

Intended use

For the calibration of coagulation assays on IL and ELECTRA™ Coagulation Systems.

Summary and principle

The Calibration plasma is prepared using citrated plasma plasmapheresed from healthy donors by means of a dedicated process to maintain the characteristics of a Normal plasma pool. It is designed for the calibration of IL and ELECTRA Coagulation Systems in the determination of PT, Fibrinogen, Single Factors, von Willebrand Factor, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, Pro-IL-Complex*, Hepatocomplex* and as reference plasma for APTT and TT.

*NOTE: Not available in all countries.

Composition

The **Calibration plasma** kit consists of:

- C** **Calibration plasma** (Cat. No. 0020003710): 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.¹ 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.² Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the Calibration plasma at 15-25°C for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation.

Reagent storage and stability

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

Stability after reconstitution:

- 24 hours at 2-8°C in the original vial for PT, Fibrinogen, APTT, TT, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Protein S.
- 8 hours at 2-8°C in the original vial for Factors, Pro-IL-Complex* and Hepatocomplex*.
- 24 hours at -20°C in the original vial for PT and APTT. Do not refreeze.

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

Instrument/test procedures

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

Refer to the instrument's Operator's Manual and/or Application Manual for the complete assay procedure instructions according to the specific tests required.

Traceability of calibrators and control materials

The reported reference values were determined over multiple runs on IL and ELECTRA Coagulation Systems using specific lots of IL reagents and against a Calibration Plasma House Standard which is traceable to the current International Standards (Fibrinogen, Antithrombin, Protein C, Protein S, Factors II, X, VII, VIII, IX and von Willebrand Factor), identified in the reference values 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.

The Calibration plasma values for the coagulation screening tests (PT, APTT and TT) were determined over multiple runs on IL and ELECTRA Coagulation Systems using specific lots of IL House Standard reagents. The reference values determined in your laboratory may vary slightly due to the different lot of reagent used.

Calibration plasma, when used as a calibrator on IL and ELECTRA Coagulation Systems according to IL recommendations, demonstrates commutability with patient samples.

Limitations

This product is designed for the calibration of coagulation assays. The Calibration plasma is subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

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






1. Richmond JY, McKinney RW eds. Biosafety in Microbiological and Biomedical Laboratories, U.S. Dept. of Health and Human Services, Public Health Service, 4th Edition, 1999.
2. 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 / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Anvendte symboler / Använda Symboler / Χρησιμοποιηθέντα σύμβολα

<p>IVD</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</p> <p>Προϊόν για διαγνωστική χρήση <i>In vitro</i></p>	<p>LOT</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 Températures 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 Συμβουλευτείτε τις οδηγίες χρήσης</p>	<p>CONTROL</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>EC REP</p> <p>Authorised representative Bevollmächtigter Representante autorizado Mandataire Rappresentanza autorizzata Representante autorizado Leverandør Auktoriserad representant Εξουσιοδοτημένος αντιπρόσωπος</p>
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