Plasminogen - 0020009000

ENGLISH - Insert revision 07/2003

CE

Intended use

Automated chromogenic assay for the quantitative determination of Plasminogen in human citrated plasma on IL Coagulation Systems.

Summary and principle

Plasminogen (Plg) in a plasma sample is activated through reaction with an excess of Streptokinase (Sk) in the presence of fibrinogen. The Plasminogen-Streptokinase complex is determined by the rate of hydrolysis of a chromogenic substrate. Dysplasminogenemia is associated with venous thrombosis.[1,2] Acquired deficiencies of Plasminogen are associated with thrombolytic therapy, sepsis and Disseminated Intravascular Coagulation.[3,4,5]

The Plasminogen kit is based on a synthetic chromogenic substrate. Plasminogen levels in patient plasma are measured automatically on IL Coagulation Systems in two stages:

1. Incubation of the plasma with Streptokinase reagent in the presence of fibrinogen.
2. Quantification of the Plasminogen-Streptokinase complexes with a synthetic chromogenic substrate. The paranitroaniline released is monitored kinetically at 405 nm and is directly proportional to the Plasminogen level in the test sample.

Composition

The **Plasminogen** kit consists of:

S **Chromogenic substrate** (Cat. No. 0020009010)**:** 2 x 2 mL vials of the lyophilized chromogenic substrate S-2403, pyroGlu-Phe-Lys-pNA·HCl (4.2 mg/vial) and bulking agent.

E **Streptokinase reagent** (Cat. No. 0020009020)**:** 2 x 2.5 mL vials of a lyophilized preparation containing Streptokinase (20,000 U/vial), fibrinogen, buffer and human serum albumin.

PRECAUTIONS AND WARNINGS:

The material in this product was tested with FDA cleared methods and found nonreactive for Hepatitis B surface Antigen (HBsAg), Anti-HCV and HIV antibodies. Handle as if potentially infectious.[6]

Avoid contact with skin and eyes (S 24/25). Do not empty into drains (S 29). Wear suitable protective clothing (S 36).

This product is For *in vitro* Diagnostic Use.

Preparation

Chromogenic substrate: Dissolve the contents of each vial with 2 mL of NCCLS Type II water or equivalent.[7] Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the substrate at 15-25°C for 30 minutes and mix gently before use.

Streptokinase reagent: Dissolve the contents of each vial with 2.5 mL of NCCLS Type II water or equivalent.[7] Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the reagent at 15-25°C for 30 minutes and mix gently before use.

Reagent storage and stability

Unopened reagents are stable until the expiration date shown on the vial when stored at 2-8°C.

Chromogenic Substrate - Stability after reconstitution: 7 days at 15°C, 3 months at 2-8°C, 6 months at -20°C in the original vial or 5 days at 15°C on the ACL Futura®/ACL Advance Systems.

Streptokinase reagent - Stability after reconstitution: 7 days at 15°C, 3 months at 2-8°C, 6 months at -20°C in the original vial or 5 days at 15°C on the ACL Futura/ACL Advance Systems.

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial.

Instrument/test procedures

Refer to the approriate 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-A3 for further instructions on specimen collection, handling and storage.[8]

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
Abnormal chromogenic control plasma Level 1/2	0008467600	0008467600
Factor Diluent	0009757600	0009757600

Quality control

Normal and abnormal controls are recommended for a complete quality control program.[9] Normal Control and Abnormal chromogenic control plasma Level 1/2 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.[10] Refer to Westgard *et al* for identification and resolution of out-of-control situations.

Results

Plasminogen results are reported in % activity. Refer to the instrument's Operator's Manual for additional information.

Limitations/interfering substances

Plasminogen results on IL Coagulation Systems are not affected by elevated levels of fibrinogen, heparin (UF or LMW heparin) up to 2 U/mL, hemoglobin up to 200 mg/dL, bilirubin up to 20 mg/dL, FDP's up to 30 mg/dL and triglycerides up to 1000 mg/dL.

Expected values

A normal range study was performed using Plasminogen kit.

System	N	Range (units)
ACL® Family	48	72.9 - 126.9 (% activity)
ACL Futura/ACL Advance	59	81.4 - 140.9 (% activity)

Ranges were calculated as recommended by the International Federation of Clinical Chemistry (IFCC).[11] These results were obtained using a specific lot of reagent. Due to many variables which may affect results, each laboratory should establish its own normal range.

Performance characteristics

Precision:

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

ACL Family	Mean (% activity)	CV % (Within run)	CV % (Total)
Normal Control	86.6	2.0	3.8
Abnormal Control	50.1	4.4	4.4

ACL Futura/ ACL Advance	Mean (% activity)	CV % (Within run)	CV % (Total)
Normal Control	82.7	3.0	3.0
Abnormal Control	52.5	1.8	1.9

Correlation:

System	slope	intercept	r	Reference method
ACL Family	1.218	-6.064	0.983	Chromogenic Plasminogen
ACL Futura/ ACL Advance	1.119	-2.818	0.989	Chromogenic Plasminogen

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

Linearity:

System	
ACL Family and ACL Futura/ACL Advance	10 - 150 (% activity)

Tests on the IL Coagulation Systems

Plasminogen60 tests (approx.)

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

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*

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
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

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