

**Quantitative determination of Plasma Proteins**
**IVD**

Store at 2-8°C.

**PRODUCT CHARACTERISTICS**

The PROT CONTROL is a liquid serum from human origin containing protein concentrations suitable to evaluate the accuracy and precision of plasma protein determinations by immunoturbidimetry method.

**REAGENTS**

PROT-CONTROL	Control. Human serum. Sodium azide 0.95 g/L. Protein concentrations are stated on the list below.
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**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**

The concentration values of the Control are traceable to Standard Reference Material ERM-DA470k/IFCC (all constituents except antithrombin III).

**STORAGE AND STABILITY**

The control 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.

Opened vials, stable for 30 days at 2-8°C.

**PROCEDURE**

To be used in immunoturbidimetric assays.

**PACKAGING**

 Ref: 1102004 Cont. 4 x 1 mL

**Determinación cuantitativa de Proteínas Plasmáticas**
**IVD**

Conservar a 2 - 8°C

**CARACTERISTICAS DEL PRODUCTO**

El PROT CONTROL es un suero líquido de origen humano que contiene concentraciones de proteínas adecuadas para la evaluación de la exactitud y precisión de proteínas plasmáticas mediante métodos inmunoturbidimétricos.

**REACTIVOS**

PROT-CONTROL	Control. Suero humano. Azida sódica 0,95 g/L. La concentración de los componentes viene indicada en la parte inferior de la hoja.
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**PRECAUCIONES**

Todos los componentes de origen humano han resultado ser negativos para el antígeno HBs, HCV y para el anti-HIV (1/2). Sin embargo, deben tratarse con precaución como potencialmente infecciosos.

**CALIBRACION**

Los valores de concentración del control son trazables al Standard Reference Material ERM-DA470k/IFCC (todos los constituyentes excepto la antitrombina III).

**CONSERVACION Y ESTABILIDAD**

El control es estable hasta la fecha de caducidad indicada en el envase cuando se mantiene el vial bien cerrado a 2-8°C, y se evita la contaminación durante su uso. No utilizar reactivos que hayan sobrepasado la fecha de caducidad.

Una vez abierto, el vial es estable 30 días a 2-8°C.

**PROCEDIMIENTO**

Se utiliza en ensayos inmunoturbidimétricos.

**PRESENTACION**

 Ref: 1102004 Cont. 4 x 1 mL

PROTEINS / PROTEINAS	METHOD / MÉTODO	CONCENTRATION / CONCENTRACIÓN (mg/dL)	RANGE / RANGO
$\alpha_1$ -antitrypsin / $\alpha_1$ -antitripsina	Immunoturbidimetry / Inmunoturbidimetría		
$\alpha_1$ -ac. glycoprotein / $\alpha_1$ -glicoproteína ac.			
Antithrombin III / Antitrombina III			
C3			
C4			
Ceruloplasmin / Ceruloplasmina			
Haptoglobin / Haptoglobina			
IgA			
IgG			
IgM			
Prealbumin / Prealbúmina			
Transferrin / Transferrina			

LOT


This Control data sheet for lot is applicable to sublots. Sequential alphabetical letter (e.g. A, B, C etc.) following the lot number. This product was manufactured, packaged and tested in accordance to SPINREACT, S.A./S.A.U. Quality System and meets all product specifications. Our Quality System has been approved by an accredited registering body to ISO 9001.

*Este Boletín de análisis es aplicable al lote y sublotes. Letras alfabéticas secuenciales (p.e. A, B, C etc.) que siguen al nº de lote. Este producto ha sido fabricado, acondicionado y controlado de acuerdo al Sistema de Calidad implantado en SPINREACT, S.A./S.A.U., cumpliendo todas sus especificaciones.*

*Nuestro Sistema de Calidad ha sido aprobado por una entidad certificadora de acuerdo a la norma ISO 9001.*

**Quantitative determination of Plasma Proteins**

**IVD**  
Store at 2-8°C.

**PRODUCT CHARACTERISTICS**

The PROT CONTROL is a liquid serum from human origin containing protein concentrations suitable to evaluate the accuracy and precision of plasma protein determinations by immunoturbidimetry method.

**REAGENTS**

PROT-CONTROL	Control. Human serum. Sodium azide 0.95 g/L. Protein concentrations are stated on the list below.
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**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**

The concentration values of the Control are traceable to Standard Reference Material ERM-DA470k/IFCC (all constituents except antithrombin III).

**STORAGE AND STABILITY**

The control 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.

Opened vials, stable for 30 days at 2-8°C.

**PROCEDURE**

To be used in immunoturbidimetric assays.

**PACKAGING**

Ref: 1102004 

Cont.
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 4 x 1 mL

**Détermination quantitative des protéines plasmatiques**

**IVD**  
Conserver à 2 - 8 °C

**CARACTÉRISTIQUES DU PRODUIT**

Le PROT CONTROL est un sérum liquide d'origine humaine qui contient des concentrations de protéines adaptées pour évaluer l'exactitude et la précision des protéines plasmatiques par des méthodes immunoturbidimétriques.

**RÉACTIFS**

PROT - CONTROL	Contrôle Sérum humain. Acide sodique 0,95 g/L. La concentration des composants est indiquées dans la partie inférieure de la feuille.
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**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 concentration du contrôle sont traçables au Standard Reference Material ERM-DA470k/IFCC (tous les constituants sauf l'antitrombine III).

**CONSERVATION ET STABILITÉ**

Le sérum de contrôle est stable jusqu'à la date d'expiration indiquée sur l'emballage, si le flacon est maintenu bien fermé à 2-8 °C et en évitant sa contamination lors de son utilisation. Ne pas utiliser de réactifs après leur date d'expiration.

Une fois ouvert, le flacon est stable 30 jours à 2-8°C.

**PROCÉDURE**

Utilisé dans des essais immunoturbidimétriques.

**PRÉSENTATION**

Réf : 1102004 

Cont.
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 4 x 1 mL

PROTEINS / PROTÉINES	METHOD / MÉTHODE	CONCENTRATION / CONCENTRATION (mg/dL)	RANGE / PLAGE
$\alpha_1$ -antitrypsin / $\alpha_1$ -antitrypsine	Immunoturbidimetry / Immunoturbidimétrie		
$\alpha_1$ -ac. glycoprotein / $\alpha_1$ -glycoprotéine ac.			
Antithrombin III / Antithrombine III			
C3			
C4			
Ceruloplasmin / Céruloplasmine			
Haptoglobin / Haptoglobine			
IgA			
IgG			
IgM			
Prealbumin / Préalbumine			
Transferrin / Transferrine			

**LOT**



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*Ce bulletin d'analyse peut s'appliquer au lot et aux sous-lots. Lettres alphabétiques séquentielles (p. ex. A, B, C etc.) que suivent le n° de lot. Ce produit a été fabriqué, conditionné et contrôlé conformément au Système de qualité mis en œuvre chez SPINREACT, S.A./S.A.U., en respectant toutes ses spécifications. Notre système de qualité a été approuvé par un organisme de certification conformément à la norme ISO 9001.*



## Controlo Geral de Proteínas/ General Protein Control

Immunoturbidimetry / Imunoturbidimetria

### Quantitative determination of Plasma Proteins

#### IVD

Store at 2-8°C.

#### PRODUCT CHARACTERISTICS

The PROT CONTROL is a liquid serum from human origin containing protein concentrations suitable to evaluate the accuracy and precision of plasma protein determinations by immunoturbidimetry method.

#### REAGENTS

PROT-CONTROL	Control. Human serum. Sodium azide 0.95 g/L. Concentrations of the constituents are stated on the list below.
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#### 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

The concentration values of the Control are traceable to Standard Reference Material ERM-DA470k/IFCC (all constituents except antithrombin III).

#### STORAGE AND STABILITY

The control 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.

Opened vials, stable for 30 days at 2-8°C.

#### PROCEDURE

To be used in immunoturbidimetric assays.

#### PACKAGING

Ref: 1102004 Cont. 4 x 1 mL

### Determinação quantitativa de Proteínas Plasmáticas

#### IVD

Armazenar a 2-8 °C.

#### CARACTERÍSTICAS DO PRODUTO

O PROT CONTROL é um soro líquido de origem humana que contém concentrações de proteínas adequadas para a avaliação do exactitude e da precisão da proteína plasmáticas através de métodos imunoturbidimétricos.

#### REAGENTES

PROT-CONTROL	Controlo. Soro humano. Azida de sódio 0,95 g/L. A concentração dos componentes vem indicada na lista da parte inferior da folha.
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#### PRECAUÇÕES

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

#### CALIBRAÇÃO

Os valores de concentração do controlo são rastreáveis no Standard Reference Material ERM-DA470k/IFCC (todos os constituintes excepto a antitrombina III).

#### CONSERVAÇÃO E ESTABILIDADE

O controlo é estável até à data de validade indicada 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.

Uma vez aberto, o vial é estável durante 30 dias a 2-8 °C.

#### PROCEDIMENTO

Utiliza-se em ensaios imunoturbidimétricos.

#### APRESENTAÇÃO

Ref: 1102004 Cont. 4 x 1 mL

PROTEINS / PROTEÍNAS	METHOD / MÉTODO	CONCENTRATION / CONCENTRAÇÃO (mg/dL)	RANGE / RANGO
$\alpha_1$ -antitrypsin / $\alpha_1$ -antitripsina	Immunoturbidimetry / Imunoturbidimetria		
$\alpha_1$ -ac. glycoprotein / $\alpha_1$ -glicoproteína ácida			
Antithrombin III / Antitrombina III			
C3			
C4			
Ceruloplasmin / Ceruloplasmina			
Haptoglobin / Haptoglobina			
IgA			
IgG			
IgM			
Prealbumin / Pré-albumina			
Transferrin / Transferrina			

LOT



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*Esta folha de análise é aplicável ao lote e sub-lotes. Letras alfabéticas sequenciais (por ex. A, B, C etc.) que sucedem ao nº de lote. Este produto foi fabricado, acondicionado e controlado de acordo com o Sistema de Qualidade implementado na SPINREACT, S.A./S.A.U., cumprindo todas as suas especificações.*

*O nosso Sistema de Qualidade foi aprovado por uma entidade certificadora em conformidade com a norma ISO 9001.*