



COAGULATION CAL

**Calibrator / Calibrador**  
Coagulation / Coagulación**Quantitative determination of coagulation factors IVD**

Store at 2 - 8°C.

**PRODUCT CHARACTERISTICS**

The calibrator is lyophilised human plasma, containing PT, APTT and Fibrinogen that allows expressing the analytical results in different units as concentration (mg/dL), percentage (%) or activity rate, by manual method.

**REAGENTS**

Calibrator. Human plasma. Sodium azide 0.95 g/L.  
Coagulation factors concentration is indicated below.

**PRECAUTIONS**

Components from human origin have been tested and found negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.

**CALIBRATION**

Reference values have been calculated from a pool of normal plasma.

**PREPARATION**

Reconstitute (→) with 1.0 mL of distilled water. Mix thoroughly, avoiding foam forming. Bring to room temperature for about 30 minutes before use.

**STORAGE AND STABILITY**

The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

After reconstitution, stable for 4 hours at room temperature (15-25°C) or 24 hours at -20°C, if frozen immediately.

**PROCEDURE**

To be used in manual assays.

COMPONENT / COMPONENTE	METHOD / MÉTODO	VALUE VALOR
PT (Prothrombin Time / Tiempo de Protombina)	According to Instructions Sheet of corresponding Spinreact reagent/ Según Hoja de Instrucciones del reactivo Spinreact correspondiente	12.0 s.
APTT (Activated Partial Thromboplastin Test / Tiempo de Tromboplastina Parcial Activada)		29.6 s.
Fibrinogen / Fibrinógeno		200 mg/dL

This Control value sheet is applicable to sublots (sequential alphabetical letter (e.g. A, B, C etc.) following the lot number)

Esta hoja de valores es aplicable al lote y sublotes (letras alfabéticas secuenciales (p.ej. A, B, C etc.) que siguen al nº de lote).



1709101

Cont.

4 x 1 mL



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PT (Prothrombin Time / Temps de prothrombine)	Schnitger&Gross	13,7 s.
APTT (Activated Partial Thromboplastin Test / Temps de Thromboplastine Partielle Activée)	Schnitger - Ellagic acid / Acide ellagique	28,6 s.
Fibrinogen / Fibrinogène	Schnitger&Gross - Fib-Clauss	239 mg/dl

This Control value sheet is applicable to sublots (sequential alphabetical letter (e.g. A, B, C etc.) following the lot number)



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APTT (Activated Partial Thromboplastin Test / Tempo de Tromboplastina Parcial Ativada)		29.1 s.
Fibrinogen / Fibrinogénio		221 mg/dl

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Cont. 4 x 1 mL

LOT

**Determinação quantitativa de fatores de coagulação IVD**

Conservar a 2 - 8°C

**CARACTERÍSTICAS DO PRODUTO**

O calibrador é um plasma humano liofilizado que contém PT, APTT e Fibrinogénio, que permite expressar o resultado analítico em diferentes unidades como concentração (mg/dl), percentagem (%) ou taxa de atividade, em métodos manuais.

**REAGENTES**

Calibrador. Plasma humano. Azida sódica 0,95 g/L.  
A sua concentração está indicada na tabela em anexo.

**PRECAUÇÕES**

Todos os componentes de origem humana foram testados e tiveram resultados negativos para o antígeno HBs, HCV e para o anti-VIH (1/2). Contudo, devem manusear-se com cuidado, como potencialmente infecciosos.

**CALIBRAÇÃO**

Os valores de referência foram calculados utilizando como calibrador um "pool" de plasmas normais.

**PREPARAÇÃO**

Reconstituir (→) com 1,0 mL de água destilada. Dissolver agitando suavemente. Evitar a formação de espuma. Deixar repousar à temperatura ambiente durante cerca de 30 minutos antes de utilizar.

**CONSERVAÇÃO E ESTABILIDADE**

O calibrador é estável até ao prazo de validade indicado na embalagem quando se mantém o vial bem fechado a 2-8 °C, e se evitam contaminações durante a sua utilização. Não utilizar reagentes que tenham ultrapassado o prazo de validade.

Após a reconstituição do vial, é estável durante 4 horas a 15-25 °C ou 24 horas a -20 °C, se congelado imediatamente.

**PROCEDIMENTO**

Utiliza-se em ensaios manuais.

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