Let’s get over COVID-19

GCMS strives to provide

complete diagnostics solutions

GCMS

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GCMS COVID-19 Diagnostics Kit





Product name	GENEDIA W COVID-19 Real Time RT-PCR kit	GENEDIA W COVID-19 Colorimetric LAMP Premix kit	GENEDIA W COVID-19 Ag	GENEDIA W ONE COVID 19 IgM/IgG	GENEDIA W COVID-19 IgM/IgG
Type	PCR			Rapid	
Method	Real Time RT-PCR	RT-LAMP	Immuno-chromatography	Immuno-chromatography	Immuno-chromatography

Introduction of GENEDIA W COVID-19 Ag

ISO 13485

GENEDIA W

COVID-19 Ag

SALIVA

643G-S

The GENEDIA W COVID-19 Ag (SALIVA) is an in vitro diagnostic single-use test and qualitative immunoassay to detect SARS-CoV-2 antigen in human saliva specimen.

Immediate on-site Antigen testing

- Allow wider testing with fast test time (15 minutes)
- Non-invasive specimen (Saliva)

Unique selling Point

Quick	➢ Fast test time **(10 ~15 minutes)**
Accurate	➢ High performance (Sensitivity: 93.33%, Specificity: 100%)
Non-invasive specimen	➢ Easier specimen collection from saliva

Summary : Clinical Performance Data

Clinical test conducted at Kangwon National University Hospital in South Korea.

Purpose of Clinical Research

Clinical performance evaluation of the GENEDIA W COVID-19 Ag was conducted by comparing the performance of RT-PCR test (AllplexTM 2019-nCoV Assay by Seegene Inc. and STANDARD M nCoV Real-Time Detection kit by SD BIOSENSOR, Inc.) from Kangwon National University Hospital.

		Comparator (RT-PCR)		Total
		Positive	Negative	
GENEDIA W COVID-19 Ag	Positive	56	0	56
	Negative	4	60	64
Total		60	60	120

Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	PPA	95% Confidence Interval
≤7	49	48	98.96%	89.15%- 99.95%
8 to 14	11	8	72.73%	39.03%- 93.98%

- Clinical sensitivity : 93.33% (95% CI : 83.80% - 98.15%)
- Clinical specificity : 100% (95% CI : 94.04% - 100%)
- Total Agreement Ratio : 96.67%

Product Package

GENEDIA W COVID-19 Ag (SALIVA)_20Test

① Test device : 20 EA

② Extraction solution : 20 EA

③ Sample developing filter cap : 20 EA

④ Sterilized swabs for sample collection : 20 EA

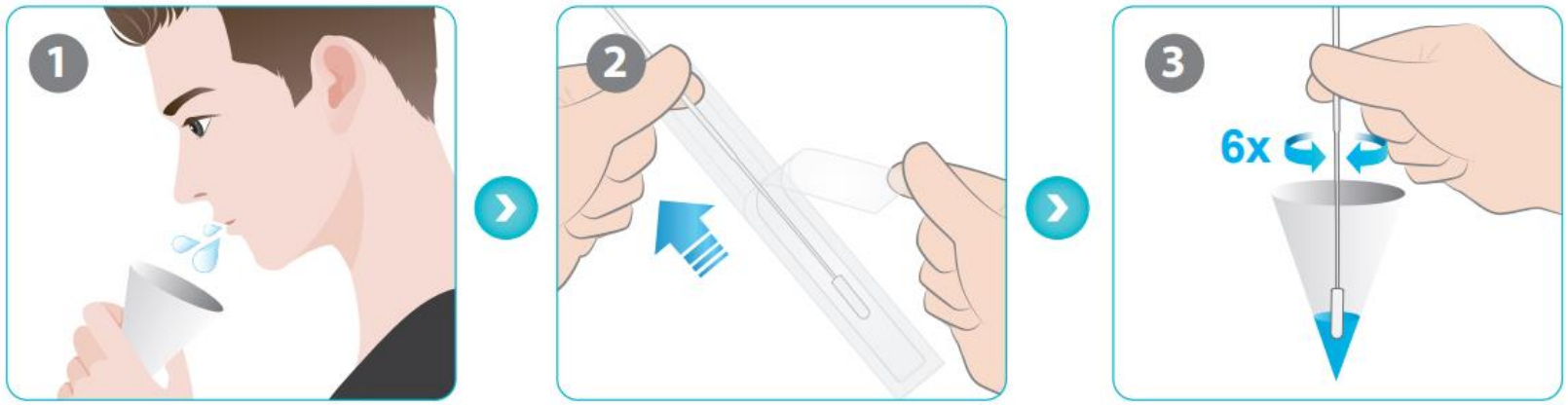
⑤ Cup for saliva collection : 20EA

⑥ Instructions for use: 1EA

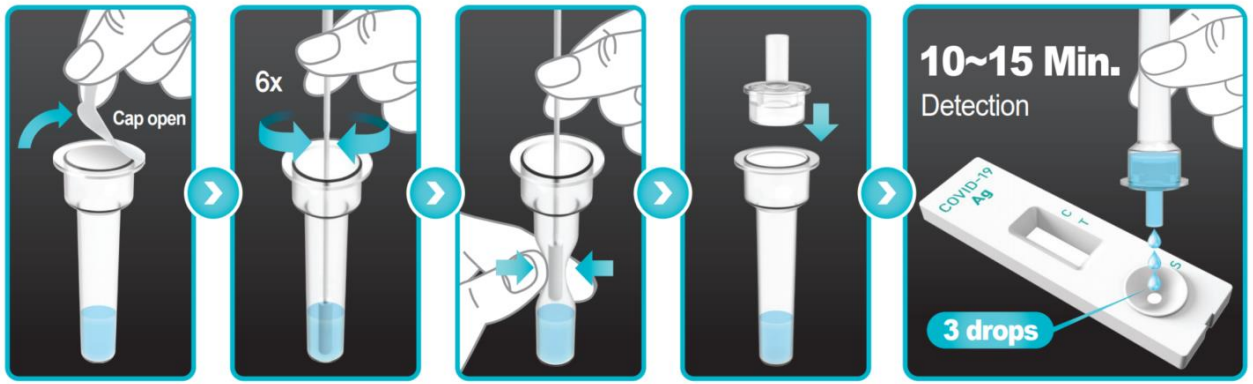
GENEDIA W COVID-19 Ag (SALIVA)_

ISO 13485

Sample Collection

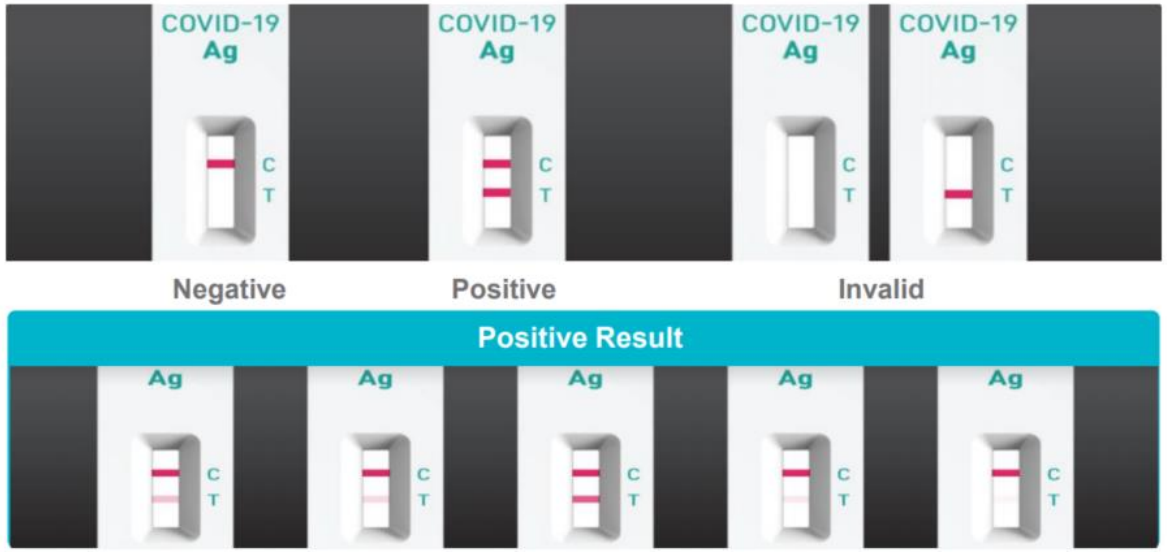


Extraction



1 STEP	2 STEP	3 STEP	4 STEP	5 STEP
Open the extraction solution tube.	Insert the patient swab sample into the extraction solution tube. Then, swirl swab at least 6 times.	Roll the swab head against the inside of the tube as you remove it.	Bind the sample developing filter cap with the extraction tube.	Add 3 drops of the extraction solution with specimen into the sample well. After 15 minutes, interpret the test results.

Interpretation of the result



If there is any blurry line or color change on the T line within 15 minutes, it should be read as positive.

Product Specification

Contents	Specification
Method	Immunochromatography
Packing Unit	20 Tests / kit
Certification	CE-IVD
Specimen	Saliva
LoD	$7.50X10^2$ $TCID_{50}$/mL
Sensitivity/Specificity	Sensitivity : 93.33% (95% CI : 83.80% - 98.15%) Specificity : 100% (95% CI : 94.04% - 100%)
Running Time	10~15 minutes

Contents	Specification
Materials provided	① Test device : 20 EA ② Extraction solution : 20 EA ③ Sample developing filter cap : 20 EA ④ Sterilized swabs for sample collection : 20 EA ⑤ Cup for saliva collection : 20EA ⑥ Instructions for use: 1EA
Expiry Date	24 months from the date of manufacture
Storage Condition	2 ~ 30 ℃ (35.6 ~ 86 °F)

CE Certification

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

Green Cross Medical Science Corp.,
26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun,
Chungcheongbuk-do, 27632
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

18 November 2021

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

GCM-07-04	GENEDIA W COVID-19 Ag	167055	15 04 80 90 00	Other Viral Antigen/Antibody Detection	III
GCM-07-05	GENEDIA W COVID-19 Ag (SALIVA)	167055	15 04 80 90 00	Other Viral Antigen/Antibody Detection	III
GCM-08	GENEDIA W COVID-19 Real-Time RT-PCR Kit	156264	16 90 90 01 90	Other Other Genetic Tests	III
GCM-09	GREENCARE LIPID	156470	21 01 29	Dedicated Multi-Parameter CC Systems	III
GCM-10	GREENCARE LIPID Profile Test Strip	156573	11 70 01 02 00	Cholesterol Test Strips	III
GCM-10-01	GREENCARE LIPID TC Test Strip	156573	11 70 01 02 00	Cholesterol Test Strips	III
GCM-11	GREENCARE PRIME Blood Glucose Test Strip	157100	11 70 01 01 00	Glucose Test Strips	III
GCM-12	GREENCARE LIPID Control Solution	157101	11 70 01 50 00	Calibrators and Controls (Blood Test Strips)	III
GCM-12-01	GREENCARE PRIME Glucose Control Solution	157101	11 70 01 50 00	Calibrators and Controls (Blood Test Strips)	III
GCM-13	GENEDIA W COVID-19 Colorimetric LAMP premix Kit	157096	15 04 40 90 00	Other Virology - NA Reagents	III
GCM-14	GENEDIA Multi Influenza Ag Rapid Test Kit	159029	15 04 80 04 00	Influenza & Para Influenza	III
GCM-14-01	Greencare Flu 2 Influenza A&B Ag	159029	15 04 80 04 00	Influenza & Para Influenza	III
GCM-15	GENEDIA Quantum FR101 (Model: GFR-100)	159414	22 03 01	Manual I.A. Instruments / Readers	III
GCM-16	GENEDIA W COVID-19 Ag External Control Swab	163076	11 50 90 90 00	Other, Other Controls Clinical Chemistry	III

18 November 2021

Dr. Michael Rinck
- Managing Director -

GCMS

Declaration of Conformity

MANUFACTURER	Green Cross Medical Science Corporation 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA
EUROPEAN REPRESENTATIVE	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
EMDA CODE,	15 04 80 90 00 Others Viral Antigen/Antibody Detection
PRODUCT NAME	GENEDIA W COVID-19 Ag (SALIVA)
CLASSIFICATION	Others IVD / Non List A, Non List B and not for self-testing
CONFORMITY ASSESSMENT	Directive 98/79/EC on IVDD, ANNEX III

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED	EN ISO 13485:2016, EN ISO 14971:2012, EN13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016
PLACE,	Chungcheongbuk-do, Republic of Korea
VALIDITY PERIOD	**2021.10 ~ 2022.10**
DATE	**2021.10.19**
SIGNATURE	Jong Kwan Ko

CE

Jong-Kwan, Ko
QMR (Quality Management Representative)

ISO Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate
No. Q5 049753 0019 Rev. 00

Holder of Certificate: Green Cross Medical Science Corporation
28, Mugeuk-ro 65beon-gil
Geumwang-eup, Eumseong-gun
Chungcheongbuk-do 27632
REPUBLIC OF KOREA

Facility(ies):
Green Cross Medical Science Corporation
28, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun,
Chungcheongbuk-do 27632, REPUBLIC OF KOREA

Green Cross Medical Science Corporation
107, Ihyeon-ro 30beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do
16924, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of Blood Bags and Cord Blood Bags

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74953577
Valid from: 2020-01-17
Valid until: 2021-06-30

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate
No. Q5 049753 0020 Rev. 00

Holder of Certificate: Green Cross Medical Science Corporation
26, Mugeuk-ro 65beon-gil
Geumwang-eup, Eumseong-gun
Chungcheongbuk-do 27632
REPUBLIC OF KOREA

Facility(ies):
Green Cross Medical Science Corporation
26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun,
Chungcheongbuk-do 27632, REPUBLIC OF KOREA

Green Cross Medical Science Corporation
107, Ihyeon-ro 30beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do
16924, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of In-Vitro Diagnostic Medical Devices: Reagents for ELISA, Immuno-Chromatographic Assay and Molecular Diagnostics, Reagents and Instruments for HbA1c measuring system, Reagents and Instruments for Cholesterol Measuring System, Reagents and Instruments for Glucose Measuring System

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74953577
Valid from: 2019-11-28
Valid until: 2021-06-30

Date, 2019-11-28

Christoph Dicks
Head of Certification/Notified Body

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GCMS Manufacturing Capability

Green Cross Medical Science (GCMS) has three manufacturing plants that are optimized for the production of Rapid, the POCT device, and hemodialysis solution respectively.
Our Eumseong plant has produced over 40 products, including RDT and PCR, and is designed with the flexibility to run manufacturing lines efficiently. We can immediately switch from A to B when the tests demand a move from the detection of antibodies to antigen tests.

Current production capacity

Product Group	Plant	Tests/ Month
COVID W Ag RDT	**Eumseong Plant**	**10,000,000**
COVID W Ab RDT	Cheonan Plant	1,300,000
COVID W RT-PCR	Eumseong Plant	1,000,000
Other RAPID (Test)	Eumseong Plant	600,000
ELISA (Test)	Eumseong Plant	1,500,000

Lead time : Maximum within 4 weeks after receiving Purchase Order

Thank you