Labels

< Strep A Rapid Test >

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Drafted by:	Date:
Reviewed by:	Date:
Approved by:	Date:

< GenSure Biotech Inc. >

Revision History

Revised chapter	Revised content	Revised reason	Revised date	Revisor
N/A	N/A	Newly released	2024/6/26	Chen Liang
Section 2.1 and section 2.2	The labels of sealed pouch and box for the 2 brands are displayed separately and the content has been adjusted. The part number and version information has been added. And an explanation to explain the differences between the colored design draft and the packaging currently used in research and development.	To bring the documentation into compliance with the requirements of the technical document assessment results from the first round, as provided by the Notified Body.	2025/3/19	Chen Liang

Catalogue

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1. Language Requirements for Labeling in the EU Member States

The target market of the Strep A Rapid Test is EU member states.

All documents, including appointment applications submitted to the notified body, was drafted in English. At the same time, the CE label, language, and IFU Control Procedure has been established to control the language requirements of EU member states in accordance with language requirements.

GenSure

Labels

Language Country	Bulgarian	Croatian	Czech	Danish	Dutch	English	Estonian	Finnish	French	German	Greek	Hungarian	Irish	Italian	Latvian	Lithuanian	Maltese	Polish	Portuguese	Romanian	Slovak	Slovenian	Spanish	Swedish	Luxembourgis	Icelandic	Norwegian	Turkish
Austria										★																		
Belgium					★				★	★																		
Bulgaria	★																											
Croatia		★																										
Cyprus						☆					☆																	
Czech			★																									
Denmark				★																								
Estonia							★																					
Finland								★																★				
France									★																			
Germany										★																		
Greece											★																	
Hungary												★																
Ireland						★																						
Italy														★														
Latvia															★													
Lithuania																★												
Luxembourg									☆	☆															☆			
Malta						☆											☆											
Netherlands					★																							
Poland																		★										
Portugal																			★									
Romania																				★								
Slovakia																					★							
Slovenia																						★						
Spain																							★					
Sweden																								★				
Iceland																										★		
Liechtenstein										★																		
Norway																											★	
Turkey																												★

Note: In the table, "★" represents "and"; ☆ "represents" or ".

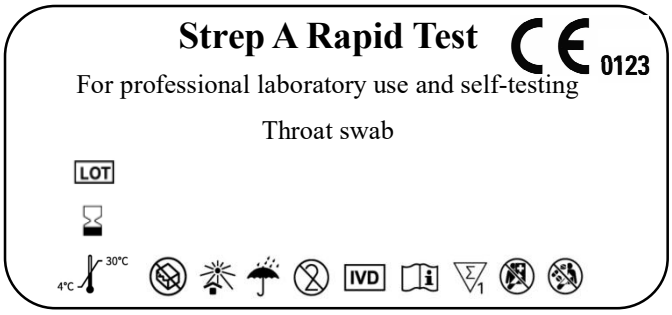
2. Information on the Label

The outer packaging of this product is a box, and the inner packaging include sealed bag, swab package, extraction buffer, and waste bag. The package should be printed or labelled with the following information:

2.1 Label of inner packaging

2.1.1 Label of sealed bag (immediate container)

The layout sketch is as follows:



Considering cost, the pre-market packaging is done using a universal sealed bag 1 labeled with printed stickers (part number and version information: C010001-P2019C-25.01).

Size: 140*60mm

After launching, it is planned to use a specifically designed Step A sealed bag for different brands (GenSure or EuroGen).

For GenSure brand (part number and version information: C010011-P2019C-25.01):

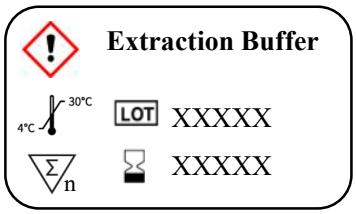
Size: 140*60mm

For EuroGen brand (part number and version information: C010019-P2019C-25.01):

Size: 140*60mm

2.1.2 Label of extraction buffer (part number and version information: C070003-P2019C-25.01)

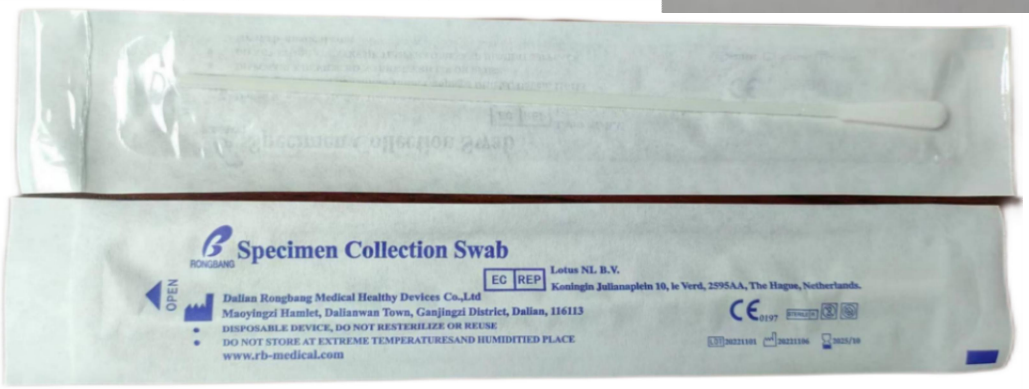
The layout sketch is as follows:



The physical image of the label of the extraction buffer for 20 T/Kit is shown in the figure on the right. For other specifications, the only difference is the number in the Summation symbol in the lower left corner of the label, which corresponds to the size of the specific specification.

2.1.3 Label of swab (part number: B090008)

Manufacturer: Dalian Rongbang Medical Healthy Devices Co., Ltd



2.1.4 Label of waste bag (part number: C070004)

2.2 Label of outer packaging (packaging box)

The layout sketch is as follows:

Strep A Rapid Test

CE 0123

For professional laboratory use and self-testing

Throat swab

CONTENTS:

- n Test cassette(s)
- n Disposable swab(s)
- n Extraction buffer
- n Waste bag(s)
- n Instructions For Use

UDI XXXXXXXXXXXX

REF XXXXX

LOT XXXXX

XXXXX

GenSure Biotech Inc.
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Email: leis@riomavix.com

IVD

4°C 30°C Store at 4-30℃/39.2-86℉ out of direct sunlight.

Children should be sampled and tested by an adult.
Keep away from children and pets.

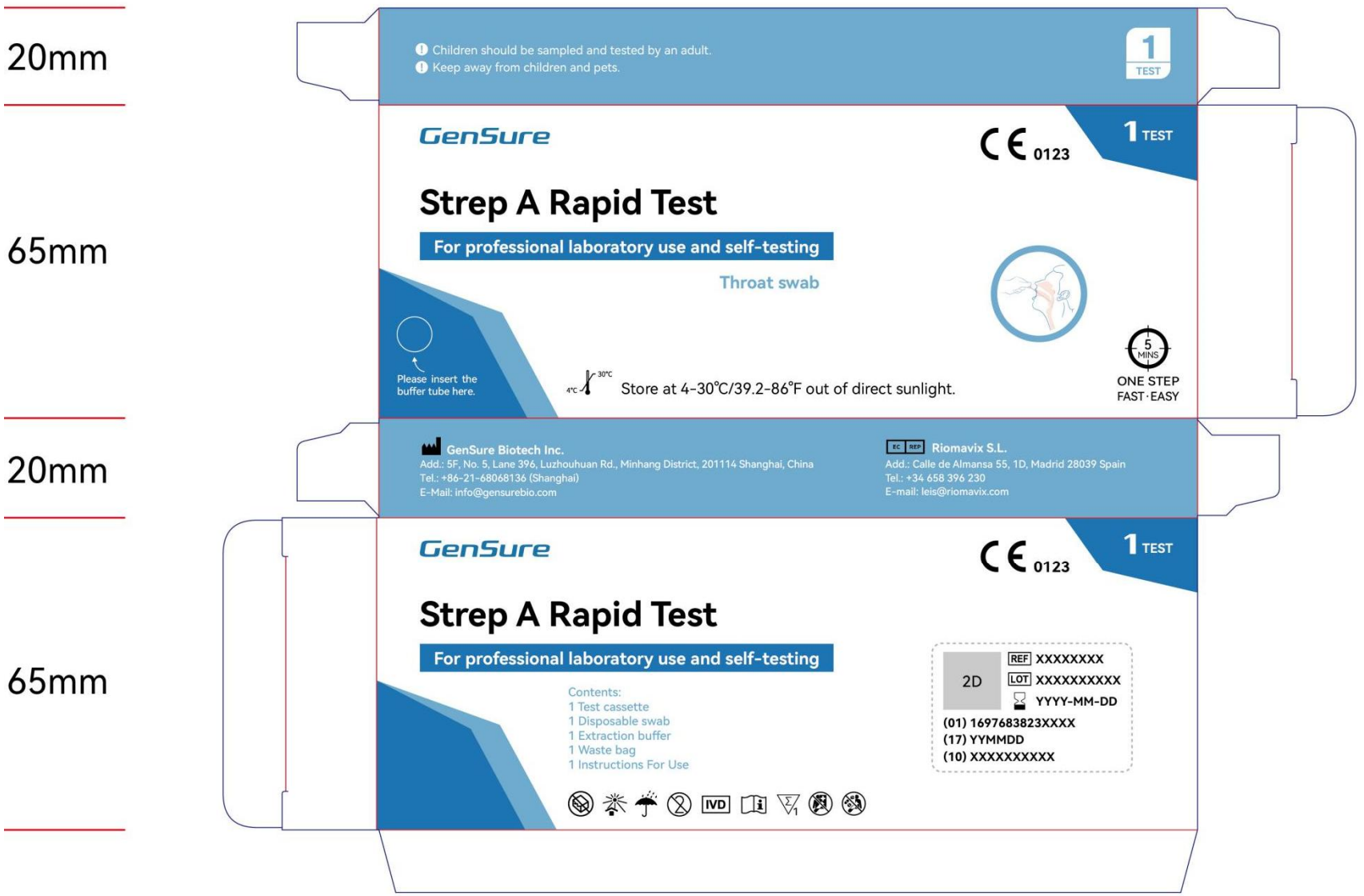
The material of these packaging boxes is cardboard.

Considering cost, the pre-market packaging is a universal box labeled with printed stickers (part number and version information: C030002-P2019C-25.01).

After launching, it is intended to use a specifically designed Step A packaging box for each specification with different brands (GenSure or EuroGen), please refer to the following illustration of the box (model draft), as well as part number and version information, while the revision date is the same as that of this document.

P2019C01　1 T/Kit (part number and version information: C030030-P2019C01-25.01):

Size: 170*65*20mm



Version:A/1

P2019C02 2 T/Kit (part number and version information: C030031-P2019C02-25.01): 170mm

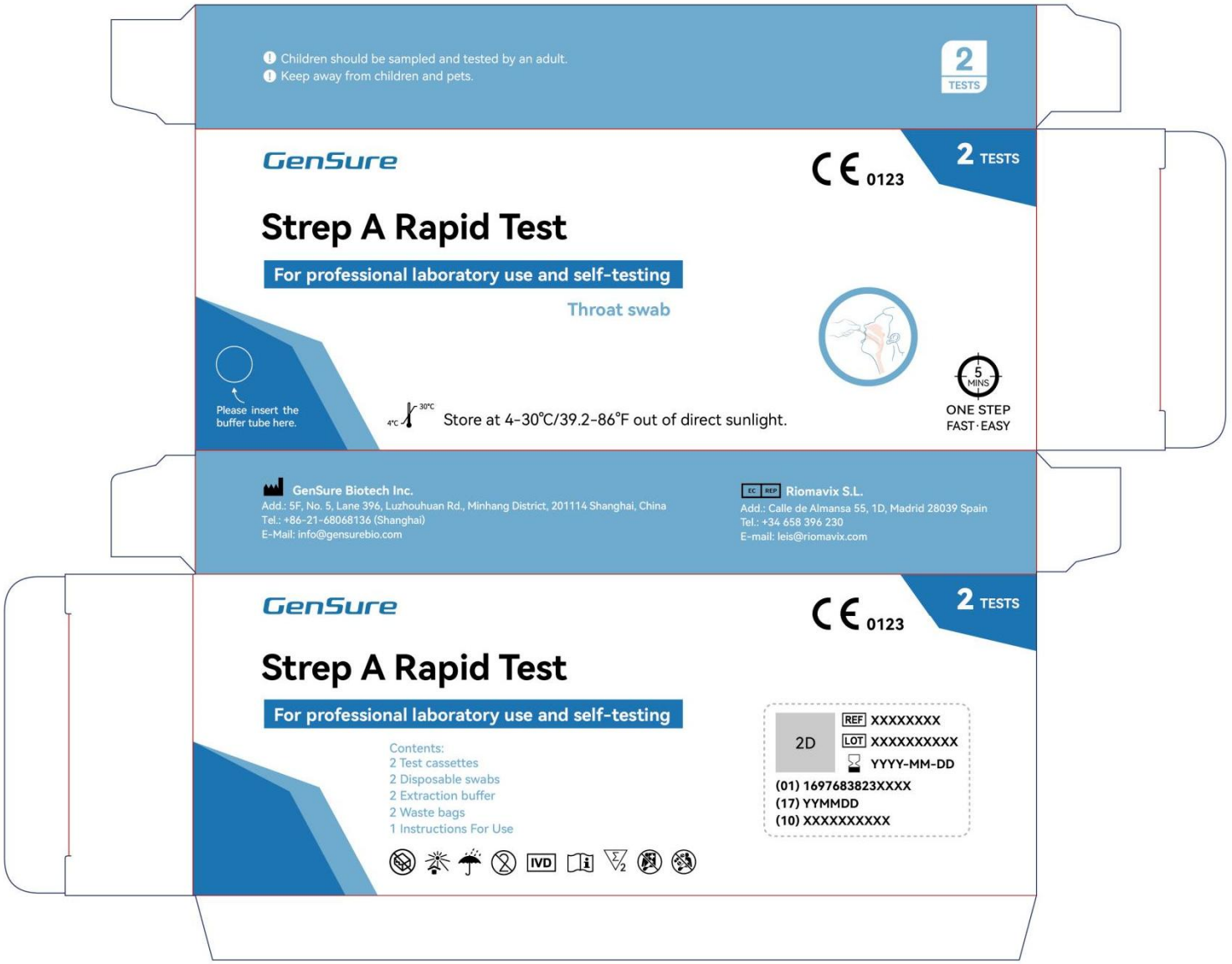
Size: 170*65*25mm

25mm

65mm

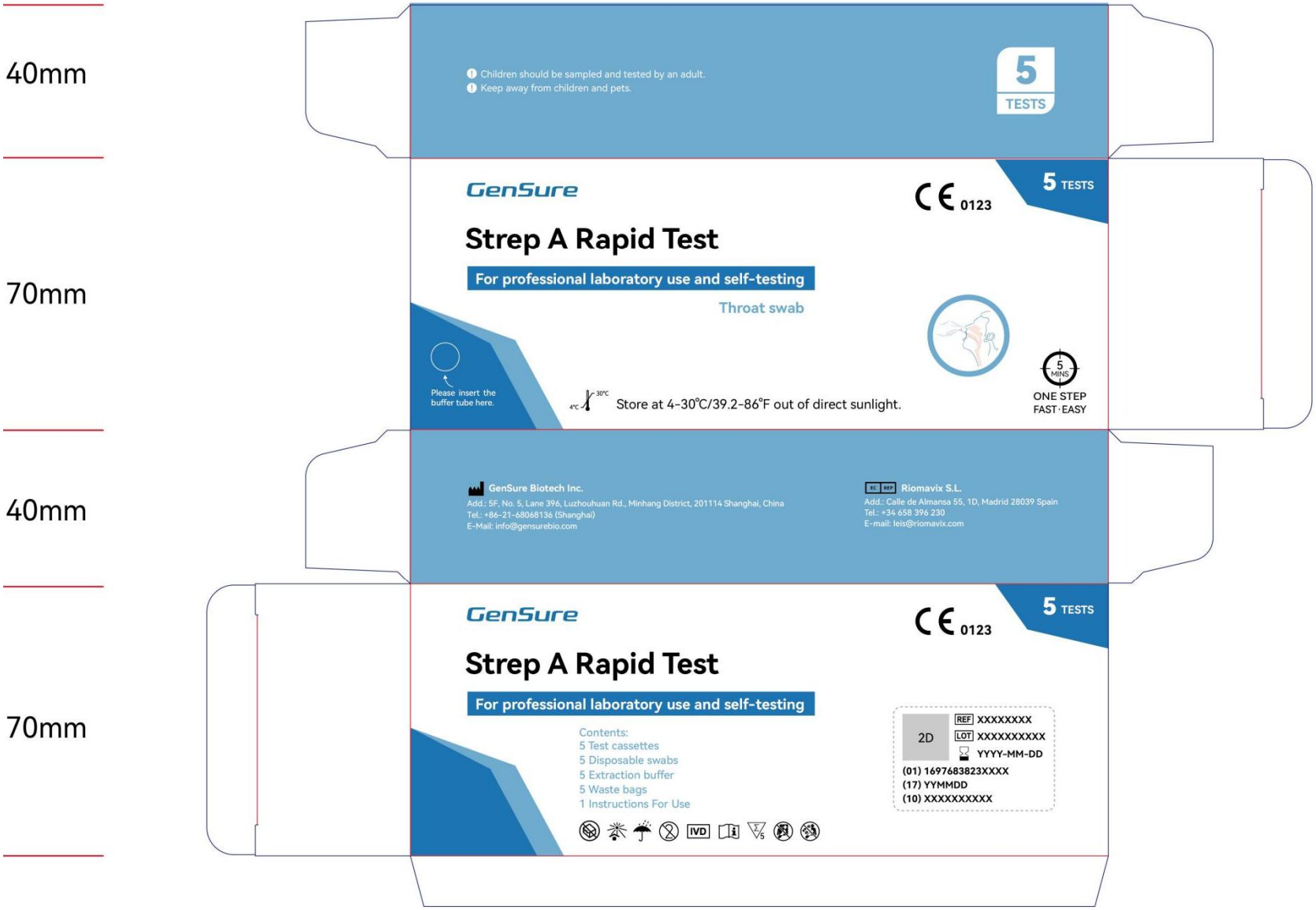
25mm

65mm



P2019C05 5 T/Kit (part number and version information: C030032-P2019C05-25.01): 180mm

Size: 180*70*40mm



GenSure

P2019C10 10 T/Kit (part number and version information: C030033-P2019C10-25.01):

Size: 180*80*70mm

Labels

180mm

80mm

80mm

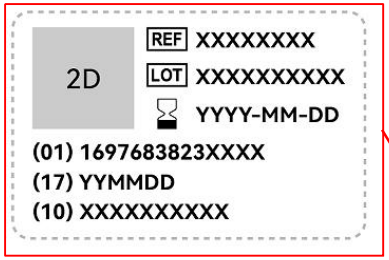
70mm

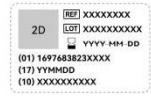
Strep A Rapid Test

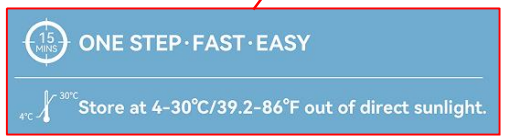
For professional laboratory use and self-testing Throat swab

Contents:

- 10 Test cassettes
- 10 Disposable swabs
- 10 Extraction buffer
- 10 Waste bags
- 1 Instructions For Use







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Keep away from children and pets.

GenSure

P2019C20 20 T/Kit (part number and version information: C030034-P2019C10-25.01)

Size: 180*150*65mm

180mm

150mm

150mm

150mm

65mm

Strep A Rapid Test

For professional laboratory use and self-testing Throat swab

Contents:

- 20 Test cassettes
- 20 Disposable swabs
- 20 Extraction buffer
- 20 Waste bags
- 1 Instructions For Use

2D REF XXXXXXXX LOT XXXXXXXXXX YYYY-MM-DD

(01) 1697683823XXXX

(17) YYMMDD

(10) XXXXXXXXXX

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Keep away from children and pets.

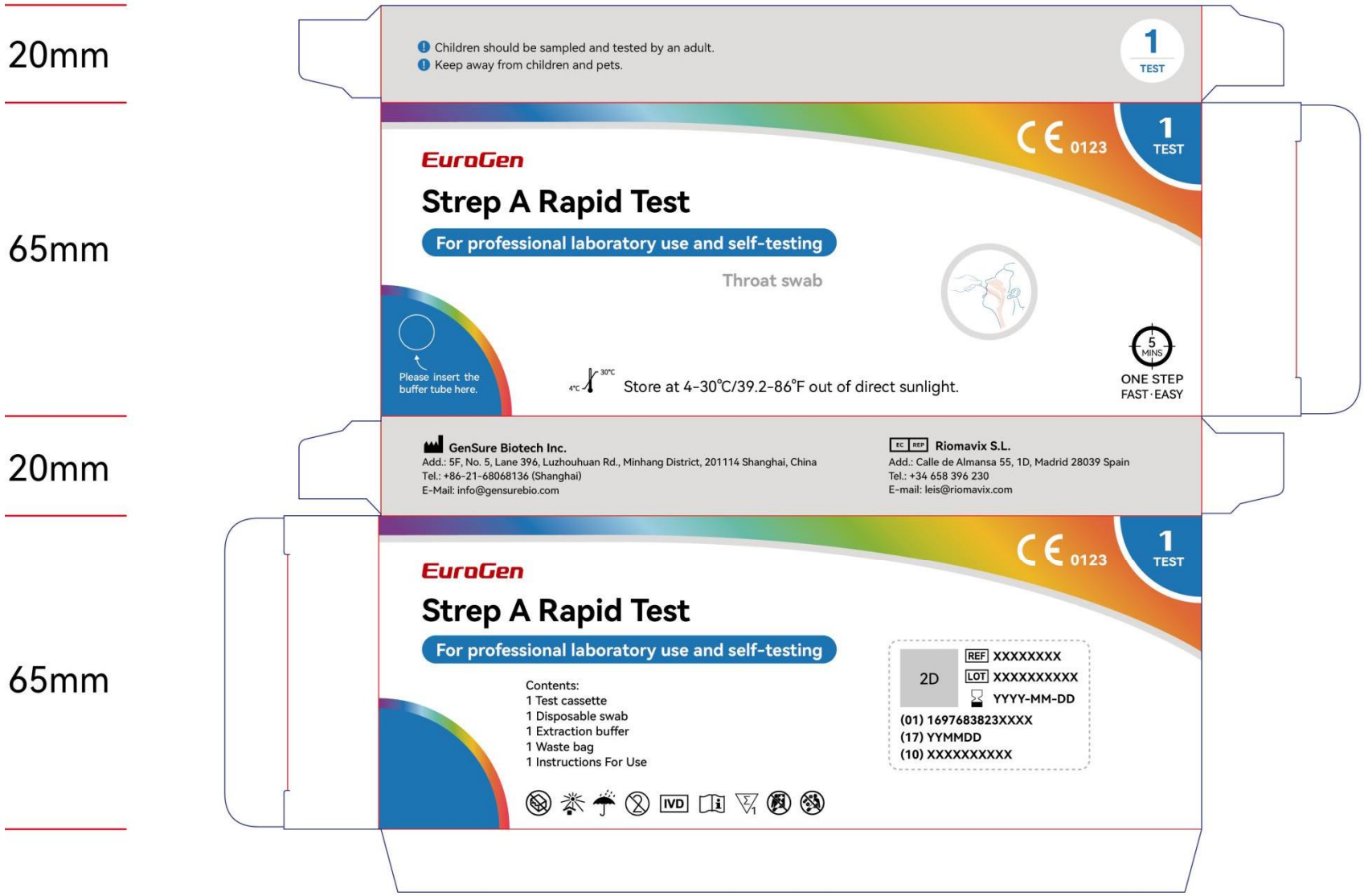
ONE STEP·FAST·EASY

Store at 4-30℃/39.2-86℉ out of direct sunlight.

IVD

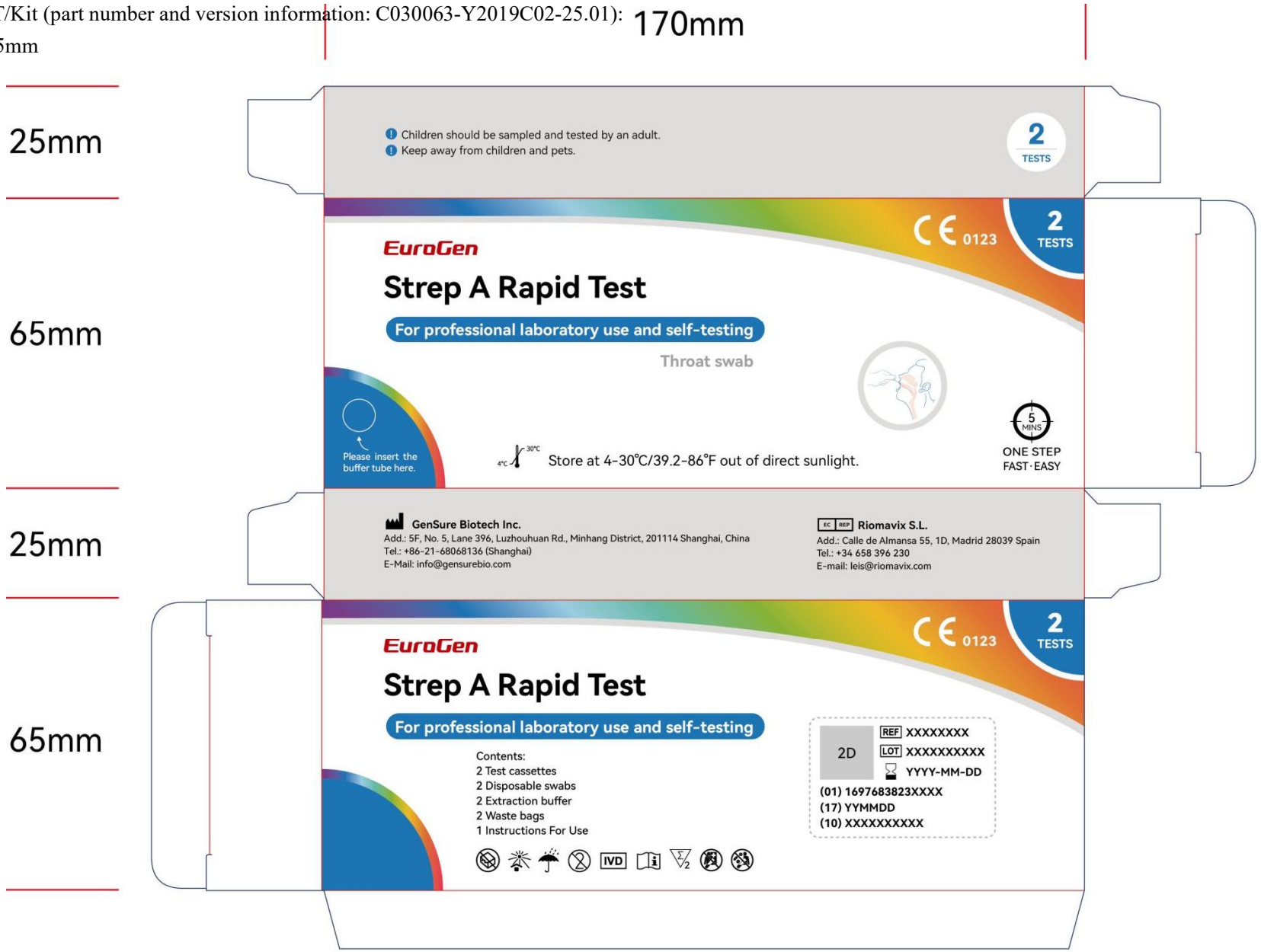
Y2019C01 1 T/Kit (part number and version information: C030062-Y2019C01-25.01):

Size: 170*65*20mm



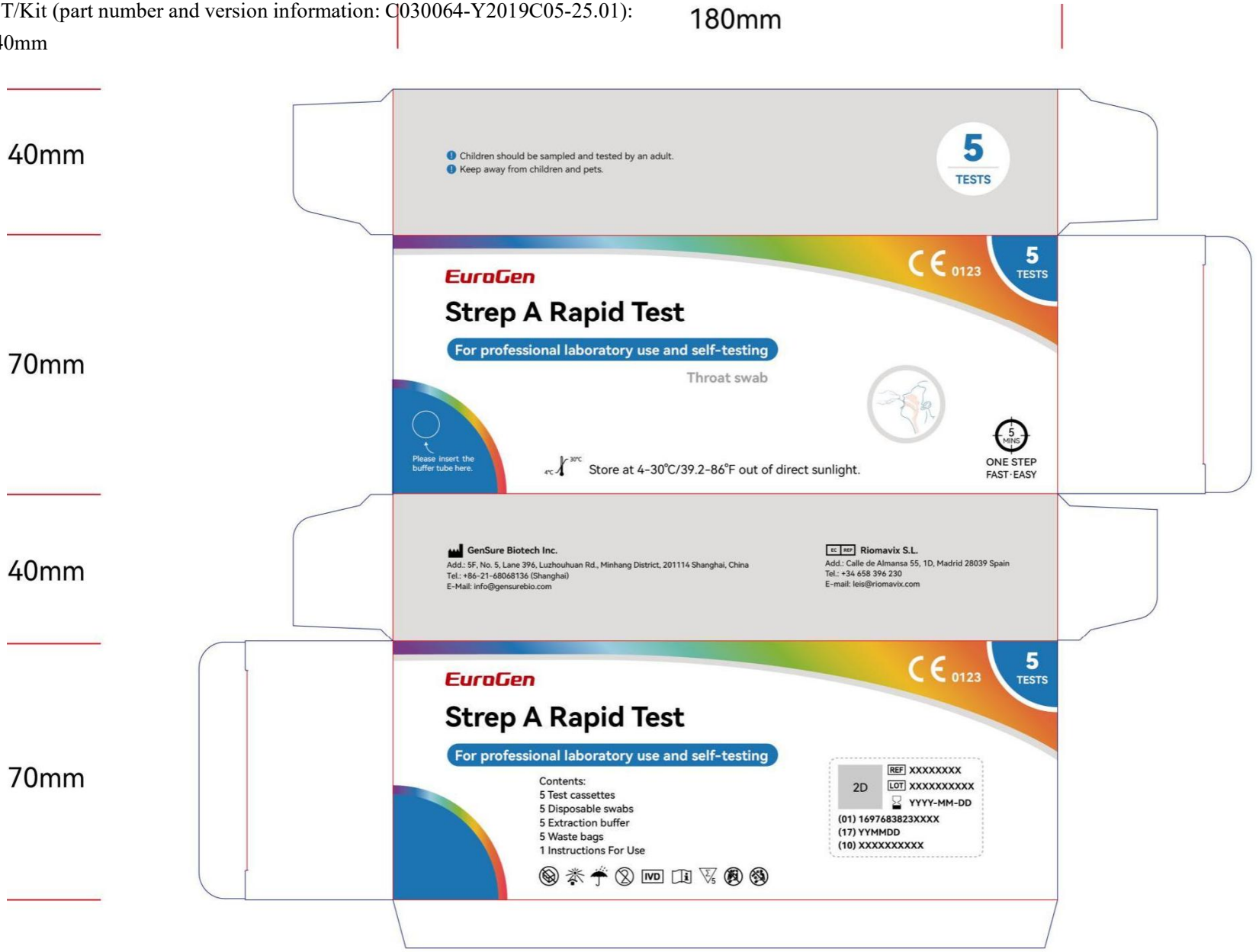
Y2019C02　2 T/Kit (part number and version information: C030063-Y2019C02-25.01):

Size: 170*65*25mm



Y2019C05　5 T/Kit (part number and version information: C030064-Y2019C05-25.01):

Size: 180*70*40mm



Labels

Y2019C10 10 T/Kit (part number and version information: C030065-Y2019C10-25.01):

Size: 180*80*70mm

180mm

80mm

80mm

70mm

Strep A Rapid Test

For professional laboratory use and self-testing

Throat swab

Contents:

- 10 Test cassettes
- 10 Disposable swabs
- 10 Extraction buffer
- 10 Waste bags
- 1 Instructions For Use

Store at 4-30℃/39.2-86℉ out of direct sunlight.

ONE STEP·FAST·EASY

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Keep away from children and pets.

2D
REF XXXXXXXX
LOT XXXXXXXXXX
YYYY-MM-DD
(01) 1697683823XXXX
(17) YYMMDD
(10) XXXXXXXXXX

EuroGen

IVD

GenSure

Labels

Y2019C20 20 T/Kit (part number and version information: C030066-Y2019C10-25.01)

Size: 180*150*65mm

180mm

150mm

150mm

150mm

65mm

Strep A Rapid Test

For professional laboratory use and self-testing

Throat swab

CONTENTS:

- 20 Test cassettes
- 20 Disposable swabs
- 20 Extraction buffer
- 20 Waste bags
- 1 Instructions For Use

2D

REF XXXXXXXX

LOT XXXXXXXXXX

YYYY-MM-DD

(01) 1697683823XXXX

(17) YYMMDD

(10) XXXXXXXXXX

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ONE STEP·FAST·EASY

EuroGen

Σ 20

IVD

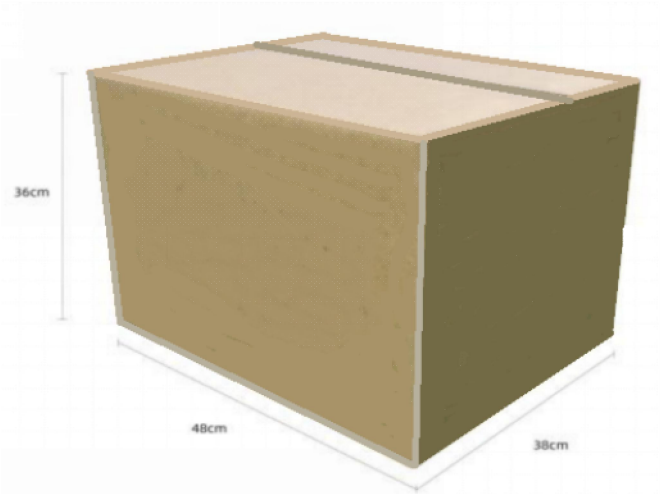
2.3 Label of shipping carton

Size: 480*380*360mm

REF NUMBER：XXXXXXX

LOT NUMBER：XXXXXXX

EXPIRY DATE：XXXXXXX

UDI XXXXXXXXXXXXXXXXXXXXXX

4℃ 30℃ Store at 4-30℃/39.2-86℉ out of direct sunlight.