**Plasminogen - 0020009000**

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

**Summary and principle**
Plasminogen (Pg) 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 Acquired deficiencies of Plasminogen are associated with thrombotic therapy, sepsis and Disseminated Intravascular Coagulation.

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. Quantitation 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 2463, pyrGlu-Phe-Lys-pNaphCl (4.2 mg/vial) and bulking agent.
- **E** Streptokinase reagent (Cat. No. 0020009020): 2 x 5 mL vials of a lyophilized preparation containing Streptokinase (20,000 U/vial), fibrinogen, 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. 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. 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.

- Avoid contact with skin and eyes (S 24/25). Do not empty into drains (S 27). 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. 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. 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 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.

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

**Limits/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.

**Performance characteristics**
Precision:

<table>
<thead>
<tr>
<th>System</th>
<th>N</th>
<th>Range (units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL Family</td>
<td>48</td>
<td>72.9 - 126.9</td>
</tr>
<tr>
<td>ACL Futura/ACL Advance</td>
<td>59</td>
<td>81.4 - 140.9</td>
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</tbody>
</table>

Ranges were calculated as recommended by the International Federation of Clinical Chemistry (IFCC),1 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.

**Tests on the IL Coagulation Systems**
Plasminogen 60 tests (approx.)
HemosIL™

Bibliography / Literatur / Bibliografia / Bibliographie / Bibliografia / Litteratur / Litteraturföreningen / Bibliografía


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Issued July 2003

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

[ ] IVD
In vitro diagnostic medical device
De uso diagnóstico in vitro
Dispositif médical de diagnostic in vitro
Per uso diagnostico in vitro
“in vitro” diagnóstico udstyr
In vitro diagnostik medicinsk produkt
Προϊόν για διαγνωστική χρήση

[ ] LOT
Batch code
Chargen-Bezeichnung
Identificación número de lote
Númerodelotto
Batch nr.
Tilvækkskod
Αρ. Παρτίδας

[ ] CONTROL
Consult instructions for use
Beilage beachten
Consultar la metodica
Lire le mode d'emploi
Vedere istruzioni per l’uso
Se vejledning for anvendelse
Ta del av instruktionen för användning

[ ] Biological risks
Biologisches Risiko
Riesgo biológico
Risque biologique
Rischio biologico
Risco biológico
Медицинский риск
Biologisk risker

[ ] Manufacturer
Hergestellt von
Fabricado por
Fabricant
Fabbricato da
Fabricado por
Producent
Tillverkare

[ ] EC REP
Authorised representative
Bevollmächtigter
Representante autorizado
Mandataire
Rappresentanza autorizzata
Representante autorizado
Leverandør
Auktoriserad representant

Εξουσιοδοτημένος αντιπρόσωπος

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301796 R4 07/2003