Plasmin Inhibitor - 002009200

**Intended use**
Automated chromogenic assay for the quantitative determination of Plasmin Inhibitor in human citrated plasma on IL Coagulation Systems.

**Summary and principle**
Plasmin Inhibitor, the major fast acting inhibitor of the fibrinolytic system, also known as Alpha -Antiplasmin, is an important regulator of the fibrinolytic system. Congenital deficiencies are associated with hemorrhagic problems. Decreased levels of Plasmin Inhibitor are observed in liver diseases and DIC. Increased levels have been reported during postoperative episodes.

The Plasmin Inhibitor kit is an assay based on synthetic chromogenic substrate and on plasmin inactivation.

**Composition**
The Plasmin Inhibitor kit consists of:

- **Buffer** (Cat. No. 0020009230): 2 x 9 mL vials of a concentrated buffer solution containing sodium chloride, methylamine and surfactant.
- **Plasmin reagent** (Cat. No. 0020009220): 2 x 2.5 mL vials of a lyophilized preparation containing human plasmin (2.5 kKat/vial), buffer, human serum albumin, stabilizers and bulking agent.
- **Chromogenic substrate** (Cat. No. 0020009210): 1 x 4 mL vial of the lyophilized chromogenic substrate S-2403, pyroGlu-Phe-Lys-pNA HCl (9 mg/vial) and bulking agent.

**Precautions and warnings:**
The material in this product was tested with FDA cleared methods and found nonreactive for Hepatitis B surfactant Antigen (HBsAg), Anti-HCV and HIV antibodies. Handle as if potentially infectious.

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 Diagnostische Use.

**Preparation**
- **Buffer**: Dilute the necessary quantity of the concentrated buffer 1:10 (1+9) with NCCLS Type II water or equivalent. Mix before use.
- **Plasmin reagent**: Dissolve the contents of each vial with 2.5 mL of Diluted Buffer. 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.
- **Chromogenic substrate**: Dissolve the vial contents with 4 mL of NCCLS Type II water or equivalent. Replace the stopper and swirl gently. Make sure of the complete reconstitution of product. Keep the substrate at 15-25°C for 30 minutes and mix gently before use.

**Reagent storage and stability**
Unopened reagents are stable until the expiration date printed on the vial when stored at 2-8°C.

- **Buffer**: Opened reagent should be kept at 2-8°C in the original vial.
- **Diluted Buffer**: Stability after dilution: 24 hours at 15°C.

- **Plasmin reagent**: Stability after reconstitution: 5 days at 15°C and 2-8°C, 3 months at -20°C in the original vial, 5 days at 15°C on the ACL 9000/ACL 10000 or 24 hours at 15°C on the ACL Futura /ACL Advance Systems.
- **Chromogenic substrate**: Stability after reconstitution: 5 days at 15°C and 2-8°C, 3 months at -20°C in the original vial, 5 days at 15-25°C on the ACL 9000/ACL 10000 or 24 hours 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 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-A3 for further instructions on specimen collection, handling and storage.

**Additional reagents and control plasmas**
The following are not supplied with the kit and must be purchased separately.

- **Americas and Pacific Rim**:
  - **Calibration plasma**: 0020000000
  - **Normal Control**: 00200003120
  - **Abnormal control**: 00200003110

- **Europe**:
  - **Calibration plasma**: 0008467300
  - **Normal Control**: 0008467300
  - **Abnormal control**: 0008467600

**Quality control**
Normal and abnormal controls are recommended for a complete quality control program. The paranitroaniline released is monitored kinetically at 405 nm and 2. Quantification of the residual plasmin activity with a synthetic chromogenic substrate.

Plasmin Inhibitor results on IL Coagulation Systems are not affected by heparin (UF heparin or LMW heparin) up to 2 U/mL, -manglobulin up to 7 mg/dL, hemoglobin up to 200 mg/dL, bilirubin up to 20 mg/dL and triglycerides up to 1000 mg/dL.

**Limitations/interfering substances**
Plasmin Inhibitor results on IL Coagulation Systems are not affected by heparin (UF heparin or LMW heparin) up to 2 U/mL, -manglobulin up to 7 mg/dL, hemoglobin up to 200 mg/dL, bilirubin up to 20 mg/dL and triglycerides up to 1000 mg/dL.

**Expected values**
A normal range study was performed using Plasmin Inhibitor kit.

- **System N**
  - **Range (units)**
    - **ACL Family**: 50
    - **ACL Futura/ACL Advance**: 60

Ranges were calculated as recommended by the International Federation of Clinical Chemistry (IFCC). 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**: 102
  - **Normal Control**: 102
  - **Abnormal Control**: 102
  - **CV % (Within run)**: 2.0
  - **CV % (Total)**: 2.5
  - **ACL Futura/ACL Advance**: 46.6
  - **Normal Control**: 46.6
  - **Abnormal Control**: 46.6
  - **CV % (Within run)**: 2.7
  - **CV % (Total)**: 3.9

- **Correlation**:
  - **System**: 1.038 0.944 0.987
  - **Comparative method**: 2.427 0.996

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

**Linearity**

- **System**: 1.0 -120 (% activity)

**Tests on the IL Coagulation Systems**
Plasmin Inhibitor: 60 tests (approx.)
Bibliography / Literatur / Bibliografia / Bibliographie / Bibliografia / Litteratur / Litteraturföreckning / Bibliografía


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

IVD
In vitro diagnostic medical device
En vitro Diagnostikum
Dispositif médical de diagnostic in vitro
Per uso diagnosticco para utilização em diagnóstico in vitro
"in vitro" diagnostic test
In vitro diagnostik medicinsk produkt
Προϊόν για διαγνωστική χρήση
In vitro

LOT
Batch code
Chargen-Bezeichnung
Identificació número de lote
Désignation du lot
Número de lote
Batch nr.
Tilvækningskod
Αρ. Παρτίδας

Use by
Verwendbar bis
Caducidad
Utilisable jusqu'à
Da utilizzare prima del
Data limite di utilizzazione
Användning
Användning
Χρήση έως

Temperature limitation
Festgelegte Temperatur
Temperatura de Almacenamiento
Températures limites de conservation
Limiti di temperatura
Temperatur begrænsning
Temperatur gränser

Consult instructions for use
Beilage beachten
Consultar la metodica
Vedere istruzioni per l'uso
Consulter les instructions de utilisation
Se vejledning for anvendelse
Ta del av instruktionen før anvendning
Συμβουλευτείτε τις οδηγίες χρήσης

CONTROL
Control
Kontrollen
Control
Controllo
Control
Kontrol
Kontroll

Biological risks
Biologisches Risiko
Riesgo biológico
Risque biologique
Rischio biologico
Risco biológico
Biologiska risker

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

Auktoriserad representant

Authorised representative
Bevollmächtigter
Representante autorizado
Mandatari
Rappresentanza autorizzata
Representante autorizado
Leverandør

Εξουσιοδοτημένος αντιπρόσωπος

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