SPINREACT CE

# COAGULATION CONTROL N

(CONTROL COAGULACION N)
CONTROL NORMAL / NORMAL 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 NORMAL concentration of coagulation factors.
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 control 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 NORMAL de los factores de coagulación.
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.

**PREPARACION**
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.

**CONSERVACION Y ESTABILIDAD**
El control es estable hasta la fecha de caducidad indicada en el envase cuando se mantiene el vial bien cerrado a 2-8ºC, y se evita la contaminación durante su uso. No utilizar reactivos que hayan sobrepasado la fecha de caducidad.
Después de la reconstitución es estable 8 horas cuando se mantiene el vial bien cerrado a 2-8ºC. Mezclar suavemente antes de cada uso. Valores erráticos, variación del color pueden ser indicativos de la deterioración del producto. Sin embargo, una escaso control del método puede ser debido a otros factores internos del test.

**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 / *MÉTODO* | RANGE / *RANGO* |
|---|---|---|
| PT (Prothrombin Time */ Tiempo de Protombina)* | According to Instructions Sheet of corresponding Spinreact reagent/ *Según Hoja de Instrucciones del reactivo Spinreact correspondiente* | 12.2 (10.4 – 14.0) s |
| APTT Activated Partial Thromboplastin Test *Tiempo de Tromboplatina Parcial Activada* | | 29.9 (25.4 – 34.4) s |
| Fibrinogen / *Fibrinógeno* | | 202 (172 - 232) 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.

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.

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

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.

REF 1709104 4 x 1 mL LOT



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SPINREACT CE

COAGULATION CONTROL N

(CONTROL COAGULACION N)
CONTROL NORMAL / NORMAL 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 NORMAL concentration of coagulation factors.
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 control 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 NORMAL de los factores de coagulación.
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.

PREPARACION
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.

CONSERVACION Y ESTABILIDAD
El control es estable hasta la fecha de caducidad indicada en el envase cuando se mantiene el vial bien cerrado a 2-8ºC, y se evita la contaminación durante su uso. No utilizar reactivos que hayan sobrepasado la fecha de caducidad.
Después de la reconstitución es estable 8 horas cuando se mantiene el vial bien cerrado a 2-8ºC. Mezclar suavemente antes de cada uso. Valores erráticos, variación del color pueden ser indicativos de la deterioración del producto. Sin embargo, una escaso control del método puede ser debido a otros factores internos del test.

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* | 12.2 (10.4 – 14.0) s |
| APTT Activated Partial Thromboplastin Test *Tiempo de Tromboplatina Parcial Activada* | | 29.9 (25.4 – 34.4) s |
| Fibrinogen / *Fibrinógeno* | | 202 (172- 232) 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.

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.

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

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.

REF 1709104 4 x 1 mL LOT

COIS05 13/06/14

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SPINREACT

CE

COAGULATION CONTROL N

CONTRÔLE NORMAL / NORMAL 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 NORMAL concentration of coagulation factors.
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 control 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 NORMAL des facteurs de coagulation.
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 complètement 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 contrôle 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, il est stable 8 heures si le flacon est bien fermé et conservé à 2-8ºC. Mélanger doucement avant chaque utilisation.
Des valeurs erratiques et une variation de la couleur peuvent indiquer la détérioration du produit. Toutefois, un faible contrôle de la méthode peut être dû à d'autres facteurs internes du test.

**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* | 14,0 (11,9 – 16,1) s |
| APTT Activated Partial Thromboplastin Test *Temps de Thromboplastine Partielle Activée* | | 28,6 (24,3 – 32,9) s |
| Fibrinogen / *Fibrinogène* | | 202 (172 - 232) 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 data 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.

Ce Bulletin d'analyse est applicable au lot et aux sous-lots. Lettres alphabétiques séquentielles (par ex. A, B, C, etc.) qui suivent le nº de lot.

REF 1709104 4 x 1 mL



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SPINREACT

CE

COAGULATION CONTROL N

CONTROL NORMAL / NORMAL CONTROL
Coagulation / Coagulación

## 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 NORMAL concentration of coagulation factors.
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 control 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 NORMAL des facteurs de coagulation.
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 complètement 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 contrôle 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, il est stable 8 heures si le flacon est bien fermé et conservé à 2-8ºC. Mélanger doucement avant chaque utilisation.
Des valeurs erratiques et une variation de la couleur peuvent indiquer la détérioration du produit. Toutefois, un faible contrôle de la méthode peut être dû à d'autres facteurs internes du test.

**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* | 14.0 (11.9 – 16.1) s |
| APTT Activated Partial Thromboplastin Test *Temps de Thromboplastine Partielle Activée* | | 28.6 (24.3– 32.9) s |
| Fibrinogen / *Fibrinogène* | | 202 (172- 232) 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 data 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.

Ce Bulletin d'analyse est applicable au lot et aux sous-lots. Lettres alphabétiques séquentielles (par ex. A, B, C, etc.) qui suivent le nº de lot.

REF 1709104 4 x 1 mL

COIS05-F 03/03/16

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# COAGULATION CONTROL N

(CONTROL COAGULAÇÃO P)
CONTROL NORMAL / NORMAL 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 NORMAL concentration of coagulation factors.
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 control 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

**CARACTERÍSTICAS 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 de sódio <0.4% como anticoagulante com um valor de concentração NORMAL dos factores de coagulação.
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 / *MÉTODO* | 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* | 13.1 (11.1 – 15.1) s |
| APTT Activated Partial Thromboplastin Test *Tempo de Tromboplatina Parcial Activada* | | 31.0 (26.3 – 35.7) s |
| Fibrinogen / *Fibrinogénio* | | 210 (178 - 242) 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 1709104 4 x 1 mL LOT


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# COAGULATION CONTROL N

(CONTROL COAGULAÇÃO P)
CONTROL NORMAL / NORMAL 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 NORMAL concentration of coagulation factors.
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 control 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

**CARACTERÍSTICAS 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 de sódio <0.4% como anticoagulante com um valor de concentração NORMAL dos factores de coagulação.
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* | 13.1 (11.1 – 15.1) s |
| APTT Activated Partial Thromboplastin Test *Tempo de Tromboplatina Parcial Activada* | | 31.0 (26.3 – 35.7) s |
| Fibrinogen / *Fibrinogénio* | | 210 (178- 242) 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 1709104 4 x 1 mL LOT

COIS05-P 13/06/14
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