SPINREACT

CE

COAGULATION CONTROL P

(CONTROL COAGULACION P)
CONTROL PATOLOGICO / PATHOLOGIC CONTROL

Quantitative determination of coagulation factors

IVD

Store at 2 - 8ºC.

PRODUCT CHARACTERISTICS

The Control is a lyophilised human plasma, used to evaluate the precision and accuracy of PT, APTT and Fibrinogen determinations in human plasma.

REAGENTS

Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization.
Coagulation factors concentration is indicated below.

PRECAUTIONS

Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.

PREPARATION

Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.

STORAGE AND STABILITY

The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.

PROCEDURE

The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Determinación cuantitativa de factores de coagulación

IVD

Conservar a 2 - 8ºC

CARACTERISTICAS DEL PRODUCTO

El Control es un plasma humano liofilizado utilizado para evaluar la precisión y exactitud en la determinación de PT, APTT y Fibrinógeno en plasma humano.

REACTIVOS

Plasma humano con citrato sódico <0.4% como anticoagulante y un nivel de concentración patológica de los factores de coagulación. Se han ajustado para producir tiempos de prolongados de protrombina y trombina parcial. Previa liofilización, se añade <1% de estabilizantes y soluciones tampón. Su concentración esta indicada en la tabla anexa.

PRECAUCIONES

Cada unidad de material usado en la preparación de este reactivo has sido testada por métodos aprobados por la FDA, resultando no reactivos a anticuerpos HBsAg, HIV y HCV. Sin embargo, dado que ningún método puede asegurar completamente que productos derivados de humanos no puedan transmitir enfermedades infecciosas, este producto debe ser manipulado como material biológico potencialmente infeccioso

PREPARACIÓN

Reconstituir con 1,0 mL de agua destilada. Mover lentamente en círculos y dejar reposar durante 15 minutos a temperatura ambiente. No invertir el frasco ni agitarlo vigorosamente.

CONSERVACIÓN Y ESTABILIDAD

El calibrador es estable hasta la fecha de caducidad indicada en el envase cuando se mantiene el vial bien cerrado a 2-8ºC, y se evita la contaminación durante su uso. No utilizar reactivos que hayan sobrepasado la fecha de caducidad. Después de la reconstitución del vial, es estable 8 horas a 2-8ºC**.** Mezclar cuidadosamente el contenido antes de cada uso.
Los valores erróneos, las variaciones de color del producto o la ausencia de vacío pueden ser indicativos del deterioro del producto. Sin embargo, un funcionamiento deficiente del control también puede deberse a otros factores de la prueba.

PROCEDIMIENTO

El Control debe tratarse como si fuera una muestra; Deben ser analizados al inicio de las pruebas y al menos una vez en cada turno, o con cada grupo de ensayos, cada vez que cambie de reactivo o realice un ajuste importante del instrumento.
Comparar los resultados obtenidos con los resultados esperados según el método y el control.

COMPONENT / *COMPONENTE*	METHOD / *METODO*	RANGE / *RANGO*
PT (*Prothrombin Time / Tiempo de Protombina)*	According to Instructions Sheet of corresponding Spinreact reagent/ *Según Hoja de Instrucciones del reactivo Spinreact correspondiente*	29.8 (25.3– 34.3) s
APTT Activated Partial Thromboplastin Test *Tiempo de Tromboplatina Parcial Activada*		60.5 (51.4 – 69.6) s
Fibrinogen / *Fibrinógeno*		182 (155 - 209) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

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

Los resultados reales dependen de muchos factores, entre los cuales se encuentran el número de lote, el tipo de reactivo y el instrumento. Los intervalos deben determinarse en cada laboratorio, cada vez que se cambie de número de lote del control, de reactivo o del instrumento.
Esta hoja de valores es aplicable al lote y sublotes. Letras alfabéticas secuenciales (p.e. A, B , C etc.) que siguen al nº de lote.

REF 1709106 4 x 1 mL LOT

SPINREACT,S.A./S.A.U. Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail: spinreact@spinreact.com

SPINREACT

CE

COAGULATION CONTROL P

(CONTROL COAGULACION P)
CONTROL PATOLOGICO / PATHOLOGIC CONTROL

Quantitative determination of coagulation factors
IVD
Store at 2 - 8ºC.
PRODUCT CHARACTERISTICS
The Control is a lyophilised human plasma, used to evaluate the precision and accuracy of PT, APTT and Fibrinogen determinations in human plasma.
REAGENTS
Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization.
Coagulation factors concentration is indicated below.
PRECAUTIONS
Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.
PREPARATION
Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.
STORAGE AND STABILITY
The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.
Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.
PROCEDURE
The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Determinación cuantitativa de factores de coagulación
IVD
Conservar a 2 - 8ºC
CARACTERISTICAS DEL PRODUCTO
El Control es un plasma humano liofilizado utilizado para evaluar la precisión y exactitud en la determinación de PT, APTT y Fibrinógeno en plasma humano.
REACTIVOS
Plasma humano con citrato sódico <0.4% como anticoagulante y un nivel de concentración patológica de los factores de coagulación. Se han ajustado para producir tiempos de prolongados de protrombina y trombina parcial. Previa liofilización, se añade <1% de estabilizantes y soluciones tampón. Su concentración esta indicada en la tabla anexa.
PRECAUCIONES
Cada unidad de material usado en la preparación de este reactivo has sido testada por métodos aprobados por la FDA, resultando no reactivos a anticuerpos HBsAg, HIV y HCV. Sin embargo, dado que ningún método puede asegurar completamente que productos derivados de humanos no puedan transmitir enfermedades infecciosas, este producto debe ser manipulado como material biológico potencialmente infeccioso
PREPARACIÓN
Reconstituir con 1,0 mL de agua destilada. Mover lentamente en círculos y dejar reposar durante 15 minutos a temperatura ambiente. No invertir el frasco ni agitarlo vigorosamente.
CONSERVACIÓN Y ESTABILIDAD
El calibrador es estable hasta la fecha de caducidad indicada en el envase cuando se mantiene el vial bien cerrado a 2-8ºC, y se evita la contaminación durante su uso. No utilizar reactivos que hayan sobrepasado la fecha de caducidad. Después de la reconstitución del vial, es estable 8 horas a 2-8ºC. Mezclar cuidadosamente el contenido antes de cada uso.
Los valores erróneos, las variaciones de color del producto o la ausencia de vacío pueden ser indicativos del deterioro del producto. Sin embargo, un funcionamiento deficiente del control también puede deberse a otros factores de la prueba.
PROCEDIMIENTO
El Control debe tratarse como si fuera una muestra; Deben ser analizados al inicio de las pruebas y al menos una vez en cada turno, o con cada grupo de ensayos, cada vez que cambie de reactivo o realice un ajuste importante del instrumento.
Comparar los resultados obtenidos con los resultados esperados según el método y el control.

COMPONENT / *COMPONENTE*	METHOD / *METODO*	RANGE / *RANGO*
*PT (*Prothrombin Time / Tiempo de Protombina)	According to Instructions Sheet of corresponding Spinreact reagent/ *Según Hoja de Instrucciones del reactivo Spinreact correspondiente*	29.8 (25.3 – 34.3) s
APTT Activated Partial Thromboplastin Test *Tiempo de Tromboplatina Parcial Activada*		60.5 (51.4 – 69.6) s
Fibrinogen / *Fibrinógeno*		182 (155– 209) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.
This Control value sheet is applicable to sublots. Sequential alphabetical letter (e.g. A, B, C etc.) following the lot number.
Los resultados reales dependen de muchos factores, entre los cuales se encuentran el número de lote, el tipo de reactivo y el instrumento. Los intervalos deben determinarse en cada laboratorio, cada vez que se cambie de número de lote del control, de reactivo o del instrumento.
Esta hoja de valores es aplicable al lote y sublotes. Letras alfabéticas secuenciales (p.e. A, B , C etc.) que siguen al nº de lote.
REF 1709106 4 x 1 mL LOT
COIS06 13/06/14
SPINREACT,S.A./S.A.U. Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail: spinreact@spinreact.com

SPINREACT

CE

COAGULATION CONTROL P

CONTRÔLE PATHOLOGIQUE / PATHOLOGIC CONTROL
Coagulation / Coagulation

Quantitative determination of coagulation factors

IVD

Store at 2 - 8ºC.

PRODUCT CHARACTERISTICS

The Control is a lyophilised human plasma, used to evaluate the precision and accuracy of PT, APTT and Fibrinogen determinations in human plasma.

REAGENTS

Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization.
Coagulation factors concentration is indicated below.

PRECAUTIONS

Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.

PREPARATION

Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.

STORAGE AND STABILITY

The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.

PROCEDURE

The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Détermination quantitative de facteurs de coagulation

IVD

Conserver à 2-8ºC

CARACTÉRISTIQUES DU PRODUIT

Le Contrôle est un plasma humain lyophilisé qui est utilisé pour évaluer la précision et l'exactitude dans la détermination de PT, APTT et fibrinogène dans le plasma humain.

RÉACTIFS

Plasma humain avec citrate de sodium <0,4 % comme anticoagulant et un niveau de concentration pathologique des facteurs de coagulation. Ils ont été réglés pour produire des temps prolongés de prothrombine et thrombine partielle. Avant la lyophilisation, on ajoute <1 % de stabilisants et solutions tampon. Sa concentration est indiquée dans le tableau en annexe.

PRÉCAUTIONS

Chaque unité de matériel utilisée dans la préparation de ce réactif a été testée par des méthodes approuvées par la FDA, ce qui implique une non réactivité face aux anticorps HBsAg, HIV et HCV. Cependant, vu qu'aucune méthode ne peut garantir entièrement que les produits dérivés d'êtres humains ne transmettront pas de maladies infectieuses, ce produit doit être manipulé comme un matériel biologique potentiellement infectieux.

PRÉPARATION

Reconstituer avec 1,0 mL d'eau distillée. Remuer lentement en cercles et laisser reposer pendant 15 minutes à température ambiante. Ne pas retourner le flacon ni l'agiter énergiquement.

CONSERVATION ET STABILITÉ

Le calibrateur est stable jusqu'à la date de péremption indiquée sur l'emballage si le flacon est bien fermé et conservé à 2-8ºC, et que l'on évite sa contamination pendant l'utilisation. Ne pas utiliser de réactifs dont la date de péremption serait dépassée. Après la reconstitution du flacon, il est stable 8 heures à 2-8ºC**.** Mélanger soigneusement le contenu avant chaque utilisation.
Les valeurs erronées, les variations de couleur du produit ou l'absence de vide peuvent indiquer que le produit est détérioré. Toutefois, un fonctionnement déficient du contrôle peut également être dû à d'autres facteurs de l'essai.

PROCÉDURE

Le Contrôle doit être traité à la manière d'un échantillon. Il doit être analysé au début des essais et, au moins, une fois à chaque tour, ou avec chaque groupe d'essais, chaque fois qu'il y a un changement de réactif ou qu'un réglage important de l'instrument est effectué.
Comparer les résultats obtenus avec les résultats attendus en fonction de la méthode et du contrôle.

COMPONENT / *COMPOSANT*	METHOD / *MÉTHODE*	RANGE / *PLAGE*
PT (*Prothrombin Time / Temps de Prothrombine)*	According to Instructions Sheet of corresponding Spinreact reagent/ *Selon fiche d'instructions du réactif Spinreact correspondante*	41,1 (34,9– 47,3) s
APTT Activated Partial Thromboplastin Test *Temps de Thromboplastine Partielle Activée*		71,2 (60,5 – 81,9) s
Fibrinogen / *Fibrinogène*		194 (165 - 223) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

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

Les résultats réels dépendent de nombreux facteurs dont le numéro de lot, le type de réactif et l'instrument. Les intervalles doivent être déterminés dans chaque laboratoire, dès que l'on change de numéro de lot, de réactif ou d'instrument.

Cette feuille de valeurs est applicable au lot et aux sous-lots. Lettres alphabétiques séquentielles (par ex. A, B, C, etc.) qui suivent le nº de lot.

REF 1709106 4 x 1 mL LOT

SPINREACT,S.A./.S.A.U. Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tél. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail : spinreact@spinreact.com

SPINREACT

CE

COAGULATION CONTROL P

CONTROL PATOLOGICO / PATHOLOGIC CONTROL
Coagulation / Coagulation

Quantitative determination of coagulation factors
IVD
Store at 2 - 8ºC.

PRODUCT CHARACTERISTICS
The Control is a lyophilised human plasma, used to evaluate the precision and accuracy of PT, APTT and Fibrinogen determinations in human plasma.

REAGENTS
Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization.
Coagulation factors concentration is indicated below.

PRECAUTIONS
Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.

PREPARATION
Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.

STORAGE AND STABILITY
The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.

PROCEDURE
The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Détermination quantitative de facteurs de coagulation
IVD
Conserver à 2-8ºC

CARACTÉRISTIQUES DU PRODUIT
Le Contrôle est un plasma humain lyophilisé qui est utilisé pour évaluer la précision et l'exactitude dans la détermination de PT, APTT et fibrinogène dans le plasma humain.

RÉACTIFS
Plasma humain avec citrate de sodium <0,4 % comme anticoagulant et un niveau de concentration pathologique des facteurs de coagulation. Ils ont été réglés pour produire des temps prolongés de prothrombine et thrombine partielle. Avant la lyophilisation, on ajoute <1 % de stabilisants et solutions tampon. Sa concentration est indiquée dans le tableau en annexe.

PRÉCAUTIONS
Chaque unité de matériel utilisée dans la préparation de ce réactif a été testée par des méthodes approuvées par la FDA, ce qui implique une non réactivité face aux anticorps HBsAg, HIV et HCV. Cependant, vu qu'aucune méthode ne peut garantir entièrement que les produits dérivés d'êtres humains ne transmettront pas de maladies infectieuses, ce produit doit être manipulé comme un matériel biologique potentiellement infectieux.

PRÉPARATION
Reconstituer avec 1,0 mL d'eau distillée. Remuer lentement en cercles et laisser reposer pendant 15 minutes à température ambiante. Ne pas retourner le flacon ni l'agiter énergiquement.

CONSERVATION ET STABILITÉ
Le calibrateur est stable jusqu'à la date de péremption indiquée sur l'emballage si le flacon est bien fermé et conservé à 2-8ºC, et que l'on évite sa contamination pendant l'utilisation. Ne pas utiliser de réactifs dont la date de péremption serait dépassée. Après la reconstitution du flacon, il est stable 8 heures à 2-8ºC. Mélanger soigneusement le contenu avant chaque utilisation.
Les valeurs erronées, les variations de couleur du produit ou l'absence de vide peuvent indiquer que le produit est détérioré. Toutefois, un fonctionnement déficient du contrôle peut également être dû à d'autres facteurs de l'essai.

PROCÉDURE
Le Contrôle doit être traité à la manière d'un échantillon. Il doit être analysé au début des essais et, au moins, une fois à chaque tour, ou avec chaque groupe d'essais, chaque fois qu'il y a un changement de réactif ou qu'un réglage important de l'instrument est effectué.
Comparer les résultats obtenus avec les résultats attendus en fonction de la méthode et du contrôle.

COMPONENT / *COMPOSANT*	METHOD / *MÉTHODE*	RANGE / *PLAGE*
*PT (*Prothrombin Time / *Temps de Prothrombine)*	According to Instructions Sheet of corresponding Spinreact reagent/ *Selon fiche d'instructions du réactif Spinreact correspondante*	41.1 (34.9 – 47.3) s
APTT Activated Partial Thromboplastin Test *Temps de Thromboplastine Partielle Activée*		71.2 (60.5 – 81.9) s
Fibrinogen / *Fibrinogène*		194 (165– 223) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

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

Les résultats réels dépendent de nombreux facteurs dont le numéro de lot, le type de réactif et l'instrument. Les intervalles doivent être déterminés dans chaque laboratoire, dès que l'on change de numéro de lot, de réactif ou d'instrument.

Cette feuille de valeurs est applicable au lot et aux sous-lots. Lettres alphabétiques séquentielles (par ex. A, B, C, etc.) qui suivent le nº de lot.

REF 1709106 4 x 1 mL LOT

COIS06-F 03/03/16

SPINREACT,S.A./S.A.U. Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail: spinreact@spinreact.com

SPINREACT

CE

COAGULATION CONTROL P

(CONTROL COAGULAÇÃO P)
CONTROL PATOLÓGICO / PATHOLOGIC CONTROL

Quantitative determination of coagulation factors
IVD
Store at 2 - 8ºC.
PRODUCT CHARACTERISTICS
The Control is a lyophilised human plasma, used to evaluate the precision and accuracy of PT, APTT and Fibrinogen determinations in human plasma.

REAGENTS
Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization. Coagulation factors concentration is indicated below.

PRECAUTIONS
Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.

PREPARATION
Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.

STORAGE AND STABILITY
The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.

PROCEDURE
The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Determinação quantitativa de factores de coagulação
IVD
Conservar a 2 - 8ºC
CARACTERÌSTICAS DO PRODUTO
O Control é um plasma humano liofilizado utilizado para avaliar a precisão e exactidão na determinação de PT, APTT e Fibrinogénio no plasma humano.

REAGENTES
Plasma humano com citrato sódico <0.4% como anticoagulante e um valor de concentração patológica dos factores de coagulação. Foram ajustados para produzir tempos prolongados de protrombina e trombina parcial. Antes da liofilização, foram adicionados <1% de estabilizantes e de solução tamponante. A concentração dos factores de coagulação está indicada na tabela abaixo.

PRECAUÇÕES
Cada unidade de material usado na preparação deste produto foi testada por um método aprovado pela FDA, com resultado não reactivo a anticorpos HBsAg, HIV e HCV. No entanto, uma vez que nenhum método pode assegurar completamente que produtos derivados de sangue humano não possam transmitir doenças infecciosas, este produto deve ser manipulado como material biológico potencialmente infeccioso.

PREPARAÇÃO
Reconstituir com 1,0 ml de água destilada. Agitar lentamente com movimentos circulares e deixar repousar durante 15 minutos à temperatura ambiente. Não inverter o frasco nem agitar vigorosamente.

CONSERVAÇÃO E ESTABILIDADE
O control é estável até ao final do prazo de validade indicada no frasco quando este é mantido bem fechado a2-8ºC, e as contaminações são evitadas durante a sua utilização. Não utilizar reagentes com prazo de validade ultrapassado.
Após a reconstituição, é estável durante 8 horas, se o frasco estiver bem fechado a 2-8ºC. Agitar suavemente antes de cada utilização.
Valores erráticos, variações da cor do produto ou falta de vácuo nos frascos podem ser indicativos da deterioração do produto. No entanto, um fraco controlo do método também pode ser devido a outros factores internos do teste.

PROCEDIMENTO
O Control deve ser tratado como se fosse uma amostra; Devem ser analisados diáriamente antes de iniciar o método e pelo menos uma vez por cada turno ou com cada grupo de ensaios. O Control também deve ser testado de cada vez que se muda de reagente ou se realiza um ajuste importante do instrumento.
Devem ser comparados os resultados obtidos com os resultados esperados de acordo com o método e o control.

COMPONENT / *COMPONENTE*	METHOD / *METODO*	RANGE / *INTERVALO*
PT (*Prothrombin Time / Tempo de Protombina)*	According to Instructions Sheet of corresponding Spinreact reagent/ *Conforme a folha de instrução do reagente Spinreact correspondente*	29.1 (24.7 – 33.5) s
APTT Activated Partial Thromboplastin Test *Tempo de Tromboplatina Parcial Activada*		57.3 (48.7 – 65.9) s
Fibrinogen / *Fibrinogénio*		201 (171 - 231) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

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

Os resultados reais dependem de muitos factores, entre os quais se encontram o número de lote, o tipo de reagente e o instrumento. Os intervalos devem ser determinados em cada laboratório, cada vez que se muda de número de lote do control, de reagente ou de instrumento.
Esta Folha de valores é aplicável a lotes e sublotes. Letras alfabéticas sequenciais (p.e. A, B , C etc.) que se seguem ao nº de lote.

REF 1709106 4 x 1 mL LOT

SPINREACT,S.A./S.A.U Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail: spinreact@spinreact.com

SPINREACT

CE

COAGULATION CONTROL P

(CONTROL COAGULAÇÃO P)
CONTROL PATOLÓGICO / PATHOLOGIC CONTROL

Quantitative determination of coagulation factors
IVD
Store at 2 - 8ºC.
PRODUCT CHARACTERISTICS
The Control is a lyophilised human plasma, used to evaluate threcision and accuracy of PT, APTT and Fibrinogendeterminations in human plasma.

REAGENTS
Human plasma collected with <0.4% sodium citrate anticoagulant, with a pathological concentration of coagulation factors; It has been adjusted to have prolonged prothrombin and partial thromboplastin times. <1.0% Stabilizers and buffers are added prior to lyophilization. Coagulation factors concentration is indicated below.

PRECAUTIONS
Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product must be handled as potencially infectious biological material.

PREPARATION
Reconstitute (→) with 1.0 mL of distilled water. Swirl gently (do not invert vial or mix vigorously) and let stand undisturbed for 15 minutes at room temperature before use.

STORAGE AND STABILITY
The calibrator is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date. After reconstitution, it's stable for 8 hours tightly closed at 2-8ºC. Gently mix contents prior to each use.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test.

PROCEDURE
The Control should be run as a sample, at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. Compare test results obtained to the expected results for the test method and control plasma.

Determinação quantitativa de factores de coagulação
IVD
Conservar a 2 - 8ºC
CARACTERÌSTICAS DO PRODUTO
O Control é um plasma humano liofilizado utilizado para avaliar a precisão e exactidão na determinação de PT, APTT e Fibrinogénio no plasma humano.

REAGENTES
Plasma humano com citrato sódico <0.4% como anticoagulante e um valor de concentração patológica dos factores de coagulação. Foram ajustados para produzir tempos prolongados de protrombina e trombina parcial. Antes da liofilização, foram adicionados <1% de estabilizantes e de solução tamponante. A concentração dos factores de coagulação está indicada na tabela abaixo.

PRECAUÇÕES
Cada unidade de material usado na preparação deste produto foi testada por um método aprovado pela FDA, com resultado não reactivo a anticorpos HBsAg, HIV e HCV. No entanto, uma vez que nenhum método pode assegurar completamente que produtos derivados de sangue humano não possam transmitir doenças infecciosas, este produto deve ser manipulado como material biológico potencialmente infeccioso.

PREPARAÇÃO
Reconstituir com 1,0 ml de água destilada. Agitar lentamente com movimentos circulares e deixar repousar durante 15 minutos à temperatura ambiente. Não inverter o frasco nem agitar vigorosamente.

CONSERVAÇÃO E ESTABILIDADE
O control é estável até ao final do prazo de validade indicada no frasco quando este é mantido bem fechado a2-8ºC, e as contaminações são evitadas durante a sua utilização. Não utilizar reagentes com prazo de validade ultrapassado.
Após a reconstituição, é estável durante 8 horas, se o frasco estiver bem fechado a 2-8ºC. Agitar suavemente antes de cada utilização.
Valores erráticos, variações da cor do produto ou falta de vácuo nos frascos podem ser indicativos da deterioração do produto. No entanto, um fraco controlo do método também pode ser devido a outros factores internos do teste.

PROCEDIMENTO
O Control deve ser tratado como se fosse uma amostra; Devem ser analisados diáriamente antes de iniciar o método e pelo menos uma vez por cada turno ou com cada grupo de ensaios. O Control também deve ser testado de cada vez que se muda de reagente ou se realiza um ajuste importante do instrumento.
Devem ser comparados os resultados obtidos com os resultados esperados de acordo com o método e o control.

COMPONENT / *COMPONENTE*	METHOD / *METODO*	RANGE / INTERVALO
*PT (*Prothrombin Time / Tempo de Protombina)	According to Instructions Sheet of corresponding Spinreact reagent/ *Conforme a folha de instrução do reagente Spinreact correspondente*	29.1 (24.7 – 33.5) s
APTT Activated Partial Thromboplastin Test *Tempo de Tromboplatina Parcial Activada*		57.3 (48.7 – 65.9) s
Fibrinogen / *Fibrinogénio*		201 (171 – 231) mg/dL

Actual results depend on many factors, including lot number, type of reagent, and instrument. Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument.

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

Os resultados reais dependem de muitos factores, entre os quais se encontram o número de lote, o tipo de reagente e o instrumento. Os intervalos devem ser determinados em cada laboratório, cada vez que se muda de número de lote do control, de reagente ou de instrumento.
Esta Folha de valores é aplicável a lotes e sublotes. Letras alfabéticas sequenciais (p.e. A, B , C etc.) que se seguem ao nº de lote.

REF 1709106 4 x 1 mL LOT

COIS06-P 13/06/14
SPINREACT,S.A./S.A.U Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99 e-mail: spinreact@spinreact.com