Ministry of Food and Drug Safety

열 람 용

[redacted]

# Certificate of Free Sales

No. of Certificate : [redacted]
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following product(s) is(are) permitted to be freely sold in overseas market only.

○ Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)

- Name : [redacted] Ltd.

- Address : [redacted]

- Registered No : Manufacturer [redacted]

| No. and date of product-license, comments | Classification |
|---|---|
| IVD-[redacted]R. 05. 2021 | IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), immunological method [3] |

※ Attached, if necessary (approved product information)
■ Model(Export Name) ☐ Medical Device Accessaries ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

Issued date : APR. 07. 2021 (Certificate No.[redacted])

Certified by [redacted]

Director
Director for Novel Products Approval
Ministry of Food and Drug Safety

[별지 제1호서식]

# 체외진단의료기기 제조(수입)허가·인증(신고)의 변경사항 보고서

| | | | | |
|---|---|---|---|---|
| 보고자 | 성 명 | [redacted] | 생년월일 | 19[redacted] |
| | 주 소 | [redacted] | | |
| 제조(수입)업자 | 업 소 명 | [redacted] | 전화번호 | 0[redacted] |
| | 소 재 지 | [redacted] | | |
| 영 업 의 구 분 | | [ √ ] 제조업 [ ] 수입업 | | |
| 업허가 번호 | | 체외 제 4610 호 | 허가·인증(신고)번호 | 체외 제허 21-251 호 |
| 명칭(제품명,품목명,모델명) | | [redacted] Antigen Rapid Test ,고위험성감염체면역검사시약,NOW Detect COVID-19 Antigen Rapid Test | 분류번호(등급) | K05[redacted] (3) |

변 경 내 용

| 항 목 | 허가·인증(신고) 받은 사항 | 변경 사항 | 일자 및 사유 |
|---|---|---|---|
| 제품명 | [redacted] Antigen Rapid Test | PAZBIO Novel Corona Virus(2021-nCoV) Detection Kit™ | 2021년04월07일 |
| | | | |
| | | | |

「체외진단의료기기법」 제4조 및 「의료기기법 시행규칙」 제26조제5항의 규정에 따라 체외진단의료기기 제조·수입허가·인증(신고)의 변경사항을 보고합니다.

2021 년 04월 [redacted]

보 고 자 [redacted]

식품의약품안전처장
한국의료기기안전정보원 귀하

210㎜ × 297㎜[백상지 80g/㎡ 또는 중질지 80g/㎡]

## Key Components (Packing Unit: 25 tests/kit)

| Components | Quantity | Store at |
|---|---|---|
| Test Device | 25 | 2 ~ 30 °C |
| Extraction Buffer Tube | 25 | |
| Nozzle Cap | 25 | |
| Sterile Swab | 25 | |
| Instructions for Use | 1 | |

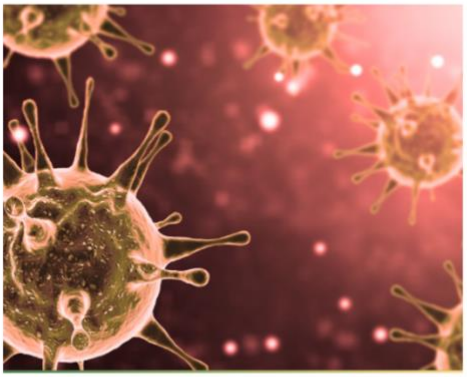
## Ordering Information

| Cat No. | Product Name | Package |
|---|---|---|
| CMP-CVR003 | PAZBIO Novel Corona Virus(2021-nCoV)-Detection Kit™ | 25 tests/kit |

# PAZBIO Novel Corona Virus (2021-nCoV)-Detection Kit™

CE

Rapid: Result within15 minutes **(reaction only in 5 minutes)**
Anywhere: No specific equipment and facilities needed
Simple: No specialized training required
Accurate: Good correlation with PCR assays
Multiple Test, Cost-effect



GMP

Management System ISO 13485:2016



We produce our own raw materials used in the diagnostic kits, so the quality and the product supply is stable. As the main raw material is produced by itself, it has good reproducibility between batches of finished products and maintains consistent clinical performance. Also, our products, COVID-19 Antibody & Antigen test, can be read within 15 minutes.

is providing more than 100 products in a wide range of partnership with local pharmacetical firms. We are continuing our research and making efforts for the development of innovative products, and will leap beyond Korea and into the world.

## Product Overview

PAZBIO Novel Corona Virus(2021-nCoV)-Detection Kit™ is a chromatographic immuno assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.

## Features and Benefits

- Rapid: Fast and reliable test results in just 15 minutes
- Easier: No special equipment needed, intuitive visual interpretation
- Easy to take samples: nasopharyngeal swab

## Product Performance

PAZBIO Novel Corona Virus(2021-nCoV)-Detection Kit™ was performed using the collected specimens and compared results to those obtained with a reagent authorized for EUA from same patients in upper respiratory tract.

| | | PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| PAZBIO Novel Corona Virus (2021-nCoV)-Detection Kit™ | Positive | 28 | 2 | 30 |
| | Negative | 1 | 29 | 30 |
| | Total | 29 | 31 | 60 |

Positive percent agreement(PPA) = 96.67%(95%C.I. 83.33%, 99.41%)
Negative percent agreement(NPA) = 93.33%(95%C.I. 78.68%, 98.15%)
Overall percent agreement(OPA) = 95.00%(95%C.I. 86.30%, 98.29%)

## Test Procedure and Results