

Ortho Clinical Diagnostics

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Statement of Copy

To whom it may concern:

We, Ortho-Clinical Diagnostics, located at
Felindre Meadows, Pencoed, Bridgend,
CF35 5PZ, United Kingdom

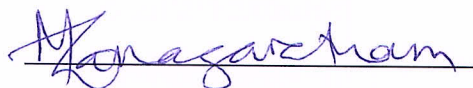
As a responsible official of Ortho-Clinical Diagnostics, I the undersigned hereby certify that
the enclosed document copies are true and accurate.

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Product labelling

Product Name	Code	Label Version
VITROS Immunodiagnosics Products CA 125 II Reagent Pack	6800038	T01/GEM1125FP/102.0 T01/LGEM1125RP/102.0 T01/JE1125/103.0 T01/JEX1125/103.0
VITROS Immunodiagnosics Products CA 125 II Calibrators	6800034	T28/G1125CL1/101.0 T19/G1125CL2/101.0 T20/G1125CL3/101.0 T01/JEC125/102.0 T01/JEXC125/102.0
VITROS Immunodiagnosics Products CA 15-3 Reagent Pack	6800039	T01/GEM1130FP/101.0 T01/LGEM1130RP/101.0 T01/JE1130/104.0 T01/JEX1130/104.0

Product Name	Code	Label Version
VITROS Immunodiagnosics Products CA 15-3 Calibrators	6800033	T28/G1130CL1/101.0 T19/G1130CL2/101.0 T20/G1130CL3/101.0 T01/JEC130/102.0 T01/JEXC130/102.0
VITROS Immunodiagnosics Products CA 19-9 Reagent Pack	6800040	T01/GEM1135FP/101.0 T01/LGEM1135RP/101.0 T01/JE1135/105.0 T01/JEX1135/105.0
VITROS Immunodiagnosics Products CA 19-9 Calibrators	6800035	T28/G1135CL1/101.0 T19/G1135CL2/101.0 T20/G1135CL3/101.0 T01/JEC135/103.0 T01/JEXC135/103.0
Anti-e (RH5) Monoclonal IgM Blend (human) BioClone for Slide, Tube and Microplate Tests	713125	CA10/d CL97/b VL205/c
Anti-Kell (Kel1) Monoclonal IgM (human) BioClone	713129	CA10/d CL96/b VL204/c



Tara Kanagaratnam
Regulatory Affairs, UK

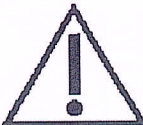
date: 28-MAR-2017

VITROS Immunodiagnostic Products CA 125 II

Reagent Pack Labels

VITROS Immunodiagnostic **Products IVD**

CA 125 II™ Reagent Pack

 8°C / 46°F
2°C / 36°F

LOT 9999   9999-99-99 **SN** 0000

T01/GEM1125FP/102.0 Ortho-Clinical Diagnostics UK

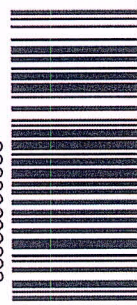
VITROS Immunodiagnostic **Products IVD**

CA 125 II™ Reagent Pack

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Ortho-Clinical Diagnostics
UK
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VITROS Immunodiagnostic Products CA 125 II

Calibrator Labels

VITROS Products
Immunodiagnostic
CA 125 II™
Calibrator



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T28/G1125CL1/101.0

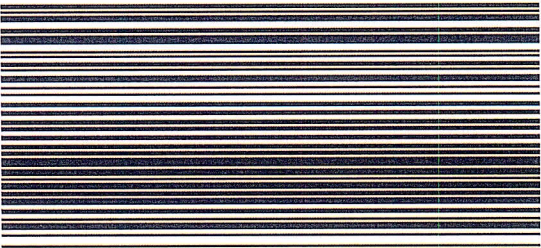
LOT 9999

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Ortho-Clinical Diagnostics UK



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VITROS Products
Immunodiagnostic
CA 125 II™
Calibrator



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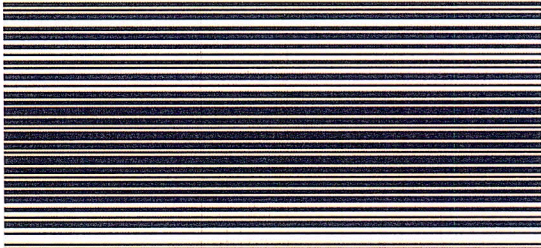
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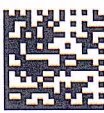
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Ortho-Clinical Diagnostics UK



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VITROS Products
Immunodiagnostic
CA 125 II™
Calibrator



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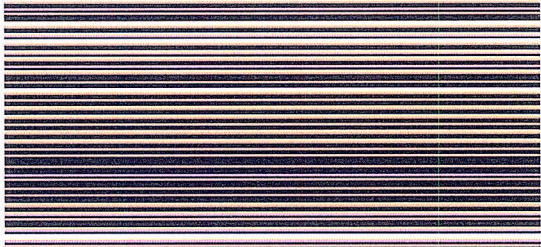
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Ortho-Clinical Diagnostics UK



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Ortho Clinical Diagnostics
Pencoed, UK

Kanagaratham

28-MAR-2017

VITROS Immunodiagnostic Products CA 125 II



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1 x CA 125 II kalibrators 1 - 3 • Etalons CA 125 II 1 - 3 • CA 125 II Kalibratoren 1 - 3 • Calibratori CA 125 II 1 - 3 • komplet kalibratorow, poziom 1-3 - CA 125 II • CA 125 II kalibratori 1-3
1 x Lot Calibration Card • Carte d'étalonnage de lot • Los-Kalibrierungskarte • Scheda di calibrazione del lotto • karta kalibracji serii • Lot Kalibrasyon Kartı • 1 x Protocol Card • Carte de protocole • Testprotokoll-Magnetkarte • Scheda dei protocolli • karta protokolu • Protokol Kartı • 24 x calibrator bar code labels • étiquettes à code à barres pour étalon • Kalibrator-Barcode-etiketten • étichette con codice a barre per calibratori • nalepkiz kodem kreskowym do kalibratora • kalibrator barked etiket

For use in the calibration of the VITROS Immunodiagnostic and Integrated Systems for the quantitative measurement of OC 125 defined antigen in human serum and plasma (EDTA or heparin) • Destinés à l'étalonnage des systèmes d'immunodiagnostic et systèmes intégrés VITROS pour le dosage quantitatif de l'antigène défini par l'anticorps OC 125 dans le sérum et le plasma humains (EDTA ou héparine) • Zur Verwendung bei der Kalibrierung der VITROS Immunodiagnostic und Integrated Systeme für die quantitative Bestimmung von OC 125 definierten Antigen in humanem Serum und Plasma (mit EDTA oder Heparin) • Da usarsi nella calibrazione dei Sistemi Integrati e per immunodiagnostica VITROS per la determinazione quantitativa dell'antigene OC 125-specifico nel siero umano e nel plasma (EDTA o eparina) • Do kalibrowania analizatorów immunodagnostycznych i zintegrowanych VITROS w celu ilościowego oznaczania antygenu zdefiniowanego OC 125 w ludzkiej surowicy i osoczu (EDTA lub heparyna) • İnsan serumu ve plazmasında (EDTA veya heparin) kantitatif OC 125 tanımlı antijen ölçümünde kullanılan VITROS immunodiagnostic ve Integrated System cihazlarının kalibrasyonunda kullanım içindir

Reactive Ingredients

OC 125 defined antigen in buffer, 1.75 mL; nominal values 24.0; 130 and 875 U OC 125 defined antigen/mL

Reagenzien

OC 125 definiertes Antigen in Puffer, 1.75 mL; Nominalwerte 24.0; 130 und 875 U OC 125 definiertes Antigen/mL

Składniki reaktywne

Antygen zdefiniowany OC 125 w buforze, 1,75 mL; wartości nominalne 24,0; 130 i 875 U antygenu zdefiniowanego OC 125/mL

Réactifs

Antigène défini par l'anticorps OC 125 dans un tampon, 1.75 mL; valeurs nominales de 24.0, 130 et 875 U d'antigène défini par l'anticorps OC 125/mL

Reagenti

Antigene OC 125-specifico in tampone, 1.75 mL; valori nominali 24.0; 130 e 875 U antigene OC 125-specifico/mL

Reaktiv Maddeler

Tamponda 1,75 mL OC 125 tanımlı antijen; nominal değerler 24,0; 130 ve 875 U OC 125 tanımlı antijen/mL

VITROS[®] Products
Immunodiagnostic
CA 125 II[™]
Calibrators

REF 680 0034

LOT 9999

9999-99-99

2°C/ 36°F 8°C/ 46°F

Ortho-Clinical Diagnostics
Pencoed, Bridgend
CF35 5PZ, UK
2016-05-05



SN 0000

Vitros is a trademark
GEM.C125
T01/JEC125/102.0

(01)107587500034
(17)999999(11)160503
(10)9999



1 x calibradores de CA 125 II 1 - 3 • calibradores de CA 125 II 1 - 3 • CA 125 II-kalibratorer 1 - 3 • CA 125 II-kalibratorer 1-3 • 1 x cartão magnético de calibração do lote • tarjeta de calibración de lote • lotspecifikt kalibreringskort • lot-kalibreringskort • 1 x cartão magnético de protocolo • tarjeta de protocolo • protokolkort • protokolkort • 24 x etiquetas de código de barras do calibrador • etiquetas de código de barras del calibrador • kalibratorstregkodemærkater • strekkodsetiketter för kalibrator



Para utilização na calibração do Sistema de Imunodiagnóstico VITROS e do Sistema Integrado VITROS para a medição quantitativa de antígeno definido pelo OC 125 no soro e plasma humanos (com EDTA ou heparina) • Para su utilización en la calibración del Sistema de Imunodiagnóstico VITROS y los sistemas integrados para la determinación cuantitativa del antígeno definido OC 125 en el suero y plasma humanos (EDTA o heparina) • Til brug ved kalibrering af VITROS Immunodiagnostic og Integrated Systems til kvantativ måling af OC 125 defineret antigen i human serum og plasma (EDTA eller heparin) • För användning vid kalibrering av VITROS immundiagnostiska och integrerade system för kvantitativ mätning av OC 125-definerat antigen i human serum och human plasma (EDTA eller heparin)

Reagentes

Antígeno definido pelo OC 125 em tampão, 1,75 mL; valores nominais de 24,0; 130 e 875 U de antígeno definido pelo OC 125/mL

Principios reactivos

Antígeno definido OC 125 en tampón, 1,75 mL; valores nominales 24,0; 130 y 875 U de antígeno definido OC 125/mL

Reaktive bestanddele

OC 125 defineret antigen i buffer, 1,75 mL; nominelle værdier 24,0; 130 og 875 U OC 125 defineret antigen/mL

Reaktiva ämnen

OC 125-definerat antigen i buffert, 1,75 mL; nominella värden 24,0; 130 och 875 U OC 125-definerat antigen/mL

Brasil: Johnson & Johnson do Brasil Ind. e Com. de Prod. para Saúde Ltda. Divisão: Johnson & Johnson Medical Brasil Rua Gerivitiba, 207 - São Paulo/SP CEP 05501-900 - Brasil CNPJ: 54516661/0001-01 Resp. Técnico.: Nancy M.R.B Lopes C.R.F.-SP Nº 10965 Somente Para Uso Diagnóstico In Vitro MS No. 10132590524 SAC: 08007075420 • Argentina: Importado por Johnson & Johnson Medical S.A. Mendoza 1259, CP: C1428DJG - CABA - Argentina Aut. Por ANMAT. Legajo Nº 16 DT: Luis De Angelis - Farmacéutico Vta. Exclusiva a lab. de análisis clínicos. USO PROF. EXCLUSIVO

T01/JEC125/102.0

SN 0000

GEM.C125

VITROS Immunodiagnostic Products CA 15-3

Reagent Pack Labels

VITROS Immunodiagnostic **Products IVD**

CA 15-3™ Reagent Pack

 8°C / 46°F
2°C / 36°F

LOT 9999   9999-99-99 **SN** 0000

T01/GEM1130FP/101.0 Ortho-Clinical Diagnostics UK

VITROS Immunodiagnostic **Products IVD**

CA 15-3™ Reagent Pack

 8°C / 46°F
2°C / 36°F



LOT 9999  9999-99-99

Ortho-Clinical Diagnostics UK
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Ortho Clinical Diagnostics
Pencoed, UK

H. Gnanagobram

28-MAR-2017

VITROS Immunodiagnostic Products CA 15-3



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1 x Reagent Pack • Cartouche de réactifs • Reagenzpack • Confezione di reagente • zestaw odczynnikowy • Reaktiv Paketi
For the quantitative measurement of DF3 defined antigen in human serum and plasma (EDTA or heparin) using the VITROS Immunodiagnostic and Integrated Systems • Destinée au dosage quantitatif de l'antigène défini par l'anticorps DF3 dans le sérum et le plasma humains (EDTA ou héparine) avec les systèmes d'immunodiagnostic et les systèmes intégrés VITROS • Für die quantitative Bestimmung von DF3-definiertem Antigen in humanem Serum und Plasma (mit EDTA oder Heparin) auf den VITROS Immunodiagnostik und Integrated Systemen • Per la determinazione quantitativa dell'antigene DF3-specifico nel siero e nel plasma umani (EDTA o eparina) utilizzando i Sistemi Integrati e per immunodiagnostica VITROS • Do ilościowego oznaczania antygenu DF3 w ludzkiej surowicy i osoczu (EDTA lub heparyna) przy użyciu analizatorów immunodiagnostycznych i zintegrowanych VITROS • VITROS Immunodiagnostic ve Integrated System kullanılarak insan serum ve plazmasındaki (EDTA veya heparin) DF3 tanımlı antijenin kantitatif ölçümü içinidir

Reactive Ingredients

100 coated wells (streptavidin, bacterial, binds ≥ 3 ng biotin/well); 20.2 mL conjugate reagent (HRP-labeled DF3 mouse monoclonal anti-DF3 defined antigen, binds $\geq 36,2$ U DF3 defined antigen/mL); 15.8 mL biotinylated antibody reagent (biotinylated 115D8 mouse monoclonal anti-DF3 defined antigen, binds $\geq 41,7$ U DF3 defined antigen/mL)

Reagenzien

100 beschichtete Wells (Streptavidin, bakterieel; bindet ≥ 3 ng Biotin/Well); 20,2 mL Konjugatreagens (HRP-gekoppelter, monoklonaler DF3-Maus-Anti-DF3-definiertes-Antigen, bindet $\geq 36,2$ U DF3-definiertes Antigen/mL); 15,8 mL biotinyliertes Antikörperreagens (Biotin-gekoppelter, monoklonaler 115D8-Maus-Anti-DF3-definiertes-Antigen, bindet $\geq 41,7$ U DF3-definiertes Antigen/mL)

Składniki reaktywne

100 opłaszczonych mikroceli (streptawidyna, bakteryjna; wiąże ≥ 3 ng biotyny/mikrocela); 20,2 mL odczynnika sprzężonego (mysie przeciwciało monoklonalne DF3 anty-DF3 znakowane za pomocą HRP, wiąże $\geq 36,2$ U antygenu DF3/mL); 15,8 mL odczynnika biotyniowanego przeciwciała (biotyniowane mysie przeciwciało monoklonalne 115D8 anty-DF3, wiąże $\geq 41,7$ U antygenu zdefiniowanego DF3/mL)

Réactifs

100 puits revêtus (streptavidine, bactérienne; se liant à ≥ 3 ng de biotine/puits); 20,2 mL de réactif conjugué (anticorps monoclonal de souris anti-antigène défini par l'anticorps DF3, marqué à la HRP; se liant à $\geq 36,2$ U d'antigène défini par l'anticorps DF3/mL); 15,8 mL de réactif d'anticorps biotinylé (anticorps biotinylé 115D8 monoclonal de souris anti-antigène défini par l'anticorps DF3; se liant à $\geq 41,7$ U d'antigène défini par l'anticorps DF3/mL)

Reagenti

100 pozzetti rivestiti (streptavidina, batterica; si lega a ≥ 3 ng biotina/pozzetto); 20,2 mL di reagente coniugato (antigene anti-DF3-specifico monoclonale di topo con HRP, si lega a $\geq 36,2$ U antigene DF3-specifico/mL); 15,8 mL di reagente anticorpo biotinilato (antigene anti-DF3-specifico monoclonale di topo 115D8 biotinilato, si lega a $\geq 41,7$ U antigene DF3-specifico/mL)

Reaktiv Maddeler

100 kapli kuyu (streptavidin, bakterieel; bağlanma ≥ 3 ng biotin/kuyu); 20,2 mL konjugat reaktifi (HRP etiketli DF3 fare monoklonal anti-DF3 tanımlı antijen, bağlanma $\geq 36,2$ U DF3 tanımlı antijen/mL); 15,8 mL biotinli antikor reaktifi (biotinli 115D8 fare monoklonal anti-DF3 tanımlı antijen, bağlanma $\geq 41,7$ U DF3 tanımlı antijen/mL)

Caution: Do not freeze • Attention: Ne pas congeler • Warnhinweis: Nicht einfrieren • Attenzione: Non congelare • Uwaga: Nie zamrażać • Dikkat: Dondumayın



VITROS[®] Products
Immunodiagnostic

CA 15-3[™]

Reagent Pack

REF 680 0039

LOT 9999

9999-99-99



2°C/36°F
8°C/46°F



Ortho-Clinical Diagnostics
Pencoed, Bridgend
CF35 5PZ, UK

2016-05-05



SN 0000

Vitros is a trademark
GEM.1130
T01/JE1130/104.0

(01)10758750006434
(17)999999(11)160505
(10)9999



1 x embalagem de reagente • kit de reactivos • reagenspakke • reagenspack

Para a medição quantitativa de antígeno definido pelo DF3 no soro e plasma humanos (com EDTA ou heparina) utilizando o Sistema de Imunodiagnóstico VITROS e o Sistema Integrado VITROS • Para la determinación cuantitativa del antígeno definido DF3 en suero y plasma humanos (EDTA o heparina) utilizando el Sistema de Imunodiagnóstico VITROS y los sistemas integrados • Til kvantitativ måling af DF3-defineret antigen i humant serum og plasma (EDTA eller heparin) ved brug af VITROS Immunodiagnostic og Integrated Systems • För kvantitativ mätning av DF3-definerat antigen i humant serum och human plasma (EDTA eller heparin) med VITROS immundiagnostiska och integrerade system



Reagentes

100 poços revestidos (estreptavidina, bacteriana; liga ≥ 3 ng de biotina/poço); 20,2 mL de reagente conjugado (antígeno DF3 definido pelo anti-DF3 monoclonal de ratinho marcado com HRP, liga $\geq 36,2$ U de antígeno definido pelo DF3/mL); 15,8 mL de reagente de anticorpo biotinilado (antígeno 115D8 definido pelo anti-DF3 monoclonal de ratinho biotinilado, liga $\geq 41,7$ U de antígeno definido pelo DF3/mL)

Reaktive bestandteile

1100 coatede brønde (streptavidin, bakterieel; binder ≥ 3 ng biotin/brønd); 20,2 mL konjugatreagens (HRP-mærket DF3-musmonoklonalt anti-DF3-defineret antigen, binder $\geq 36,2$ U DF3-defineret antigen/mL); 15,8 mL biotinyleret antistofreagens (biotinyleret 115D8-musmonoklonalt anti-DF3-defineret antigen, binder $\geq 41,7$ U DF3-defineret antigen/mL)

Principios reactivos

100 pocillos recubiertos (estreptavidina, bacteriana; se fija a ≥ 3 ng biotina/pocillo); 20,2 mL de reactivo conjugado (monoclonal de ratón anti-antígeno definido DF3 marcado con HRP, se fija a $\geq 36,2$ U de antígeno definido DF3/mL); 15,8 mL de reactivo de anticuerpo biotinilado (monoclonal de ratón 115D8 biotinilado anti-antígeno definido DF3, se fija a $\geq 41,7$ U de antígeno definido DF3/mL)

Reaktiva ämnen

100 belagda brunnar (streptavidin, bakterieel; binder ≥ 3 ng biotin/brunn); 20,2 mL konjugatreagens (HRP-märkt DF3-musmonoklonalt anti-DF3-definerat antigen, binder $\geq 36,2$ U DF3-definerat antigen/mL); 15,8 mL biotinylerat antikropsreagens (biotinylerat 115D8 musmonoklonalt anti-DF3-definerat antigen, binder $\geq 41,7$ U DF3-definerat antigen/mL)

Precauções: Não congelar • Precaución: No congelar • Forsigtig: Må ikke nedfryses • Försiktighet: Får ej frysförvaras

Brasil: Johnson & Johnson do Brasil Ind. e Com. de Prod. para Saúde Ltda. Divisão: Johnson & Johnson Medical Brasil Rua Gerivalda, 207 - São Paulo/SP CEP 05501-900 - Brasil CNPJ: 54516661/0001-01 Resp. Técnico.: Nancy M.R.B. Lopes C.R.F.-SP Nº 10965 Somente Para Uso Diagnóstico In Vitro MS No. 10132590482 SAC: 08007075420 • Argentina: Importado por Johnson & Johnson Medical S.A. Mendoza 1259, CP: C1428DUG - CABA - Argentina Aut. Por ANMAT. Legajo Nº 16 DT: Luis De Angellis - Farmacéutico Vta. Exclusiva a lab. de análisis clínicos. USO PROF. EXCLUSIVO

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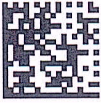
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VITROS Immunodiagnostic Products CA 15-3

Calibrator Labels

VITROS Products
Immunodiagnostic
CA 15-3™
Calibrator



2°C/
36°F

8°C/
46°F

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T28/G1130CL1/101.0

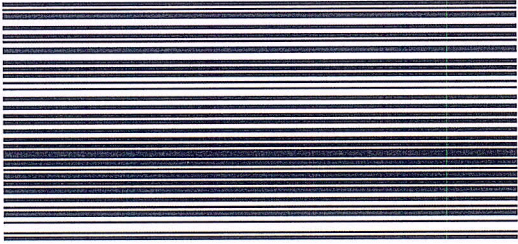
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IVD

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Ortho-Clinical Diagnostics UK



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VITROS Products
Immunodiagnostic
CA 15-3™
Calibrator



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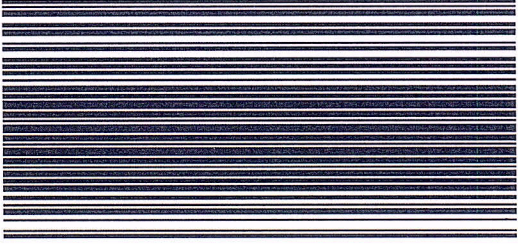
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IVD

SN 0000

Ortho-Clinical Diagnostics UK



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VITROS Products
Immunodiagnostic
CA 15-3™
Calibrator



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T20/G1130CL3/101.0

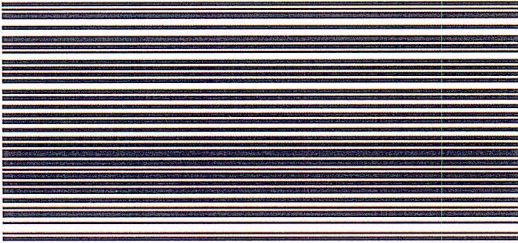
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IVD

SN 0000

Ortho-Clinical Diagnostics UK



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Ortho Clinical Diagnostics
Pencoed, UK
Benagasham
28-MAR-2017

VITROS Immunodiagnostic Products CA 15-3



1 x CA 15-3 calibrators 1 - 3 • Etalons CA 15-3 1 - 3 • CA 15-3 Kalibratoren 1 - 3 • Calibratori CA 15-3 1 - 3 • komplet kalibratorów, poziom 1-3 - CA 15-3 • CA 15-3 kalibratorleri 1-3
 1 x Lot calibration card • Carte d'étalonnage de lot • Los-Kalibrierungskarte • Scheda di calibrazione del lotto • karta kalibracji serii • Lot kalibrasyon kartı • 1 x Protocol card • Carte de protocole • Testprotokoll-Magnetkarte • Scheda dei protocolli • karta protokolu • Protokol Kartı • 24 x calibrator bar code labels • étiquettes à code à barres pour étalon • Kalibrator-Barcodeetiketten • étichette con codice a barre per calibratori • nalepkiz kodem kreskowym do kalibratora • kalibrator barkod etiket



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VITROS Products
 Immunodiagnostic
CA 15-3™

Calibrators

REF 680 0033

LOT 9999

9999-99-99

2°C/ 36°F 8°C/ 46°F

Ortho-Clinical Diagnostics
 Pencoed, Bridgend
 CF35 9PZ, UK
 2016-05-05



SN 0000

Vitros is a trademark
 GEM.C130
 T01/JEC130/102.0

(01)10958750000331
 (17)9999999999999999
 (10)9999



Reactive Ingredients

DF3 defined antigen in buffer, 1.75 mL; nominal values 15, 50 and 250 U DF3 defined antigen/mL

Reagenzien

DF3-definiertes Antigen in Puffer, 1.75 mL; Nominalwerte 15, 50 und 250 U DF3-definiertes Antigen/mL

Składniki reaktywne

Antygen zdefiniowany DF3 w buforze, 1,75 mL; wartości nominalne 15; 50 i 250 U antygenu zdefiniowanego DF3/mL

Réactifs

Antigène défini par l'anticorps DF3 dans un tampon, 1,75 mL; valeurs nominales de 15, 50 et 250 U d'antigène défini par l'anticorps DF3/mL

Reagenti

Antigene DF3-spezifisch in Puffer, 1,75 mL; nominali 15; 50 e 250 U antigene DF3-spezifisch/mL

Reaktiv Maddeler

Tamponda DF3 tanımlı antijen, 1,75 mL; nominal değerler 15, 50 ve 250 U DF3 tanımlı antijen/mL



1 x calibradores de CA 15-3 1 - 3 • calibradores para CA 15-3 1 - 3 • CA 15-3 kalibratorer 1 - 3 • CA 15-3-kalibratorer 1 - 3 • 1 x cartão magnético de calibração do lote • tarjeta de calibración de lote • lotspecifikt kalibreringskort • lot-kalibreringskort • 1 x cartão magnético de protocolo • tarjeta de protocolo • protokolkort • protokollkort • 24 x etiquetas de código de barras do calibrador • etiquetas de código de barras del calibrador • kalibratorstregkodemærkater • streckkodsetiketter för kalibrator



Para utilização na calibração do Sistema de Imunodiagnóstico VITROS e do Sistema Integrado VITROS para a medição quantitativa de antígeno definido pelo DF3 no soro e plasma humanos (com EDTA ou heparina) • Para utilización en la calibración del Sistema de Imunodiagnóstico VITROS y los sistemas integrados para la determinación cuantitativa del antígeno definido DF3 en el suero y plasma humanos (EDTA o heparina) • Til brug ved kalibrering af VITROS Immunodiagnostic og Integrated Systems til kvantativ måling af DF3-defineret antigen i humant serum og plasma (EDTA eller heparin) • För användning vid kalibrering av VITROS immundiagnostiska och integrerade system för kvantitativ mätning av DF3-definerat antigen i humant serum och human plasma (EDTA eller heparin)

Reagentes

Antígeno definido pelo DF3 em tampão, 1,75 mL; valores nominais de 15; 50 e 250 U de antígeno definido pelo DF3/mL

Principios reactivos

Antígeno definido DF3 en tampón, 1,75 mL; valores nominales 15; 50 y 250 U de antígeno definido DF3/mL

Reaktive bestanddele

DF3-defineret antigen i buffer, 1,75 mL; nominelle værdier 15; 50 og 250 U DF3-defineret antigen/mL

Reaktiva ämnen

DF3-definerat antigen i buffert, 1,75 mL; nominella värden 15; 50 och 250 U DF3-definerat antigen/mL

Brasil: Johnson & Johnson do Brasil Ind. e Com. de Prod. para Saúde Ltda. Divisão: Johnson & Johnson Medical Brasil Rua Gerivitiba, 207 - São Paulo/SP CEP 05501-900 - Brasil CNPJ: 54516661/0001-01 Resp. Técnico.: Nancy M.R.B Lopes C.R.F.-SP Nº 10965 Somente Para Uso Diagnóstico In Vitro MS No. 10132590522 SAC: 08007075420 • Argentina: Importado por Johnson & Johnson Medical S.A. Mendoza 1259, CP: C1428DJG - CABA - Argentina Aut. Por ANMAT. Legajo Nº 16 DT: Luis De Angelis - Farmacéutico Vta. Exclusiva a lab. de análisis clínicos. USO PROF. EXCLUSIVO

T01/JEXC 130/102.0

SN 0000

GEM.C130

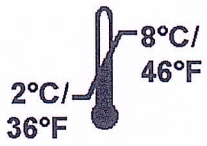
VITROS Immunodiagnostic Products CA 19-9

Reagent Pack Labels

VITROS Immunodiagnostic **Products IVD**

CA 19-9™ Reagent Pack



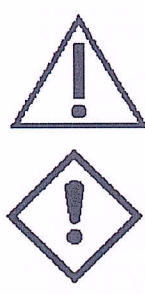


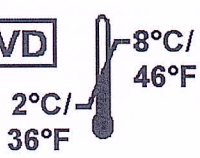
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T01/GEM1135FP/101.0 Ortho-Clinical Diagnostics UK

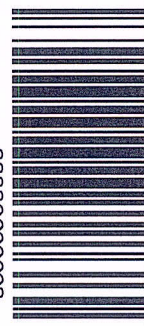
VITROS Immunodiagnostic **Products IVD**

CA 19-9™ Reagent Pack





LOT 9999 

 9999-99-99 

Ortho-Clinical Diagnostics
UK
SN 0000
T01/LGEM1135RP/101.0

VITROS Immunodiagnostic Products CA 19-9



www.orthoclinical.com

1 x Reagent Pack • Cartouche de réactifs • Reagenzpack • Confezione di reagente • zestaw odczynnikowy • Reaktiv Paketi
For the quantitative measurement of 1116-NS-19-9 defined antigen in human serum and plasma (EDTA or heparin) using the VITROS Immunodiagnostic and Integrated Systems • Cestree
au dosage quantitatif de l'antigène défini par l'anticorps 1116-NS-19-9 dans le sérum et le plasma humains (EDTA ou héparine) avec les systèmes d'immunodiagnostic et systèmes intégrés
VITROS • Für die quantitative Bestimmung von 1116-NS-19-9-definiertem Antigen in humanem Serum und Plasma (mit EDTA oder Heparin) auf den VITROS Immunodiagnostik und
Integrated Systemen • Per la determinazione quantitativa dell'antigene 1116-NS-19-9-specifico nel siero e nel plasma umani (eparina o EDTA) utilizzando i Sistemi Integrati e per
immunodiagnostica VITROS • Do ilościowego oznaczenia antygenu zdefiniowanego 1116-NS-19-9 w ludzkiej surowicy i osoczu (EDTA lub heparyna) przy użyciu analizatorów
immunodiagnostycznych i zintegrowanych VITROS • VITROS Immunodiagnostische und Integrated Systemen kulanlarak insan serum ve plazmasındaki (EDTA veya heparin) 1116-NS-19-9
tanımlı antijenin kantitatif ölçümü için dir.

Reactive Ingredients

100 coated wells (streptavidin, bacterial binds ≥ 3 ng biotin/well); 20.0 mL conjugate reagent (HRP-mouse monoclonal anti 1116-NS-19-9 defined antigen, binds ≥ 336 U 1116-NS-19-9 defined antigen/mL); 13.4 mL biotinylated antibody reagent (biotin-mouse monoclonal anti 1116-NS-19-9 defined antigen, binds ≥ 559 U 1116-NS-19-9 defined antigen/mL)

Reagenzien

100 beschichtete Wells (Streptavidin, bakteriel; bindet ≥ 3 ng Biotin/Well); 20,0 mL Konjugatreagens (HRP-gekoppelter, monoklonaler Maus-Anti-1116-NS-19-9-definiertes Antigen, bindet ≥ 336 U 1116-NS-19-9-definiertes Antigen/mL); 13,4 mL biotinyliertes Antikörperreagens (Biotin-gekoppelter, monoklonaler Maus-Anti-1116-NS-19-9-definiertes Antigen, bindet ≥ 559 U 1116-NS-19-9-definiertes Antigen/mL)

Składniki reaktywne

100 opłaszczonych mikrocel (streptawidyna, bakteryjna; wiąże ≥ 3 ng biotyny/mikrocela); 20,0 mL odczynnika sprzężonego (mysie przeciwciała monoklonalne anty-antygenu zdefiniowany 1116-NS-19-9 znakowane za pomocą HRP, wiąże ≥ 336 U antygenu zdefiniowanego 1116-NS-19-9/mL); 13,4 mL odczynnika biotyniowanego przeciwciała (biotyniowane mysie przeciwciała monoklonalne anty-1116-NS-19-9, wiąże ≥ 559 U antygenu zdefiniowanego 1116-NS-19-9/mL)

Caution: Do not freeze • Attention: Ne pas congeler • Warnhinweis: Nicht einfrieren • Attenzione: Non congelare • Uwaga: Nie zamrażać • Dikkat: Dondumayın

Réactifs

100 puits revêtus (streptavidine, bactérienne; se liant à ≥ 3 ng de biotine/puits); 20,0 mL de réactif conjugué (HRP-anticorps monoclonal de souris anti-antigène défini par l'anticorps 1116-NS-19-9, se liant à ≥ 336 U d'antigène défini par l'anticorps 1116-NS-19-9/mL); 13,4 mL de réactif d'anticorps biotinylé (biotine-anticorps monoclonal de souris anti-antigène défini par l'anticorps 1116-NS-19-9, se liant à ≥ 559 U d'antigène défini par l'anticorps 1116-NS-19-9/mL)

Reagenti

100 pozzetti rivestiti (streptavidina, batterica; si lega a ≥ 3 ng biotina/pozzetto); 20,0 mL di reagente coniugato (antigene anti-1116-NS-19-9-specifico monoclonale di topo con HRP, si lega a ≥ 336 U antigene 1116-NS-19-9-specifico/mL); 13,4 mL di reagente anticorpo biotinilato (antigene anti-1116-NS-19-9-specifico monoclonale di topo biotinilato, si lega a ≥ 559 U antigene 1116-NS-19-9-specifico/mL)

Reaktiv Maddeler

100 kapli kuyu (streptavidin, bakteriyel; bağlanma ≥ 3 ng biotin/kuyu); 20,0 mL konjugat reaktifi (HRP-fare monoklonal anti 1116-NS-19-9 tanımlı antijen, bağlanma ≥ 336 U 1116-NS-19-9 tanımlı antijen/mL); 13,4 mL biotinli antikor reaktifi (biyotin-fare monoklonal anti 1116-NS-19-9 tanımlı antijen, bağlanma ≥ 559 U 1116-NS-19-9 tanımlı antijen/mL)



VITROS Products
Immunodiagnostic
CA 19-9™
Reagent Pack

REF 680 0040

LOT 9999



9999-99-99



2°C/36°F



8°C/46°F



46°F



2°C/36°F



8°C/46°F



46°F



2°C/36°F



8°C/46°F



46°F



2°C/36°F



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VITROS Immunodiagnostic Products CA 19-9

Calibrator Labels

VITROS Products
Immunodiagnostic
CA 19-9™
Calibrator



2°C/
36°F



8°C/
46°F

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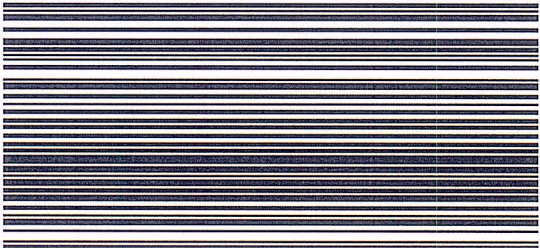
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LOT 9999

SN 9999-99-99

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VITROS Products
Immunodiagnostic
CA 19-9™
Calibrator



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36°F



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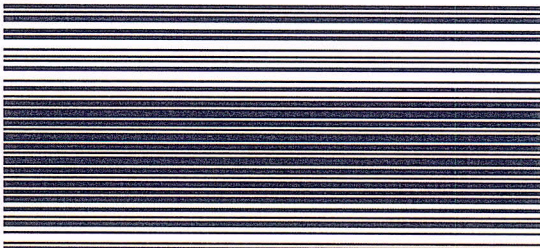
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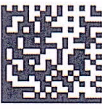
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VITROS Products
Immunodiagnostic
CA 19-9™
Calibrator



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36°F



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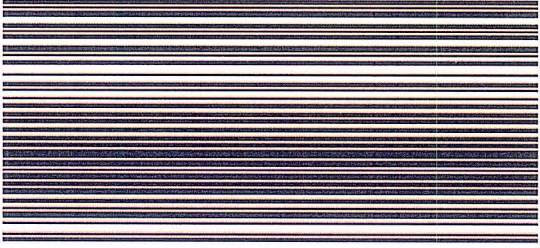
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IVD

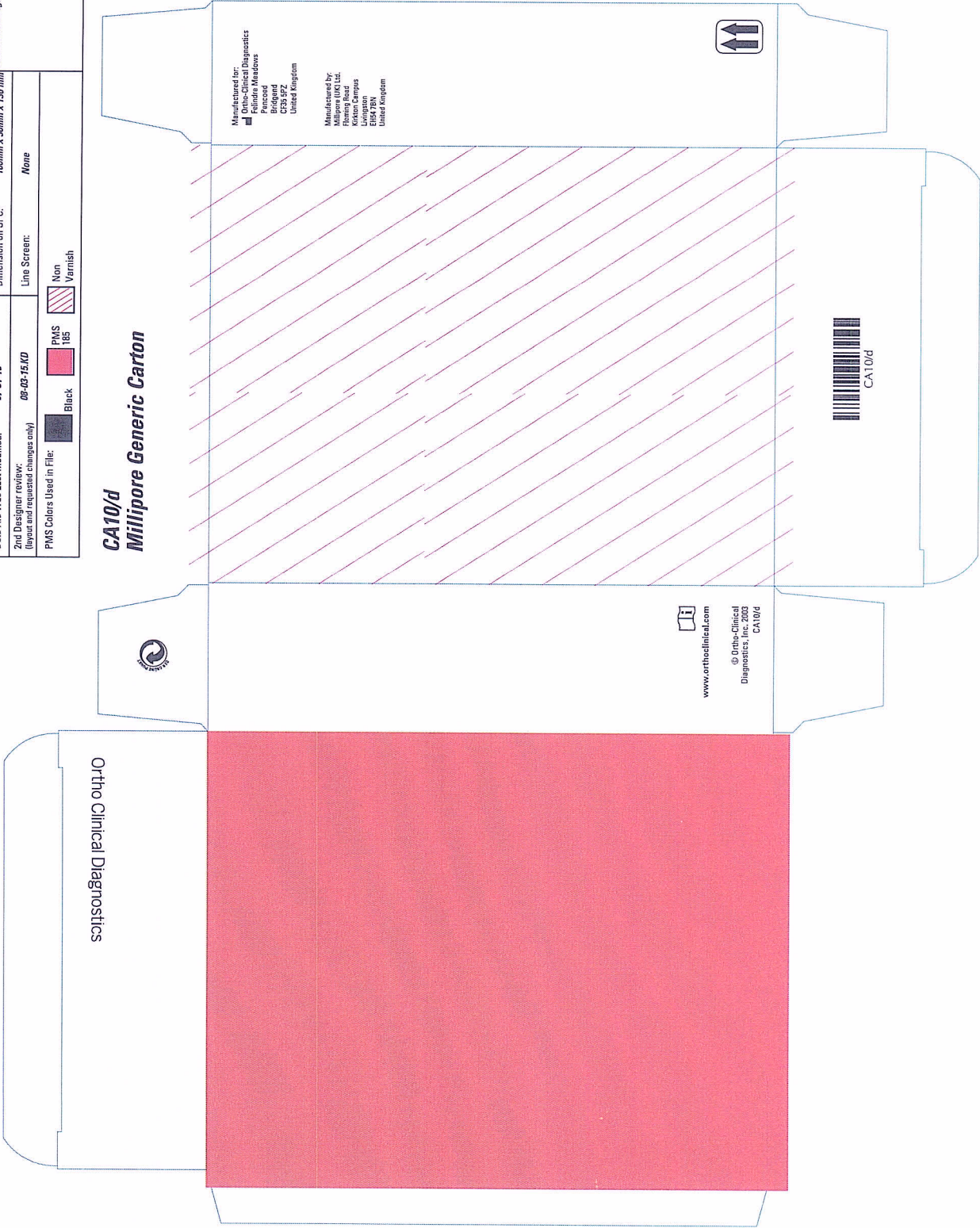
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OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	Candace Rechsteiner	SPC Number in OTIS:	SPC50889	07-31-15 CR used CA10d CHMU to create CA10/d for Crimson Phase 2 per marked up PDF from CC
Date File Was Last Modified:	07-31-15	Dimension on SPC:	106mm x 36mm x 136 mm	06-02-15: KD signed.
2nd Designer review: (layout and requested changes only)	09-03-15: KD	Line Screen:	None	
PMS Colors Used in File:	Black		PMS 185	
			Non Vernish	



Ortho Clinical Diagnostics
Pencoe, UK
Kay Schmitt
28-MK-2017

OCD Mechanical Info.

FOR OCD USE ONLY - REFER TO SPECIFICATION

Date Copy Control Approved File:	8/14/12 CC	Designer Who First Created File:	Kim DePaola	OTHER: 06/5/12: CR created using approved CL97a, rolled tailcode to CL97b for GS1. This label doesn't receive any Legal Mfg revisions. 6/14/12 CR made revs per KTs review of file. 6/18/12: KD signed. 6/22/12 CR added slash back to file name in artwork only per meeting 6.22.12 with Millipore. 6/22/12 KD signed 8/24/12 CR entered CC and Eng approval dates (no spec)
Date Pkg. Engineering Approved File:	08/20/12 BB BLB	Date File Was Last Modified:	06/22/12	
Dimension on Specification:	80mm x 50mm	Designer Who Last Modified File:	Candace Rechsteiner	
Drawing #	NA	Line Screen:	None	
PMS Colors Used in File:	Black	Designer review: (layout and requested changes only)	6/22/12.KD	

CL97/b
Carton Label

Anti-e (RH5)
BioClone®
1 x 5 mL

CL97/b
CE 0123
REF 713125
IVD
2°C-8°C

LOT

NOTE: Cyan blue box does not print. Indicates GS1 area.

Ortho Clinical Diagnostics
Pencoe, UK

Handwritten signature
28-MAR-2017



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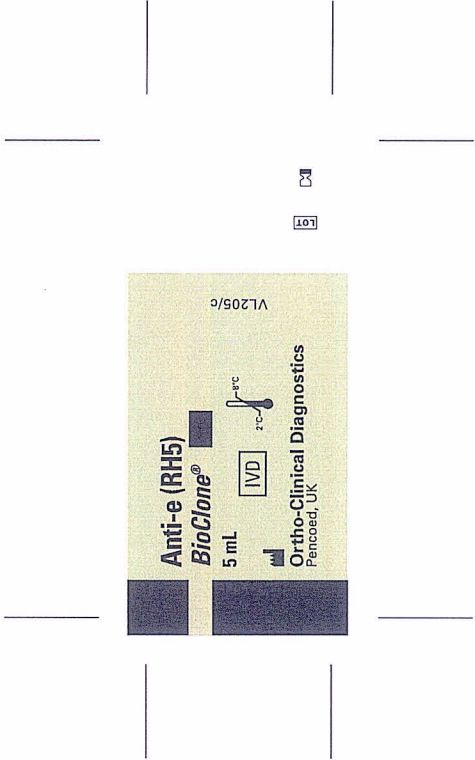
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10

OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	Kim DePaola	SPC Number in OTIS:	SPC50887	08-04-15: KD used VL205/bCRMU, rolled to VL205/c per marked up PDF for Phase 2 of Crimson Project. 08-04-15 KT signed.
Date File Was Last Modified:	08-04-15	Dimension on SPC:	65mm x 25mm	
2nd Designer review: (layout and requested changes only)	08-04-15 KT	Line Screen:	None	
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VL205/c
Vial Label



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Pencoe, UK
Haragadum

28-MAR-2017



Y-axis label

X-axis label

Y-axis label

X-axis label

Y-axis label

Y-axis label

X-axis label

Y-axis label

X-axis label

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X-axis label

Y-axis label

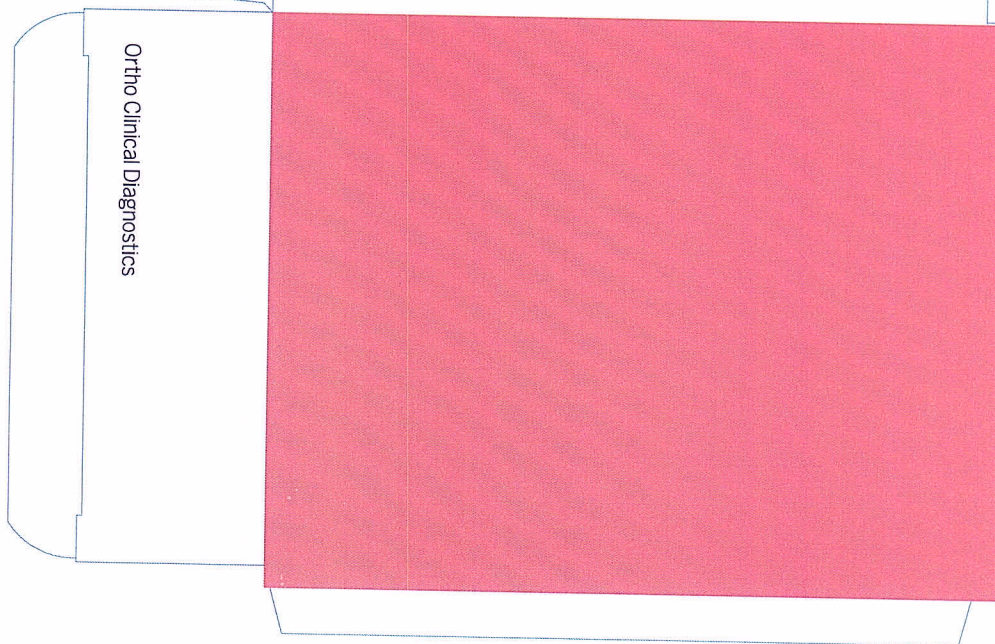
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Y-axis label

OCD Mechanical Info. - FOR INTERNAL USE ONLY

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Date File Was Last Modified:	07-31-15	Dimension on SPC:	106mm x 35mm x 135 mm	08-03-15: KD signed.
2nd Designer review: (repost and requested changes only)	08-03-15:KD	Line Screen:	None	
PMS Colors Used in File:	Black		Non Varnish	

CA10/d
Millipore Generic Carton



Ortho Clinical Diagnostics



Manufactured for:
Ortho-Clinical Diagnostics
Pencoed
Cardiff
CF23 5PZ
United Kingdom

Manufactured by:
Pencoed
Cardiff
Cardiff Campus
E154 3PW
United Kingdom



CA10/d

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Pencoed, UK

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28-MAR-2017

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CA10/d

OCD Mechanical Info. FOR OCD USE ONLY - REFER TO SPECIFICATION

Date Copy Control Approved File: 8/14/12 CC		Designer Who First Created File: Kim DePaola	OTHER: 6/18/12: KD rolled tail code, made revisions for GS1 - removed HBIC, placed area for GS1 into per KD proposed label mockup. 6/18/12 KT signed. 6/22/12 CR added slash back to file name in artwork only per meeting 6.22.12 with Millipore. 6/22/12 KD signed 8/22/12 CR entered CC and Eng approval dates (no spec)
Date Pkg. Engineering Approved File: 8/20/12 BB BLB		Date File Was Last Modified: 6/22/12	
Dimension on Specification: 80mm x 50mm		Designer Who Last Modified File: Candace Rechsteiner	
Drawing # NA	LBL NA	Designer review: (layout and requested changes only)	
Line Screen: None		6/22/12 KD	
PMS Colors Used in File:			
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CL96/b
Millipore Carton Label

CL96/b

IVD

2°C-8°C

CE

0123

REF

713129

Anti-Kell (KEL1)

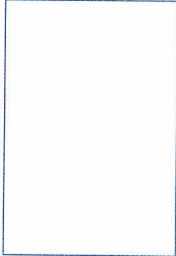
BioClone®

1 x 5 mL

LOT



NOTE: Cyan blue box does not print. Indicates GS1 area.

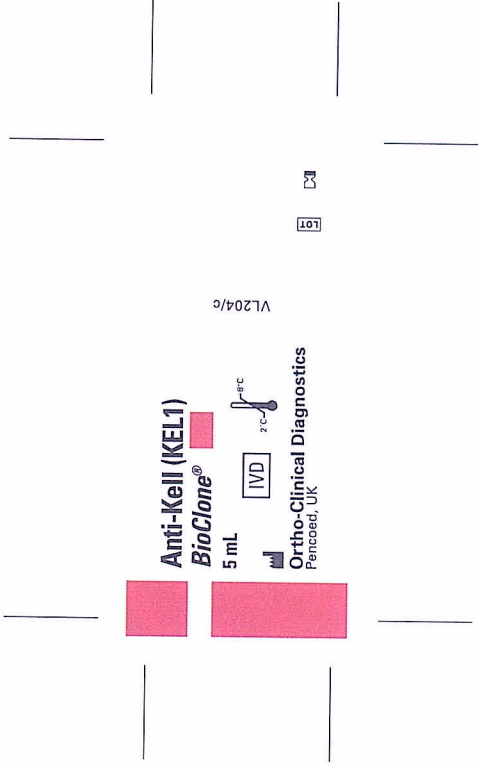


Ortho Clinical Diagnostics
Pencoe, UK
Handwritten signature
28-MAR-2017

OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	Kim DePaola	SPC Number in OTIS:	SPC50888	08-04-15: KD used VL204/c CRMU, rolled to VL204/c per marked up PDF for Phase 2 of Crimson Project. 08-04-15 KT signed.
Date File Was Last Modified:	08-04-15	Dimension on SPC:	65mm x 25mm	
2nd Designer review: (layout and requested changes only)	08-04-15 KT	Line Screen:	None	
PMS Colors Used in File:		Black PMS 185		

VL204/c
Vial Label



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28-MAR-2017

