

**Normal Control ASSAYED - 0020003110****Intended use**

For the Quality Control of coagulation assays in the normal range.

**Summary and principle**

The Normal Control is prepared using human citrated plasma from healthy donors. It is intended for the assessment of precision and accuracy of tests performed on IL Coagulation Systems: PT, APTT, TT, Fibrinogen, Single Factors, von Willebrand Factor, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, Pro-IL-Complex\* and Hepatocomplex\*.

It is intended for the assessment of precision and accuracy of tests performed on the ELECTRA™ Systems: PT, APTT, Clauss Fibrinogen, Single Factors, Antithrombin, Plasminogen and Protein C.

Values for all analytes are within the normal range.

\*NOTE: Not available in all countries.

**Composition**

The **Normal Control** kit consists of:

**N** **Normal Control** (Cat. No. 0020003100): 10 x 1 mL vials of lyophilized human plasma containing buffer, stabilizers and preservatives.

**PRECAUTIONS AND WARNINGS:**

The material in this product was tested by FDA approved test methods and found nonreactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV antibodies. Handle as if potentially infectious.<sup>1</sup>

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**

Dissolve the contents of each vial with 1 mL of NCCLS Type II water or equivalent.<sup>2</sup> Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the control at 15-25°C for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation.

**Reagent storage and stability**

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

Stability after reconstitution:

- at 2-8°C in the original vial for PT, Fibrinogen, APTT, TT, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Protein S: 24 hours
- at 2-8°C in the original vial for the remaining parameters (Factors, Pro-IL-Complex\* and Hepatocomplex\*): 8 hours
- at 15-25°C in the original vial for PT, Fibrinogen, APTT, TT, Antithrombin, Plasminogen, Plasmin Inhibitor and Protein C: 24 hours
- at 15-25°C in the original vial for Factors and Protein S: 4 hours
- at 15-25°C on-board the ACL® 8000/9000/10000 for PT, Fibrinogen and APTT: 24 hours
- at 15-25°C on-board the ACL Futura®/ACL Advance for PT, Fibrinogen and APTT: 24 hours
- at 18°C on-board the ELECTRA instruments for PT and APTT: 24 hours

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

**Instrument/test procedures**

After reconstitution the Normal Control should be handled in the same manner as fresh citrated plasma.

**Traceability of calibrators and control materials**

The reported values were determined over multiple runs on IL Coagulation and ELECTRA Systems using a specific lot of reagent and against a Calibration Plasma House Standard which is traceable to the current International Standards, identified in the acceptance range table.

For the tests where International Standards are not available, these parameters (i.e. Plasminogen, Plasmin Inhibitor, Factors V, XI and XII, Pro-IL-Complex\* and Hepatocomplex\*) have been assigned against a House Standard which is traceable to a frozen normal plasma pool of 100 donors.

**Limitations**

This product is designed as a normal control for monitoring coagulation assays. The control is subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

**Expected values**

The reported ranges were determined over multiple runs on IL Coagulation and ELECTRA Systems using specific lots of reagents. The mean of the control range determined in your laboratory may vary due to the lot of reagent used.

**Performance characteristics****Precision:**

Within run precision was assessed over multiple runs using specific lots of reagents and control. The coefficient of variation obtained in this study was below 3% for PT, below 5% for APTT, Thrombin Time, Clauss Fibrinogen, PT-based Fibrinogen, Antithrombin, Protein C, Plasminogen, Plasmin Inhibitor, von Willebrand Factor and Protein S and below 10% for single Factors, ProClot, Pro-IL-Complex\* and Hepatocomplex\*.






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

- Richmond JY, McKinney RW eds. Biosafety in Microbiological and Biomedical Laboratories, U.S. Dept. of Health and Human Services, Public Health Service, 4<sup>th</sup> Edition, 1999.
  - National Committee for Clinical Laboratory Standards. Preparation and Testing of Reagent Water in the Clinical Laboratory, Third Edition, NCCLS Document C3-A3; Vol. 17 No. 18.
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**Symbols used / Verwendete Symbole / Simbolos utilizados / Symboles utilisés / Simboli impiegati / Simbolos utilizados / Anvendte symboler / Använda Symboler /**

**Χρησιμοποιηθέντα σύμβολα**

<b>TARGET VALUE</b>	Target Value / Referenzwert-Zielwert / Valor de referencia / Valeur cible / Valore di riferimento / Valor-Alvo / Reference værdi / Åsatt värde / Τιμή Στόχου
<b>ACCEPTANCE RANGE</b>	Acceptance range / Referenzbereich / Rango esperado / Valeur usuelles / Intervallo di accettabilità / Intervalo de aceitação / Accept område / Acceptorat område / Αποδεκτό εύρος
<b>WHO STD</b>	WHO Standard Code / WHO Standard Code / Código del Estándar OMS / Code standard OMS / Codice OMS / Código Padrão WHO / WHO standard kode / WHO Standard Norm / Κωδικός προτύπου WHO
<b>PRODUCT NAME</b>	IL Product name / IL Produktname / Nombre del kit IL / Nom du kit IL / Kit IL / Designação do kit IL / IL Produkt navn / IL Produkt namn / Ονομασία προϊόντος IL
<b>UNITS</b>	Measurement units / Messeinheiten / Unidades de medida / Unités de mesure / Unità di misura / Unidades de Medida / Måle enhed / Matenheter / Μονάδες μέτρησης

<p><b>IVD</b></p> <p><i>In vitro</i> diagnostic medical device  <i>In-vitro</i> Diagnostikum                  De uso diagnóstico <i>in vitro</i>                  Dispositif médical de diagnostic <i>in vitro</i>                  Per uso diagnostico <i>in vitro</i>                  Dispositivo médico para utilização em diagnóstico <i>in vitro</i>                  "in vitro" diagnostisk udstyr  <i>In vitro</i> diagnostisk medicinsk produkt                  Προϊόν για διαγνωστική χρήση <i>In vitro</i></p>	<p><b>LOT</b></p> <p>Batch code                  Chargen-Bezeichnung                  Identificación número de lote                  Désignation du lot                  Numero del lotto                  Número de lote                  Batch nr.                  Tillverkningskod                  Αρ. Παρτίδας</p>	<p></p> <p>Use by                  Verwendbar bis                  Caducidad                  Utilisable jusqu'à                  Da utilizzare prima del                  Data limite de utilização                  Anvendelse                  Användning                  Χρήση έως</p>	<p></p> <p>Temperature limitation                  Festgelegte Temperatur                  Temperatura de Almacenamiento                  Temperaturas limites de conservation                  Limiti di temperatura                  Limite de temperatura                  Temperatur begrænsninger                  Temperatur gräns                  Περιορισμοί θερμοκρασίας</p>	<p></p> <p>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</p>	<p><b>CONTROL</b></p> <p>Control                  Kontrollen                  Control                  Contrôle                  Controllo                  Controllo                  Kontrol                  Kontroll                  Υλικό ποιοτικού ελέγχου</p>	<p></p> <p>Biological risks                  Biologisches Risiko                  Riesgo biológico                  Risque biologique                  Rischio biologico                  Risco biológico                  Miljø oplysninger                  Biologiska risker                  Βιολογικοί κίνδυνοι</p>	<p></p> <p>Manufacturer                  Hergestellt von                  Fabricado por                  Fabricant                  Prodotto da                  Fabricado por                  Producent                  Tillverkare                  Κατασκευαστής</p>	<p><b>EC REP</b></p> <p>Authorised representative                  Bevollmächtigter                  Representante autorizado                  Mandataire                  Rappresentanza autorizzata                  Representante autorizado                  Leverandør                  Auktoriserad representant                  Εξουσιοδοτημένος αντιπρόσωπος</p>
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