



COAGULATION CONTROL N

(CONTROL COAGULACION N)
CONTROL NORMAL / NORMAL CONTROL**Quantitative determination of coagulation factors**IVD
Store at 2 - 8°C.**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 potentially 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 2-8°C 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 2-8°C. 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 coagulaciónIVD
Conservar a 2 - 8°C**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 ha 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 2-8°C, 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 2-8°C. 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 Tromboplastina 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.

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

REF 1709104 4 x 1 mL LOT

COIS05 13/06/14

IMPORTADORES EXCLUSIVOS: LAB CENTER DE MEXICO S.A. DE C.V.
TEL : 01 (55) 5360-6772 Y 01 800 500 SPIN (7746)
www.spinreact.com.mx asesoriatecnica@spinreact.com.mx

COAGULATION CONTROL N

(CONTROL COAGULACION N)
CONTROL NORMAL / NORMAL CONTROL**Quantitative determination of coagulation factors**IVD
Store at 2 - 8°C.**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 potentially 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 2-8°C 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 2-8°C. 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.

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 Tromboplastina 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.

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

REF 1709104 4 x 1 mL LOT

COIS05 13/06/14

IMPORTADORES EXCLUSIVOS: LAB CENTER DE MEXICO S.A. DE C.V.
TEL : 01 (55) 5360-6772 Y 01 800 500 SPIN (7746)
www.spinreact.com.mx asesoriatecnica@spinreact.com.mx