



SPINCHEM

SPINCHEM 1 / SPINCHEM 2
Human Control serum
Suero Control humano**Serum control multicomponent for clinical chemistry assays IVD**

Store at 2 - 8°C.

PRODUCT CHARACTERISTICS

SPINCHEM 1 or SPINCHEM 2 is a human lyophilised serum. With most constituent concentrations and activities in the normal (Spinchem 1) or pathologic (Spinchem 2) range. It's intended for control of accuracy for use with manual and automated analytical procedures.

REAGENTS

Human serum. Enzymes (human, bovine and porcine). Nonprotein constituents and bacteriostatic agents. The concentration / activities of the components are lot-specific. The exact values and ranges valid for reagents are given informational purpose in the value sheet.

PRECAUTIONS

Contains human sourced material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Consider all blood derivatives potentially infectious. Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical device. Wear suitable gloves and eye/face protection. In case of an accident, seek medical device immediately and show this container or label.

PREPARATION

-Using a Class A volumetric pipette, carefully add the exact amount of distilled or deionized water as specified on the vial label to the control material.
-Swirl the vial gently and allow to stand at room temperature for 5 to 10 minutes.
-Swirl contents until homogeneous. DO NOT VORTEX. Remove the sample required for testing.
Improper handling and/or storage of the control can affect results. Inaccurate reconstitution of the control and errors in assay technique can cause erroneous results.

STORAGE AND STABILITY

The Control serum 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 or if there is visible evidence of microbial growth. Store tightly capped when not use.

- After reconstitution is stable for:
At 2°C to 8°C 10 days
- Direct Bilirubin (stored protected from light):
At 2°C to 8°C 5 days
- Alkaline phosphatase may increase in activity with time.

BIBLIOGRAPHY

1. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.
2. International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: *A Protocol for the Conversion of Clinical Laboratory data*, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226

PACKAGING

SPINCHEM 1 Ref: 1002015 4 x 5 mL
SPINCHEM 2 Ref: 1002025 4 x 5 mL

Suero control multiparamétrico para ensayos de Bioquímica clínica IVD

Conservar a 2 - 8°C

CARACTERÍSTICAS DEL PRODUCTO

SPINCHEM 1 o SPINCHEM 2 es un suero humano liofilizado. Con concentraciones y actividad en el intervalo normal (Spinchem 1) o patológico (Spinchem 2). Sirve para controlar la exactitud o la precisión de las técnicas tanto manuales como automatizadas.

REACTIVOS

Suero humano. Enzimas (humanas, bovinas y porcinas). Constituyentes no proteicos y agentes bacteriostáticos. La concentración / actividades de los componentes son específicas del lote. Los valores de cada parámetro están incluidos en la Hoja de Valores de cada lote.

PRECAUCIONES

Contiene material de origen humano. Ningún método de prueba conocido puede ofrecer una completa garantía de que los productos derivados de sangre humana no transmitan agentes infecciosos. Considerar todos los derivados sanguíneos como potencialmente infecciosos. Evitar el contacto con la piel y los ojos. En caso de contacto con los ojos, enjuague inmediatamente con abundante agua y consultar con un médico. Usar guantes adecuados y protección para los ojos / cara. En caso de accidente, consultar con un médico de inmediato y mostrar este envase o etiqueta.

PREPARACIÓN

-Utilizar una pipeta volumétrica Clase A, añadir cuidadosamente la cantidad exacta de agua destilada o desionizada según lo especificado en la etiqueta del vial al material de control.
-Invertir el vial suavemente y deje reposar a temperatura ambiente durante 5 a 10 minutos.
- Invertir los contenidos hasta homogeneizarlos. NO UTILIZAR VORTEX. Retirar la muestra requerida para la prueba.
El uso y/o almacenamiento inadecuado del control puede afectar los resultados. La reconstitución inexacta del control y los errores en la técnica de ensayo pueden causar resultados erróneos.

CONSERVACIÓN Y ESTABILIDAD

El Suero 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 o con signos evidentes de contaminación microbiana.

Conservar los viales bien cerrados después de su uso.

- Después de la reconstitución del vial, es estable:
De 2°C a 8°C 10 días
- Bilirrubina Directa (conservado protegido de la luz):
De 2°C a 8°C 5 días
- La fosfatasa alcalina puede aumentar su actividad con el tiempo.

BIBLIOGRAFÍA

1. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.
2. International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: *A Protocol for the Conversion of Clinical Laboratory data*, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226

PRESENTACIÓN

SPINCHEM 1 Ref: 1002015 4 x 5 mL
SPINCHEM 2 Ref: 1002025 4 x 5 mL



SPINCHEM

SPINCHEM 1 / SPINCHEM 2
Human Control serum
Sérum Contrôle humain**Serum control multicomponent for clinical chemistry assays
IVD**

Store at 2 - 8°C.

PRODUCT CHARACTERISTICS

SPINCHEM 1 or SPINCHEM 2 is a human lyophilised serum.
With most constituent concentrations and activities in the normal (Spinchem 1) or pathologic (Spinchem 2) range.
It's intended for control of accuracy for use with manual and automated analytical procedures.

REAGENTS

Human serum. Enzymes (human, bovine and porcine).
Nonprotein constituents and bacteriostatics agents.
The concentration / activities of the components are lot-specific.
The exact values and ranges valid for reagents are given informational purpose in the value sheet.

PRECAUTIONS

Contains human sourced material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Consider all blood derivatives potentially infectious.
Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical device. Wear suitable gloves and eye/face protection. In case of an accident, seek medical device immediately and show this container or label.

PREPARATION

-Using a Class A volumetric pipette, carefully add the exact amount of distilled or deionized water as specified on the vial label to the control material.
-Swirl the vial gently and allow to stand at room temperature for 5 to 10 minutes.
-Swirl contents until homogeneous. DO NOT VORTEX. Remove the sample required for testing.
Improper handling and/or storage of the control can affect results. Inaccurate reconstitution of the control and errors in assay technique can cause erroneous results.

STORAGE AND STABILITY

The Control serum 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 or if there is visible evidence of microbial growth. Store tightly capped when not use.

- After reconstitution is stable for:
At 2°C to 8°C 10 days
- Direct Bilirubin (stored protected from light):
At 2°C to 8°C 5 days
- Alkaline phosphatase may increase in activity with time.

BIBLIOGRAPHY

1. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.
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PACKAGING

SPINCHEM 1 Ref: 1002015 4 x 5 mL
SPINCHEM 2 Ref: 1002025 4 x 5 mL

**Sérum contrôle multiparamétrique pour essais de Biochimie
clinique**IVD
Conserver à 2-8°C**CARACTÉRISTIQUES DU PRODUIT**

SPINCHEM 1 ou SPINCHEM 2 est un sérum humain lyophilisé.
Avec des concentrations et une activité dans l'intervalle normal (Spinchem 1) ou pathologique (Spinchem 2).
Il sert à contrôler l'exactitude ou la précision des techniques manuelles et automatisées.

RÉACTIFS

Sérum humain. Enzymes (humaines, bovines et porcines).
Constituants non protéiques et agents bactériostatiques.
La concentration / l'activité des composants sont spécifiques à chaque lot. Les valeurs de chaque paramètre sont incluses dans la Feuille de Valeurs de chaque lot.

PRÉCAUTIONS

Contient du matériel d'origine humaine. Aucune méthode de test connue ne peut offrir une assurance complète que les produits dérivés du sang humain ne transmettront pas d'agents infectieux. Considérer tous les dérivés du sang comme potentiellement infectieux.
Éviter le contact avec la peau et les yeux. En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un appareil médical. Porter des gants appropriés et un appareil de protection des yeux/du visage. En cas d'accident, consulter immédiatement un dispositif médical et lui montrer l'emballage ou l'étiquette.

PRÉPARATION

-À l'aide d'une pipette volumétrique de classe A, ajoutez soigneusement la quantité exacte d'eau distillée ou déminéralisée spécifiée sur l'étiquette du flacon au matériau de contrôle.
-Tourner doucement le flacon et laisser reposer à température ambiante pendant 5 à 10 minutes.
-Swirl contenu jusqu'à homogène. NE PAS VORTEX. Retirez l'échantillon requis pour les tests. Une manipulation et / ou un stockage incorrect du contrôle peut affecter les résultats. Une reconstitution inexacte du contrôle et des erreurs de technique de dosage peuvent entraîner des résultats erronés.

CONSERVATION ET STABILITÉ

Le Sérum contrôle est stable jusqu'à la date de péremption indiquée sur l'emballage si le flacon est bien fermé et conservé à 2-8°C, et que l'on évite la contamination pendant son utilisation. Ne pas utiliser de réactifs qui auraient dépassé la date de péremption ou présentant des signes évidents de contamination microbienne.

- Conserver les flacons bien fermés après emploi.
- Après la reconstitution du flacon, il est stable :
De 2°C à 8°C 10 jours
 - Bilirubine Directe (conserver à l'abri de la lumière) :
De 2°C à 8°C 5 jours
 - Phosphatase alcaline peut augmenter l'activité avec le temps.

BIBLIOGRAPHIE

1. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.
2. International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: *A Protocol for the Conversion of Clinical Laboratory data*, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226

PRÉSENTATION

SPINCHEM 1 Ref: 1002015 4 x 5 mL
SPINCHEM 2 Ref: 1002025 4 x 5 mL





SPINCHEM

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Human Control serum
Soro Controlo humano**Serum control multicomponent for clinical chemistry assays
IVD**

Store at 2 - 8°C.

PRODUCT CHARACTERISTICS

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It's intended for control of accuracy for use with manual and automated analytical procedures.

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Nonprotein constituents and bacteriostatics agents.
The concentration / activities of the components are lot-specific.
The exact values and ranges valid for reagents are given informational purpose in the value sheet.

PRECAUTIONS

Contains human sourced material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Consider all blood derivatives potentially infectious.
Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical device. Wear suitable gloves and eye/face protection. In case of an accident, seek medical device immediately and show this container or label.

PREPARATION

-Using a Class A volumetric pipette, carefully add the exact amount of distilled or deionized water as specified on the vial label to the control material.
-Swirl the vial gently and allow to stand at room temperature for 5 to 10 minutes.
-Swirl contents until homogeneous. DO NOT VORTEX. Remove the sample required for testing.
Improper handling and/or storage of the control can affect results. Inaccurate reconstitution of the control and errors in assay technique can cause erroneous results.

STORAGE AND STABILITY

The Control serum 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 or if there is visible evidence of microbial growth. Store tightly capped when not use.

- After reconstitution is stable for:
At 2°C to 8°C 10 days
- Direct Bilirubin (stored protected from light):
At 2°C to 8°C 5 days
- Alkaline phosphatase may increase in activity with time.

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PACKAGING

SPINCHEM 1 Ref: 1002015 Cont. 4 x 5 mL
SPINCHEM 2 Ref: 1002025 Cont. 4 x 5 mL

**Soro controlo multiparamétrico para ensaios de Bioquímica
clínica**IVD
Conservar a 2 - 8°C**CARACTERÍSTICAS DO PRODUTO**

SPINCHEM 1 ou SPINCHEM 2 são um soro humano liofilizado.
Com concentrações e atividades da maioria dos constituintes no intervalo normal (Spinchem 1) ou patológico (Spinchem 2).
Destina-se a controlar a exactidão ou a precisão das técnicas tanto manuais como automatizadas.

REAGENTES

Soro humano. Enzimas (humanas, bovinas e suínas). Constituintes não-proteicos e agentes bacteriostáticos.
A concentração /atividade dos componentes são específicos de cada lote. Os valores de cada parâmetro estão incluídos na Folha de Valores de cada lote.

PRECAUÇÕES

Contém material de origem humana. Nenhum método de teste conhecido pode oferecer uma garantia completa de que produtos derivados de sangue humano não transmitirão agentes infectantes. Considere todos os derivados de sangue potencialmente infectados.
Evitar o contacto com a pele e os olhos. Em caso de contacto com os olhos, lave imediatamente com água em abundância e procure um médico. Use luvas adequadas e proteção para os olhos / rosto. Em caso de acidente, procure imediatamente um dispositivo médico e mostre este recipiente ou etiqueta.

PREPARAÇÃO

-Usando uma pipeta volumétrica Classe A, adicione cuidadosamente a quantidade exacta de água destilada ou desionizada, conforme especificado no rótulo do frasco, ao material de controlo.
-Agite o frasco suavemente e deixe repousar à temperatura ambiente durante 5 a 10 minutos.
-Agite moderadamente até o produto ficar homogéneo. NÃO USE O VÓRTEX. Remova a amostra necessária para o teste. O manuseio e/ou armazenamento inadequado do controlo podem afetar os resultados. A reconstituição imprecisa do controlo e os erros na técnica de análise podem causar resultados erróneos.

CONSERVAÇÃO E ESTABILIDADE

O soro controlo é estável até à data de validade referida na embalagem, quando o frasco é mantido bem fechado a 2-8°C, e se evita a contaminação durante a utilização. Não utilizar reagentes cujo prazo de validade já tenha sido ultrapassado ou com sinais evidentes de contaminação microbiana.
Conservar os frascos bem fechados depois da utilização.
- Depois da reconstituição do frasco, é estável:
Entre 2°C e 8°C - 10 dias
- Bilirrubina directa (conservado protegido da luz):
Entre 2°C e 8°C - 5 dias
- Fosfatase alcalina pode aumentar em atividade com o tempo.

BIBLIOGRAFIA

1. Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.
2. International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: *A Protocol for the Conversion of Clinical Laboratory data*, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226

APRESENTAÇÃO

SPINCHEM 1 Ref: 1002015 Cont. 4 x 5 mL
SPINCHEM 2 Ref: 1002025 Cont. 4 x 5 mL

