

## 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
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<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 table for 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

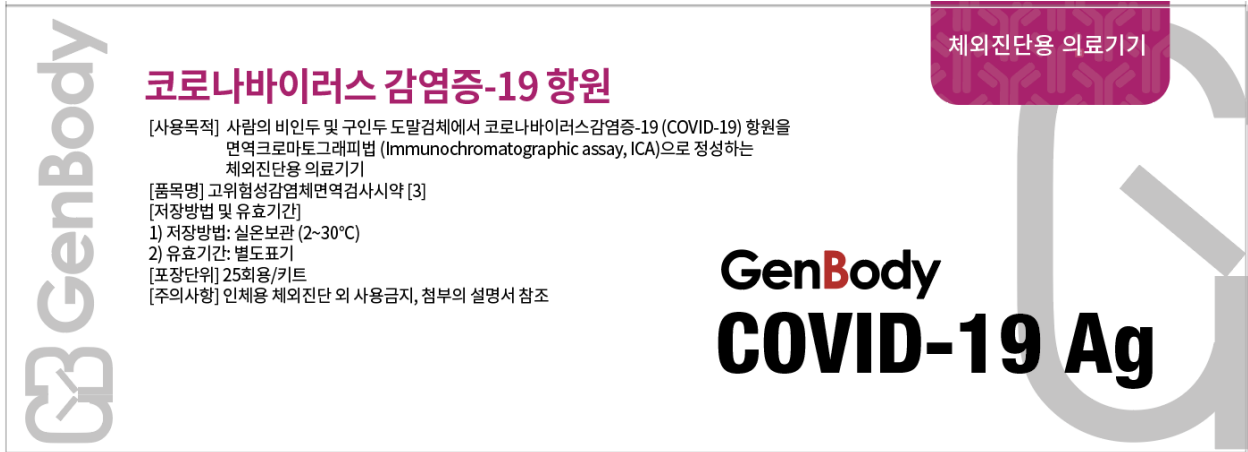


- Front view



**Technical File**

- Back view



- Top view

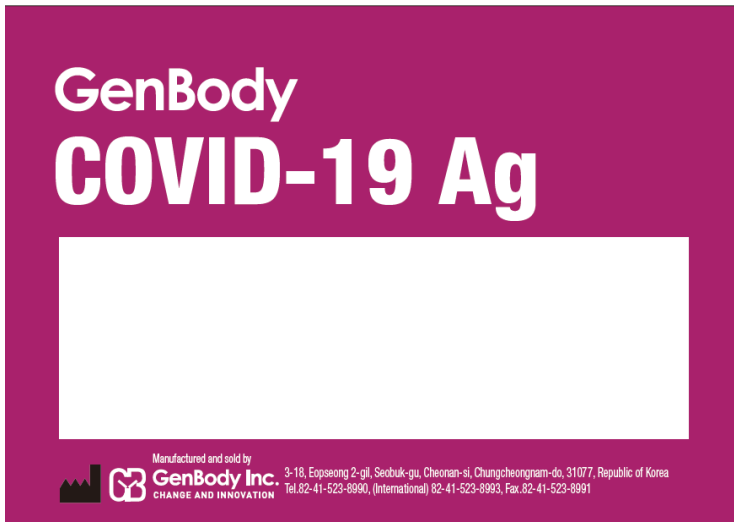


**Technical File**

- Side view -1



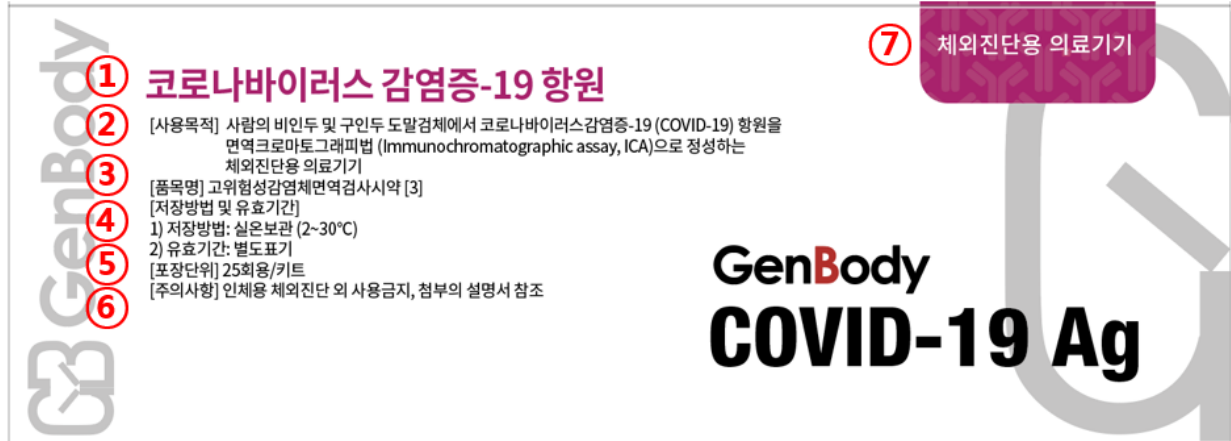
- Side view – 2





## Technical File

### 1.1. Korean Translation in box



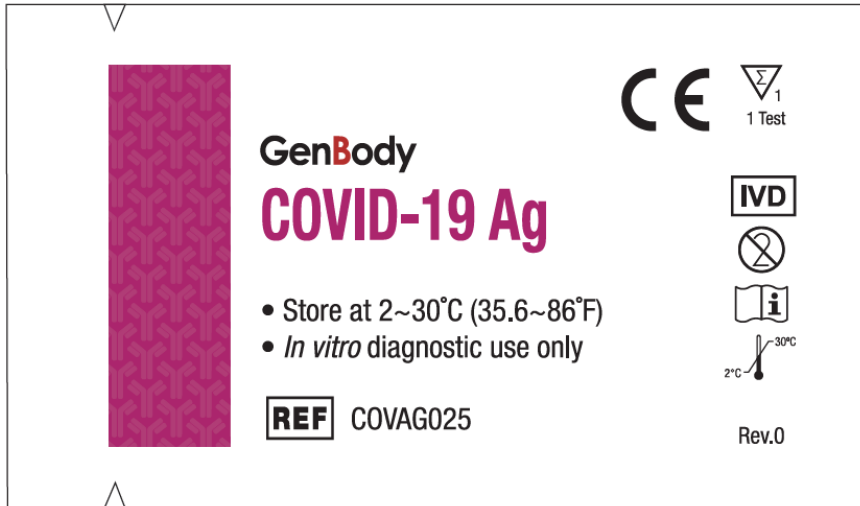
No.	Korean	English
①	코로나바이러스 감염증-19 항원	COVID-19 Ag
②	[사용목적] 사람의 비인두 및 구인두 도말검체에서 코로나바이러스감염증-19 (COVID-19) 항원을 면역크로마토그래피법 (Immunochromatographic assay, ICA)으로 정성하는 체외진단용 의료기기	[INTENDED USE] GenBody COVID-19 Ag kit is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal and oropharyngeal swab from human.
③	[품목명] 고위험성감염체면역검사시약 [3]	[Class] immuno assay for high risk infectious disease [Class 3]
④	[저장방법 및 유효기간] 1) 저장방법: 실온보관 (2~30°C) 2) 유효기간: 제조일로부터 12 개월	[STORAGE & EXPIRATION] 1) stored between 2 to 30 °C. 2) Expiration date of this kit is 12 months after its manufacture date.
⑤	[포장단위] 25 회용/키트	[Packing] 25 tests/kit
⑥	[주의사항] 인체용 체외진단 외 사용금지, 첨부 설명서 참조	[Caution] For in vitro diagnostic only, please refer to the attached IFU
⑦	체외진단용 의료기기	In-vitro diagnostic (IVD)

2. Labeling on Inner components

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

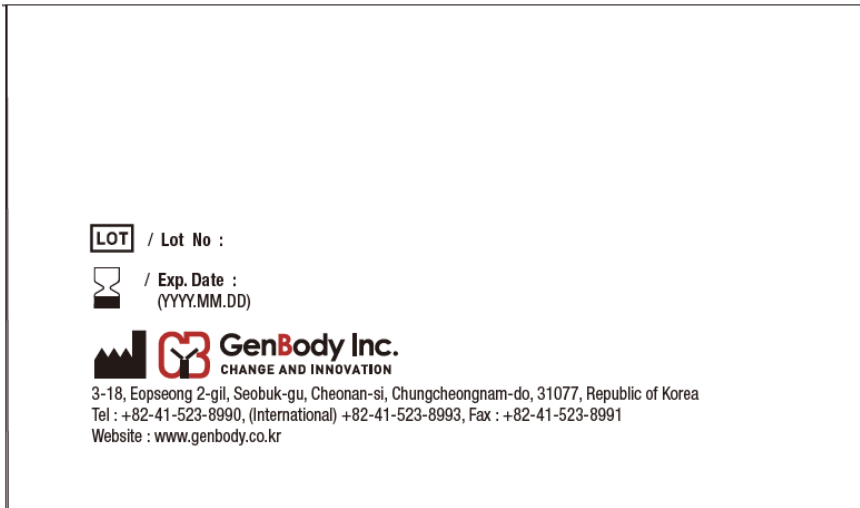
- Pouch Front view

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

