



CE

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)

REF 1709101

Cont. 4 x 1 mL

LOT



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).



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COMPONENT / COMPOSANT	METHOD / MÉTHODE	VALUE VALEUR
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

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Détermination quantitative de facteurs de coagulation

IVD

Conserver à 2 - 8 °C

CARACTÉRISTIQUES DU PRODUIT

Le calibrateur est un plasma humain lyophilisé contenant du PT, de l'APTT et du fibrinogène, qui permet d'exprimer les résultats analytiques dans différentes unités, telles que la concentration (mg/dL), le pourcentage (%) ou le taux d'activité, par des méthodes manuelles.

RÉACTIFS

Calibrateur. Plasma humain. Azoture de sodium 0,95 g/L.
Leur concentration est indiquée dans le tableau annexe.

PRÉCAUTIONS

Tous les composants d'origine humaine ont donné des résultats négatifs à l'antigène HBs, HCV et à l'anti-VIH (1/2).

Ils doivent, néanmoins, être traités avec précaution comme potentiellement infectieux.

ÉTALONNAGE

Les valeurs de référence ont été calculées en utilisant comme calibrateur un « pool » de plasmas normaux.

PRÉPARATION

Reconstituer (→) avec 1,0 ml d'eau distillée. Dissoudre en agitant doucement. Éviter la formation de mousse. Laisser reposer à température ambiante 30 minutes avant de l'utiliser.

CONSERVATION ET STABILITÉ

Le calibrateur est stable jusqu'à la date d'expiration indiquée sur l'emballage, si le flacon est maintenu bien fermé à 2-8 °C et s'il n'est pas contaminé durant son utilisation. Ne pas utiliser de réactifs après leur date d'expiration.

Après la reconstitution du flacon, il est stable pendant 4 heures à 15-25 °C ou 24 heures à -20 °C, s'il est immédiatement congelé.

PROCÉDURE

Il est utilisé lors d'essais manuels.

Cette fiche de valeurs est applicable au lot et sous-lot (lettres alphabétiques séquentielles (par ex. A, B, C etc.) suivant le n° de lot).

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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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