patient PT in second}}{\text{Mean Normal PT in seconds}} \right)^{ISI}$$

At a known ISI, the INR value of a sample is dependent upon the ratio of the sample clotting time, and the mean clotting time of a number of normal patients samples.⁴

IL adopted the standardization protocol by assigning the ISI value on each type of IL coagulation system for each batch of thromboplastin using the corresponding International Reference Preparation as reference.





RecombiPlasTin 2G Human Recombinant Tissue Factor

The Solutions for Standardization

- Two advanced technologies: recombinant protein engineering for Tissue Factor and synthetic phospholipids providing lot-to-lot consistency
- Instrument-based ISI approximately 1.0 calibrated to the WHO standard for accurate INR results
- Highly purified recombinant tissue factor assures reagent uniformity, purity and increased product stability

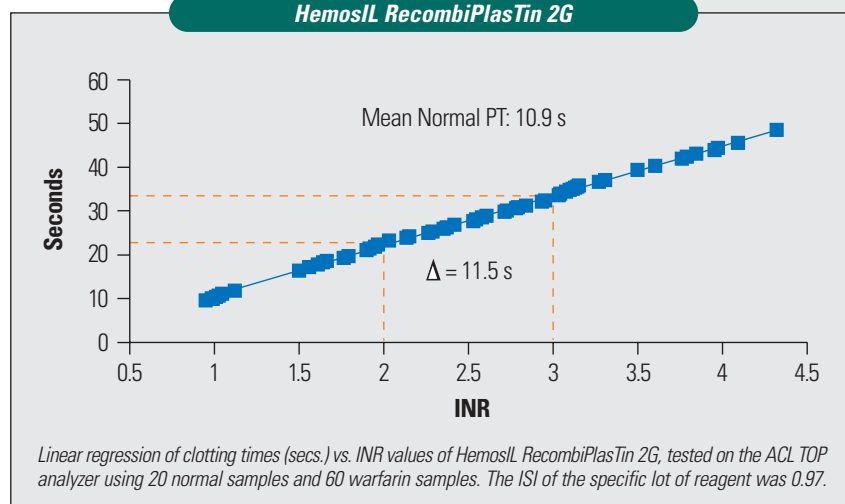
The Solutions for Better Patient Care

- Superior sensitivity to extrinsic coagulation factors (Factor II, V, X), and especially Factor VII, due to improved characteristics of recombinant tissue factor
- Ideal for monitoring oral anticoagulant therapy due to its high sensitivity, comparable to the International Reference Preparation
- Significantly improved performance characteristics that advance clinical laboratory PT testing, and improve disease state management

The Solutions for Value

- Lot-to-lot consistency of recombinant source material simplifies conversion to new lot
- Excellent stability minimizes reagent waste
- PT-based Fibrinogen

HemosIL RecombiPlasTin 2G



Complete PT Testing Solutions

HemosIL Family of PT Reagents

PT Reagent	RecombiPlasTin 2G	PT Fibrinogen HS Plus	PT Fibrinogen HS	PT Fibrinogen
Part Number and Size	0020002950 5 + 5 x 8 mL 0020003050 5 + 5 x 20 mL	0008469810 5 + 5 x 8 mL	0008468210 10 x 8 mL	0009756710 10 x 8 mL
ISI Range	1.0	1.2	1.4	2.0
Tissue Factor	Human Recombinant	Rabbit Brain Thromboplastin extract	Rabbit Brain Thromboplastin extract	Rabbit Brain Thromboplastin extract
Phospholipids	Synthetic			
Reconstituted Stability at 2-8°C	10 days	5 days	3 days	5 days
Heparin Insensitivity	Up to 1.0 IU/mL	Up to 0.5 IU/mL	Up to 0.5 IU/mL	Up to 1.0 IU/mL
Factor VII Sensitivity	+++	++	++	+
PT-based Fibrinogen	✓	✓	✓	✓

Instrument Applications

	RecombiPlasTin 2G	PT Fibrinogen HS Plus	PT Fibrinogen HS	PT Fibrinogen
ACL TOP®	✓	✓	✓	✓
ACL™ Advance	✓	✓	✓	✓
ACL ELITE®/ELITE PRO - ACL 8/9/10000	✓	✓	✓	✓
ACL 100-7000	✓	✓	✓	✓

References

1. "Guide to Anticoagulant Therapy Part 2: Oral Anticoagulant Tables," American Heart Association Medical/Scientific Statement, <http://www.americanheart.org/Scientific/statements/1994/039402tl-6.html>.
2. Hassett, Andrea Cortese, Ph.D. "Laboratory Monitoring of Anticoagulant Therapy," Transfusion Medicine Update, February, 1999.
3. Opartkiatiku, Nasarat, "Standardization of Coagulation Tests," Southeast Asian Journal Trop Med Public Health, 1999; Vol.30, Supplement 3, p.79-85.
4. Ts'ao, C. and Neofotistos, Demetra, "The Use and Limitations of the INR System," American Journal of Hematology, 47:12-26, (1994).

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