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## DC-CAL

### Human Based Serum Calibrator For Clinical Chemistry Assays

CATALOGUE NUMBER: SE-035

SIZE: 5 x 3 mL

#### INTENDED USE

For in vitro diagnostic use as a calibrator in clinical chemistry assays.

#### CHARACTERISTICS

The DC-Cal is a human based, lyophilized serum. The concentrations and activities of the analytes are optimized for the calibration of clinical chemistry systems using DCL methodologies.

#### INSTRUCTIONS FOR USE

DC-Cal is provided as a lyophilized product and is reconstituted with the diluent provided.

1. Tap calibrator serum vial lightly to dislodge lyophilized material.
2. Pipette exactly 3.0 mL of the diluent into the vial of lyophilized material.
3. Replace the stopper. Allow 30 minutes for reconstitution. Swirl gently several times during the reconstitution period and mix by inversion prior to use. Make sure no residual material remains on the bottom of the vial.

#### STABILITY AND STORAGE

The unreconstituted DC-Cal is stable until the expiry date stated on the vial label at 2-8°C.

When reconstituted with the diluent provided, the DC-Cal is stable for 72 hours at 2-8°C, with the following exceptions: Direct Bilirubin should be performed within 8 hours. Assays for Alkaline Phosphatase, Total Bilirubin, and Creatine Kinase should be performed within 24 hours.

#### PRECAUTIONS

Human serum was used in the manufacture of this product. Each donor unit used in the preparation of this product has been tested and found nonreactive for Hepatitis B surface antigen (HBsAg) and HIV antibody. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all human based blood products and patient samples are considered potentially hazardous and should be handled in accordance with good laboratory practices.

## DC-CAL

### Calibrateur à base de sérum humain pour les analyses chimiques cliniques

NUMÉRO DE CATALOGUE: SE-035

FORMAT: 5 x 3 mL

#### USAGE DESTINÉ

Pour le diagnostic in vitro. Le DC-CAL sert de calibrateur dans les analyses de chimie clinique.

#### CARACTÉRISTIQUES

Le DC-Cal est un produit lyophilisé à base de sérum humain. Les concentrations et l'activité des analyses ont été optimisées pour l'étalonnage des systèmes de chimie clinique qui font appel aux méthodologies de DCL.

#### MODE D'EMPLOI

Le DC-Cal est un produit lyophilisé qu'il faut reconstituer avec le diluent fourni.

1. Frapper doucement l'éprouvette de sérum d'étalonnage pour décoller le produit lyophilisé.
2. Pipetter exactement 3 mL de diluent dans l'éprouvette de produit lyophilisé.
3. Remettre le bouchon. Attendre 30 minutes pour la reconstitution. Tourner doucement plusieurs fois pendant la période de reconstitution et mélanger par inversion avant l'utilisation. Il faut s'assurer qu'il ne reste aucun résidu dans le fond de l'éprouvette.

#### STABILITÉ ET CONSERVATION

Le DC-Cal non reconstitué est stable jusqu'à la date de péremption indiquée sur l'étiquette à 2-8°C.

Lorsqu'il a été reconstitué avec le diluent fourni, le DC-Cal est stable pendant 72 heures à 2-8°C sauf pour les applications suivantes : le dosage de la bilirubine directe doit être fait dans les 8 heures et ceux de la phosphatase alcaline, de la bilirubine totale et de la créatine-kinase doivent être faits dans les 24 heures.

#### PRÉCAUTIONS

On a utilisé du sérum humain pour fabriquer ce produit. Toutes les unités dont on s'est servi pour la préparation de ce produit ont été testées pour les antigènes d'enveloppe de l'hépatite B (HBsAg) et pour les anticorps anti-VIH et elles ont donné des résultats négatifs. Aucune méthode d'analyse connue ne permet de garantir que les produits dérivés du sang humain ne transmettront pas d'agent d'infection. Il faut donc traiter tous les produits sanguins et tous les échantillons provenant de patients comme étant potentiellement infectieux et les manipuler selon de bonnes pratiques de laboratoire.

ESPAÑOL

## DC-CAL

### Calibrador de Suero Humano para Ensayos de Química Clínica

NÚMERO DE CATÁLOGO: SE-035

TAMAÑO: 5 x 3 mL

#### USO

Para uso de diagnóstico IN VITRO como un calibrador para ensayos de química clínica.

#### CARACTERISTICAS

El DC-Cal es un suero humano liofilizado. Las concentraciones y actividades de los analitos se optimizan para la calibración de sistemas de química clínica al utilizar los métodos de DCL.

#### INSTRUCCIONES PARA SU USO

Se proporcionan el DC-Cal como un producto liofilizado, y un diluyente para su reconstitución.

1. Dé golpecitos ligeros al vial del suero del calibrador para que salga el material liofilizado.
2. Pipetee exactamente 3.0 mL del diluyente en el vial del material liofilizado.
3. Reemplace el tapón. Deje pasar 30 minutos para la reconstitución. Durante el periodo de reconstitución, revuelva varias veces, con movimientos giratorios suaves, y mezcle de arriba hacia abajo y viceversa antes de usarlo. Asegúrese que no queden residuos en el fondo del vial.

#### ESTABILIDAD Y ALMACENAMIENTO

El DC-Cal no reconstituído será estable hasta la fecha de caducidad indicada en la etiqueta del vial cuando se mantenga a una temperatura de 2-8°C.

El DC-Cal será estable por 72 horas cuando se mantenga a una temperatura de 2-8°C si se reconstituye con el diluyente proporcionado. Existen las siguientes excepciones: el calibrador deberá usarse dentro de un período de 8 horas con el ensayo de la Bilirubina Directa, y dentro de un período de 24 horas con los ensayos de Alcalina Fosfatasa, Bilirubina Total y de Creatina Kinasa.

#### PRECAUCIONES

Se utilizó suero humano en la fabricación de este producto. Se probó cada unidad de suero donado utilizada en la preparación de este producto habiéndose encontrado que no reaccionó al antígeno de superficie de la Hepatitis B (HBsAg) ni al anticuerpo del HIV. Ningún método de prueba puede asegurar en absoluto que los productos derivados de la sangre humana no vayan a transmitir agentes infecciosos. Por lo tanto, todos los productos a base de sangre humana y las muestras de pacientes se consideran como un peligro potencial, por lo que deben manejarse de acuerdo a métodos de laboratorio adecuados.

**BECKMAN COULTER SYNCHRON® SYSTEMS**

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Albumin	200-05/45	3.6 g/dL	36 g/L
Bilirubin (Direct) Blanked	202-S7	2.00 mg/dL	34.2 µmol/L
Bilirubin (Total) Blanked	202-04, 204-S7	3.9 mg/dL	67 µmol/L
Bilirubin (Direct) Blanked	247-10/30/50A/50B	2.30 mg/dL	39.3 µmol/L
Bilirubin (Total) Blanked	243-10/30 284-10/30/50A/50B	4.0 mg/dL	68 µmol/L
Calcium	140-20/24	9.7 mg/dL	2.42 mmol/L
Carbon Dioxide	288-30/36/80	25 mEq/L	25 mmol/L
	299-30/17/50/80	25 mEq/L	25 mmol/L
Cholesterol <sup>(1)</sup>	225-26/28/S7	181 mg/dL	4.68 mmol/L
	234-60	178 mg/dL	4.60 mmol/L
Creatinine	221-30/50	4.0 mg/dL	354 µmol/L
Glucose	235-60/17	168 mg/dL	9.3 mmol/L
Serum Iron	102-15/25	155 µg/dL	27.8 µmol/L
	150-26E/F	215 µg/dL	38.5 µmol/L
	157-10/30	229 µg/dL	41.0 µmol/L
Magnesium	125-12/50	2.7 mg/dL	1.11 mmol/L
Phosphorus	117-10/30	5.0 mg/dL	1.61 mmol/L
Total Protein	200-55/70	5.7 g/dL	57 g/L
Triglyceride <sup>(2)</sup>	236-60/17	190 mg/dL	2.15 mmol/L
Triglyceride <sup>(3)</sup>	236-60/17	190 mg/dL	2.15 mmol/L
Urea (BUN)	275-06/11/13, 283-17/30	48 mg/dL	17.1 mmol/L
Uric Acid	237-60	6.1 mg/dL	363 µmol/L

1. Cholesterol values agree with Abell-Kendall reference method values (using fresh patient samples) recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
2. Triglyceride calibration value agrees with the chloroform/silicic acid reference method values recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
3. Triglyceride value is referenced to NIST Standard Reference Material. Recommended for customers subscribing to CQAP-Online, CAP, and MLE surveys.

SYNCHRON is a registered trademark of Beckman Coulter, Inc.

**BAYER DIAGNOSTICS EXPRESS® SYSTEMS**

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Albumin	200-05/45	3.7 g/dL	37 g/L
Bilirubin (Direct) Blanked	202-S7	3.40 mg/dL	58.1 µmol/L
Bilirubin (Total) Unblanked	202-04, 204-S7	5.1 mg/dL	87 µmol/L
Bilirubin (Total) Blanked	243-10/30	4.2 mg/dL	72 µmol/L
	284-10/30/50A/50B	4.1 mg/dL	70 µmol/L
Calcium	140-20/24	9.7 mg/dL	2.42 mmol/L
Carbon Dioxide	214-10	25 mEq/L	25 mmol/L
	299-30/17/50/80	25 mEq/L	25 mmol/L
Chloride	152-S7	109 mEq/L	109 mmol/L
Cholesterol <sup>(1)</sup>	206-15/50	196 mg/dL	5.07 mmol/L
	225-26/28/S7	192 mg/dL	4.97 mmol/L
	234-60	182 mg/dL	4.71 mmol/L
Creatinine	221-30/50	4.1 mg/dL	362 µmol/L
Glucose	201-38	165 mg/dL	9.2 mmol/L
	220-32, 223-50	156 mg/dL	8.7 mmol/L
	235-60/17	162 mg/dL	9.0 mmol/L
Serum Iron	102-15/25	190 µg/dL	34.0 µmol/L
	157-10/30	230 µg/dL	41.2 µmol/L
Magnesium	125-12/50	2.9 mg/dL	1.19 mmol/L
Phosphorus	115-S7	5.1 mg/dL	1.65 mmol/L
	117-10/30	5.4 mg/dL	1.74 mmol/L
Total Protein	200-55/70	6.2 g/dL	62 g/L
Triglyceride <sup>(2)</sup>	210-75	201 mg/dL	2.27 mmol/L
Triglyceride <sup>(3)</sup>	210-75	206 mg/dL	2.33 mmol/L
	218-15	206 mg/dL	2.33 mmol/L
Triglyceride <sup>(2)</sup>	236-60/17	187 mg/dL	2.11 mmol/L
Triglyceride <sup>(3)</sup>	236-60/17	192 mg/dL	2.17 mmol/L
Urea (BUN)	275-06/11/13 283-17/30	48 mg/dL	17.1 mmol/L
Uric Acid	220-94/S4	5.7 mg/dL	339 µmol/L
Uric Acid	237-60	5.8 mg/dL	345 µmol/L

1. Cholesterol values agree with Abell-Kendall reference method values (using fresh patient samples) recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
2. Triglyceride calibration value agrees with the chloroform/silicic acid reference method values recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
3. Triglyceride value referenced to NIST Standard Reference Material. Recommended for customers subscribing to CQAP-Online, CAP, and MLE surveys.

Express is a registered trademark of Bayer Diagnostics.

**COBAS MIRA® AND MIRA-S® SYSTEMS**

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Albumin	200-05/45	3.7 g/dL	37 g/L
Bilirubin (Direct) Unblanked	202-S7	3.20 mg/dL	54.7 µmol/L
Bilirubin (Total) Unblanked	202-04, 204-S7	4.7 mg/dL	80 µmol/L
Bilirubin (Direct) Blanked	247-10/30/50A/50B	2.60 mg/dL	44.5 µmol/L
Bilirubin (Total) Blanked	243-10/30	3.8 mg/dL	65 µmol/L
	284-10/30/50A/50B	3.8 mg/dL	65 µmol/L
Calcium	140-20/24	9.5 mg/dL	2.37 mmol/L
Carbon Dioxide	214-10	25 mEq/L	25 mmol/L
	299-30/17/50/80	25 mEq/L	25 mmol/L
Chloride	152-S7	109 mEq/L	109 mmol/L
Cholesterol <sup>(1)</sup>	206-15/50	168 mg/dL	4.34 mmol/L
	225-26/28/S7	174 mg/dL	4.50 mmol/L
	234-60	172 mg/dL	4.45 mmol/L
Creatinine	221-30/50	4.0 mg/dL	354 µmol/L
Glucose	201-38	179 mg/dL	9.9 mmol/L
	220-32, 223-50	162 mg/dL	9.0 mmol/L
	235-60/17	159 mg/dL	8.8 mmol/L
Serum Iron	150-26	225 µg/dL	40.3 µmol/L
	157-10/30	213 µg/dL	38.1 µmol/L
Magnesium	125-12/50	2.7 mg/dL	1.11 mmol/L
Phosphorus	115-S7	6.1 mg/dL	1.97 mmol/L
	117-10/30	5.3 mg/dL	1.71 mmol/L
Total Protein	200-55/70	6.2 g/dL	62 g/L
Triglyceride <sup>(2)</sup>	210-75	189 mg/dL	2.13 mmol/L
Triglyceride <sup>(3)</sup>	210-75	189 mg/dL	2.13 mmol/L
	218-15	189 mg/dL	2.13 mmol/L
Triglyceride <sup>(2)</sup>	236-60/17	172 mg/dL	1.94 mmol/L
Triglyceride <sup>(3)</sup>	236-60/17	175 mg/dL	1.98 mmol/L
Urea (BUN)	275-06/11/13 283-30/17	48 mg/dL	17.1 mmol/L
Uric Acid	220-94/S4	5.4 mg/dL	321 µmol/L
Uric Acid	237-60	5.4 mg/dL	321 µmol/L

1. Cholesterol values agree with Abell-Kendall reference method values (using fresh patient samples) recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
2. Triglyceride calibration value agrees with the chloroform/silicic acid reference method values recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
3. Triglyceride value is referenced to NIST Standard Reference Material. Recommended for customers subscribing to CQAP-Online, CAP, and MLE surveys.

Mira is a registered trademark of Roche Diagnostics.

**HITACHI® SYSTEMS**

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Albumin	200-05/45	3.7 g/dL	37 g/L
Bilirubin (Direct) Blanked	247-10/30/50A/50B	2.60 mg/dL	44.5 µmol/L
Bilirubin (Total) Blanked	<del>284-10/30/50A/50B</del> 243-10/30	3.9 mg/dL	67 µmol/L
Calcium	140-20/24	9.9 mg/dL	2.47 mmol/L
Carbon Dioxide	299-30/17/50/80	25 mEq/L	25 mmol/L
	288-30/36/80	25 mEq/L	25 mmol/L
Chloride	152-S7	110 mEq/L	110 mmol/L
Cholesterol <sup>(1)</sup>	225-26/28/S7	182 mg/dL	4.71 mmol/L
	234-60	180 mg/dL	4.65 mmol/L
Creatinine	221-30/50	3.9 mg/dL	345 µmol/L
Glucose	235-60/17	166 mg/dL	9.2 mmol/L
Serum Iron	102-15/25	197 µg/dL	35.3 µmol/L
	150-26E/F	233 µg/dL	41.7 µmol/L
	157-10/30	223 µg/dL	39.9 µmol/L
Magnesium	125-12/50	2.8 mg/dL	1.15 mmol/L
Phosphorus	117-10/30	5.3 mg/dL	1.71 mmol/L
Total Protein	200-55/70	6.0 g/dL	60 g/L
Triglyceride <sup>(2)</sup>	236-60/17	192 mg/dL	2.17 mmol/L
Triglyceride <sup>(3)</sup>	236-60/17	192 mg/dL	2.17 mmol/L
Urea (BUN)	275-06/11/13	48 mg/dL	17.1 mmol/L
	283-30/17	49 mg/dL	17.5 mmol/L
Uric Acid	220-94/S4	6.0 mg/dL	357 µmol/L
	237-60	6.1 mg/dL	363 µmol/L

**ENZYMES**

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Alkaline Phosphatase	328-10/30	218 U/L	218 U/L
ALT	318-10/30/50A/50B	140 U/L	140 U/L
	343-25	140 U/L	140 U/L
Amylase	321-07	528 U/L	528 U/L
	341-10/40	502 U/L	502 U/L
AST	319-10/30/50A/50B	116 U/L	116 U/L
Creatine Kinase	310-40/42/46/56	272 U/L	272 U/L
	326-10/30	313 U/L	313 U/L
GGT	324-10/50A/50B	91 U/L	91 U/L
LDH	327-10/30	227 U/L	227 U/L

1. Cholesterol values agree with Abell-Kendall reference method values (using fresh patient samples) recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
2. Triglyceride calibration value agrees with the chloroform/silicic acid reference method values recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
3. Triglyceride value is referenced to a NIST Standard Reference Material. Recommended for customers subscribing to CQAP-Online, CAP, and MLE surveys.

Hitachi is a registered trademark of Roche Diagnostics.

**ALL INSTRUMENT MEAN**

All instrument mean values have been calculated for those products that are value assigned on all analyzers represented in this insert.

CONSTITUENT	DCL METHOD CAT. NO.	CALIBRATION VALUE	
		CONVENTIONAL UNITS	SI UNITS
Albumin	200-05/45	3.7 g/dL	37 g/L
Bilirubin (Direct) Blanked	247-10/30/50A/50B	2.50 mg/dL	42.8 µmol/L
Bilirubin (Total) Blanked	<sup>243-10/30</sup> 284-10/30/50A/50B	4.0 mg/dL	68 µmol/L
Calcium	140-20/24	9.7 mg/dL	2.42 mmol/L
Carbon Dioxide	299-30/17/50/80	25 mEq/L	25 mmol/L
Chloride	152-S7	109 mEq/L	109 mmol/L
Cholesterol <sup>(1)</sup>	234-60	178 mg/dL	4.60 mmol/L
Creatinine	221-30/50	4.0 mg/dL	354 µmol/L
Glucose	235-60/17	164 mg/dL	9.1 mmol/L
Serum Iron	157-10/30	224 µg/dL	40.1 µmol/L
Magnesium	125-12/50	2.8 mg/dL	1.15 mmol/L
Phosphorus	117-10/30	5.3 mg/dL	1.71 mmol/L
Total Protein	200-55/70	6.0 g/dL	60 g/L
Triglyceride <sup>(2)</sup>	236-60/17	185 mg/dL	2.09 mmol/L
Triglyceride <sup>(3)</sup>	236-60/17	187 mg/dL	2.11 mmol/L
Urea (BUN)	283-30/17	48 mg/dL	17.1 mmol/L
Uric Acid	237-60	5.9 mg/dL	351 µmol/L

1. Cholesterol values agree with Abell-Kendall reference method values (using fresh patient samples) recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
2. Triglyceride calibration value agrees with the chloroform/silicic acid reference method values recommended by the Centers For Disease Control (CDC) and the Canadian External Quality Assessment Laboratory.
3. Triglyceride value is referenced to a NIST Standard Reference Material. Recommended for customers subscribing to CQAP-Online, CAP, and MLE surveys.

INSE035-23J  
January 16, 2006