

## Labels-Instruction for use

Product:	<b>GenBody COVID-19 Ag</b>
Date:	<b>2020-06-15</b>

Prepared by / date	Reviewed by / date	Approved by / date
<b>Senior Researcher</b>	<b>R&amp;D Director</b>	<b>QMR</b>
<b>Seo seul ki</b>	<b>Jedae Moon</b>	<b>Jung Young Choi</b>
<b>2020-06-15</b>	<b>2020-06-15</b>	<b>2020-06-15</b>

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**Technical File****0. Revision history**

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Revision History		
Rev.O	2020. 06. 02	Release of the GenBody COVID-19 Ag's labeling and packing information
Rev 0.1	2020. 06. 09	Addition of Korean translation
Rev. 1	2020. 06. 15	Updated information

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**1. Labels**

**1.1. The instructions for use have to be understandable for laymen and to be easily recognized.**


1) Product Name

**GenBody COVID-19 Ag**

2) Catalog number

**REF** COVAG025

3) Expiration date

 2020-12 (example)


4) Temperature limit

 2°C 30°C


5) In vitro diagnostic medical device

**IVD** Qualitative test  
SAR2-CoV-2 antigen

6) Manufacturer

 GenBody Inc.  
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do  
31077, Republic of Korea  
Tel: +82-41-523-8990 Fax: +82-41-523-8991

7) Batch code

 L3001 (example)

8) Contains sufficient for 25 tests

 25

9) Caution, consult accompanying documents



10) Do not reuse



11) Consult instructions for use



12) European representative



MT Promedt Consulting GmbH Altenhofstr. 80  
D-66386 St.Ingbert, Germany, Tel +49 6894-5810 20

13) CE symbol



**Technical File**

1. Development figure of outer container  
**GenBody COVID-19 Ag (Cat. No.COVAG025)**

- Full view

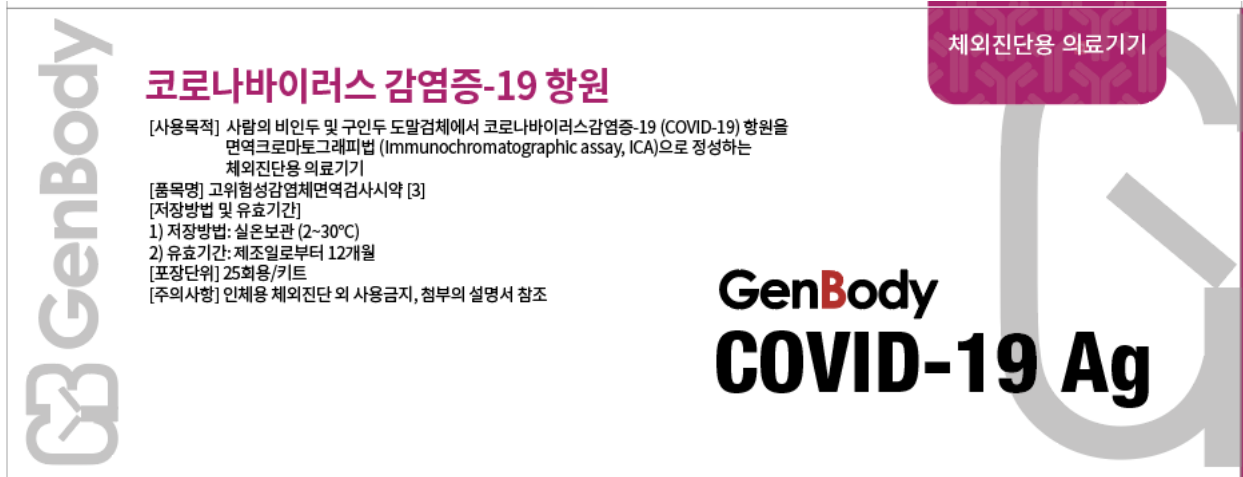


- Front view

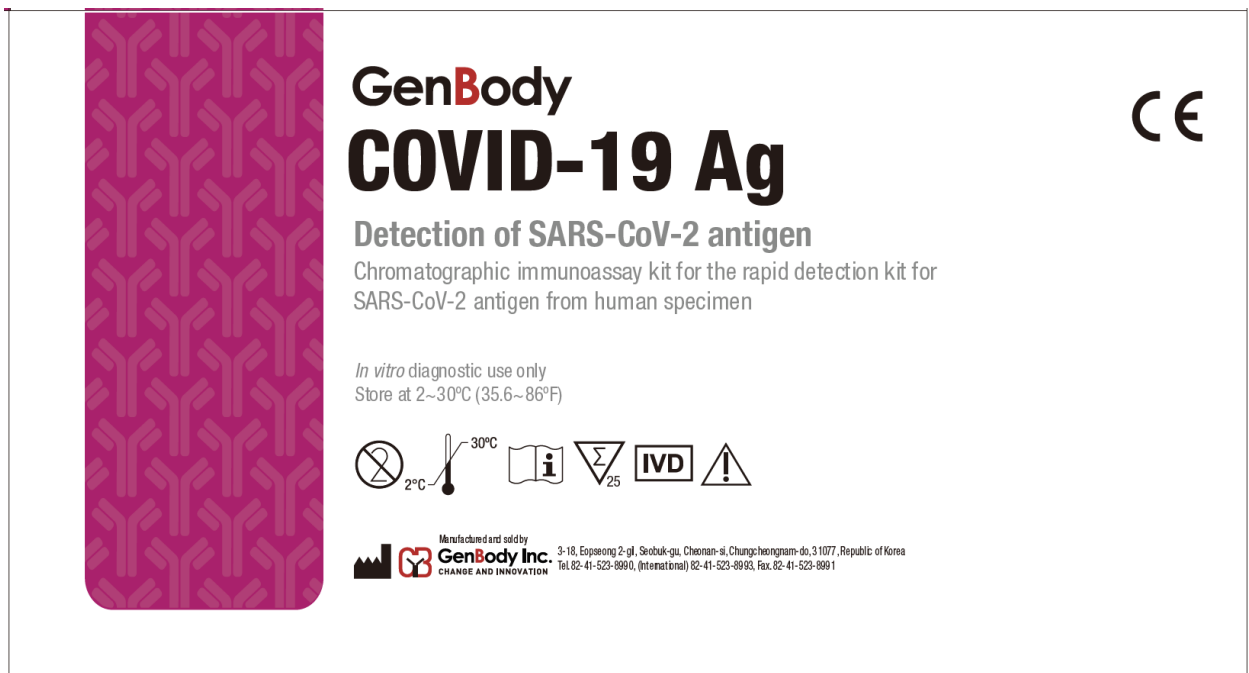


## Technical File

- Back view



- Top view

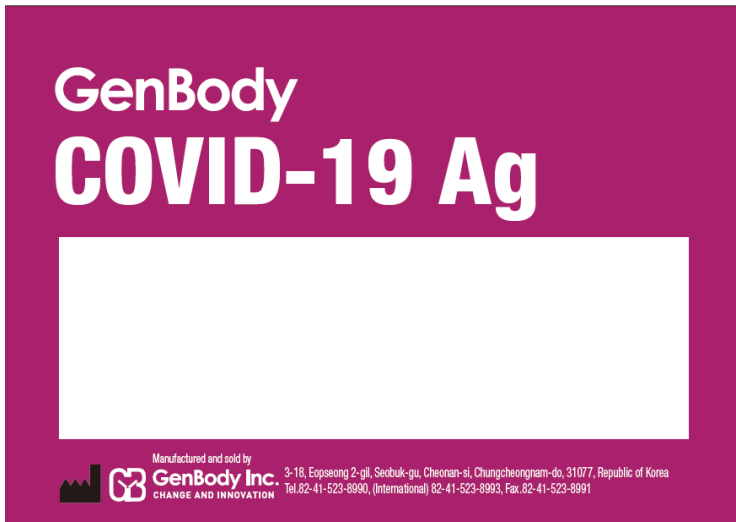


**Technical File**

- Side view -1



- Side view – 2



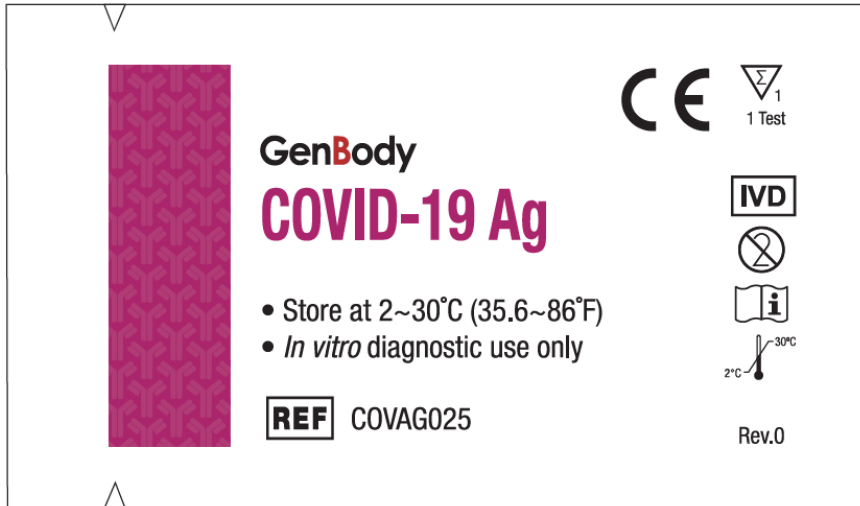


2. Labeling on Inner components

**GenBody COVID-19 Ag (Cat. No.COVAG025)**

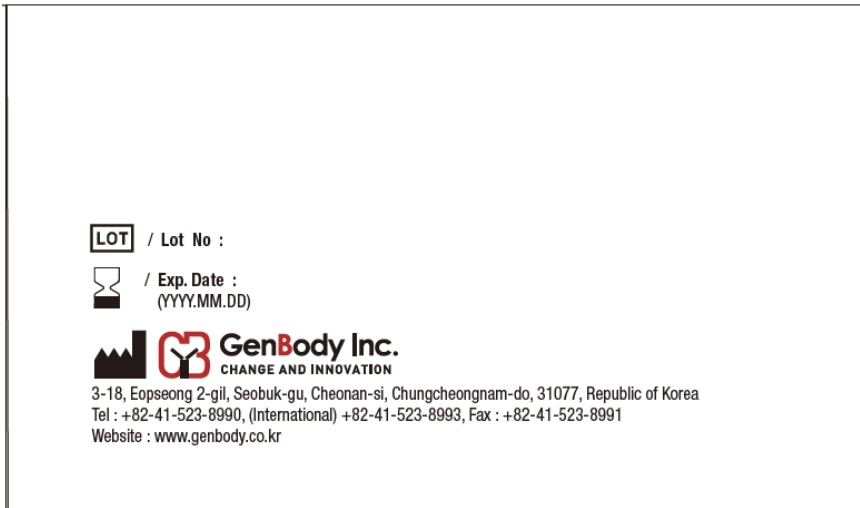
- Pouch Front view

Dimensions(Height(H) X Width(W)): 70 X 120 mm



- Pouch Back view

Dimensions(Height(H) X Width(W)): 70 X 120 mm



3. Device view

➤ Cat.No. COVAG025

