# Omicron Variant Performance Study Report

COVID-19 Antigen Detection Kit

**Sponsor:**

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NEWGENE Bioengineering

# Content

# SPONSOR - INVESTIGATION - STUDY COORDINATION

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# Evaluation of COVID-19 Antigen Detection Kit For Omicron Variant

New Gene (Hangzhou) Bioengineering Co., Ltd.

## 1. BACKGROUND

The COVID-19 pandemic, caused by the severe acute respiratory syndrome coronavirus 2 virus (SARS-CoV-2), has been ravaging the world for more than two years. Many efforts have been made to curb the spread of SARS-CoV-2 in societies. Rapid and accurate detection of SARS-CoV-2 is crucial to limit virus transmission. Antigen immunochromatographic tests have been widely used in point of care settings due to it is a fast, cheap, easy-to-use method [1]. However, new variants of SARS-CoV-2, mainly variants of concern (VOC), with increased transmissibility, have brought additional challenges to the current prevention and control measures of SARS-CoV-2. Recently, omicron variant of SARS-CoV-2 has rapidly replaced delta variant in a short period in many European countries [2], the daily omicron infection case is more than ten times the peak of delta wave [3]. Numerous mutations have been identified in the receptor-binding domain of spike glycoprotein of the omicron variant [4], which raised the concerns about the performance of current rapid antigen kits that are solely targeting the spike protein of omicron variant may be impaired (thus not combined with the nucleocapsid protein) as well as the viral load measured at different time points and at different sites (e.g. throat and nose) after Omicron infection. Therefore, an evaluation of the performance of rapid antigen tests for the omicron variant is needed [5].

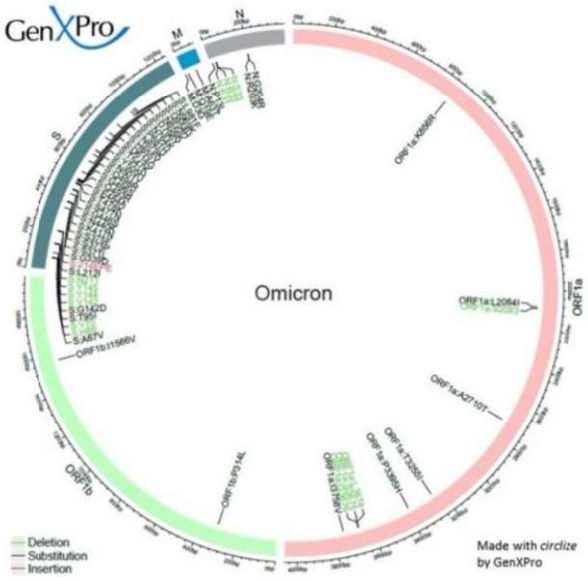


**Figure 1. Omicron genome of SARS-CoV-2 with accumulations of mutations in S-Gene [6].**

# 2. PURPOSE

The objective of this study was to evaluate the performance of the New Gene COVID-19 Antigen Detection Kit for the detection of the omicron variant of SARS-CoV-2.

# 3. PRODUCT INFORMATION:

## 3.1 Detection System

| | |
|---|---|
| **Manufacturer Name** | New Gene (Hangzhou) Bioengineering Co., Ltd. |
| **Test Name** | COVID-19 Antigen Detection Kit |
| **Pack Size(s)** | 25 tests/kit |
| **Contents of Kit** | Aluminum Foil Pouch, Test Card, Desiccant, Instructions for User, Sampling Swab, Sample Extraction Tube & Tube Cap |
| **Lot No.** | 20211120-01 |
| **Prod. Date** | 2021-11-20 |
| **Exp. Date** | 2023-11-19 |
| **Product Storage (temperature range)** | 2-30°C |
| **Shelf-life (months)** | 24 months |
| **Manufacturing Site (country)** | Hangzhou, China |

## 3.2. Reference PCR Method

| | | | |
|---|---|---|---|
| **Reference Method** | TaqPath™ COVID-19 CE-IVD RT-PCR Kit | | |
| **Pack Size(s)** | 1,000 reactions | **Shelf-life (months)** | 12 months |
| **Cat No.** | A48067 | **Manufacturer** | Thermo Fisher Scientific Inc. |
| **Storage** | -30°C to -10°C; TaqPath™ COVID-19 Control, ≤ -70°C keep away from light | | |

| **Product Name** | **Product No.** | **Lot No.** | **Expiration Date** |
|---|---|---|---|
| TaqPath™ COVID-19 Control | A48105 | 248106 | 16-Dec-22 |
| TaqPath™ COVID-19 Control Dilution Buffer | A48099 | 2201105 | 14-Jan-23 |
| TaqPath™ 1-Step Multiplex Master Mix | A48111 | 01206471 | 20-Dec-22 |
| TaqPath™ COVID-19 RT-PCR CE-IVD KIT | A48012 | 2201238 | 20-Dec-22 |

## 3.3 Variant of Concern Reagents Used in the Evaluation

| | | | |
|---|---|---|---|
| **Reference Method** | Omicron-specific PCR test for new Variant of Concern | | |
| **Pack Size(s)** | 96-10.000 reactions | **Catalog Number** | 031522 |
| **Expiration Date** | 2023-01-30 | **Storage** | -30°C to -10°C |
| **Lot No.** | C52-32-32 | **Shelf-life (months)** | 12 months |
| **Contents of kit** | GenXPro Covid-2 (Delta, Omicron) detection kit | | |
| **Manufacturer** | GenXPro GmbH, Altenhöferallee 3, 60438 Frankfurt am Main, Germany | | |

# 4. PRINCIPLE

The New Gene COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the nucleocapsid protein of SARS-CoV-2 in nasal swab. The device is composed of four parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2. The reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. When the sample is added into the sample well, conjugates absorbed in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). The absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking effect has occurred.

# 5. STUDY DETAILS

| | |
|---|---|
| **Study Design:** | Prospective performance evaluation studies were sampled at multiple independent sites in Sweden. The purpose of this study was to establish the performance of New Gene COVID-19 Antigen Detection Kit for the omicron variant. Presence of symptoms, duration of symptoms were collected for all enrolled samples.<br>The nasal swab sample was tested with the New Gene COVID-19 Antigen Detection Kit according to the manufacturer's instructions in iLab Medical Laboratory. The same NPS sample was tested by reference RT-PCR method in same laboratory. The result of the New Gene COVID-19 Antigen kit was compared with the result of the RT-PCR assay to validate the performance of the New Gene COVID-19 Antigen Detection Kit for the detection of the omicron variant of SARS-CoV-2. |
| **ƒFEvaluation Period:** | 20220121 to 20220206 |
| **Sample Type:** | Nasal swabs |
| **Inclusion Criteria:** | 1. Individuals were ≥18 years old;<br>2. Samples from individuals who were symptomatic and suspected of COVID-19, as well as asymptomatic individuals;<br>3. The RT-PCR test on nasopharyngeal swabs was positive for SARS-CoV-2. ;<br>4. At all ages, male or female (try to cover all age groups). |
| **Exclusion Criteria:** | 1. Sample collection, shipment and storage do not meet relevant requirements;<br>2. Abnormal experimental results caused by operation errors and/or kit failure. |
| **Sample Size:** | A total of 150 nasopharyngeal swabs from healthcare settings were registered in this study. Among them, 41 samples were tested SARS-CoV-2 positive by RT-PCR. |

| | |
|---|---|
| **Reference Method:** | RT-PCR assay was used as the reference method. The RNA was extracted from nasopharyngeal swabs using Total RNA Purification 96-Well Kit (Norgen Biotek, Canada), and the TaqPath™ COVID-19 CE-IVD RT-PCR Kit (Thermo Fisher Scientific, USA) was used for RT-PCR test. The run was on Roche ® 480 Light Cycle II system (Roche Diagnostics, Switzerland). |
| **Laboratory Verification Performance** | 1. Sensitivity was calculated as the proportion of samples tested true positive by New Gene COVID-19 Antigen Detection Kit among all positive samples tested by the RT-PCR method. The sensitivity is reported as a percentage.<br>2. Specificity was not available in this study.<br>3. The 95% confidence intervals (CI) were calculated to assess the level of uncertainty introduced by sample size. |

# 6. EVALUATION SITE DETAILS

| | |
|---|---|
| **Country** | Sweden |
| **Location of Laboratory Verification Site(s) (city, town)** | Gothenburg |
| **Health Care Level of Site(s)** | Community Testing Clinic |
| **Sample Collection** | iLab Medical AB |
| **Research Unit** | iLab Medical AB |
| **Address** | Järnbrotts Prästväg 2,<br>421 47 Västra Frölunda |
| **Laboratory Validation (Variant of Concern Test)** | iLab Medical |

# 7. TEST RESULT

## 7.1 Study Cohort

| | |
|---|---|
| **Country** | Sweden |
| **Total N (valid PCR results)** | 41 |
| **Age [mean (min-max), N]** | 31.32 (19-50), 41 |
| **Gender [%F, (n/N)]** | 41.46% (17/41) |
| **Positivity [%, (n/N)]** | 97.56% (40/41) |
| **Symptoms Present[1] [%Yes, (n/N)]** | 21.95% (9/41) |
| **Days From Symptom Onset[1]** | |
| **Days < 0-3 (n, %)** | 7, 77.8% |
| **Days 4-7 (n, %)** | 0% |
| **Days 8+ (n, %)** | 2, 22.2 % |
| **PCR Ct [median; N]** | 23; 41 |
| **Ct ≥ 30 (n, %)** | 5, 12% |
| **25 < Ct < 30 (n, %)** | 8, 20% |
| **Ct ≤ 25 (n, %)** | 28, 68% |

*[1]Note: data on the onset of symptoms are only available for individuals who tested positive for PCR..*

# 8. RESULT ANALYSIS

## 8.1. Laboratory Verification Performance against the Reference Method

The performance of New Gene COVID-19 Antigen Detection Kit was established with 41 nasal swabs collected from symptomatic individuals who were suspected of COVID-19 as well as asymptomatic individuals..

| New Gene COVID-19 Antigen Detection Kit | Reference RT-PCR Method | | |
|---|---|---|---|
| | + | - | Total |
| + | 40 | 0 | 40 |
| - | 1 | 0 | 1 |
| Total | 41 | 0 | 41 |
| **Sensitivity** = 40/41 = 97.6% (95% CI: 87.1% ~ 99.9%) | | | |
| **Specificity Not available** | | | |

## 8.2 Laboratory Verification Performance against the Reference Method – by Cycle Threshold Counts

The performance of the New Gene COVID-19 Antigen Detection Kit with positive results stratified by the reference assay cycle threshold (Ct) counts was assessed. As presented in the table below, the positive agreement of the New Gene COVID-19 Antigen Detection Kit is higher with samples of a Ct count < 30.

| New Gene COVID-19 Antigen Detection Kit | Reference RT-PCR Method | | |
|---|---|---|---|
| | Pos. (Ct ≤ 25) | Pos. (25 < Ct < 30) | Pos. (Ct ≥ 30) |
| Positive | 28 | 8 | 4 |
| Negative | 0 | 0 | 1 |
| Total | 28 | 8 | 5 |
| Positive Agreement (95% CI) | 100% (87.9% ~ 100%) | 100% (67.6% ~ 100%) | 80% (37.6% ~ 96.4%) |

# 9. CONCLUSION

The evaluations showed that New Gene COVID-19 Antigen Detection Kit has a good agreement with reference RT-PCR Method for omicron variant. The laboratory verification sensitivity of New Gene COVID-19 Antigen Detection Kit is 97.6%, and it is 100% sensitive for samples with Ct value < 30.

All the New Gene COVID-19 Antigen Detection Kit tested in this work perform well. The tests show great sensitivity. The laboratory evaluation might differ from the performance on the field due to the limited sample range and close monitoring is needed by professionals. From the results of 41 tested samples, it presents that the New Gene COVID-19 Antigen Detection Kit developed by New Gene (Hangzhou) Bioengineering Co., Ltd. meets the requirement of intended use.

# 10. SIGNATURES&APPROVAL

Evaluation site: Göteborg, Västra Götalands län, Sweden

Principal evaluator: Shokoofeh Naghdipour, Dr. Huaqing Li

Reported by: _____

Date: 2022-02-10

Signature: _____

Stamp: iLab LABORATORY iLab Medical AB

# 11. REFERENCE

1. Kubina R, Dziedzic A: **Molecular and Serological Tests for COVID-19 a Comparative Review of SARS-CoV-2 Coronavirus Laboratory and Point-of-Care Diagnostics**. *Diagnostics* 2020, **10**(6).

2. **Weekly epidemiological update: Omicron variant of concern (VOC) – week 2 (data as of 20 January 2022) EU/EEA** [https://www.ecdc.europa.eu/en/news-events/weekly-epidemiological-update-omicron-variant-concern-voc-week-2-data-20-january-2022]

3. Murray CJ: **COVID-19 will continue but the end of the pandemic is near**. *The Lancet* 2022.

4. Saxena SK, Kumar S, Ansari S, Paweska JT, Maurya VK, Tripathi AK, Abdel-Moneim AS: **Characterization of the novel SARS-CoV-2 Omicron (B.1.1.529) variant of concern and its global perspective**. *J Med Virol* 2021.

5. Joint Research Centre (2022, January 26). **Additional information for manufacturers.** Retrieved from https://covid-19-diagnostics.jrc.ec.europa.eu/manufacturers-info

6. GenXPro GmbH. (2022). **Omicron-specific PCR test for new Variant of Concern.** Retrieved from https://genxpro.net/sars-cov-2-omicron-pcr-test/

# 12. ANNEX I - LABORATORY VERIFICATION DATA LIST

| No. | Gender | Age | Sample Collection Date | Symptom Days | Symptoms when specimen collected: A: please describe the symptom(like Cough, Fever, Dizzy…) B:Asymptomatic | Result | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Antigen Rapid Test | | | | PCR Result | | | | | |
| | | | | | | Antigen Lot Number | Specimen Type | New Gene Testing Date | Antigen test result | PCR Confirmation Date | Specimen Type | ORF1ab CT Value | SARS-CoV-2 variant type | PCR operation date | Result |
| Omi01 | M | 20 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 21.06 | Omicron | 20220204 | Positive |
| Omi02 | F | 33 | 20220204 | 0-3 | Cough, Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 20.59 | Omicron | 20220204 | Positive |
| Omi03 | M | 29 | 20220204 | 8+ | Cough, Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 21.67 | Omicron | 20220204 | Positive |
| Omi04 | M | 46 | 20220204 | 0-3 | Cough, Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 21.21 | Omicron | 20220204 | Positive |
| Omi05 | F | 42 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 20.95 | Omicron | 20220204 | Positive |
| Omi06 | F | 19 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 20.62 | Omicron | 20220204 | Positive |
| Omi07 | M | 36 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.17 | Omicron | 20220204 | Positive |
| Omi08 | M | 50 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 20.00 | Omicron | 20220204 | Positive |
| Omi09 | M | 44 | 20220204 | 0-3 | Cough, Dizzy | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 21.29 | Omicron | 20220204 | Positive |
| Omi10 | M | 32 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 20.93 | Omicron | 20220204 | Positive |
| Omi11 | F | 24 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.64 | Omicron | 20220204 | Positive |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Omi12 | F | 26 | 20220204 | 8+ | Dizzy,Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.78 | Omicron | 20220204 | Positive |
| Omi13 | M | 43 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.15 | Omicron | 20220204 | Positive |
| Omi14 | M | 22 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.00 | Omicron | 20220204 | Positive |
| Omi15 | M | 41 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.21 | Omicron | 20220204 | Positive |
| Omi16 | M | 27 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.35 | Omicron | 20220204 | Positive |
| Omi17 | M | 28 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.51 | Omicron | 20220204 | Positive |
| Omi18 | M | 39 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 21.49 | Omicron | 20220204 | Positive |
| Omi19 | M | 28 | 20220204 | 0-3 | Cough, Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.14 | Omicron | 20220204 | Positive |
| Omi20 | M | 29 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 24.03 | Omicron | 20220204 | Positive |
| Omi21 | M | 32 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.56 | Omicron | 20220204 | Positive |
| Omi22 | M | 29 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.44 | Omicron | 20220204 | Positive |
| Omi23 | M | 28 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.84 | Omicron | 20220204 | Positive |
| Omi24 | F | 28 | 20220204 | 0-3 | Cough, Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 24.49 | Omicron | 20220204 | Positive |
| Omi25 | F | 27 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 22.54 | Omicron | 20220204 | Positive |
| Omi26 | M | 29 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.89 | Omicron | 20220204 | Positive |
| Omi27 | F | 28 | 20220204 | 0-3 | Dizzfy,Fever | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 25.03 | Omicron | 20220204 | Positive |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Omi28 | F | 27 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.88 | Omicron | 20220204 | Positive |
| Omi29 | F | 35 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 23.49 | Omicron | 20220204 | Positive |
| Omi30 | F | 34 | 20220204 | NA | B | 20211120-01 | Nasal | 20220204 | Positive | 20220204 | Nasopharyngeal | 25.19 | Omicron | 20220204 | Positive |
| Omi31 | M | 22 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 26.26 | Omicron | 20220204 | Positive |
| Omi32 | F | 34 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 26.64 | Omicron | 20220204 | Positive |
| Omi33 | F | 33 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 25.73 | Omicron | 20220204 | Positive |
| Omi34 | M | 39 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 25.83 | Omicron | 20220204 | Positive |
| Omi35 | F | 29 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 28.96 | Omicron | 20220204 | Positive |
| Omi36 | M | 37 | 20220204 | 0-3 | Dizzy,Fever | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 27.79 | Omicron | 20220204 | Positive |
| Omi37 | F | 33 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 30.2 | Omicron | 20220204 | Positive |
| Omi38 | F | 21 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 30.14 | Omicron | 20220204 | Positive |
| Omi39 | F | 23 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 30.71 | Omicron | 20220204 | Positive |
| Omi40 | F | 24 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Positive | 20220204 | Nasopharyngeal | 31.08 | Omicron | 20220204 | Positive |
| Omi41 | M | 34 | 20220204 | NA | B | 20211120-01 | Nasal | 20220206 | Negative | 20220204 | Nasopharyngeal | 32.66 | Omicron | 20220204 | Positive |