PT-Fibrinogen HS PLUS - 0008469810

ENGLISH - Insert revision 12/2004

CE

Intended use

A very high sensitivity calcium thromboplastin for simultaneous determinations of Prothrombin Time (PT) and Fibrinogen (Fib), for evaluation of the extrinsic coagulation pathway and monitoring Oral Anticoagulant Therapy in human citrated plasma on the IL Coagulation Systems.

Principle

The PT-FIB HS PLUS is a lyophilized rabbit brain extract with an optimal concentration of calcium ions. This product is manufactured with high sensitivity to Factor II, V, VII and X, comparable to International Reference Preparations, making it particularly suitable for monitoring OAT.[1]

Composition

The **PT-Fibrinogen HS PLUS** kit consists of:

T **Thromboplastin** (Cat. No. 0008469820): 5 x 8.5 mL vials of rabbit brain thromboplastin with stabilizers, polybrene and buffer.

B **Buffer** (Cat. No. 0008469822): 5 x 8.5 mL vials of buffer with $CaCl_2$ and preservative.

PRECAUTIONS AND WARNINGS:
Avoid contact with skin and eyes (S 24/25). Do not empty into drains (S 29).
Wear suitable protective clothing (S 36).
The Buffer contains sodium azide that may form explosive azides in metal plumbing. Use proper disposal procedures.
Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot.

This product is For *in vitro* Diagnostic Use.

Preparation

Dissolve the contents of each vial of thromboplastin by pouring the entire contents of one vial of buffer into the reagent vial. Replace the stopper and swirl gently. **DO NOT try to pipette the exact volume required for reconstitution of Thromboplastin reagent.** Make sure of the complete reconstitution of the product. Keep the reagent at 15-25°C for 30 minutes (ACL® Family) and overnight at 2-8°C (ACL Futura®/ACL Advance) and invert to mix before use. Do not shake.

Reagent storage and stability

Unopened reagent is stable until the expiration date shown on the vial, when stored at 2-8°C.
Stability after reconstitution: 5 days at 2-8°C in the original vial, 12 hours at 15°C on the IL Coagulation Systems under continuous stirring. For optimal stability remove reagent from the system and store it at 2-8°C in the original vial.

Instrument/test procedures

Refer to the appropriate IL instrument's Operator's Manual and/or Application Manual for the complete assay procedure instructions.

Specimen collection and preparation

Nine parts of freshly drawn venous blood are collected into one part trisodium citrate. Refer to NCCLS Document H21-A4 for further instructions on specimen collection, handling and storage.[2]

Additional reagents and control plasmas

The following are not supplied with the kit and must be purchased separately.

	Americas and Pacific Rim Cat. No.	Europe Cat. No.
Calibration plasma	0020000000	0008467300
Normal Control	0020003120	0020003110
Low Abnormal Control	0020003220	0020003210
High Abnormal Control	0020003320	0020003310
Low Fibrinogen Control	0020004200	0020004200
Sample diluent	0009756800	0009756800
Factor diluent	0009757600	0009757600
Cleaning solution	0009831700	0009831700

Quality control

Normal and Abnormal controls are recommended for a complete quality control program.[3,4] Normal Control, Low Abnormal Control, High Abnormal Control and Low Fibrinogen Control are designed for this program. Each laboratory should establish its own mean and standard deviation and should establish a quality control program to monitor laboratory testing. Controls should be analyzed at least once every 8 hour shift in accordance with good laboratory practice. Refer to the instrument's Operator's Manual for additional information. Refer to Westgard *et al* for identification and resolution of out-of-control situations.[5]

Results

Patient results may be reported in the following units:

PT: seconds, % activity, Ratio, INR
Fibrinogen: mg/dL, g/L

Refer to the instrument's Operator's Manual for additional information.

Limitations/interfering substances

PT results may be affected by many commonly administered drugs and further studies should be made to determine the source of unexpected abnormal results. Fibrinogen assay results (PT-based method) may be affected by degradation products (fibrin or fibrinogen) in the plasma assayed.[6]
No interference on the IL Coagulation Systems up to:

	Heparin	Hemoglobin	Triglycerides	Bilirubin
PT	0.5 U/mL	100 mg/dL	700 mg/dL	15 mg/dL
FIB	1.0 U/mL	100 mg/dL	700 mg/dL	15 mg/dL

Expected values

A normal range study was performed using PT-Fibrinogen HS PLUS reagent.

Assay	System	N	Range (units)
PT	ACL® Family	35	11.8 - 15.1 (seconds)
PT	ACL Futura®/ACL Advance	36	11.5 - 14.6 (seconds)
Fibrinogen	ACL Family	36	169 - 515 (mg/dL)
Fibrinogen	ACL Futura/ACL Advance	36	140 - 533 (mg/dL)

These results were obtained using a specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should establish its own reference range.

Performance characteristics

Precision:
Within run and total (run to run and day to day) precision were assessed over multiple runs using both normal and abnormal samples.

ACL Family	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal Control	12.9	0.93	0.93
Low Abnormal Control	25.0	1.68	1.92
High Abnormal Control	33.9	1.80	1.92

ACL Futura/ ACL Advance	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal Control	12.6	0.71	0.95
Low Abnormal Control	24.7	3.12	4.13
High Abnormal Control	34.5	4.09	7.19

ACL Family	Mean (Fibrinogen mg/dL)	CV % (Within run)	CV % (Total)
Normal Control	282	4.86	5.89
Low Fibrinogen Control	87	4.6	8.0

ACL Futura/ ACL Advance	Mean (Fibrinogen mg/dL)	CV % (Within run)	CV % (Total)
Normal Control	273	2.10	4.30
Low Fibrinogen Control	101	7.06	7.81

Correlation:

Assay	system	slope	intercept	r	Reference method
PT	ACL Family	0.934	1.63	0.998	PT on ACL
PT	ACL Futura/ACL Advance	1.12	-1.81	0.995	PT HS PLUS on ACL
Fib	ACL Family	0.934	40.8	0.983	Fib (PT based) on ACL
Fib	ACL Futura/ACL Advance	1.11	-19.4	0.950	Fib (PT HS PLUS based) on ACL

These precision and correlation results were obtained using specific lots of reagents and controls.

Fibrinogen Linearity:

System	
ACL Futura/ACL Advance	80 - 700 mg/dL
ACL Family	75 - 1000 mg/dL

Due to many variables which may affect results, each laboratory should establish its own Linearity Range.

Thromboplastin certification

Variable PT results may occur when samples are tested with thromboplastins of various sources and/or using different techniques (manual, semi/fully automated).[7,8] The ICSH (International Committee for Standardization in Haematology) and the ICTH (International Committee on Thrombosis and Haemostasis) have proposed the ISI (International Sensitivity Index) as a standardization to calculate INR (International Normalized Ratio) and give comparable PT results for OAT patients.[9]
Each batch of PT-FIB HS PLUS is calibrated against a House Standard with an ISI certified against the correspondent international reference standard (CRM 149S) according to the WHO recommendations.[10]
ISI values in the insert sheet are measured using IL Coagulation Systems.
Results in INR are automatically given when the ISI value is entered in the IL Coagulation Systems.
The INR is calculated as follows:

$$INR = (\text{Patient's PT/Mean of PT normal range})^{ISI}$$

The ISI values of this lot are reported in the last section of this insert sheet.

Therapeutic range

For OAT indications[11] and duration of treatment make reference to local guidelines.

Bibliography / Literatur / Bibliografía / Bibliographie / Bibliografia /Bibliografia / Litteratur / Litteraturförteckning / Βιβλιογραφία

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Symbols used / Verwendete Symbole / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Anvendte symboler / Använda Symboler / Χρησιμοποιηθέντα σύμβολα

VALUE Value / Wert / Valor / Valeur / Valore / Valor / Værdi / Värde / Τιμή

IVD
In vitro diagnostic medical device
In-vitro Diagnostikum
De uso diagnóstico *in vitro*
Dispositif mèdical de diagnostic *in vitro*
Per uso diagnostico *in vitro*
Dispositivo médico para utilização em diagnóstico *in vitro*
"in vitro" diagnostisk udstyr
In vitro diagnostisk medicinsk produkt
Προϊόν για διαγνωστική χρήση *In vitro*

LOT
Batch code
Chargen-Bezeichnung
Identificación número de lote
Désignation du lot
Numero del lotto
Número de lote
Batch nr.
Tillverkningskod
Αρ. Παρτίδας

Use by
Verwendbar bis
Caducidad
Utilisable jusqu'à
Da utilizzare prima del
Data límite de utilização
Anvendelse
Användning
Χρήση έως

Temperature limitation
Festgelegte Temperatur
Temperatura de Almacenamiento
Températures limites de conservation
Limiti di temperatura
Límite de temperatura
Temperatur begrænsninger
Temperatur gräns
Περιορισμοί θερμοκρασίας

Consult instructions for use
Beilage beachten
Consultar la metódica
Lire le mode d'emploi
Vedere istruzioni per l'uso
Consultar as instruções de utilização
Se vejledning for anvendelse
Ta del av instruktionen före användning
Συμβουλευτήτε τις οδηγίες χρήσης

CONTROL
Control
Kontrollen
Control
Contrôle
Controllo
Controlo
Kontrol
Kontroll
Υλικό ποιοτικού ελέγχου

Biological risks
Biologisches Risiko
Riesgo biológico
Risque biologique
Rischio biologico
Risco biológico
Miljø oplysninger
Biologiska risker
Βιολογικοί κίνδυνοι

Manufacturer
Hergestellt von
Fabricado por
Fabricant
Prodotto da
Fabricado por
Producent
Tillverkare
Κατασκευαστής

EC REP
Authorised representative
Bevollmächtigter
Representante autorizado
Mandataire
Rappresentanza autorizzata
Representante autorizado
Leverandør
Auktoriserad representant
Εξουσιοδοτημένος αντιπρόσωπος