

Mẫu nội dung nhãn phụ

Thuốc thử xét nghiệm định tính kháng nguyên Streptococcus nhóm B, *Haemophilus influenzae* type b, *Streptococcus pneumoniae*, *Neisseria meningitidis* nhóm A, B, C, Y, W135 và *Escherichia coli* K1

Chủng loại: Wellcogen™ Bacterial Antigen Kit

Mã sản phẩm: R30859602

Số lưu hành: 2503389ĐKLH/BYT-HTTB.

Số lô: Xem “” trên nhãn gốc.

Hạn sử dụng: Xem “” (năm/tháng/ngày) trên nhãn gốc.

Tên / Địa chỉ chủ sở hữu thiết bị y tế: Remel Europe Limited / Remel House, Clipper Boulevard West, Crossways, Dartford, Kent, DA2 6PT, Vương quốc Anh.

Xuất xứ: Vương quốc Anh.

Tên / Địa chỉ chủ sở hữu số lưu hành: Văn Phòng Đại Diện Life Technologies Holdings Pte. Ltd. tại Thành phố Hồ Chí Minh / Phòng 0911, tầng 9, số 2Bis-4-6, đường Lê Thánh Tôn, phường Sài Gòn, Thành phố Hồ Chí Minh, Việt Nam.

Tên / Địa chỉ cơ sở bảo hành: Sản phẩm không có chế độ bảo hành.

Hướng dẫn bảo quản: Bảo quản ở 2°C - 8°C.

Cảnh báo, hướng dẫn sử dụng: Xem trong *Hướng dẫn sử dụng* HOẶC *Website*:

Table with 2 columns: Field Name, Value. Fields include Company Name, Address, Product name, Product code, Title, Form Control No., and Type of Document.

1. PRIMARY LABELLING

Grid of 12 primary labels for Wellcogen kits. Each label shows dimensions (24 mm x 40 mm), product name, lot number, and expiration date. Includes labels for Control, Test, and various bacterial antigens like H. influenzae b, S. pneumoniae, and N. meningitidis.

2. SECONDARY LABELLING/PACKAGING

Diagram of a secondary label for the Wellcogen Bacterial Antigen Kit. Shows dimensions (95 mm x 30 mm), barcode, lot number, and manufacturer information (Thermo Fisher Diagnostics B.V.).

Company Name	Remel Europe Limited
Address	Remel House, Clipper Boulevard West Crossways, Dartford, Kent, DA2 6PT
Product name	Wellcogen Bacterial Antigen Kit
Product code	R30859602
Title	Primary and Secondary Packaging and Labelling
Form Control No.	DF-FORM-1101
Type of Document	Form Control Document

2. SECONDARY LABELLING/PACKAGING

200 mm +/-

REF R30859602 (ZL26)

Wellcogen™ Bacterial Antigen Kit

EN: Latex test to detect Streptococcus Group B, *H. influenzae* type b, *S. pneumoniae*, *N. meningitidis* ABCY W135 and *E. coli* K1 antigens

FR: Test au latex pour la détection des antigènes du streptocoque du groupe B, de *H. influenzae* de type b, de *S. pneumoniae*, de *N. meningitidis* groupes A, B, C, Y et W-135 et de *E. coli* K1

DE: Latextest zum Nachweis von Streptococcus Gruppe B, *H. influenzae* Typ b, *S. pneumoniae*, *N. meningitidis* ABCY W135 und *E. coli* K1 Antigenen

ES: Prueba de látex para la detección de antígenos de Streptococcus grupo B, *H. influenzae* tipo b, *S. pneumoniae*, *N. meningitidis* ABCY W135 y *E. coli* K1

IT: Test al lattice per il rilevamento degli antigeni di Streptococco del Gruppo B, di *H. influenzae* tipo b, di *S. pneumoniae*, di *N. meningitidis* ABCY W135 e di *E. coli* K1

CS: Latexový test pro stanovení antigenů streptokoků skupiny B, *H. influenzae* typu b, *S. pneumoniae*, *N. meningitidis* ABCY W135 a *E. coli* K1

DA: Latex-test til detektion af streptokokgruppe B, *H. influenzae* type b, *S. pneumoniae*, *N. meningitidis* ABCY W135 og *E. coli* K1 antigener

EL: Δοκιμασία λάτεξ για ανίχνευση αντιγόνων από στρεπτόκοκκο ομάδας B, *H. influenzae* τύπου b, *S. pneumoniae*, *N. meningitidis* των ομάδων ABCY W135 και *E. coli* K1

NO: Latekstest for å påvise Streptococcus gruppe B, *H. influenzae* type b, *S. pneumoniae*, *N. meningitidis* ABCY W135 og *E. coli* K1-antigener

PL: Test lateksowy do wykrywania antygenów Streptococcus grupy B, *H. influenzae* typu b, *S. pneumoniae*, *N. meningitidis* ABCY W135 oraz *E. coli* K1

PT-PT: Teste de látex para detecção dos antígenos de Estreptococos do Grupo B, *H. influenzae* tipo b, *S. pneumoniae*, *N. meningitidis* ABCY W135 e *E. coli* K1

SV: Latextest för att detektera Streptococcus grupp B-, *H. influenzae* typ b-, *S. pneumoniae* -, *N. meningitidis* ABCY W135- och *E. coli* K1-antigener

BR-PT: Teste de látex para detectar os antígenos de Streptococcus do grupo B, *H. influenzae* do tipo b, *S. pneumoniae*, *N. meningitidis* do tipo ABCY W135 e *E. coli* do tipo K1

TEST LATEX

1-5

CONTROL LATEX

6-10

- 1 Streptococcus B.
- 2 *H. influenzae* b.
- 3 *S. pneumoniae*.
- 4 *N. meningitidis* ACY W135.
- 5 *N. meningitidis* B/E. coli K1.
- 6 Streptococcus B.
- 7 *H. influenzae* b.
- 8 *S. pneumoniae*.
- 9 *N. meningitidis* ACY W135.
- 10 *N. meningitidis* B/E. coli K1.

CONTROL 2.3 ml

CONTROL 2 x 3.6 ml

1C13ZL26P

remel

140 mm +/-

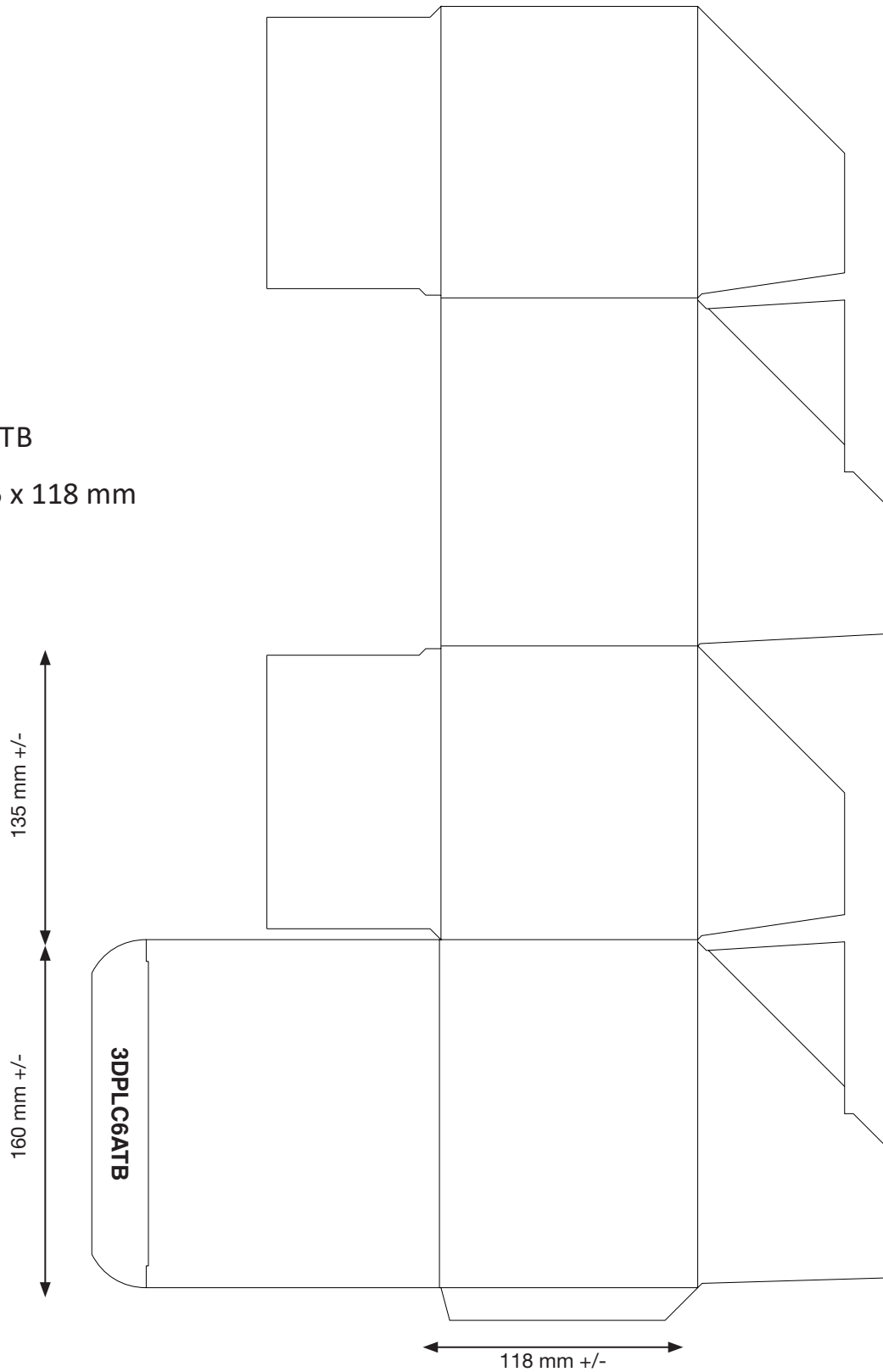
* All tolerances +/- 1mm

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Packaging and Labelling -DF-FORM-1101

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3DPLC6ATB
160 x 135 x 118 mm



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3. PACKAGING COMPONENT DETAILS

Part code	Description	Packaging
W71UZL26N	Polyvalent Positive Control	2 X 5ml Clear glass Bottle + 14mm FD Stopper + Blue Cap
W74NUSA13	ZL26 Negative Control	1 X 3ml Plastic Bottle + 8mm Dropper Tip + White Cap
W74CLUSA2	ZL20 Control Latex	1 X 3ml Plastic Bottle + 20µL dropper + Royal Blue Cap
W74CLUSA4	ZL21 Control Latex	1 X 3ml Plastic Bottle + 20µL dropper + Royal Blue Cap
W74CLUSA6	ZL22 Control Latex	1 X 3ml Plastic Bottle + 20µL dropper + Royal Blue Cap
W74CLUSA8	ZL23 Control Latex	1 X 3ml Plastic Bottle + 20µL dropper + Royal Blue Cap
W74US10CL	ZL24 Control Latex	1 X 3ml Plastic Bottle + 20µL dropper + Royal Blue Cap
W74TLUSA1	ZL20 Test Latex	1 X 3ml Plastic Bottle + 20µL dropper + Pink Cap
W74TLUSA3	ZL21 Test Latex	1 X 3ml Plastic Bottle + 20µL dropper + Pale Blue Cap
W74TLUSA5	ZL22 Test Latex	1 X 3ml Plastic Bottle + 20µL dropper + Yellow Cap
W75TLUSA7	ZL23 Test Latex	1 X 3ml Plastic Bottle + 20µL dropper + Grey Cap
W75TLUSA9	ZL24 Test Latex	1 X 3ml Plastic Bottle + 20µL dropper + Brown Cap
26TILEREM	Disposable Reaction Cards	2 x 7 Colour Tile (26 pk)
WBIN8275J	Disposable Mixing Sticks	5 x Wooden Stick Bundles (100)
WBIN1818S	Disposable Droppers	1 x 30 Polypipettes
WBIN8275J	Black Rubber Teat	1 x Black Rubber Teat (No.10)

IFU				
Product code	IFU #	Date of issue	Insert Slip	Date of issue
R30859602	X7713C	June 2024	N/A	N/A

Control Change History				
Date	Revision	Description of Change	Reason for change	Approved by
19/09/2024	6	MOC-2024-0862	Update label and IFU to amend instructions and data	S. Murray

Approved Artwork Locations

External Labels

All artwork saved as Label Part code

P drive / QA-RA / Master Artwork / CLP Artwork / Wellcogen / Vial Labels / Master

P drive / QA-RA / Master Artwork / CLP Artwork / Wellcogen / Carton Labels / Master

Internal Labels (Full and composites)

All artwork saved as Part or Filling code and suffixed with version number

P drive / In-House Labels / Labels / Master

* All tolerances +/- 1mm