Performance Evaluation

GENEDIA W COVID-19 Ag

2020-08-13

Prepared by / Date	Reviewed by / Date	Approved by / Date
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Revision History

Rev no.	Date	Description
1	2020.08.13	Release of the product performance evaluation report

1. Performance evaluation plan

1.1 Purpose

To confirm the performance and effectiveness of GENEDIA W COVID-19 Ag through the performance evaluation test with reference to the CLSI guideline.

1.2 Test guidance / regulation documents

- European harmonized standard EN13612:2002,
- NCCLS (EP05-A3, EP07-A3)

1.3 Information of the test diagnostic kit

- Kit name : GENEDIA W COVID-19 Ag
- Batch No : 3 Lots (643X2001, 643X2002, 643X2003)

1.4 Intended Use

The GENEDIA W COVID-19 Ag is an in vitro diagnostic single-use test and qualitative immunoassay to detect SARS-CoV-2 antigen in nasopharyngeal swab and sputum specimen from human. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of being infected and asymptomatic patients.

1.5 Information of specimen

Nasopharyngeal swab and sputum specimen from human

2. Analytical Sensitivity

2.1. Limit of Detection (LOD)

2.1.1. Purpose

This report is intended to define limit of detection (LOD) on GENEDIA W COVID-19 Ag.

2.1.2. Introduction

The Limit of Detection (LOD) is determined by serial dilution of 2 types of SARS-CoV-2 Ag. 1) Heat-Inactivated SARS-CoV-2 Virus, 2) Recombinant SARS-CoV-2 Ag. The negative sample (extraction solution) and low concentration samples were measured and limit of detection was determined.

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.28

2.1.3. Materials and Test Procedure

(1) Material

- **Test specimen**

Specimen type
Heat-Inactivated SARS-CoV-2 Virus
Recombinant SARS-CoV-2 Ag

- **Test device (Sample 1. Heat-Inactivated SARS-CoV-2 Virus)**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2001 / 2020.07.09
	643X2002 / 2020.07.13
	643X2003 / 2020.07.15

- **Test device (Sample 2. Recombinant SARS-CoV-2 Ag)**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2001 / 2020.07.09

(2) Test procedure

- **Heat-Inactivated SARS-CoV-2 Virus**

STEP 1 Prepare a sample diluted with Heat-Inactivated SARS-CoV-2 Virus in various concentration.

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 20 times repeated test for each sample (3 lot).

STEP 3 The minimum concentration that is judged as positive for 95% or more is set as the detection of the limit(LOD) of this product

- **Recombinant SARS-CoV-2 Ag**

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in various concentration.

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 20 times repeated test for each sample (1 lot).

STEP 3 The minimum concentration that is judged as positive for 95% or more is set as the detection of the limit(LOD) of this product

2.1.4. Acceptance criteria

LOD= With naked eyes, judged as positive for 95% or more is set as the detection of the limit(LOD) of this product

2.1.5. Results

- **Heat-Inactivated SARS-CoV-2 Virus**

Lot 643X2001

No.	Concentration ($TCID_{50}$/mL)	Repeat	Number of positive result	Positive rate (%)
1	1,000	20	20	100 %
2	750	20	20	100 %
3	500	20	15	75 %
4	250	20	1	5 %
5	125	20	0	0 %
6	0	20	0	0 %

Lot 643X2002

No.	Concentration ($TCID_{50}$/mL)	Repeat	Number of positive result	Positive rate (%)
1	1,000	20	20	100 %
2	750	20	20	100 %
3	500	20	16	80 %
4	250	20	2	10 %
5	125	20	0	0 %
6	0	20	0	0 %

Lot 643X2003

No.	Concentration ($TCID_{50}$/mL)	Repeat	Number of positive result	Positive rate (%)
1	1,000	20	20	100 %
2	750	20	20	100 %
3	500	20	15	75 %
4	250	20	1	5 %
5	125	20	0	0 %
6	0	20	0	0 %

- **Recombinant SARS-CoV-2 Ag**

Lot 643X2001

No.	Concentration (ng/mL)	Repeat	Number of positive result	Positive rate (%)
1	200	20	20	100 %
2	100	20	20	100 %
3	75	20	14	70 %
4	50	20	2	10 %
5	0	20	0	0 %

2.1.6. Conclusion

The analytical sensitivity study was performed with serial diluted Heat-Inactivated SARS-CoV-2 Virus and recombinant SARS-CoV-2 Ag. With naked eyes, judged as positive for 95% or more is set as the detection of the limit(LOD) of this product

According to the result, Heat-Inactivated SARS-CoV-2 Virus sample's LOD is 750 $TCID_{50}$/mL, and recombinant SARS-CoV-2 Ag sample's LOD is 100 ng/mL.

2.2 Hook Effect

2.2.1. Purpose

This report is intended to verify the hook effect of high titer Heat-Inactivated SARS-CoV-2 Virus and recombinant SARS-CoV-2 Ag.

2.2.2. Introduction

The Hook effect is observed in sandwich immunoassay, where at very high concentrations of the analyte, the assay signal is saturated and leveled off. This phenomenon occurs due to the elevated number of analyte molecules that bind to both the capture and detection antibody, thereby preventing them from forming sandwich immune complexes. In fact, the signal response might decrease at extremely high concentrations and fall in the calibration curve range. This effect then leads to a misleading lower analyte concentration while the actual analyte concentration is much higher. Therefore, in sandwich immunoassay, the maximum allowed concentration is the one that corresponds to the onset of the saturated signal.

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.28

2.2.3. Materials and Test Procedure

(1) Material

- **Test specimen**

Specimen type
Heat-Inactivated SARS-CoV-2 Virus
Recombinant SARS-CoV-2 Ag

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2001 / 2020.07.09

(2) Test procedure

- **Heat-Inactivated SARS-CoV-2 Virus**

STEP 1 Prepare a sample diluted with Heat-Inactivated SARS-CoV-2 Virus in 16,000 (LOD's 21.34 fold), 8,000, 4,000 $TCID_{50}$/mL

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 20 times repeated test for each sample (1 lot)

- **Recombinant SARS-CoV-2 Ag**

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 10,000 (LOD's 100 fold), 5,000, 2,500, 1,250, 625 ng/mL.

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 20 times repeated test for each sample (1 lot)

2.2.4. Acceptance criteria

Check whether the hook effect occurs in high titer sample. Must be positive.

The signal strength of the inspection line should not decrease as concentration is increase.

2.2.5. Results

- **Heat-Inactivated SARS-CoV-2 Virus**

Lot 643X2001

No.	Concentration ($TCID_{50}$/mL)	Result / Hook effect
1	4,000	Positive / No Hook effect
2	8,000	Positive / No Hook effect
3	16,000	Positive / No Hook effect

- **Recombinant SARS-CoV-2 Ag**

Lot 643X2001

No.	Concentration (ng/mL)	Result / Hook effect
1	625	Positive / No Hook effect
2	1,250	Positive / No Hook effect
3	2,500	Positive / No Hook effect
4	5,000	Positive / No Hook effect
5	10,000	Positive / No Hook effect

2.2.6. Conclusion

There was no Hook effect in Heat-Inactivated SARS-CoV-2 Virus (16,000 $TCID_{50}$/mL) and recombinant SARS-CoV-2 Ag (10,000 ng/mL).

2.3 Inclusivity test

2.3.1. Purpose

This report is intended to verify the reactivity and inclusivity of ATCC VR-1986HK(NCBI accession No: MN985325.1) with various strain of SARS-CoV-2 by *In silico* testing.

2.3.2. Introduction

This test conducted by NCBI BLAST function

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.30

2.3.3. Materials and Test Procedure

(1) Material

- **Test strain**

No	Strain	NCBI Accession No
1	2019-nCoV/USA-WA1/2020 (USA-WA1) (Strain used for development)	MN985325.1
2	Wuhan-Hu-1	MN908947.3
3	2019-nCoV_HKU-SZ-002a_2020	MN938384.1
4	SARS-CoV-2/human/USA/CA-CDC-CA1/2020	MN994467.1
5	SARS-CoV-2/human/USA/CA-CDC-CA2/2020	MN994468.1
6	BetaCoV/Korea/SNU01/2020	MT039890.1
7	2019-nCoV_HKU-SZ-005b_2020	MN975262.1
8	SARS-CoV-2/human/USA/AZ-CDC-AZ1/2020	MN997409.1
9	2019-nCoV WHU01	MN988668.1
10	2019-nCoV WHU02	MN988669.1
11	SARS-CoV-2/human/USA/IL-CDC-IL1/2020	MN988713.1
12	SARS-CoV-2/human/USA/WA-S1476/2020	MT821795.1

No	Strain	NCBI Accession No
13	SARS-CoV-2/human/USA/CA-QDX-185/2020	MT786799.1
14	SARS-CoV-2/human/USA/SEARCH-0725-IPL/2020	MT811339.1
15	SARS-CoV-2/human/USA/SEARCH-0713-SAN/2020	MT811332.1

(2) Test procedure

- **NCBI BLAST function**

2.3.4. Acceptance criteria

Criteria	Acceptance criteria (Match rate)
Match rate	Match rate > 99.9 %

2.3.5. Results

Strain	NCBI Accession No	% Homology
Wuhan-Hu-1	MN908947.3	99.99
2019-nCoV_HKU-SZ-002a_2020	MN938384.1	99.99
SARS-CoV-2/human/USA/CA-CDC-CA1/2020	MN994467.1	99.98
SARS-CoV-2/human/USA/CA-CDC-CA2/2020	MN994468.1	99.98
BetaCoV/Korea/SNU01/2020	MT039890.1	99.96
2019-nCoV_HKU-SZ-005b_2020	MN975262.1	99.99
SARS-CoV-2/human/USA/AZ-CDC-AZ1/2020	MN997409.1	99.99
2019-nCoV WHU01	MN988668.1	99.99
2019-nCoV WHU02	MN988669.1	99.99
SARS-CoV-2/human/USA/IL-CDC-IL1/2020	MN988713.1	99.97
SARS-CoV-2/human/USA/WA-S1476/2020	MT821795.1	99.96
SARS-CoV-2/human/USA/CA-QDX-185/2020	MT786799.1	99.94
SARS-CoV-2/human/USA/SEARCH-0725-IPL/2020	MT811339.1	99.96

Strain	NCBI Accession No	% Homology
SARS-CoV-2/human/USA/SEARCH-0713-SAN/2020	MT811332.1	99.97

2.3.6. Conclusion

As a result of in silico analysis of 14 strains, it was confirmed that all 14 strains were more than 99.9% consistent with ATCC VR-1986HK used in this product development. Therefore, it was confirmed that GENEDIA W COVID-19 Ag products can exhibit comprehensive reactivity to various strains of SARS-CoV-2.

3 Analytical Specificity

3.1 Interference test

3.1.1. Purpose

The purpose of this test is to check whether the interfering substance affects the reagent when testing the reagent using several interfering substances (various chemical substances).

3.1.2. Introduction

Chemical substance's interference test

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.29

3.1.3. Materials and Test Procedure

(1) Material

- **Test interference material**

No	Interference material	Manufacturer	Test concentration
1	Conjugated Bilirubin	SIGMA ALDRICH	5 mg/mL
2	Cholesterol	SIGMA ALDRICH	15 mg/mL
3	Triglyceride mixture	SIGMA ALDRICH	20 mg/mL
4	Sodium Heparin	SIGMA ALDRICH	30 mg/mL
5	Sodium Citrate	SIGMA ALDRICH	10 mg/mL
6	K_3-EDTA	ACROS ORGANICS	20 mg/mL
7	Albumin	SIGMA ALDRICH	30 mg/mL
8	Hemoglobin	SIGMA ALDRICH	40 mg/mL
9	(R)-(-)-Phenylephrine hydrochloride	SIGMA ALDRICH	1 mg/mL
10	Beclomethasone	SIGMA ALDRICH	500 ng/mL
11	Benzocaine	SIGMA ALDRICH	1 mg/mL
12	Dexamethasone	SIGMA ALDRICH	10 mg/mL
13	Flunisolide	SIGMA ALDRICH	500 ng/mL
14	Menthol	SIGMA ALDRICH	10 mg/mL
15	Mucin	SIGMA ALDRICH	1 mg/mL

No	Interference material	Manufacturer	Test concentration
16	Mupirocin	SIGMA ALDRICH	500 ng/mL
17	Oxymetazoline hydrochloride	SIGMA ALDRICH	0.05 mg/mL
18	Tobramycin	SIGMA ALDRICH	500 ng/mL
19	Oseltamivir phosphate	SIGMA ALDRICH	500 ng/mL
20	Acetaminophen	SIGMA ALDRICH	30 µg/mL
21	Acetylsalicylic acid	SIGMA ALDRICH	652 µg/mL
22	Ibuprofen	SIGMA ALDRICH	500 µg/mL
23	Zanamivir	SIGMA ALDRICH	1 mg/mL

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2002 / 2020.07.13

(2) Test procedure

STEP 1 Prepare interference substance and mix with test sample (RP 201, 101, 102, 103).

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 3 times repeated test for each sample (1 lot)

3.1.4. Acceptance criteria

Positive sample(RP101, 102, 103) – Positive

Negative sample(RP201) – Negative

3.1.5. Results

No.	Interference material	Test concentration	Test sample	Result
1	Conjugated Bilirubin	5 mg/mL	RP201	Neg
			RP101/102/103	Pos
2	Cholesterol	15 mg/mL	RP201	Neg
			RP101/102/103	Pos
3	Triglyceride mixture	20 mg/mL	RP201	Neg
			RP101/102/103	Pos
4	Sodium Heparin	30 mg/mL	RP201	Neg
			RP101/102/103	Pos
5	Sodium Citrate	10 mg/mL	RP201	Neg
			RP101/102/103	Pos
6	K_3-EDTA	20 mg/mL	RP201	Neg
			RP101/102/103	Pos
7	Albumin	30 mg/mL	RP201	Neg
			RP101/102/103	Pos
8	Hemoglobin	40 mg/mL	RP201	Neg
			RP101/102/103	Pos
9	(R)-(-)-Phenylephrine hydrochloride	1 mg/mL	RP201	Neg
			RP101/102/103	Pos
10	Beclomethasone	500 ng/mL	RP201	Neg
			RP101/102/103	Pos
11	Benzocaine	1 mg/mL	RP201	Neg
			RP101/102/103	Pos
12	Dexamethasone	10 mg/mL	RP201	Neg
			RP101/102/103	Pos
13	Flunisolide	500 ng/mL	RP201	Neg
			RP101/102/103	Pos
14	Menthol	10 mg/mL	RP201	Neg
			RP101/102/103	Pos

No.	Interference material	Test concentration	Test sample	Result
15	Mucin	1 mg/mL	RP201	Neg
			RP101/102/103	Pos
16	Mupirocin	500 ng/mL	RP201	Neg
			RP101/102/103	Pos
17	Oxymetazoline Hydrochloride	0.05 mg/mL	RP201	Neg
			RP101/102/103	Pos
18	Tobramycin	500 ng/mL	RP201	Neg
			RP101/102/103	Pos
19	Oseltamivir Phosphate	500 ng/mL	RP201	Neg
			RP101/102/103	Pos
20	Acetaminophen	30 µg/mL	RP201	Neg
			RP101/102/103	Pos
21	Acetylsalicylic acid	652 µg/mL	RP201	Neg
			RP101/102/103	Pos
22	Ibuprofen	500 µg/mL	RP201	Neg
			RP101/102/103	Pos
23	Zanamivir	1 mg/mL	RP201	Neg
			RP101/102/103	Pos

3.1.6. Conclusion

The GENEDIA W COVID-19 Ag product was evaluated for interference response to various endogenous and exogenous substances that may exist in the sample, and as a result, it was confirmed that there was no interference effect up to the test concentration for a total of 23 substances.

3.2 Cross reactivity test

3.2.1. Purpose

The purpose of this study is to confirm cross-reactivity with other pathogens that cause similar or different symptoms from the target pathogen.

3.2.2. Introduction

Various other pathogen's cross reactivity test

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.30

3.2.3. Materials and Test Procedure

(1) Material

- **Test Cross reactive material**

No	Cross reactive material	Supplier / type	Test concentration
1	Legionella pneumoniae	ATCC/live	>0.5X10^3 CFU/mL
2	Mycoplasma pneumonia	ATCC/live	1.50X10^6 CFU/mL
3	Human Coronavirus NL63	NBK(KOREA)/live virus	1/40 dilution
4	Human Coronavirus NL63 (Heat-inactivated)	Zeptometrix/ Heat inactivated	0.85X10^4 $TCID_{50}$/mL
5	Human Coronavirus 229E	Korea Bank for Pathogenic Viruses /live virus	0.50X10^4 PFU/mL
6	Betacoronavirus (OC43)	Korea Bank for Pathogenic Viruses /live virus	3.40X10^6 PFU/mL
7	MERS-CoV (Heat-inactivated)	Zeptometrix/ Heat inactivated	0.85X10^4 $TCID_{50}$/mL
8	Coronavirus-SARS Stock	Zeptometrix/ For gene analysis	1/20 dilution
9	Influenza A_H1N1_A/PR/8/34	ATCC/live virus	1.95X10^6 PFU/mL

No	Cross reactive material	Supplier / type	Test concentration
10	Influenza A_H3N2_A/Aichi/2/68	ATCC/live virus	$1.55X10^5$ PFU/mL
11	Influenza B (Yamagata)_ B/Florida/4/2006	ATCC/live virus	$0.55X10^8$ $CEID_{50}$/mL
12	Influenza B (Victoria)_ B/HongKong/5/72	ATCC/live virus	$0.50X10^8$ $CEID_{50}$/mL
13	Rhinovirus 14	Korea Bank for Pathogenic Viruses /live virus	$0.6X10^4$ PFU/mL
14	Enterovirus 70	Korea Bank for Pathogenic Viruses /live virus	$4.40X10^6$ PFU/mL
15	Enterovirus 71	Korea Bank for Pathogenic Viruses /live virus	$0.70X10^4$ PFU/mL
16	RSV A_Long	Korea Bank for Pathogenic Viruses /live virus	$1.20X10^5$ PFU/mL
17	RSV B_9320	Korea Bank for Pathogenic Viruses /live virus	$2.30X10^4$ PFU/mL
18	Parainfluenza 1	Korea Bank for Pathogenic Viruses /live virus	$1.95X10^4$ PFU/mL
19	Parainfluenza 2	Korea Bank for Pathogenic Viruses /live virus	$1.00X10^6$ PFU/mL
20	Parainfluenza 3	Korea Bank for Pathogenic Viruses /live virus	$0.80X10^5$ PFU/mL
21	Parainfluenza 4a	Korea Bank for Pathogenic Viruses /live virus	$2.30X10^7$ PFU/mL
22	Parainfluenza 4b	Korea Bank for Pathogenic Viruses /live virus	$1.20X10^7$ PFU/mL
23	Metapneumovirus	Korea Bank for Pathogenic Viruses /live virus	$0.70X10^4$ PFU/mL
24	Adenovirus 1	Korea Bank for Pathogenic Viruses /live virus	$2.00X10^7$ PFU/mL
25	Adenovirus 3	Korea Bank for Pathogenic Viruses /live virus	$2.00X10^4$ PFU/mL
26	Streptococcus pneumonia	ATCC/live bacteria	$>0.5X10^3$ CFU/mL
27	Haemophilus influenza	ATCC/live bacteria	$>0.5X10^3$ CFU/mL

No	Cross reactive material	Supplier / type	Test concentration
28	Candida albicands gu5	ATCC/live bacteria	1/20 dilution
29	Bordetella pertussis 18323	ATCC/live bacteria	$0.55X10^8$ CFU/mL
30	Streptococcus pyogenes strain Type 1	ATCC/live bacteria	$>0.5X10^3$ CFU/mL
31	Chlamydophila pneumonia 2023	ATCC/live bacteria	$2.00X10^6$ IFU/mL

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2003 / 2020.07.15

(2) Test procedure

STEP 1 Prepare cross reactive material and mix with test sample (RP 201, 101, 102, 103).

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 3 times repeated test for each sample (1 lot)

3.2.4. Acceptance criteria

Positive sample(RP101, 102, 103) – Positive

Negative sample(RP201) – Negative

3.2.5. Results

No.	Cross reactive material	Test concentration	Test sample	Result
1	Legionella pneumoniae	>0.5X10^3 CFU/mL	RP201	Neg
			RP101/102/ 103	Pos
2	Mycoplasma pneumonia	1.50X10^6 CFU/mL	RP201	Neg
			RP101/102/ 103	Pos
3	Human Coronavirus NL63	1/40 dilution	RP201	Neg
			RP101/102/ 103	Pos
4	Human Coronavirus NL63 (Heat-inactivated)	0.85X10^4 $TCID_{50}$/mL	RP201	Neg
			RP101/102/ 103	Pos
5	Human Coronavirus 229E	0.50X10^4 PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
6	Betacoronavirus (OC43)	3.40X10^6 PFU/mL	RP201	Neg
			RP101/102 /103	Pos
7	MERS-CoV (Heat-inactivated)	0.85X10^4 $TCID_{50}$/mL	RP201	Neg
			RP101/102/ 103	Pos
8	Coronavirus-SARS Stock	1/20 dilution	RP201	Neg
			RP101/102/ 103	Pos
9	Influenza A_H1N1_A/PR/8/34	1.95X10^6 PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
10	Influenza A_H3N2_A/Aichi/2/68	1.55X10^5 PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
11	Influenza B (Yamagata)_ B/Florida/4/2006	0.55X10^8 $CEID_{50}$/mL	RP201	Neg
			RP101/102/ 103	Pos
12	Influenza B (Victoria)_	0.50X10^8 $CEID_{50}$/mL	RP201	Neg

No.	Cross reactive material	Test concentration	Test sample	Result
	B/HongKong/5/72		RP101/102 /103	Pos
13	Rhinovirus 14	$0.6X10^4$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
14	Enterovirus 70	$4.40X10^6$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
15	Enterovirus 71	$0.70X10^4$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
16	RSA A_Long	$1.20X10^5$ PFU/mL	RP201	Neg
			RP101/102 /103	Pos
17	RSV B_9320	$2.30X10^4$ PFU/mL	RP201	Neg
			RP101/102 /103	Pos
18	Parainfluenza 1	$1.95X10^4$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
19	Parainfluenza 2	$1.00X10^6$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
20	Parainfluenza 3	$0.80X10^5$ PFU/mL	RP201	Neg
			RP101/102 /103	Pos
21	Parainfluenza 4a	$2.30X10^7$ PFU/mL	RP201	Neg
			RP101/102 /103	Pos
22	Parainfluenza 4b	$1.20X10^7$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
23	Metapneumovirus	$0.70X10^4$ PFU/mL	RP201	Neg
			RP101/102/ 103	Pos
24	Adenovirus 1	$2.00X10^7$ PFU/mL	RP201	Neg

No.	Cross reactive material	Test concentration	Test sample	Result
			RP101/102/ 103	Pos
25	Adenovirus 3	2.00X10^4 PFU/mL	RP201	Neg
			RP101/102 /103	Pos
26	Streptococcus pneumonia	>0.5X10^3 CFU/mL	RP201	Neg
			RP101/102/ 103	Pos
27	Haemophilus influenza	>0.5X10^3 CFU/mL	RP201	Neg
			RP101/102 /103	Pos
28	Candida albicands gu5	1/20 dilution	RP201	Neg
			RP101/102/ 103	Pos
29	Bordetella pertussis 18323	0.55X10^8 CFU/mL	RP201	Neg
			RP101/102/ 103	Pos
30	Streptococcus pyogenes strain Type 1	>0.5X10^3 CFU/mL	RP201	Neg
			RP101/102/ 103	Pos
31	Chlamydophila pneumonia 2023	2.00X10^6 IFU/mL	RP201	Neg
			RP101/102/ 103	Pos

3.2.6. Conclusion

As a result of evaluating the cross-reactivity of possible microorganisms and viruses in the sample, the GENEDIA W COVID-19 Ag product was found to not cause cross-reaction up to the test concentration of a total of 31 microorganisms and viruses.

4 Precision evaluation

4.1 Between Lot Precision

4.1.1. Purpose

The purpose of this test is to confirm the reproducibility between lot to lot GENEDIA W COVID-19 Ag.

4.1.2. Introduction

Inter-lot test(lot to lot)

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.29

4.1.3. Materials and Test Procedure

(1) Material

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2001 / 2020.07.09
	643X2002 / 2020.07.13
	643X2003 / 2020.07.15

(2) Test procedure

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 4 concentration. (Including Negative)

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag, 3 times repeated test for each sample (3 lot)

4.1.4. Acceptance criteria

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

4.1.5. Results

Sample	Repeat	Lot 1 (643X2001)	Lot 2 (643X2002)	Lot 3 (643X2003)
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid

4.1.6. Conclusion

Using 3 lots of GENEDIA W COVID-19 Ag, one person repeatedly tested three times to confirm the reproducibility between lot, and as a result, it was confirmed that all of them met the criteria for reproducibility.

4.2 Between People Precision

4.2.1. Purpose

The purpose of this test is to confirm the reproducibility between person to person GENEDIA W COVID-19 Ag.

4.2.2. Introduction

Inter-person test (person to person)

Tester: Jin-Woo Jeon, Na-Reum Ha, Tae-Yong Kim

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.28

4.2.3. Materials and Test Procedure

(1) Material

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2003 / 2020.07.15

(2) Test procedure

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 4 concentration. (Including Negative)

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag,
3 person test - 3 times repeated test - for each sample (1 lot)

4.2.4. Acceptance criteria

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

4.2.5. Results

Sample	Repeat	Person 1 (Jin-Woo Jeon)	Person 2 (Na-Reum Ha)	Person 3 (Tae-Yong Kim)
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid

4.2.6. Conclusion

Using 1 lots of GENEDIA W COVID-19 Ag, 3 people repeatedly tested 3 times to confirm the reproducibility between people, and as a result, it was confirmed that all of them met the criteria for reproducibility.

4.3 Between Site Precision

4.3.1. Purpose

The purpose of this test is to confirm the reproducibility between site to site GENEDIA W COVID-19 Ag.

4.3.2. Introduction

Inter-site test(site to site)

Test site :

- Green Cross Medical Science Research Center
- Green Cross Medical Science IVD Room
- Green Cross Medical Science QC Room

Test date : 2020.07.20-24

4.3.3. Materials and Test Procedure

(1) Material

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2002 / 2020.07.13

(2) Test procedure

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 4 concentration. (Including Negative)

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag,
3 site test - 5 times repeated test - for 5 day, each sample (1 lot)

4.3.4. Acceptance criteria

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

4.3.5. Results

Sample	Test date	Repeat	Site 1 (Laboratory)	Site 2 (IVD room)	Site 3 (QC room)
RP101	2020.07.20	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.21	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.22	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.23	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.24	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
RP102	2020.07.20	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.21	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid

Sample	Test date	Repeat	Site 1 (Laboratory)	Site 2 (IVD room)	Site 3 (QC room)
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.22	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.23	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.24	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
RP103	2020.07.20	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.21	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.22	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.23	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
	2020.07.24	1	Positive/Valid	Positive/Valid	Positive/Valid
		2	Positive/Valid	Positive/Valid	Positive/Valid
		3	Positive/Valid	Positive/Valid	Positive/Valid
		4	Positive/Valid	Positive/Valid	Positive/Valid
		5	Positive/Valid	Positive/Valid	Positive/Valid
RP201	2020.07.20	1	Negative/Valid	Negative/Valid	Negative/Valid
		2	Negative/Valid	Negative/Valid	Negative/Valid

Sample	Test date	Repeat	Site 1 (Laboratory)	Site 2 (IVD room)	Site 3 (QC room)
		3	Negative/Valid	Negative/Valid	Negative/Valid
		4	Negative/Valid	Negative/Valid	Negative/Valid
		5	Negative/Valid	Negative/Valid	Negative/Valid
	2020.07.21	1	Negative/Valid	Negative/Valid	Negative/Valid
		2	Negative/Valid	Negative/Valid	Negative/Valid
		3	Negative/Valid	Negative/Valid	Negative/Valid
		4	Negative/Valid	Negative/Valid	Negative/Valid
		5	Negative/Valid	Negative/Valid	Negative/Valid
	2020.07.22	1	Negative/Valid	Negative/Valid	Negative/Valid
		2	Negative/Valid	Negative/Valid	Negative/Valid
		3	Negative/Valid	Negative/Valid	Negative/Valid
		4	Negative/Valid	Negative/Valid	Negative/Valid
		5	Negative/Valid	Negative/Valid	Negative/Valid
	2020.07.23	1	Negative/Valid	Negative/Valid	Negative/Valid
		2	Negative/Valid	Negative/Valid	Negative/Valid
		3	Negative/Valid	Negative/Valid	Negative/Valid
		4	Negative/Valid	Negative/Valid	Negative/Valid
		5	Negative/Valid	Negative/Valid	Negative/Valid
	2020.07.24	1	Negative/Valid	Negative/Valid	Negative/Valid
		2	Negative/Valid	Negative/Valid	Negative/Valid
		3	Negative/Valid	Negative/Valid	Negative/Valid
		4	Negative/Valid	Negative/Valid	Negative/Valid
		5	Negative/Valid	Negative/Valid	Negative/Valid

4.3.6. Conclusion

Using 1 lots of GENEDIA W COVID-19 Ag, 3 site repeatedly tested 5 times and 5 days to confirm the reproducibility between site, and as a result, it was confirmed that all of them met the criteria for reproducibility.

4.4 Between Day Precision

4.4.1. Purpose

The purpose of this test is to confirm the reproducibility between day to day GENEDIA W COVID-19 Ag.

4.4.2. Introduction

Inter-day test (day to day)

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.23-29

4.4.3. Materials and Test Procedure

(1) Material

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2003 / 2020.07.15

(2) Test procedure

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 4 concentration. (Including Negative)

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag,

2 times repeated test – 5 day(morning / afternoon) - for each sample (1 lot)

4.4.4. Acceptance criteria

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

4.4.5. Results

Sample	Repeat	Day 1 (2020.07.23)	Day 2 (2020.07.24)	Day 3 (2020.07.27)	Day 4 (2020.07.28)	Day 5 (2020.07.29)
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	4	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid

4.4.6. Conclusion

Using 1 lots of GENEDIA W COVID-19 Ag, repeatedly tested 4 times per day(morning/afternoon) during 5 days to confirm the reproducibility between day, and as a result, it was confirmed that all of them met the criteria for reproducibility.

4.5 Reproducibility

4.5.1. Purpose

The purpose of this test is to confirm the reproducibility for 20 days GENEDIA W COVID-19 Ag.

4.5.2. Introduction

Reproducibility test (20 days)

Test site / Test date : Green Cross Medical Science Research Center / 2020.07.16-2020.08.12

4.5.3. Materials and Test Procedure

(1) Material

- **Test sample**

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

- **Test device**

Product name	GENEDIA W COVID-19 Ag
Lot # / Date of production	643X2001 / 2020.07.09

(2) Test procedure

STEP 1 Prepare a sample diluted with Recombinant SARS-CoV-2 Ag in 4 concentration. (Including Negative)

STEP 2 According to the IFU of the GENEDIA W COVID-19 Ag,

2 times repeated test – 20 day(morning / afternoon) - for each sample (1 lot)

4.5.4. Acceptance criteria

Sample No	Sample information	Classification
RP 101	Recombinant SARS-CoV-2 Ag	High conc.
RP 102		Middle conc.
RP 103		Low conc.
RP 201	Negative sample	Extraction solution

4.5.5. Results

Sample	Repeat	Day 1	Day 2	Day 3	Day 4	Day 5
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	4	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid

Sample	Repeat	Day 6	Day 7	Day 8	Day 9	Day 10
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	4	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid

Sample	Repeat	Day 11	Day 12	Day 13	Day 14	Day 15
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid

Sample	Repeat	Day 11	Day 12	Day 13	Day 14	Day 15
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	4	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid

Sample	Repeat	Day 16	Day 17	Day 18	Day 19	Day 20
RP101	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP102	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP103	1	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	2	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	3	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
	4	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid	Positive/Valid
RP201	1	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	2	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	3	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid
	4	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid	Negative/Valid

4.5.6. Conclusion

Using 1 lots of GENEDIA W COVID-19 Ag, repeatedly tested 4 times per day(morning/afternoon) during 2 days to confirm the reproducibility, and as a result, it was confirmed that all of them met the criteria for reproducibility.