



Protein Calibrator 5 Level Series

Liquid human based calibrator series for use as a calibrator in immunoturbidimetric assays

REF

A00704

Cont.

5x 1 mL

Protein Calibrator 5 Level Series

COMPOSITION

The Protein Calibrator Series are based on defibrinated human plasma, liquid stabilized and filtered through a 0.2 µ pore-size filter.

Sodium azide 0.095 %

PREPARATION

The Calibrators are liquid, ready to use.

STABILITY AND STORAGE

Storage: at 2 – 8 °C
 Stability: up to the expiration date
 Stability after opening: 6 weeks at 2 – 8 °C
 DO NOT FREEZE!

DIRECTIONS FOR USE

- Use this Calibrator in the same manner as specified with the reagent and/or instrument being used.
- Allow the Calibrator to equilibrate to room temperature (22 – 28 °C) prior to use.
- The Calibrator should not be allowed to stand for repeated long periods of time (up to 6 hours) at room temperature. Keep vials tightly capped at all times when not in use to avoid microbial contamination. Keep vials refrigerated when not in use

WARNINGS AND PRECATIONS

- For in Vitro Diagnostic use.
- Each individual donation intended for use in manufacture of protein calibrator was tested for hepatitis B surface antigen (HBsAg), anti-hepatitis C (anti-HCV) and anti-HIV 1 and HIV 2 by FDA required tests. Since no test method can assure that products derived from human blood do not contain HIV-1/2 and Hepatitis B and Hepatitis C virus, this material and all patient samples should be handled as though capable of transmitting infectious diseases.
- Reagents containing sodium azide must be handled with due caution: Do not ingest or allow to contact skin or mucous membranes! Sodium azide can form explosive azides when contacting heavy metals such as copper or lead.

WASTE MANAGEMENT

Please refer to local legal requirements.

Protein Kalibrator 5 Level Serie

Flüssigkalibratoren auf Humanbasis für quantitative Bestimmungen mittels immunturbidimetrischer Methode

REF

A00704

Cont.

5x 1 mL

Protein Kalibrator 5 Level Serie

ZUSAMMENSETZUNG

Die DIALAB Protein Kalibratorserie basiert auf von Fibrin befreitem Humanplasma, flüssig-stabil und durch einen Filter mit 0,2 µ Porengröße gefiltert.

Natriumazid 0.095 %

VORBEREITUNG

Die Kalibratoren sind flüssig und gebrauchsfertig.

STABILITÄT UND LAGERUNG

Lagerung: bei 2 – 8 °C
 Haltbarkeit: bis zum Ablaufdatum
 Stabilität nach den Öffnen: 6 Wochen bei 2 – 8 °C
 NICHT EINFRIEREN!

TESTDURCHFÜHRUNG

- Der Kalibrator muss wie im Beipacktext des verwendeten Reagenz/Instruments beschrieben verwendet werden.
- Der Kalibrator muss vor Gebrauch auf Raumtemperatur (22 – 28 °C) gebracht werden.
- Der Kalibrator sollte nicht für wiederholt längere Zeit (bis zu 6 Stunden) bei Raumtemperatur gelagert werden. Die Fläschchen immer fest verschlossen halten, wenn sie nicht in Gebrauch sind, um mikrobielle Kontamination zu vermeiden. Wenn nicht in Gebrauch, die Fläschchen gekühlt lagern.

WARNUNGEN UND VORSICHTSMASSNAHMEN

- Für die In-Vitro-Diagnostik.
- Jede Spende, die für die Verwendung in der Produktion von Proteinkalibratoren gedacht ist, wurde auf Hepatitis B Oberflächenantigen (HBsAg), Anti-Hepatitis C (Anti-HCV) und Anti-HIV 1 und HIV 2 unter Verwendung einer FDA-geprüften Methode getestet. Da keine Methode 100%ige Sicherheit bietet, dass Produkte humanen Ursprungs kein HIV-1/2, Hepatitis B oder Hepatitis C Viren enthalten, sollte dieses Material und sämtliche Patientenproben wie potentiell infektiöses Material gehandhabt werden.
- Reagenzien, die Natriumazid beinhalten, müssen mit Vorsicht behandelt werden: Nicht verschlucken und Kontakt mit Haut und Schleimhäuten vermeiden! Natriumazid kann explosive Azide bilden, wenn es mit Schwermetallen wie Kupfer oder Blei in Kontakt kommt.

ABFALLBESEITIGUNG

Die lokalen Bestimmungen sind zu beachten.

LOT SPECIFIC ASSAY DATA / LOTSPEZIFISCHE WERTE

Values and expiry date are lot specific. / Werte und Ablaufdatum sind lotspezifisch

LOT: 320		EXP: 2017/10				
Parameter	Parameter	Assigned Values * / Bestimmte Werte *				
		Level 1	Level 2	Level 3	Level 4	Level 5
Albumin	Albumin	745.0 mg/dL	1,491.0 mg/dL	2,981.0 mg/dL	5,963.0 mg/dL	11,925.0 mg/dL
α-1 Antitrypsin	α-1 Antitrypsin	27.0 mg/dL	54.0 mg/dL	109.0 mg/dL	217.0 mg/dL	434.0 mg/dL
α-2 Macroglobulin	α-2 Macroglobulin	48.0 mg/dL	95.0 mg/dL	190.0 mg/dL	380.0 mg/dL	760.0 mg/dL
α-1 Acid Glycoprotein	α-1 Saures Glycoprotein	14.0 mg/dL	28.0 mg/dL	57.0 mg/dL	113.0 mg/dL	226.0 mg/dL
Ceruloplasmin	Ceruloplasmin	6.0 mg/dL	13.0 mg/dL	25.0 mg/dL	51.0 mg/dL	101.0 mg/dL
Haptoglobin	Haptoglobin	22.0 mg/dL	44.0 mg/dL	88.0 mg/dL	176.0 mg/dL	351.0 mg/dL
Transferrin	Transferrin	53.0 mg/dL	106.0 mg/dL	212.0 mg/dL	425.0 mg/dL	849.0 mg/dL
IgA	IgA	37.0 mg/dL	75.0 mg/dL	150.0 mg/dL	300.0 mg/dL	599.0 mg/dL
IgG	IgG	181.0 mg/dL	362.0 mg/dL	724.0 mg/dL	1,448.0 mg/dL	2,896.0 mg/dL
IgM	IgM	22.0 mg/dL	45.0 mg/dL	90.0 mg/dL	180.0 mg/dL	359.0 mg/dL
Complement C3	Komplement C3	27.0 mg/dL	55.0 mg/dL	109.0 mg/dL	218.0 mg/dL	436.0 mg/dL
Complement C4	Komplement C4	5.0 mg/dL	9.0 mg/dL	19.0 mg/dL	37.0 mg/dL	74.0 mg/dL
Antithrombin III	Antithrombin III	5.0 mg/dL	10.0 mg/dL	20.0 mg/dL	41.0 mg/dL	81.0 mg/dL
C1 Esterase Inhibitor **	C1 Esterase Inhibitor **	5.0 mg/dL	10.0 mg/dL	21.0 mg/dL	41.0 mg/dL	82.0 mg/dL
Kappa Light Chain **	Kappa Leichtkette **	45.0 mg/dL	89.0 mg/dL	178.0 mg/dL	357.0 mg/dL	713.0 mg/dL
Lambda Light Chain **	Lambda Leichtkette **	24.0 mg/dL	48.0 mg/dL	97.0 mg/dL	194.0 mg/dL	387.0 mg/dL
Prealbumin	Präalbumin	5.0 mg/dL	9.0 mg/dL	19.0 mg/dL	38.0 mg/dL	75.0 mg/dL

* Values are traceable to ERM-DA470k from IFCC. / * Werte auf ERM-DA470k des IFCC rückführbar.
 ** Values based on Siemens standard material. / ** Werte basieren auf Siemens Standardmaterial.



Calibrador de Proteína Série de 5 Níveis

Calibradores Líquidos de base humana para uso como calibrador em ensaios imunoturbidimétricos

REF

Cont.

A00704 5x 1 mL Calibrador de Proteína Série de 5 Níveis

COMPOSIÇÃO

O set de calibradores Dialab é baseado em plasma humano desfibrinado, líquido estabilizado e filtrado através de membrana de 0.2 µ.
 Azida sódica 0.095 %

PREPARAÇÃO

O set de calibradores de proteína é líquido, pronto para uso.

ESTABILIDADE E ARMAZENAMENTO

Armazenamento: 2 – 8 °C
 Estabilidade: até a data de validade
 Estabilidade após aberto: 6 semanas de 2 – 8 °C
 NÃO CONGELAR!

INSTRUÇÕES PARA USO

- Use esses calibradores da mesma maneira como especificado com o reagente e/ou equipamento a ser usado.
- Deixar os calibradores em equilíbrio com a temperatura ambiente (22 – 28 °C) antes de usar
- Os calibradores não pode ser deixado em temperatura ambiente por longos períodos de tempo (acima de 6 horas). Mantenha os frascos sempre fechados quando não estiver sendo utilizado para evitar contaminação microbiana. Manter os frascos refrigerados quando não estiverem em uso.

CUIDADOS E PRECAUÇÕES

- Para uso de diagnóstico in vitro
- Cada doação individual pretendida pra uso na fabricação do calibrador de proteínas foi testada para Antígeno de superfície da hepatite B (HBsAg), anti hepatite C (anti-HCV) e anti-HIV 1 e HIV 2 pelos testes requeridos pelo FDA. Nenhum método de teste pode assegurar que os produtos derivados de sangue humano não contenham HIV-1/2 e vírus da Hepatite B e Hepatite C, este material e todas as amostras de pacientes devem ser manuseadas como potencialmente capazes de transmitir doenças infecciosas.
- O reagente contém Azida sódica deve ser manipulado com cuidado: não ingerir, evite contato com a pele ou membranas da mucosa! Azida Sódica forma Azida de Cobre ou Chumbo o qual pode ocasionar explosões no encanamento do laboratório. Deixe fluir água em abundância após descartar produtos que contenham Azida Sódica.

GESTÃO DE RESÍDUOS

Atentar-se à legislação sobre descarte correto de resíduos de laboratório.

VALORES ATRIBUÍDOS

Valores e data de validade são lote específicas.

LOT: 320		EXP: 2017/10				
Parâmetro	PT	Valores Atribuídos *				
		Level 1	Level 2	Level 3	Level 4	Level 5
Albumina		745.0 mg/dL	1,491.0 mg/dL	2,981.0 mg/dL	5,963.0 mg/dL	11,925.0 mg/dL
α-1 Antitripsina		27.0 mg/dL	54.0 mg/dL	109.0 mg/dL	217.0 mg/dL	434.0 mg/dL
α-2 Macroglobulina		48.0 mg/dL	95.0 mg/dL	190.0 mg/dL	380.0 mg/dL	760.0 mg/dL
α-1 Glicoproteína Ácida		14.0 mg/dL	28.0 mg/dL	57.0 mg/dL	113.0 mg/dL	226.0 mg/dL
Ceruloplasmina		6.0 mg/dL	13.0 mg/dL	25.0 mg/dL	51.0 mg/dL	101.0 mg/dL
Haptoglobina		22.0 mg/dL	44.0 mg/dL	88.0 mg/dL	176.0 mg/dL	351.0 mg/dL
Transferrina		53.0 mg/dL	106.0 mg/dL	212.0 mg/dL	425.0 mg/dL	849.0 mg/dL
IgA		37.0 mg/dL	75.0 mg/dL	150.0 mg/dL	300.0 mg/dL	599.0 mg/dL
IgG		181.0 mg/dL	362.0 mg/dL	724.0 mg/dL	1,448.0 mg/dL	2,896.0 mg/dL
IgM		22.0 mg/dL	45.0 mg/dL	90.0 mg/dL	180.0 mg/dL	359.0 mg/dL
Complemento C3		27.0 mg/dL	55.0 mg/dL	109.0 mg/dL	218.0 mg/dL	436.0 mg/dL
Complemento C4		5.0 mg/dL	9.0 mg/dL	19.0 mg/dL	37.0 mg/dL	74.0 mg/dL
Antitrombina III		5.0 mg/dL	10.0 mg/dL	20.0 mg/dL	41.0 mg/dL	81.0 mg/dL
Inibidor C1 esterase **		5.0 mg/dL	10.0 mg/dL	21.0 mg/dL	41.0 mg/dL	82.0 mg/dL
Cadeia Leve Kappa **		45.0 mg/dL	89.0 mg/dL	178.0 mg/dL	357.0 mg/dL	713.0 mg/dL
Cadeia Leve Lambda **		24.0 mg/dL	48.0 mg/dL	97.0 mg/dL	194.0 mg/dL	387.0 mg/dL
Pré Albumina		5.0 mg/dL	9.0 mg/dL	19.0 mg/dL	38.0 mg/dL	75.0 mg/dL

* Os valores são atribuídos do ERM-DA470k de IFCC.
 ** Valores atribuídos do material padrão da Dade Behring.

