

ФОТО

Реагенты in-vitro диагностические для гематологического анализатора DxH 500 (см. Приложение)

Приложение:

1. Дилуэнт DxH 500 (DxH 500 Diluent)
2. Лизирующий реагент DxH 500 (DxH 500 Lyse)
3. Очиститель DxH 500 (DxH 500 Cleaner)
4. Контроль DxH 500 (DxH 500 CONTROL)
5. Калибратор DxH 500 (DxH 500 CALIBRATOR).

IVD

REF B36845

10 L

REACTIVE INGREDIENTS/ 成分:

Sodium Salts/ ナトリウム塩 < 15 g/L

Stabilizers/ 安定剤 < 1 g/L

CE

May produce an allergic reaction.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one
[EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one
[EC# 220-239-6](3:1) < 0.0015%



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー



Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Printed in Germany
Made in Germany
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DxH 500 Diluent

Rx Only

REF B36845

For use as an isotonic buffered diluent used in conjunction with a DxH 500 Lyse reagent for counting and sizing blood cells on the DxH 500 Series hematology analyzers. Use with only DxH 500 Lyse reagent./ Para su uso como un diluyente tamponado con solución isotónica en combinación con un reactivo DxH 500 Lyse para el recuento y la determinación del tamaño de células sanguíneas en los analizadores hematológicos de la serie DxH 500. Uso únicamente con el reactivo DxH 500 Lyse./ DxH 500 Serisi hematoloji analizörlerindeki kan hücrelerinin sayımı ve boyutlandırılması için DxH 500 Lyse reaktifi ile birlikte izotonik tamponlu bir dilüent olarak kullanılır. Sadece DxH 500 Lyse reaktifıyla kullanın.



The label contains the following information:

- Top left: QR code
- Top right: QR code
- Top right edge: B36844-AA
- Center: B36844-AA
- Bottom left: QR code
- Bottom left: REF B36845
- Bottom left: C: 0391
- Bottom left: V: a8fcf
- Bottom left: LOT 0008170
- Bottom left: 2017-01-20
- Bottom center: A55156-AA
- Bottom right: Two vertical barcodes with codes +H628B368451Q and +\$\$\$1701200008170Q3 B36844-AA

DxH 500 Diluent

REF B36845

DxH 500 Diluent

SDS



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COULTER**

IVD

Rx Only

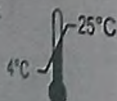
REF: B36A46

Enzyme kit agent for quantitative determination of hemoglobin, and the counting, sizing, and optical measurement of leukocytes on DxH 500 Systems. Use only with DxH 500 Diluent and DxH 500 Cleaner / Agente limpiador DxH 500.

Agente limpiador para la determinación cuantitativa de la hemoglobina y para el recuento, la determinación del tamaño y la medición óptica de los leucocitos en los sistemas DxH 500. Utilizar únicamente con el diluyente DxH 500 y el agente limpiador DxH 500. Hemoglobina kanlıları için enzim kit parçalaması maddesi ve Eksoygenim DxH 500 Sistemleri için boyutlandırılması ve optik ölçümü. Sadece DxH 500 Diluent ve 500 Temizleyiciyle kullanın.



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REACTIVE INGREDIENTS/ 成分

Detergents/ 洗剤: 0.8 - 2.0 g/L

Saponin/ サポニン: 0.1 - 2.0 g/L

Other Detergents/ 他の洗剤: 0.1 - 2.0 g/L

Quaternary Ammonium Salts/ 第四級アンモニウム塩

May produce an allergic reaction

Glutaraldehyde < 0.1%

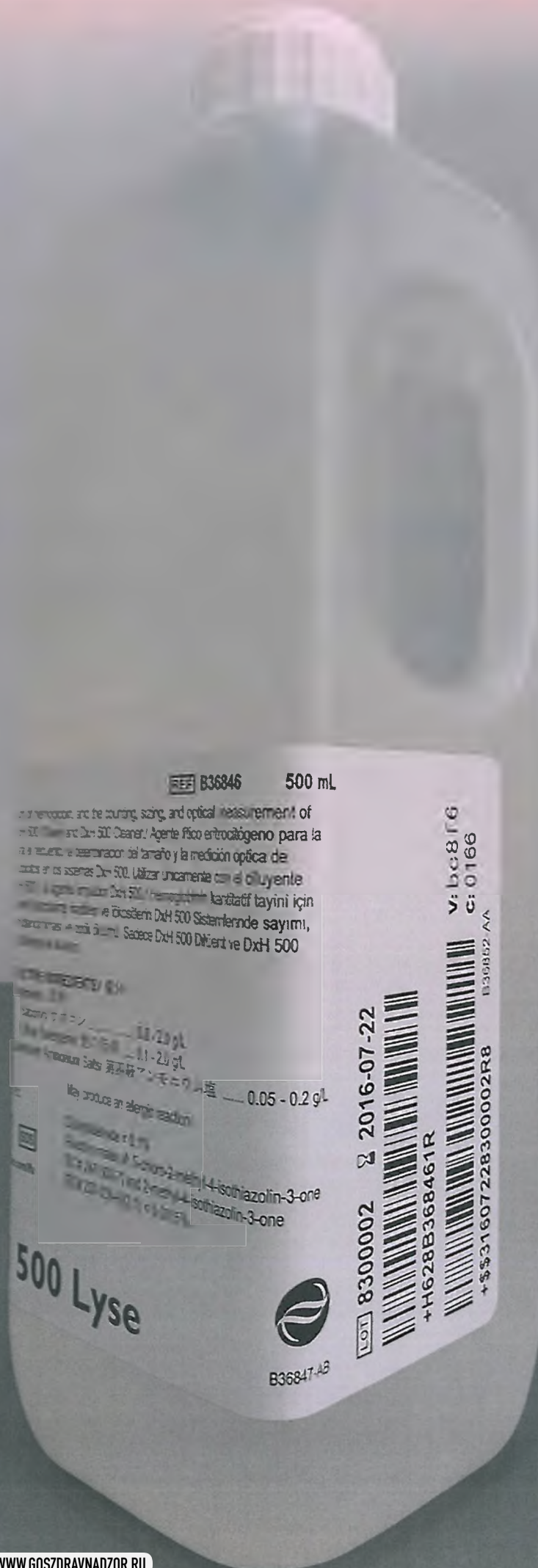
Reaction mass of 5-chloro-2-methyl-4-isothiazol-3-one

[EC# 247-500-7] and 2-methyl-4-isothiazol-3-one

[EC# 220-239-5] (3:1) < 0.0015%



DxH 500 Lyse



B36846 500 mL

for verococci and the counting, sizing, and optical measurement of
- 500 Lyse and 500 Cleaner. Agente físico-entrocitogénico para la
de la muestra y el contador del tamaño y la medición óptica de
estas en los aseros Dx-500. Utilizar únicamente con el diluyente
- 500 Lyse y 500 Cleaner. Agente físico-entrocitogénico para la
de la muestra y el contador del tamaño y la medición óptica de
estas en los aseros Dx-500. Utilizar únicamente con el diluyente

500 Lyse

500 Lyse 11.23 g/L

500 Lyse 11.23 g/L

May produce an allergic reaction

Contains 4-isothiazolin-3-one

Contains 4-isothiazolin-3-one

500 Lyse

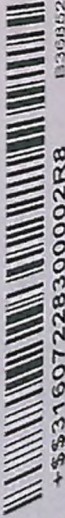


B36847-48

LOT 8300002 2016-07-22



+H628B368461R



+\$316072283000002R8

v: bc8 f6

c: 0166

B36846 AA

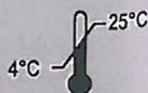
IVD

Rx Only

Erythrocyte lytic agent for quantitative determination of leukocytes on DxH 500 Systems. Use only with
determinación cuantitativa de la hemoglobina



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Co. Clare, Ireland



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DxH

[REF] B36846

...ation of hemoglobin, and the counting, sizing, and optical measurement of
... DxH 500 Diluent and DxH 500 Cleaner./ Agente lítico eritrocitógeno para
... y para el recuento, la determinación del tamaño y la medición óptica de
... leucocitos en los sistemas DxH 500. Utilizar únicamente con el diluyente
... DxH 500 y el agente limpiador DxH 500./ Hemoglobinin kantitatif tayarı
... eritrosit parçalama maddesi ve lökositlerin DxH 500 Sistemlerinde sayma
... boyutlandırılması ve optik ölçümü. Sadece DxH 500 Dilüent ve DxH 500
... Temizleyiciyle kullanın.

REACTIVE INGREDIENTS/ 成分:

Detergents/ 洗剤:

Saponin/ サポニン 0.8 - 2.0 g/L

Other Detergents/ 他の洗剤 0.1 - 2.0 g/L

Quaternary Ammonium Salts/ 第四級アンモニウム塩 0.05 - 1.0 g/L

May produce an allergic reaction.

Glutaraldehyde < 0.1%

Reaction mass of: 5-chloro-2-methyl-4-isothiazolone
[EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one
[EC# 220-239-6](3:1) < 0.0015%



SDS

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H 500 Lyse

REF 836868

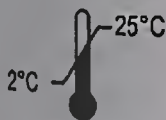
DxH 500 Systems for components that come in contact with blood samples / Usar en los sistemas DxH 500, para los componentes que están en contacto con las muestras de sangre / Kan örnekleriyle temas halindeki komponentlerde kullanım için temizleme maddesi

REACTIVE INGREDIENTS: A solution of a proteolytic enzyme
成分: 蛋白質分解酵素溶液



DANGER

May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties
Avoid breathing vapours.
Wear protective gloves, protective clothing and eye face protection
In case of inadequate ventilation, wear respiratory protection
IF INHALED: Remove person to fresh air and keep at rest until comfortable for breathing.
If skin irritation or rash occurs: Get medical advice/attention
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.



ベクマン・コールター株式会社
東京都三丁目5番7号
ミッドスター



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Subtilisin 0.1 - 0.5%
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 220-239-8] (3:1) and 2-methyl-4-isothiazolin-3-one [EC# 220-239-8] (1:1)

DxH 500 Cleaner

REF B36868

500 mL

Do not contact with blood samples. / Un agente de
no entrar en contacto con las muestras de sangre. /
Bakteriell temizleme maddesi.

It is a solution of a proteolytic enzyme /
Bakteriyel



It causes skin reaction.

It causes asthma symptoms or breathing difficulties if inhaled.

Precautions:

Wear gloves, protective clothing and eye/face protection.

In case of ventilation, wear respiratory protection.

Remove person to fresh air and keep at rest in a position

resting.

If an allergic reaction occurs: Get medical advice/attention.

In case of respiratory symptoms: Call a POISON CENTER or

toxicologist.

2-methyl-4-isothiazolin-3-one [EC# 247-500-7]
2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) < 0.05%

Cleaner

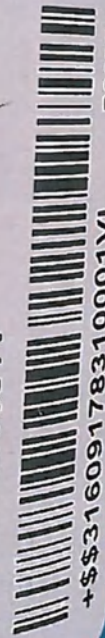


B36869-AB

LOT 8310001 2016-09-17



+H628B368681V



V: c0af3

C: 1609

B36852-AA

+\$31609178310001VI



Rx Only

A cleaning agent for use on DxH 500 Systems for components that come in contact with blood.
para utilizar en los sistemas DxH 500, para los componentes que están en contacto con la sangre.
DxH 500 Sistemlerinde kan örnekleriyle temas halindeki komponentlerde kullanılmak üzere tasarlanmıştır.



Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland



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Made in USA
Beckman Coulter, Inc.



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REACTIVE INGREDIENTS: A solution of 1% Subtilisin and 0.1% 2-methyl-4-isothiazolin-3-one.
成分：蛋白質分解酵素溶液

DANGER

May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Avoid breathing vapours.
Wear protective gloves, protective clothing and eye protection.
In case of inadequate ventilation, wear respiratory protection.
IF INHALED: Remove person to fresh air. If not comfortable for breathing, seek medical attention.
If skin irritation or rash occurs: Get medical attention.
If experiencing respiratory symptoms: Seek medical attention from a doctor/physician.

Subtilisin 0.1 - 0.5%
Reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one



DxH 500 Clean



CE

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B36871-AA



...control designed to monitor values on multi parameter
...Please refer to the assay table for specific instrument models. / El control
...señala antes de analizar y diseñado para controlar los valores en
...de varios parámetros. Consulte la tabla de análisis para obtener
...de instrumentos específicos. / DxH 500 Kontrol, hematoloji hücre
...parametre değerlerini takip etmek için tasarlanan test edilmiş tam kan
...test modelleri için lütfen test tablosuna bakın.

...Folheto ilustrativo/ Gebrauchsinformation/ Prospecto/ Folhetos informativos/
...Příloha/ Příloha/ Příloha/ Příloha/ Příloha/ Příloha/ Příloha/ Příloha/
...Ambalaj/ Prospektus/ Pakkevedlegg/ 添付文書

...成分:

...安定化ト血液

...biologically sourced material.
...Human, Swine and Porcine



WARNING
H315, H316, H319
Potassium Hydroxide < 1%

DxH 500 Control

DxH 500 Control

IVD

Rx Only

Contents:

- 2 x 2.3 mL ABNORMAL LOW
- 2 x 2.3 mL NORMAL
- 2 x 2.3 mL ABNORMAL HIGH

DxH 500 Control is an assayed whole blood control designed to monitor values on multi parameter hematology cell counters. Please refer to the assay table for specific instrument models./ El control DxH 500 es un control de sangre entera analizado y diseñado para controlar los valores en contadores celulares hematológicos de varios parámetros. Consulte la tabla de análisis para obtener información sobre modelos de instrumentos específicos./ DxH 500 Kontrol, hematoloji hücre sayacılarındaki çoklu parametre değerlerini takip etmek için tasarlanan test edilmiş tam kan kontrolüdür. Spesifik cihaz modelleri için lütfen test tablosuna bakın.

Pachaga Instrukcja/ Follato illustrativo/ Gebrauchsinformation/ Prospecto/ Folhetos informativos/ Prospektus/ Příložená informace/ Pakuotės įdėklas/ Ulotka w opakowaniu/ Проложене інформації в упаковці/ Ambalaj Prospektüsü/ Pakkevedlegg/ 附件文書

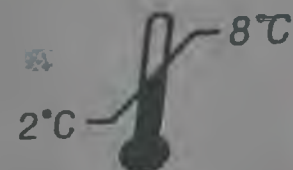
Residual Ingredients: 10.5% :

Sodium Chloride 0.9% : 0.9%

Potassium Hydroxide 0.5% : 0.5%



WARNING
H315, H316, H319
Potassium Hydroxide < 1%



IVD

Rx Only

Contents:

2 x 2.3 mL ABNORMAL LOW

2 x 2.3 mL NORMAL

2 x 2.3 mL ABNORMAL HIGH

DxH 500 Control is an assayed whole blood control designed to monitor values on multi parameter hematology cell counters. Please refer to the assay table for specific instrument models./ El control DxH 500 es un control de sangre entera analizado y diseñado para controlar los valores en contadores celulares hematológicos de varios parámetros. Consulte la tabla de análisis para obtener información sobre modelos de instrumentos específicos./ DxH 500 Kontrol, hematoloji hücre sayacılarındaki çoklu parametre değerlerini takip etmek için tasarlanan test edilmiş tam kan kontrolüdür. Spesifik cihaz modelleri için lütfen test tablosuna bakın.

Package Insert/ Notice/ Foglietto illustrativo/ Gebrauchsinformation/ Prospecto/ Folhetos informativos/ Pakkeindlæg/ Bipacksedel/ Příložené informace/ Pakuotės įdėklas/ Ulotka w opakowaniu/ Листок-вкладыш в упаковке/ Ambalaj Prospektüsü/ Pakkevedlegg/ 添付文書

Reactive Ingredients:/ 成分 :

Stabilized Human Blood/ 安定ヒト血液

Product contains biologically sourced material:
Human, Bovine and Porcine



WARNING

H315, H316, H319

Potassium Hydroxide < 1%

DxH 500 Control

REF B36872



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LOT

160751

(01)15099590671884

(17)160605

(10)160751



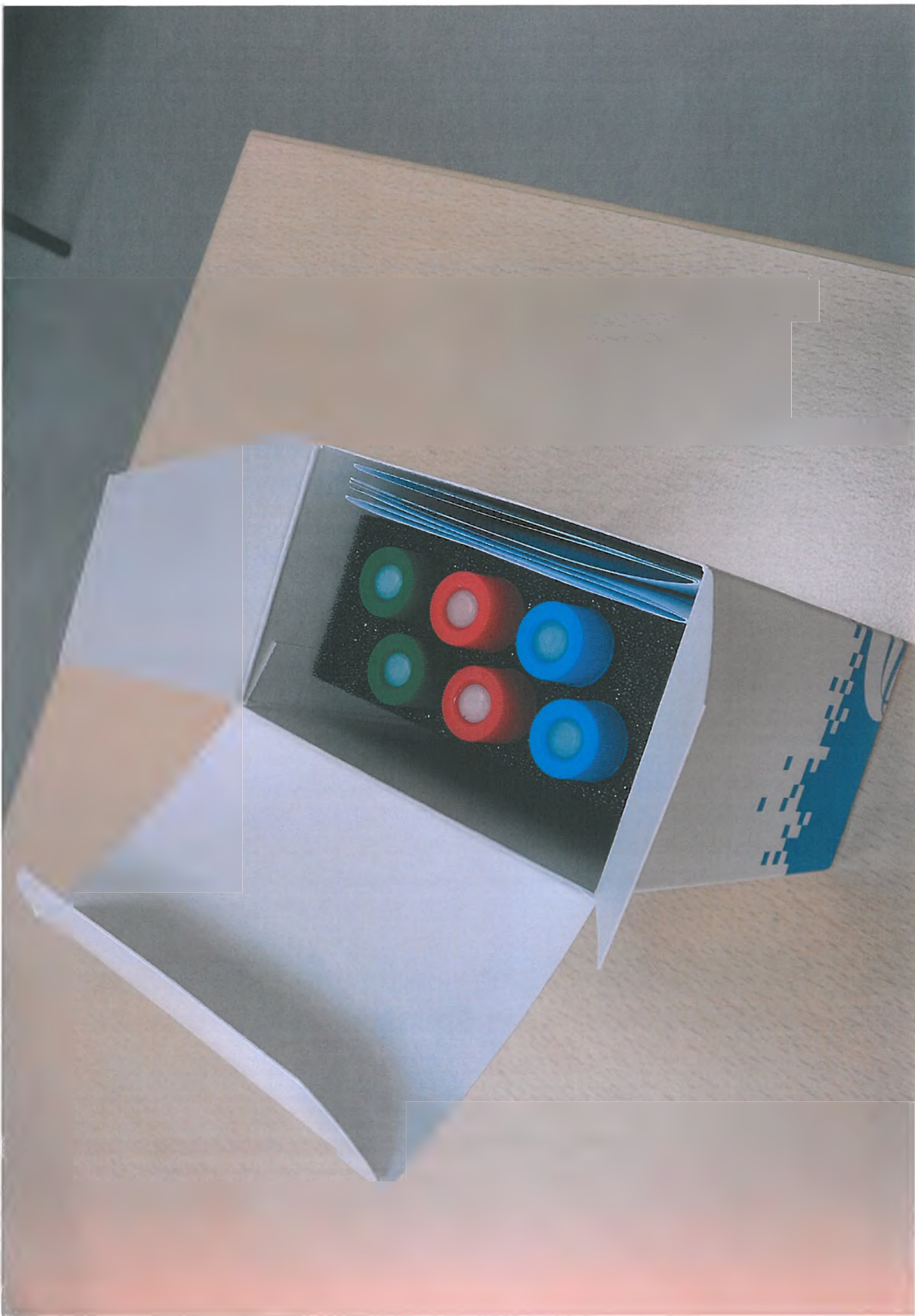
2016-06-05



+H628B368721Q



+\$3160605160751QE



12



Rx Only

Contents:

2 x 2.3 mL ABNORMAL LOW
2 x 2.3 mL NORMAL
2 x 2.3 mL ABNORMAL HIGH

DxH 500 Control is an assayed whole blood control designed to monitor values on multi-parameter hematology cell counters. Please refer to the assay table for specific instrument models. El control DxH 500 es un control de sangre entera analizado y diseñado para controlar los valores en contadores celulares hematológicos de varios parámetros. Consulte la tabla de análisis para obtener información sobre modelos de instrumentos específicos. DxH 500 Kontrol, hematoloji hücre sayacılarındaki çoklu parametre değerlerini takip etmek için tasarlanan test edimsiz lam kan kontrolüdür. Spesifik cihaz modelleri için lütfen test tablosuna bakın.

Package Insert/ Notice/ Foglietto illustrativo/ Gebrauchsinformation/ Prospekt/ Folhetos informativos/ Pakkeindlæg/ Bipskedel/ Příložená informace/ Pakuotės įdėjimas/ Ulotka w opakowaniu/ Листок-вкладыш в упаковке/ Ambalaj Prospektüsü/ Pakkevedlegg/ 添付文書

Reactive Ingredients: / 成分:
Stabilized Human Blood/ 安定ヒト血液

Product contains biologically sourced material:
Human, Bovine and Porcine



WARNING
H315, H316, H319
Potassium Hydroxide < 1%

DxH 500 Control

Table of Expected Results									
Abnormal Low					Normal				
LOT 351607511					LOT 361607512				
2016-06-05					2016-06-05				
DxH 500 Systems					DxH 500 Systems				
14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days	14 Open Vial Days
Unit	Unit	Unit	Unit	Unit	Unit	Unit	Unit	Unit	Unit
WBC	WBC	WBC	WBC	WBC	WBC	WBC	WBC	WBC	WBC
10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L
4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
RDW	RDW	RDW	RDW	RDW	RDW	RDW	RDW	RDW	RDW
%	%	%	%	%	%	%	%	%	%
11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5
PLT	PLT	PLT	PLT	PLT	PLT	PLT	PLT	PLT	PLT
10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L
150	150	150	150	150	150	150	150	150	150
MPV	MPV	MPV	MPV	MPV	MPV	MPV	MPV	MPV	MPV
fL	fL	fL	fL	fL	fL	fL	fL	fL	fL
9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
PCT	PCT	PCT	PCT	PCT	PCT	PCT	PCT	PCT	PCT
%	%	%	%	%	%	%	%	%	%
0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
BA#	BA#	BA#	BA#	BA#	BA#	BA#	BA#	BA#	BA#
10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L	10 ⁹ /L
0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
LY	LY	LY	LY	LY	LY	LY	LY	LY	LY
%	%	%	%	%	%	%	%	%	%
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
MO	MO	MO	MO	MO	MO	MO	MO	MO	MO
%	%	%	%	%	%	%	%	%	%
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
%	%	%	%	%	%	%	%	%	%
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
EO	EO	EO	EO	EO	EO	EO	EO	EO	EO
%	%	%	%	%	%	%	%	%	%
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
BA	BA	BA	BA	BA	BA	BA	BA	BA	BA
%	%	%	%	%	%	%	%	%	%
30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0

Opened tubes are stable for 14

Table of Expected Results

14 Open Vial Days		Abnormal Low LOT 351607511 2016-06-05		Normal LOT 361607512 2016-06-05		Abnormal High LOT 371607513 2016-06-05	
		DxH 500 Systems	±	DxH 500 Systems	±	DxH 500 Systems	±
x10 ³ /μL	WBC	2.40	0.40	7.40	1.10	18.20	2.50
x10 ³ /μL	RBC	2.44	0.15	4.75	0.20	5.18	0.25
g/dL	HGB	6.60	0.40	14.60	0.60	17.60	0.80
%	HCT	19.4	2.0	42.3	2.5	51.3	3.0
fL	MCV	79.5	5.0	89.0	5.0	99.0	5.0
pg	MCH	27.0	2.5	30.7	2.5	34.0	2.5
g/dL	MCHC	34.0	3.0	34.5	3.0	34.3	3.0
%	RDW	14.3	3.0	12.3	3.0	11.7	3.0
fL	RDW-SD	35.5	5.0	37.5	5.0	40.4	5.0
x10 ³ /μL	PLT	76.0	20.0	275.0	40.0	510.0	60.0
fL	MPV	9.50	1.20	8.30	1.20	8.20	1.20
x10 ³ /μL	LY#	0.73	0.17	2.22	0.45	2.64	0.92
x10 ³ /μL	MO#	0.05	0.05	0.19	0.19	0.53	0.48
x10 ³ /μL	NE#	1.46	0.22	4.70	0.80	14.00	1.28
x10 ³ /μL	EO#	0.15	0.10	0.29	0.23	1.02	0.73
x10 ³ /μL	BA#	0.01	0.01	0.01	0.01	0.02	0.02
%	LY	30.60	7.00	30.00	6.00	14.50	5.00
%	MO	2.10	2.10	2.50	2.50	2.90	2.60
%	NE	61.00	9.00	63.50	8.00	76.90	7.00
%	EO	6.20	4.00	3.90	3.00	5.60	4.00
%	BA	0.10	0.10	0.10	0.10	0.10	0.10

Opened tubes are stable for 14 days, provided they are handled properly.



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Manufactured for:
Beckman Coulter Ireland Ltd.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland
www.beckmancoulter.com



DxH 500 Control



Beckman Coulter Ireland, Inc. Co. Clare, Ireland
Coulter, Inc.

Printed in USA
B36875-AA

DxH 500 Control



DxH 500 Control



Beckman Coulter Ireland, Inc. Co. Clare, Ireland
Coulter, Inc.

Printed in USA
B36877-AA

DxH 500 Control



DxH 500 Control



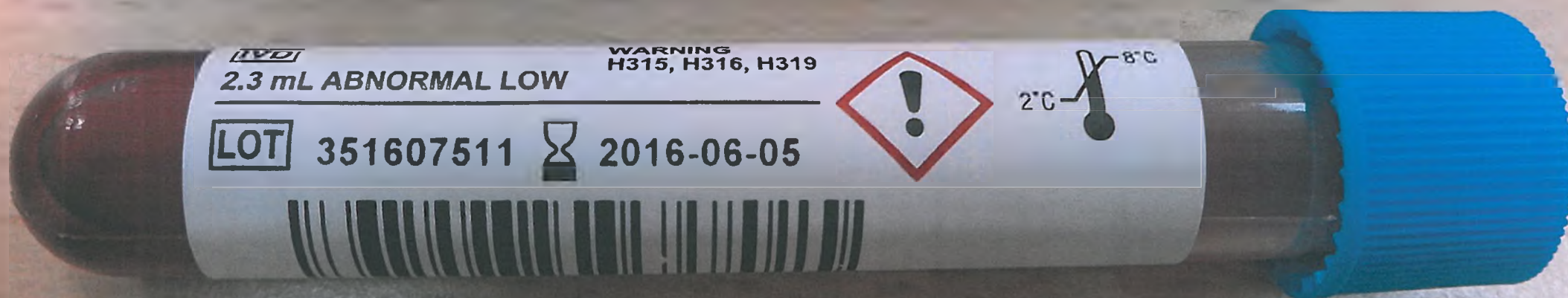
Beckman Coulter Ireland, Inc. Co. Clare, Ireland
Coulter, Inc.

Printed in USA
B36874-AA

DxH 500 Control











Manufactured for: Beckman Coulter Ireland, Inc. Co. Clare, Ireland
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Printed in USA
B36874-AA



DxH 500 Control



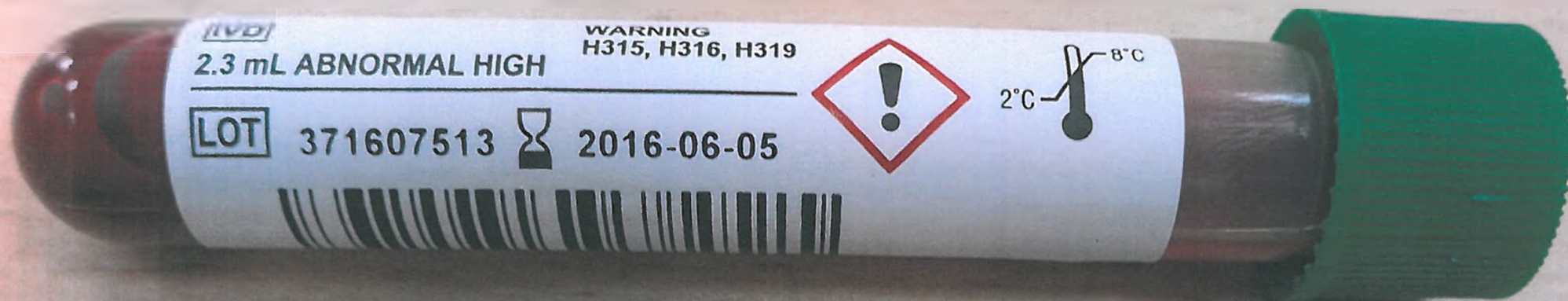
Manufactured for: Beckman Coulter Ireland, Inc. Co. Clare, Ireland
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Printed in USA
B36874-AA



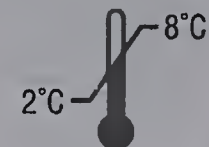
DxH 500 Control





IVD

Rx Only



Contents:

2 x 2 mL

DxH 500 Calibrator is designed for use in the calibration of Beckman Coulter hematology analyzers. Please refer to the assay table for specific instrument models./ El calibrador DxH 500 está diseñado para su uso en la calibración de analizadores hematológicos de Beckman Coulter. Consulte la tabla de análisis para obtener información sobre modelos de instrumentos específicos./ DxH 500 Kalibratör, Beckman Coulter hematoloji analizörlerinin kalibrasyonunda kullanım için tasarlanmıştır. Spesifik cihaz modelleri için lütfen test tablosuna bakın.

Package Insert/ Notice/ Foglietto illustrativo/ Gebrauchsinformation/ Prospekt/ Folhetos informativos/ Pakkeindlæg/ Bipsædelt/ Příložená informace/ Pakuotės įdėklas/ Ulotka w opakowaniu/ Листок-вкладыш в упаковке/ Ambalaj Prospektüsü/ Pakkevedlegg/ 添付文書

Reactive Ingredients:/ 成分 :

Stabilized Human Blood/ 安定ヒト血液

Product contains biologically sourced material:
Human, Bovine and Porcine



WARNING

H315, H316, H319

Potassium Hydroxide < 1%

DxH 500 Calibrator

REF B36880



Printed in USA Made in USA
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B36870-AA



**BECKMAN
COULTER**

LOT

491607800

(01)15099590671990



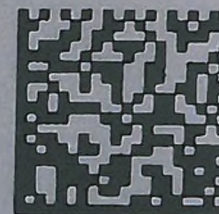
2016-05-05

(17)160505

(10)491607800



+H628B368801P



+\$\$3160505491607800PR



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

製造販売元：ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー



www.beckmancoulter.com/ifu

LOT

491607800

(01)15099590671990

(17)160505

(10)491607800



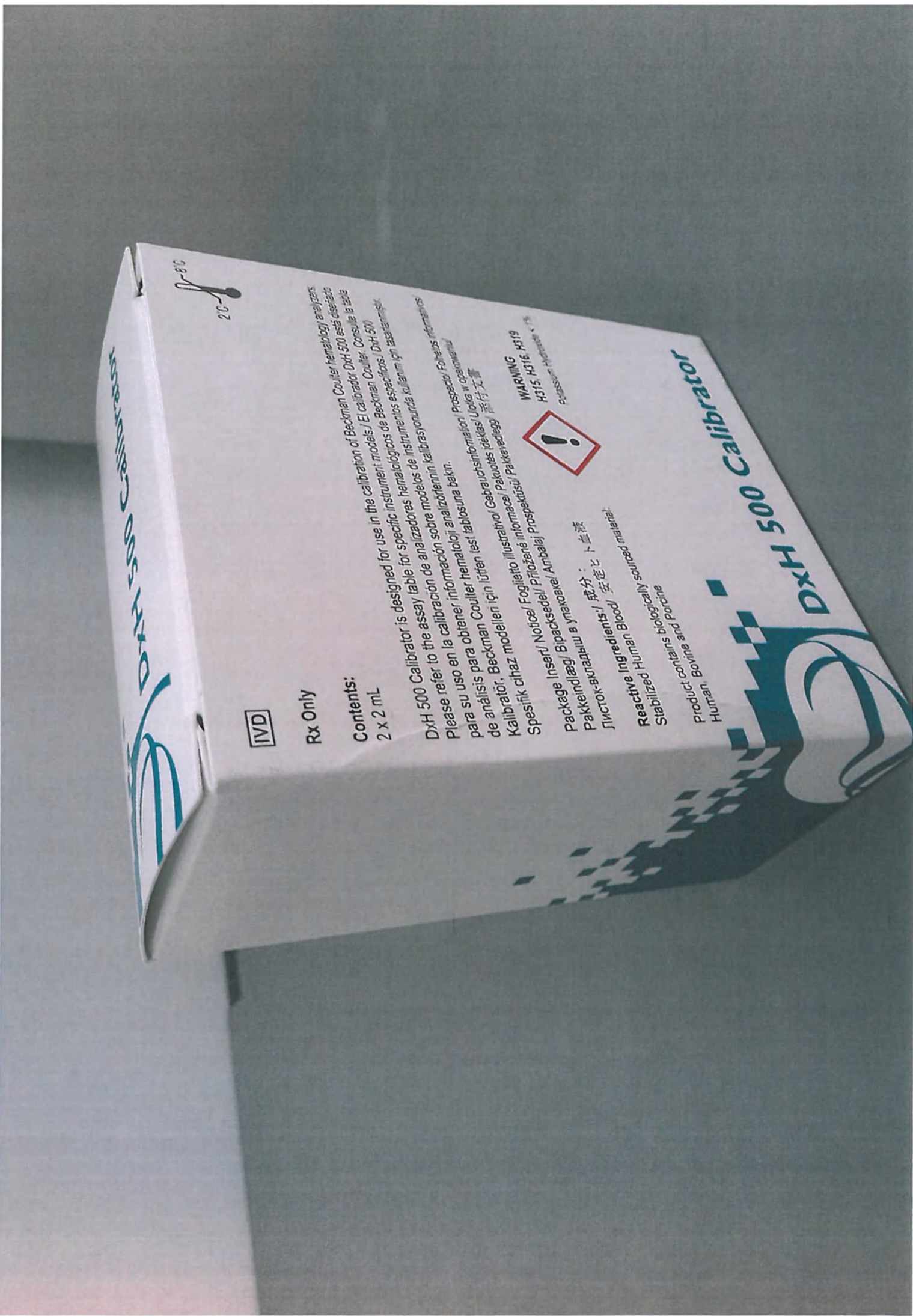
2016-05-05



+H628B368801P



+\$3160505491607800PR



IVD

Contents:
2 x 2 mL

Contents:

x 2 mL

DH-500 Calibrator is designed for use in the calibration of Beckman Coulter hematology analyzers. Please refer to the assay table for specific instrument models. El calibrador DH-500 está diseñado para su uso en la calibración de analizadores hematológicos de Beckman Coulter. Consulte la tabla de análisis para obtener información sobre modelos de instrumentos específicos. DH-500 se diseñó para su uso en la calibración de analizadores hematológicos de Beckman Coulter.

Kalibrátor Beckman Coulter hematoloji analizatorunun kalibrasyonu için kullanılır.

consistit dintr-un

警告
 H315, H316, H319
 Potassium Hydroxide
 警告
 H315, H316, H319
 Potassium Hydroxide
 警告
 H315, H316, H319
 Potassium Hydroxide

WARNING
H315, H316, H319
Potassium Hydroxide

Писток-ВН-10

Reactive Inj.
Stabilized Human Blood

product contains biologically active Human, Bovine and Porcine

DxH 500 Calibrator

B36884-AA

5 Open Vial Days

107

2016-05-05

US-1 Units

DxH 500
Systems

006

715014

450

13.90



Beckman Coulter Ireland, Inc. Co. Clare, Ireland
Coulter, Inc.

Printed in USA
B36882-AA

DxH 500 Calibrator



ed for: Beckman Coulter Ireland, Inc. Co. Clare, Ireland
xman Coulter, Inc.

Printed in USA
B36882-AA

DxH 500 Calibrator







IVD

B36884-AA

DxH 500 Calibrator

For Use with DxH 500 Diluent

5 Open Vial Days	LOT 491607800
	2016-05-05

DxH 500 Systems	US-1 Units	Parameters
9.00	$\times 10^3/\mu\text{L}$	WBC
4.50	$\times 10^6/\mu\text{L}$	RBC
13.90	g/dL	HGB
90.0	fL	MCV
255.0	$\times 10^3/\mu\text{L}$	PLT
8.30	fL	MPV



Opened tubes/vials are stable for 5 days, provided they are handled properly.



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Manufactured for:
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 Lismeehan
 O'Callaghan's Mills
 Co. Clare, Ireland
www.beckmancoulter.com



For Use with DxH 500 Diluent

5 Open Vial Days	LOT 491607800
	 2016-05-05

DxH 500 Systems	US-1 Units	Parameters
9.00	$\times 10^3/\mu\text{L}$	WBC
4.50	$\times 10^6/\mu\text{L}$	RBC
13.90	g/dL	HGB
90.0	fL	MCV
255.0	$\times 10^3/\mu\text{L}$	PLT
8.30	fL	MPV



Opened tubes/vials are stable for 5 days, provided they are handled properly.

ПРОШТО, ПРОНУМЕРОВАНО
И СКРЕПЛЕНО ПЕЧАТЬЮ
тридцать восемь 38
ЛИСТОВ

[Handwritten signature]



Образцы Маркировки медицинского изделия

Реагенты in-vitro диагностические для гематологического анализатора DxH 500 (см. Приложение)

Приложение:

- 1. Дилуент DxH 500 (DxH 500 Diluent)**
- 2. Лизирующий реагент DxH 500 (DxH 500 Lyse)**
- 3. Очиститель DxH 500 (DxH 500 Cleaner)**
- 4. Контроль DxH 500 (DxH 500 Control)**
- 5. Калибратор DxH 500 (DxH 500 Calibrator).**

		Только для диагностики ин витро	
Дилуэнт DxH 500 (DxH 500 Diluent)			B36845
10 л			
Соли натрия <15 г/л			
Стабилизаторы <1 г/л			
«Реагенты in-vitro диагностические для гематологического анализатора DxH 500»			
РУ			
Анализ клеток крови включает в себя перемешивание части пробы цельной крови с дилуэнт, что обеспечивает возможность анализа эритроцитов и тромбоцитов. Дилуэнт используется в комбинации с литическим реагентом для определения гемоглобина, подсчета лейкоцитов (белых кровяных телец) и определения субпопуляций лейкоцитов. Длюэнт DxH 500 представляет собой осмотически сбалансированный, pH-нейтральный раствор органических буферов, анестетиков, гермицидов и солей натрия. Дилуэнт действует как электролит и стабилизатор объема клетки для подсчета эритроцитов и тромбоцитов. Дилуэнт используется с лизирующим реагентом DxH 500 для подсчета и дифференциации лейкоцитов и измерения гемоглобина.			
	Опасно, раздражающий		
	Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 30°C 2°C	Хранить при температуре от +2°C до +30°C
			Срок годности:
	Опасно, раздражающий		
	Обратитесь к руководству по эксплуатации		
	Сделано в Германии	Авторизованный представитель в РФ:	ООО "Бекмен Культер", Москва, Россия, 109004, Станиславского 21, стр.3

		Только для диагностики ин витро	
Лизирующий реагент DxH 500 (DxH 500 Lyse)		B36846	
500 мл			
Сапонин 0,8–2,0 г/л Другие детергенты 0,1–2,0 г/л Четвертичные соли аммония 0,05–0,2 г/л			
«Реагенты in-vitro диагностические для гематологического анализатора DxH 500»			
ру			
Лизирующий реагент DxH 500 представляет собой реагент, не содержащий цианида, и используется для подготовки пробы разбавленной цельной крови к количественному определению гемоглобина, а также подсчета и классификации лейкоцитов с дифференцировкой на субпопуляции.			
Реагент для лизиса эритроцитов , количественного определения гемоглобина и подсчета, определения размера и оптического измерения лейкоцитов на анализаторах DxH 500.			
Использовать только с дилуентом DxH 500 и очистителем DxH 500.			
	Опасно, раздражающий		
	Бекмен Культиер Айзленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 25°C 4°C	Хранить при температуре от +4°C до +25°C
			Срок годности:
	Опасно, раздражающий		
	Обратитесь к руководству по эксплуатации		
	Сделано во Франции	Авторизованный представитель в РФ:	ООО “Бекмен Культиер”, Москва, Россия, 109004, Станиславского 21, стр.3

		Только для диагностики ин витро	
Очиститель DxH 500 (DxH 500 Cleaner)		B36848	
500 мл			
Раствор протеолитического фермента			
«Реагенты in-vitro диагностические для гематологического анализатора DxH 500»			
ру			
Не содержащий азида и формальдегида биологически разлагаемый очиститель, имеющий в своем составе протеолитические ферменты, помогающие в удалении белковых отложений.			
Очиститель DxH 500 предназначен для использования с теми компонентами систем DxH, которые контактируют с пробами крови.			
	Опасно, раздражающий		
	Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 25°C	Хранить при температуре от +2°C до +25°C
			Срок годности:
	Опасность для здоровья человека		
	Обратитесь к руководству по эксплуатации		
	Сделано во США	Авторизованный представитель в РФ:	ООО "Бекмен Культер", Москва, Россия, 109004, Станиславского 21, стр.3

		Только для диагностики ин витро	
Контроль DxH 500 (DxH 500 Control)		B36872	
6 флаконов по 2,3 мл			
2 x 2,3 мл аномально низкий			
2 x 2,3 мл нормальный			
2 x 2,3 мл аномально высокий			
«Реагенты in-vitro диагностические для гематологического анализатора DxH 500»			
РУ			
Контроль DxH 500 представляет собой проанализированную контрольную цельную кровь, предназначенную для мониторинга значений многопараметрических гематологических анализаторов. Конкретные модели инструментов см. в таблице ожидаемых результатов.			
Общепринятой лабораторной практикой является использование стабильного контроля для мониторинга эксплуатационных характеристик анализаторов. Его измерение осуществляют так же, как пробы пациентов.			
	Опасно, раздражающий	H315, H316, H319	
	Бекмен Культер Айзленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 8°C 2°C	Хранить при температуре от +2°C до +8°C
			Срок годности:
	Опасность для здоровья человека		
	Обратитесь к руководству по эксплуатации		
	Сделано во США	Авторизованный представитель в РФ:	ООО “Бекмен Культер”, Москва, Россия, 109004, Станиславского 21, стр.3

Первичная упаковка Контроль DxH 500 (DxH 500 Control):

			
Контроль DxH 500 (DxH 500 Control): 2,3 мл аномально низкий			 Опасно, раздражающий H315, H316, H317
Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 	  8°C 2°C	

			
Контроль DxH 500 (DxH 500 Control): 2,3 мл нормальный			 Опасно, раздражающий H315, H316, H317
Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 	  8°C 2°C	

			
Контроль DxH 500 (DxH 500 Control): 2,3 мл аномально высокий			 Опасно, раздражающий H315, H316, H317
Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 	  8°C 2°C	

		Только для диагностики ин витро	
Калибратор DxH 500 (DxH 500 Calibrator)		B36880	
2 флакона по 2 мл			
2 флакона х 2 мл стабилизированной цельной крови			
«Реагенты in-vitro диагностические для гематологического анализатора DxH 500» ру			
Калибратор DxH 500 предназначен для калибровки гематологических анализаторов Beckman Coulter. Конкретные модели инструментов см. в таблице ожидаемых результатов. Гематологические анализаторы требуют периодической калибровки для получения точных результатов. Этот калибратор является препаратом стабилизированной цельной крови, который можно использовать для проверки и коррекции калибровки выбранных гематологических анализаторов. Значения для калибратора DxH 500 получены при повторном анализе на инструментах, эксплуатируемых и обслуживаемых согласно инструкциям производителя. Инструменты калибруют по цельной крови, используя значения, определенные с помощью эталонных методов.			
	Опасно, раздражающий	H315, H316, H319	
	Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 2°C 8°C	Хранить при температуре от +2°C до +8°C
			Срок годности:
	Обратитесь к руководству по эксплуатации		
Сделано во США		Авторизованный представитель в РФ:	ООО "Бекмен Культер", Москва, Россия, 109004, Станиславского 21, стр.3

Первичная упаковка **Калибратор DxH 500 (DxH 500 Calibrator):**

			
Калибратор DxH 500 (DxH 500 Calibrator):			
2 мл		Опасно, раздражающий H315, H316, H317	
Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 	  2°C 8°C	

			
Калибратор DxH 500 (DxH 500 Calibrator):			
2 мл		Опасно, раздражающий H315, H316, H317	
Бекмен Культер Айэленд, Инк., Лисмеган, О'Каллаган'с Миллз, графство Клэр, Ирландия	 	  2°C 8°C	

11
ПРОШИТО, ПРОНУМЕРОВАНО
И СКРЕПЛЕНО ПЕЧАТЬЮ 7



Фото и этикетки

Реагенты in-vitro диагностические для гематологического анализатора DxH 500 (см. Приложение)

Приложение:

- 1. Дилуэнт серии DxH 500 (DxH 500 Series Diluent)**
- 2. Лизирующий реагент серии DxH 500 (DxH 500 Series Lyse)**
- 3. Очиститель серии DxH 500 (DxH 500 Series Cleaner)**
- 4. Контроль серии DxH 500 (DxH 500 Series Control)**
- 5. Калибратор серии DxH 500 (DxH 500 Series Calibrator).**

2017 г.

DxH 500 Series Diluent

10 L

REF B36845

SDS



www.beckmancoulter.com/ifu

**BECKMAN
COULTER**

IVD

REF B36845

10 L

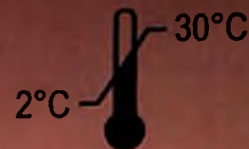


REACTIVE INGREDIENTS:/ 成分:

Sodium Salts/ ナトリウム塩 < 15 g/L

Stabilizers/ 安定剤 < 1 g/L

Printed in Germany
Made in Germany
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May produce an allergic reaction.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one
[EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one
[EC# 220-239-6](3:1) < 0.0015%

製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー



Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

DxH 500 Series
Diluent

IVD

Rx Only in the U.S.A.

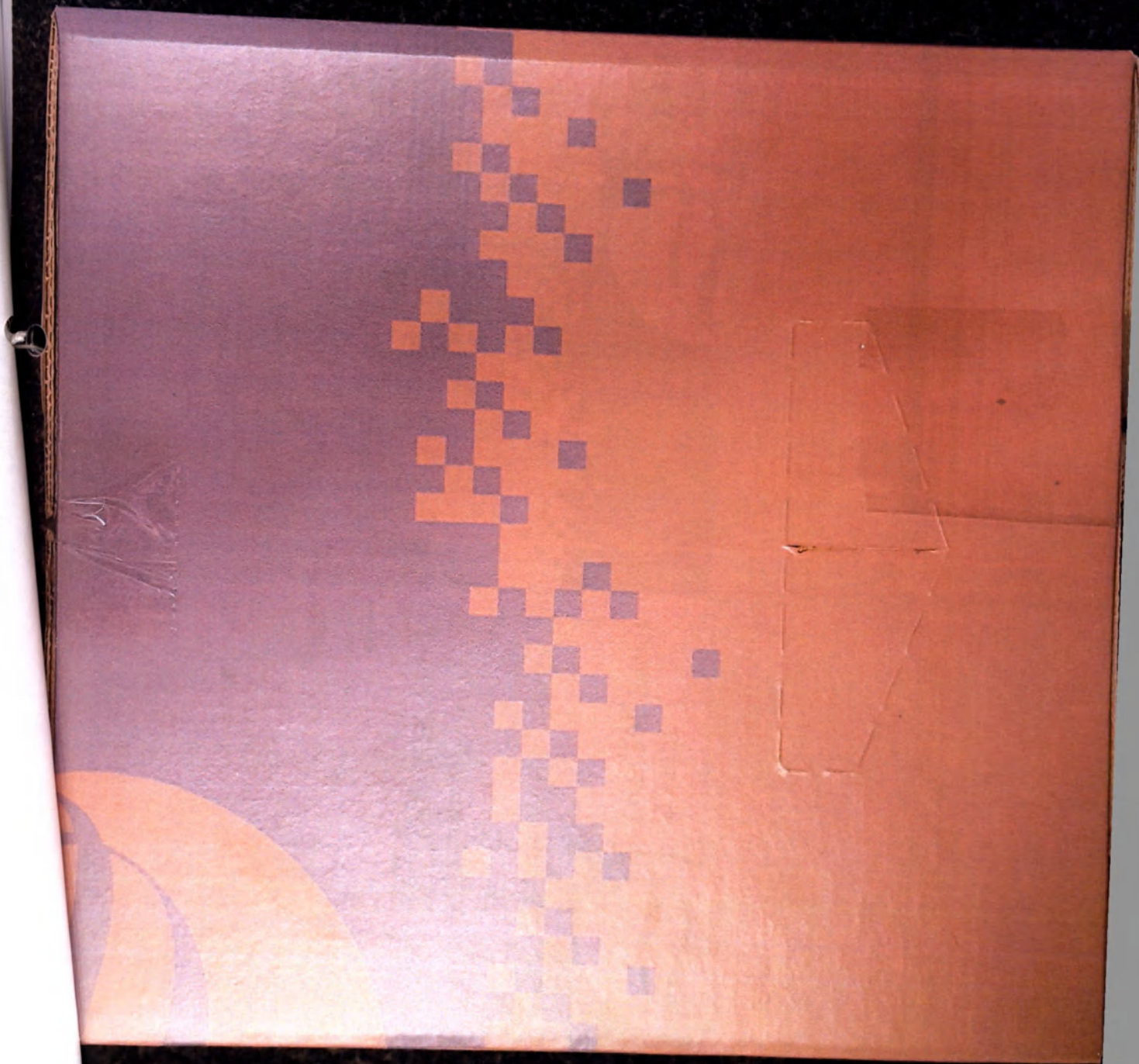
REF B36845

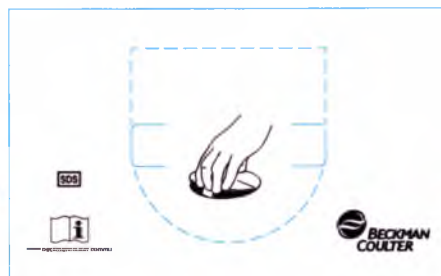
For use as an isotonic buffered diluent used in conjunction with a cyanide-free lytic agent for counting and sizing blood cells on the DxH 500 Series Systems. Use only with DxH 500 Series Lyse reagent./ Para utilizar como diluyente tamponado isotónico junto con un agente lítico sin cianuro para el recuento y la determinación del tamaño de las células sanguíneas en los sistemas de la serie DxH 500. Usar solo con el reactivo de lisis de la serie DxH 500./ DxH 500 Serisi Sistemlerinde kan hücrelerinin sayımı ve boyutlandırılması için siyanür içermeyen litik ajanla ile birlikte izotonik tamponlu bir dilüent olarak kullanılır. Sadece DxH 500 Serisi Parçalama reaktifi ile kullanın.



DxH 500 Series
Diluent







10 L

REF B36845

REACTIVE INGREDIENTS/成分:
 Sodium Salts/ナトリウム塩 < 15 g/L
 Stabilizers/安定剤 < 1 g/L

May produce an allergic reaction

Reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one (ECHA 247-500-7) and 2-methyl-4-isothiazolin-3-one (ECHA 228-863-1) < 0.0015%

製造販売元: ベクトン・コールター株式会社
 東京都中央区有明二丁目5番2号
 100有明ビル5F

Manufactured for:
 Beckman Coulter Ireland Inc.
 Limerick
 O'Callaghan's Mills
 Co. Clare, Ireland

CE

Printed in Germany
 Made in Germany
 © 2018 Beckman Coulter, Inc.

2°C - 30°C

5

Barcode Hold Area
 4" x 4"

DxH 500 Series Diluent

REF B36845

10 L

DxH 500 Series Diluent

REF B36845

Rx Only in the U.S.A.

For use as an isotonic buffered diluent used in conjunction with a cyanide-free lytic agent for counting and sorting blood cells on the DxH 500 Series Systems. Use only with DxH 500 Series Lytic reagent. / Para utilizar como diluyente tamponado isotónico junto con un agente lítico sin cianuro para el recuento y la determinación del tamaño de las células sanguíneas en los sistemas de la serie DxH 500. Usar solo con el reactivo de lisis de la serie DxH 500 / DxH 500 Series Systeemende kan functioneren samen met boytandilumies voor brijen van bloedcellen. Het agent is bedoeld voor gebruik met de diluent dxh500 kulturen. Sedoce DxH-500 Serie Parçalaması sadece kulturen için kullanılır.

DxH 500 Series Diluent

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to '4print.zip' file for all printing specifications.			
Special Instructions: N/A			
Description: CORR; WRAP; DXH 500 SERIES DILUENT 10L - Krefeld		Ink Color(s): GCM #90, GCM #970	
Part Number: B36781	Revision: AD	Label Size: N/A	Scale: 1 : 1

REF B36846 500 mL

of hemoglobin, and the counting,
H 500 Series Systems. Use only
eater./ Agente lítico eritrocitógeno
a y para el recuento, la
eucocitos en los sistemas de la
e DxH 500 y el limpiador de la
ntrosit parçalama maddesi ve
ayutlandırılması ve optik ölçümü.
temizleyiciyle kullanın.



Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー

Printed in USA Made in France
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B36847-AC



500 Series Lyse

IVD Rx Only in the U.S.A.

Erythrocyte lysis agent for quantitative determination of hemoglobin, and the counting, sizing and optical measurement of leukocytes on DxH 500 Series Systems. Use only with DxH 500 Series Diluent and DxH 500 Series Cleaner / Agente lítico eritrocítico para la determinación cuantitativa de la hemoglobina y para el recuento, la determinación del tamaño y la medición óptica de leucocitos en los sistemas de la serie DxH 500. Usar solo con el diluyente de la serie DxH 500 y el limpiador de la serie DxH 500. Hemoglobinin kantitatif tayini için eritrosit parçalama maddesi ve lökositlerin DxH 500 Serisi Sistemlerinde sayımı, boyutlandırılması ve optik ölçümü. Sadece DxH 500 Serisi Dilüent ve DxH 500 Serisi Temizleyiciyle kullanın.

REF B36846 500 mL

REACTIVE INGREDIENTS / 成分:

Detergents / 洗剤:

Saponin / ナポニン 0.8 - 2.0 g/L

Other Detergents / その他洗剤 0.1 - 2.0 g/L

Quaternary Ammonium Salts /

高価級アンモニウム塩 0.05 - 0.2 g/L

May produce an allergic reaction.

Glutaraldehyde < 0.1%

Reaction mass of:

5-methyl-2-methyl-4-isothiazolin-3-one [EC#

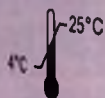
247-500-7] and 2-methyl-4-isothiazolin-3-one

[EC# 220-239-8] (2:1) < 0.0015%

505



www.beckmancoulter.com/lyse



Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
30°C有明ウエストタワー



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DxH 500 Series Lyse

[VD] Rx Only in the U.S.A.

[REF] B36846 500 mL

Erythrocyte lytic agent for quantitative determination of hemoglobin, and the counting, sizing and optical measurement of leukocytes on DxH 500 Series Systems. Use only with DxH 500 Series Diluent and DxH 500 Series Cleaner / Agente lítico eritrocítico para la determinación cuantitativa de la hemoglobina y para el recuento, la determinación del tamaño y la medición óptica de leucocitos en los sistemas de la serie DxH 500. Usar solo con el diluyente de la serie DxH 500 y el limpiador de la serie DxH 500 / Hemoglobinin kantitatif layini için eritrosit parçalama maddesi ve lökositlerin DxH 500 Serisi Sistemlerinde sayımı, boyutlandırılması ve optik ölçümü. Sadece DxH 500 Serisi Dilüent ve DxH 500 Serisi Temizleyiciyle kullanın.

0.75" x 0.75"
2D BARCODE
HOLD AREA
DO NOT
VARNISH

REACTIVE INGREDIENTS / 成分:

Detergents / 洗剤:

Saponin / サポニン 0.8 - 2.0 g/L

Other Detergents / 他の洗剤 0.1 - 2.0 g/L

Quaternary Ammonium Salts /

第四級アンモニウム塩 0.05 - 0.2 g/L

May produce an allergic reaction.

Glutaraldehyde < 0.1%

Reaction mass of:

5-chloro-2-methyl-4-isothiazolin-3-one [EC#

247-500-7] and 2-methyl-4-isothiazolin-3-one

[EC# 220-239-6] (3:1) < 0.0015%



www.beckmancoulter.com/ifu



Manufactured for
Beckman Coulter Ireland Inc.
Lismeshan
O'Callaghan's Mills
Co. Clare, Ireland



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TDC有明ウエストタワー

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B36847-AC



2" x 1"
GS1 BARCODE HOLD AREA
DO NOT VARNISH



DxH 500 Series Lyse

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: N/A

Description: LBL; SEC, DXH 500 SERIES LYSE

Ink Color(s): 100% Black, PMS 2602C, Varnish

Part Number: B36847

Revision: AC

Label Size: 3.75" x 3.75"

Scale: 1 : 1

REF B36869

For Use Only in the U.S.A.

Cleaning agent for use on DxH 500 Series Systems for components that come in contact with blood samples. / Un agente de limpieza para utilizar en los sistemas de la serie DxH 500 para componentes que están en contacto con las muestras de sangre. / Temizleme ajanı kullanılmak üzere DxH 500 Serisi Sistemlerde kan örnekleriyle temas halindeki bileşenlerin temizliği için kullanılır.

ACTIVE INGREDIENTS: A solution of a proteolytic enzyme / 2017-10-18

DANGER

May cause allergic skin reaction.
May cause dizziness or asthma symptoms or breathing difficulties if inhaled.
Avoid breathing vapors.
Wear protective gloves, protective clothing and eye/face protection.
In case of inadequate ventilation, wear respiratory protection.
If swallowed: Remove person to fresh air and keep at rest in position comfortable for breathing.
If skin irritation or rash occurs: Get medical advice/attention.
If respiratory symptoms occur: Call a POISON CENTER or doctor/physician.

Contains 1% - 1.5%
Active mass of 5-chloro-2-methyl-4-isothiazolin-3-one
CAS 100-01-7 and 2-methyl-4-isothiazolin-3-one
CAS 100-02-1 (92.1) < 0.05%

2°C - 25°C

DxH 500 Series Clean



Manufactured for:
Beckman Coulter International
Limerick
O'Callaghan's Mills
Co. Clonsilla, Ireland

製造販売元: ベックマン・コールター
東京都江東区有明三丁目5番18
TOC有明ウエストタワー

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B36869-AC

LOT 8310013

2017-10-18

2016-10-19

QR code

(01)15999504/151
(11)161825
(17)171818
(10)8310013
864129-48

[IVD] Rx Only in the U.S.A.

A cleaning agent for use on DxH 500 Series Systems for components that come in contact with blood samples. / Un agente de limpieza para utilizar en los sistemas de la serie DxH 500 Serisi Sistemlerinde kan örnekleriyle temas halindeki komponentlerde kullanım için temizleme maddesi.

REACTIVE INGREDIENTS: A solution of a proteolytic enzyme/
成分: 蛋白質分解酵素溶液

DANGER

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing vapours.

Wear protective gloves, protective clothing and eye/face protection.

In case of inadequate ventilation, wear respiratory protection.

IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

If skin irritation or rash occurs: Get medical advice/attention.

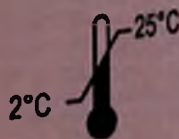
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Subtilisin 0.1 - 0.5%

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one

[EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one

[EC# 220-239-6](3:1) < 0.05%



www.beckmancoulter.com/ifu



DxH 500 Series



REF B36868 500 ml

Use for components that come in contact
with blood or in systems of the DH 500
series. /
Utiliser pour les composants qui entrent en contact
avec le sang ou dans les systèmes de la série DH 500.



B36868-AB



Manufactured for:
Berkman Coulter Inc.
Lismohan
O'Callaghan's Mills
Co. Clare, Ireland



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TQC有明ウエストタワー

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B36868-AC



LOT 8310013 c: 0868
2017-10-18 v: e593d
2016-10-19



(01)150995906/1877
(11)161019
(17)171018
(10)8310013
864129-AB

DH 500 Series Cleaner



IVD

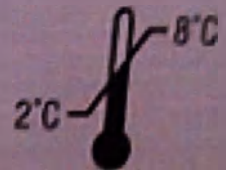
Rx Only in the U.S.A.

Contents:

2 x 2.3 mL ABNORMAL LOW

2 x 2.3 mL NORMAL

2 x 2.3 mL ABNORMAL HIGH



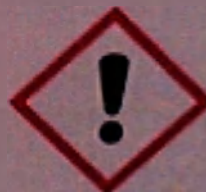
DxH 500 Series Control is an assayed whole blood control designed to monitor values on multi parameter hematology cell counters. Refer to the Table of Expected Results for specific instrument models. / El control de la serie DxH 500 es un control de sangre entera analizada diseñado para controlar los valores en contadores celulares hematológicos de varios parámetros. Consulte los modelos de instrumentos específicos en la tabla de resultados esperados. / DxH 500 Serisi Kontrol, çok parametrelili hematoloji hücre sayacılarındaki değerleri izlemek için tasarlanan test edilmiş tam kan kontrolüdür. Belirli cihaz modelleri için Beklenen Sonuçlar Tablosu'na bakın.

Package Insert/ Notice/ Gebrauchsinformation/ Foglietto illustrativo/ Prospecto/ Folhetos informativos/ Pakoindlæg/ Bipskedel/ Pakavedlegg/ Evénro ovcuonolog/ 添付文書/ 包装说明书/ Pakuotės įdėtas/ Terméktájékoztató/ Uloška w opakowaniu/ Příložená informace/ Příbalový leták/ 첨부 설명서/ Ambakaj Prospektüsü/ Листок-вкладыш с указанием/ Листовка/ 包裝內附說明/ Completare pentru pachet/ Upulstivo u pakovanju/ Folheto informativo

Reactive Ingredients: / 成分:

Stabilized Human Blood/ 安定ヒト血液

Product contains biologically sourced material:
Human, Bovine and Porcine



WARNING

H315, H316, H319

Potassium Hydroxide < 1%

**DxH 500 Series
Control**



Внимание!
ВНИМАНИЕ!
ВНИМАНИЕ!

ВНИМАНИЕ!
ВНИМАНИЕ!
ВНИМАНИЕ!

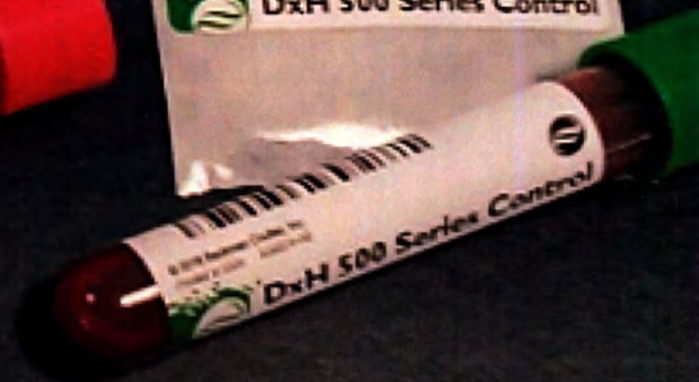
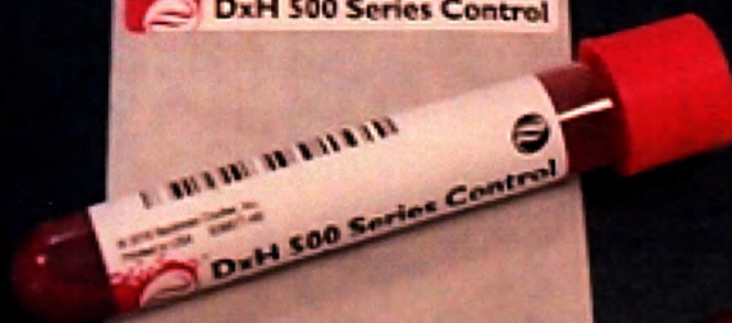
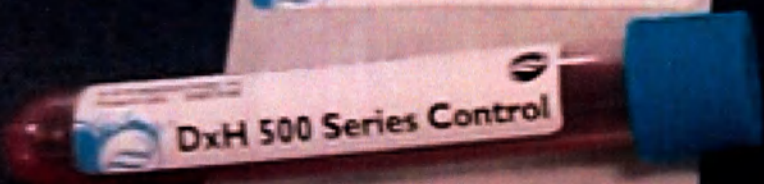
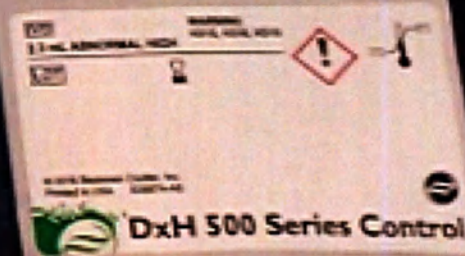
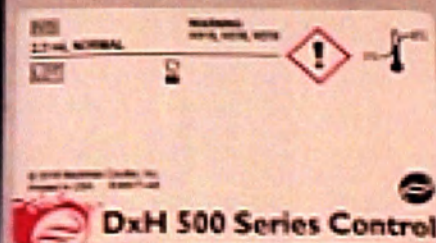
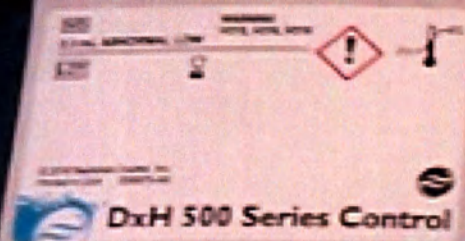
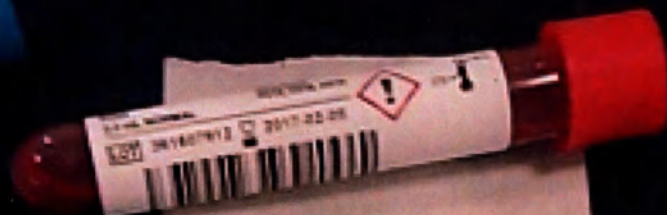
ВНИМАНИЕ!
ВНИМАНИЕ!
ВНИМАНИЕ!

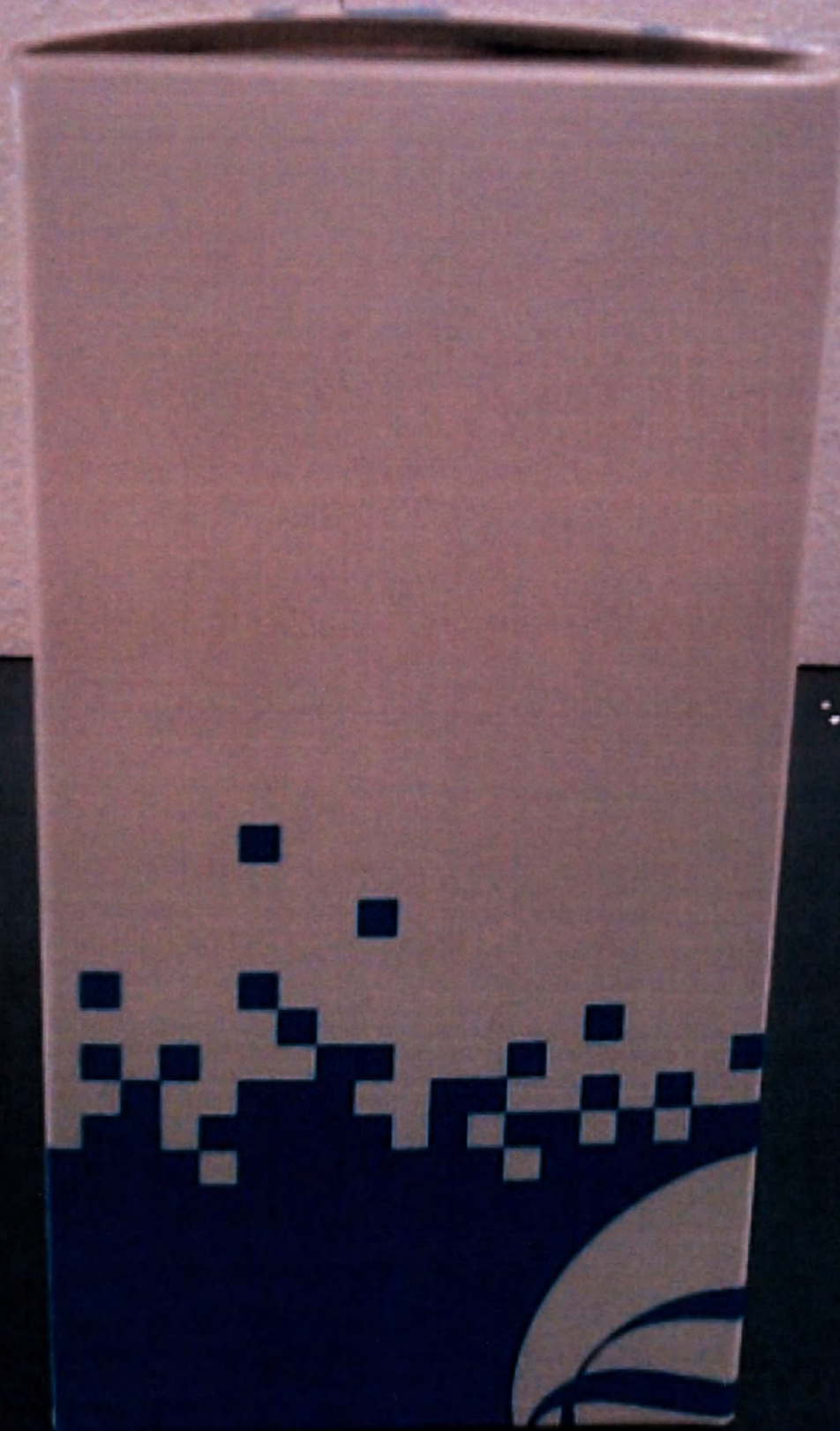


DxH 500 Series
Control



ВНИМАНИЕ!
ВНИМАНИЕ!
ВНИМАНИЕ!







Manufactured for:
Beckman Coulter Ireland Inc.
Usmeehan
O'Callaghan's Mills
Co. Clare, Ireland

SDS



製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー

www.beckmancoulter.com/ru

LOT

160791

(01)13099590671884

(17)170205

(10)160791



2017-02-05

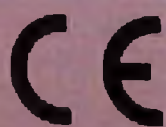


H6288368721Q



4553170205160791QF

REF B36872



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B36871-AB



**BECKMAN
COULTER**



**DxH 500 Series
Control**

Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

製造販売元: ベクマン・コールター株式会社
東京都江東区有明一丁目6番7号
TOKYO有明エントウワー

ISO

www.beckmancoulter.com/ifu

HOLD AREA
3-7/8" x 1-3/8"

IVD

Rx Only in the U.S.A.

Contents:
2 x 2.3 mL ABNORMAL LOW
2 x 2.3 mL NORMAL
2 x 2.3 mL ABNORMAL HIGH

DxH 500 Series Control is an assayed whole blood control designed to monitor values on multi parameter hematology cell counters. Refer to the Table of Expected Results for specific instrument models. / El control de la serie DxH 500 es un control de sangre entera analizada diseñado para controlar los valores en contadores celulares hematológicos de varios parámetros. Consulte los modelos de instrumentos específicos en la tabla de resultados esperados. / DxH 500 Sensi Kontrol, çok parametrelik hematoloji hücre saygınlardaki değeren izlemek için tasarlanan test edilmeyim tam kan kontrolüdür. Belirli cihaz modelleri için Beklenen Sonuçlar Tablosu'na bakın.

Package Insert/ Notice/ Gebrauchsinformation/ Foglietto illustrativo/ Prospecto/ Folhetos informativos/ Pakkeindlæg/ Bipsaksedel/ Pakkevedlegg/ Evénro oúnuvotioy/ 說明書/ 取扱説明書/ Paquetes de información/ Termékdokumentáció/ Ulotka w opakowaniu/ Příložené informace/ Příbalový leták/ 製藥說明書/ Ambalaj Prospektüsü/ Листок-вкладыш в упаковке/ Листок-вкладыш/ 包裝內附說明/ Completare pentru pachet/ Uputstvo u pakovanju/ Folheto informativo

Reactive Ingredients: / 成分:
Stabilized Human Blood/ 安定ヒト血漿
Product contains biologically sourced material:
Human, Bovine and Porcine



WARNING
H315, H316, H319
Potassium Hydroxide < 1%



REF B36872



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B36871-AB



**DxH 500 Series
Control**

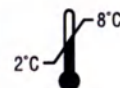
Special Instructions: N/A			
Description: CSH, DxH 500 SERIES CONTROL		Lot Category: 999% Blank, PMS 300C, PMS 600C	
Part Number: B36871	Version: A0	Label Size: 3-3/8" x 2-3/8" x 4-1/8"	Batch: 1:1

IVD

2.3 mL NORMAL

LOT

WARNING
H315, H316, H319



2" x 7/16"
Hold Area for Barcode

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Printed in USA B36877-AB



DxH 500 Series Control

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: Reduce 50%

Description: LBL; PRI, DXH 500 SERIES CONTROL - NORMAL

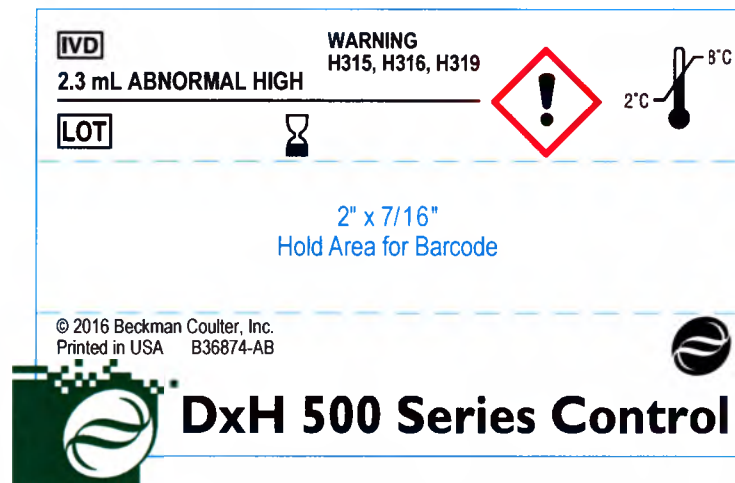
Ink Color(s): 100% Black, PMS 186C

Part Number: B36877

Revision: AB

Label Size: 2" x 1-1/4"

Scale: 2 : 1



THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: Reduce 50%

Description: LBL; PRI, DXH 500 SERIES CONTROL - HIGH

Ink Color(s): 100% Black, PMS 186C, PMS 356C

Part Number: B36874

Revision: AB

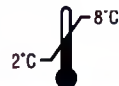
Label Size: 2" x 1-1/4"

Scale: 2 : 1

IVD

2.3 mL ABNORMAL LOW

WARNING
H315, H316, H319



LOT



2" x 7/16"
Hold Area for Barcode

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Printed in USA B36875-AB



DxH 500 Series Control

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: Reduce 50%

Description: LBL; PRI, DXH 500 SERIES CONTROL - LOW

Ink Color(s): 100% Black, PMS 186C, PMS 2925C

Part Number: B36875

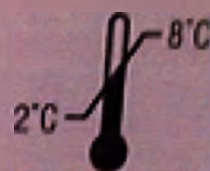
Revision: AB

Label Size: 2" x 1-1/4"

Scale: 2 : 1

IVD

Rx Only In the U.S.A.



Contents: 2 x 2 mL

DxH 500 Series Calibrator is designed for the determination of calibration factors for the DxH 500 Series Systems in conjunction with specific DxH 500 Series reagents. Refer to the Table of Expected Results for specific instrument models / El calibrador de la serie DxH 500 se ha diseñado para la determinación de los factores de calibración para los sistemas de la serie DxH 500 junto con los reactivos de la serie DxH 500 específicos. Consulte los modelos de instrumentos específicos en la tabla de resultados esperados / DxH 500 Serisi Kalibratör DxH 500 Serisi Sistemlerinin spesifik DxH 500 Serisi reaktifleriyle birlikte kalibrasyon faktörlerinin tespit edilmesi için tasarlanmıştır. Belirli cihaz modelleri için Beklenen Sonuçlar Tablosu'na bakın.

Package Insert/ Notice/ Gebrauchsinformation/ Foglétto ilustrativo/ Prospecto/ Folhetos informativos/ Pakkelndlæg/ Bipecksedel/ Pakkevedlegg/ Ένθετο συσκευασίας/ 添付文書/ 包装说明书/ Pakuotės įdėklas/ Termékutájékoztató/ Ulotka w opakowaniu/ Příložená informace/ Příbalový leták/ 첨부 설명서/ Ambalaj Prospektüsü/ Листок-вкладыш в упаковке/ Листовка/ 包裝內附說明/ Completare pentru pachet/ Uputstvo u pakovanju/ Folheto informativo

Reactive Ingredients/ 成分 :

Stabilized Human Blood/ 安定ヒト血液

Product contains biologically sourced material:

Human, Bovine and Porcine



WARNING

H315, H316, H319

Potassium Hydroxide < 1%



DxH 500 Series Calibrator

Manufactured for:
Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland



SDS



www.beckmancoulter.com/ifu

製造販売元: ベックマン・コールター株式会社
東京都江東区有明三丁目5番7号
TOC有明ウエストタワー

LOT 491608600



2017-01-05

(01)15099530671990

(17)170105

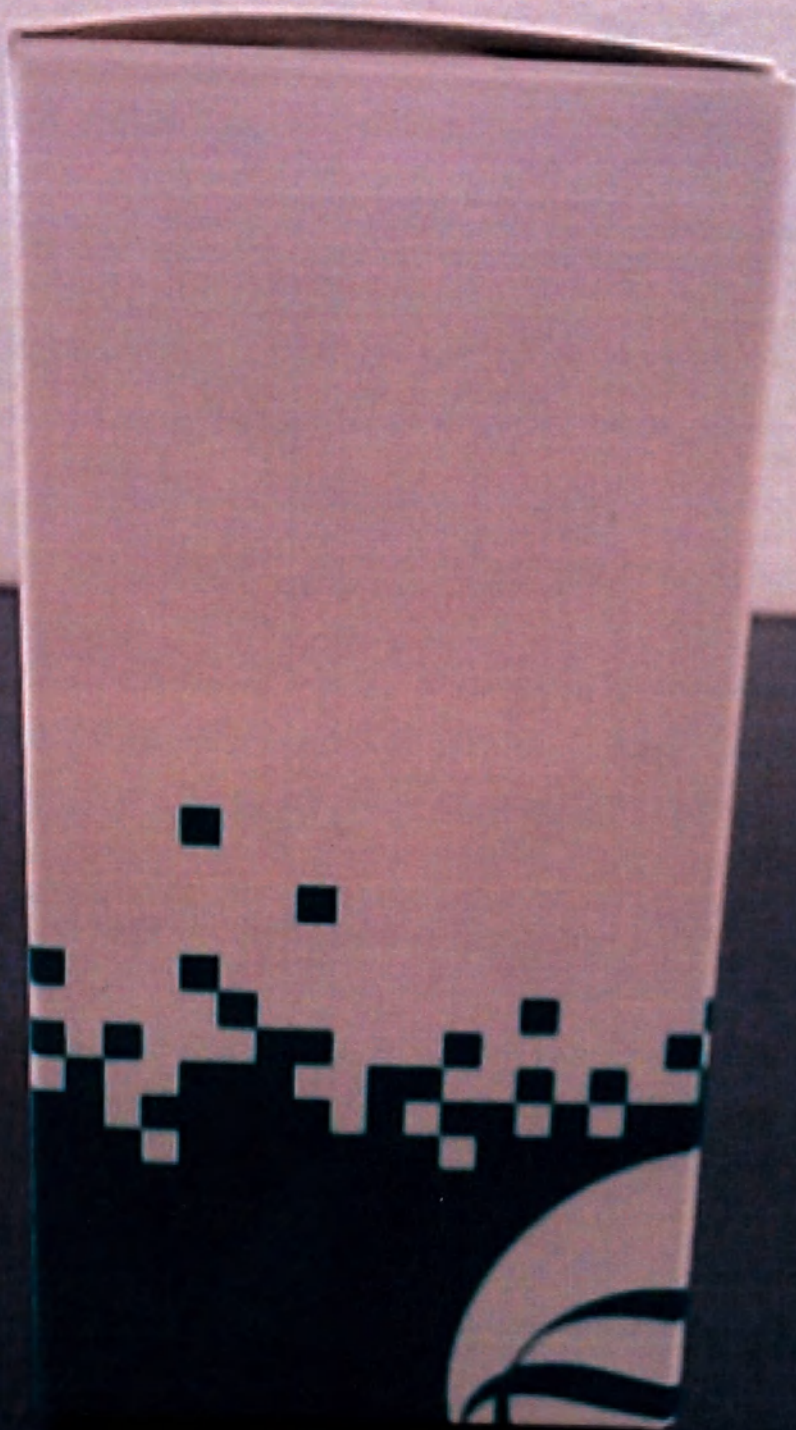
(10)491608600



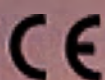
+H628036001P



+S53170105491608600FN



REF B36800



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B36870-AB





Only in the U.S.A.

Contenido: 2 x 2 vol.



DH 500 Series Calibrator is designed for the determination of calibration factors for the DH 500 Series Systems in conjunction with specific DH 500 Series reagents. Refer to the Table of Expected Results for specific instrument models / (3) calibrator de la serie DH 500 se ha diseñado para la determinación de los factores de calibración para los sistemas de la serie DH 500 junto con los reactivos de la serie DH 500 específicos. Consulte los modelos de instrumentos específicos en la lista de resultados esperados / DH 500 Series Calibrator DH 500 Series Sistemlerinin spesifik DH 500 Serisi reaktifleriyle birlikte kalibrasyon faktörlerini hesaplamak için tasarlanmıştır. Belirli cihaz modellerini beklenen Sonuçlar Tablosu'na bakın.

[illegible]

Active Ingredients / 成分：

Stallard Human Blood 

Product contains biologically sourced material:
Human, Bovine and Porcine



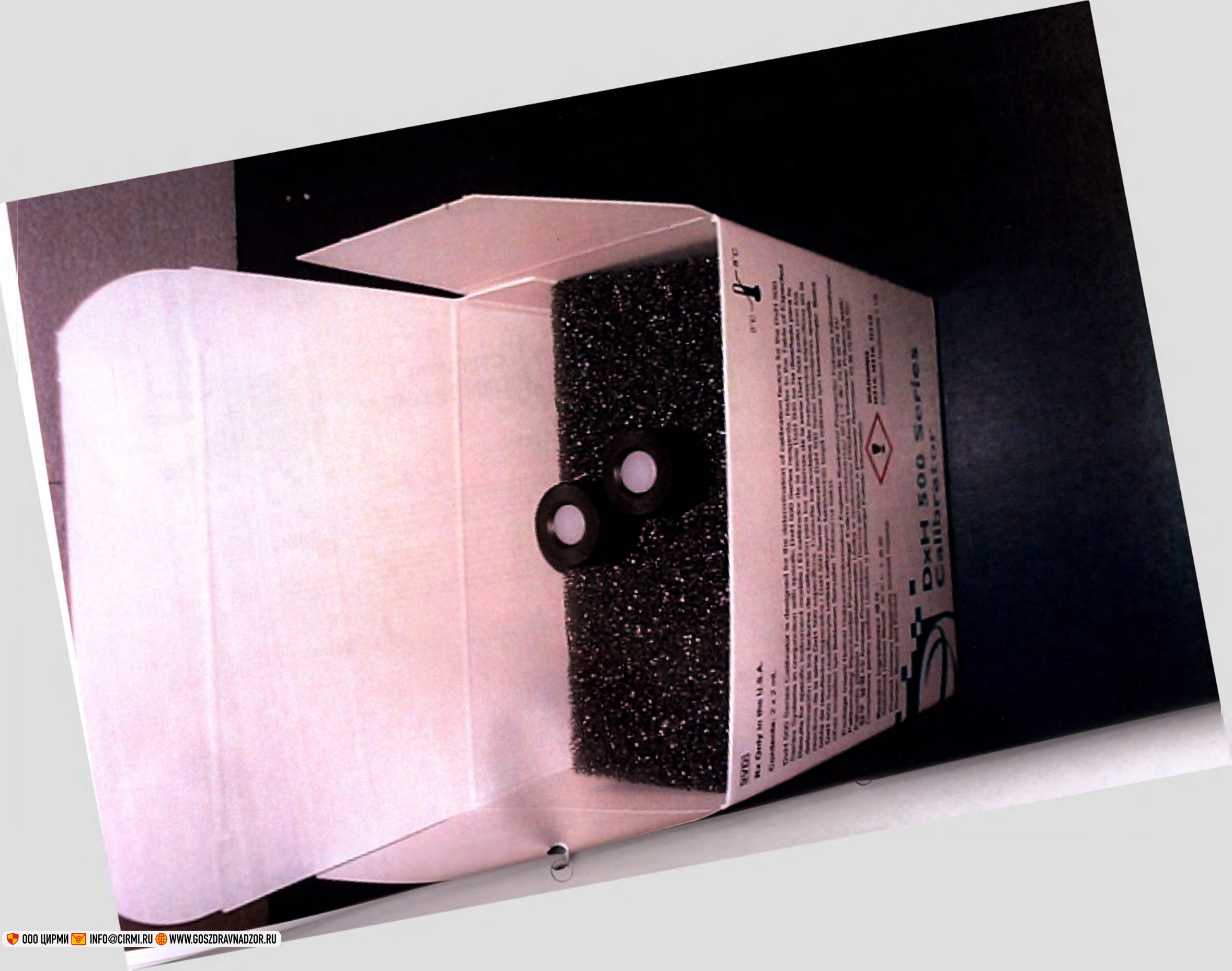
WARNING

DATE: 04/10/00 04:10

potassium hydroxide = 1%

DxH 500 Series Calibrator





製造販売元：ベックマン・コールター株式会社
東京都江東区有明一丁目5番7号
有明ウエストタワー



www.beckmancoulter.com/ifu

IVD

Rx Only in the U.S.A.

Contents: 2 x 2 mL

DxH 500 Series Calibrator is designed for the determination of calibration factors for the DxH 500 Series Systems in conjunction with specific DxH 500 Series reagents. Refer to the Table of Expected Results for specific instrument models / El calibrador de la serie DxH 500 se ha diseñado para la determinación de los factores de calibración para los sistemas de la serie DxH 500 junto con los reactivos de la serie DxH 500 específicos. Consulte los modelos de instrumentos específicos en la tabla de resultados esperados / DxH 500 Series Kalibratör DxH 500 Series Sistemlerle spesifik DxH 500 Series reaktiflerle birlikte kalibrasyon faktörlerini belirlemek ve diğerleri için basarilarinagibi. Belirli cihaz modelleri için Beklenen Sonuçlar Tablosu'na bakın

Package insert/ Notice/ Gebrauchsinformation/ Foglietto illustrativo/ Prospecto/ Folheto informativo/
Pakendingsel/ Backsedel/ Pakkevedlegg/ Евѣсто описанiя/ 添付文書/ 包裝說明書/
Pakuotes įdėjimas/ Termaktdokumente/ Ulotka w opakowaniu/ Příložená informace/ Příbalový leták/
제품 설명서/ Ambale/ Prospektus/ Листок-вкладыш в упаковке/ Листовка/ 包裝內附說明/
Complezarea pentru pachet/ Uputstvo u pakovanju/ Folheto informativo

Reactive Ingredients / 成分:
Stabilized Human Blood/ 安定ヒト血液
Product contains biologically sourced material from Human, Bovine and Porcine



WARNING
H315, H316, H319
Potassium Hydroxide < 1%



REF B36880



Printed in USA Made in USA
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B36870-AB



3-7/8" x 1-3/8"

DxH 500 Series Calibrator

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: N/A

Description: CTN; DXH 500 SERIES CALIBRATOR

Ink Color(s): 100% Black, PMS 321C, PMS 186C

Part Number: B36870

Revision: AB

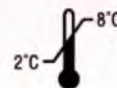
Label Size: 3-7/8" x 2-1/4" x 4-1/2"

Scale: 1 : 1

IVD

2 mL

WARNING
H315, H316, H319



LOT



2" x 7/16"
Hold Area for Barcode

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DxH 500 Series Calibrator

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: Reduce 50%

Description: LBL; PRI, DXH 500 SERIES CALIBRATOR

Ink Color(s): 100% Black, PMS 321C, PMS 186C

Part Number: B36882

Revision: AB

Label Size: 2" x 1-1/4"

Scale: 2 : 1

ПРОШУ, ПРОНУМЕРОВАНО
И СКРЕПЛЕНО ПЕЧАТЬЮ

тридцать
пять листов

35

[Signature]

