GenBody Inc.
(주)젠바디

Technical File

Performance Evaluation

Product:	**GenBody COVID-19 Ag**
Date:	**2020-07-15**

Prepared by / date	Reviewed by / date	Approved by / date
Researcher	**R&D Director**	**QMR**
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2020. 07. 15	**2020. 07. 15**	**2020. 07. 15**

0. Revision history

Revision History		
Rev. O	2020. 06. 02	Release of the performance evaluation result for the GenBody COVID-19 Ag
Rev. 1	2020. 06. 15	Updated information
Rev. 1.1	2020. 06. 30	Updated information
Rev. 1.2	2020. 07. 15	Updated information of mistyping

1 Performance Evaluation Plan

1.1 Purpose

To confirm the performance and effectiveness of GenBody COVID-19 Ag through the performance evaluation test and clinical trial designed with reference to the CLSI guideline

1.2 Responsibility

- Test specialist name : Seo seul ki at the GenBody Biotech Institute
- Team leader/first reviewer : Jedae Moon at the GenBody Biotech Institute.

1.3 Test guidance / regulation documents

- GenBody Inc.'s performance evaluation test guide document for diagnostic kit
- European harmonised standard EN13612:2002 and EN23640:2015,
- NCCLS (EP17-A2, EP06-A, EP07-A2, MM17-A, EP05-A3, EP12-A2, EP10-A3, EP09-A2)

1.4 Information of the test diagnostic kit

- Kit name : GenBody COVID-19 Ag
- Catalog No. : COVAG025
- Batch No : 3 Lots (FMFOS25201, FMFOS25202, FMFOS25203)

1.5 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.

1.6 Information of instruments

Not applicable

1.7 Information of specimen

Human nasopharyngeal swab and oropharyngeal swab

1.8 Test Design

Test Item		Reference for Test Method
Analytical Sensitivity	Limit of Detection	EP17-A2
Analytical Specificity	Cross Reactivity	EP07-A2
	Substance	MM17-A
Interfering substance		EP07-A2
Whole system failure rate		EP05-A3
Precision assay		EP05-A3
Reproducibility assay	Inter-Operator	EP05-A3
	Intra-Instrument	EP05-A3
	Inter-batch	EP05-A3
Clinical evaluation	Diagnostic sensitivity	EP12-A2
	Diagnostic specificity	EP12-A2

2 Analytical performance evaluation

2.1 Analytical Sensitivity / Reference Material

2.1.1 Protocols

- Material: SARS-CoV-2 Iisolate: USA-WA1/2020) Culture Fluid (Heat inactivated) (Zeptomatrix corp.)

No	Serial dilution
P1	1/50x
P2	1/100x
P3	1/200x
P4	1/400x
P5	1/800x
P6	1/1600x
P7	1/3200x
P8	1/6400x
P9	1/12800x
P10	1/25600x
P11	1/51200x

- Method: serial dilution of material spiked in matrix
- No. of tests: single per sample
- Test Kit: GenBody COVID-19 Ag
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Result analysis

Smaple	Type / Serial dliution	$TCID_{50}$/ml	FMFOS25201
P1	1/50x	2.3×10^5	Pos
P2	1/100x	1.15×10^5	Pos
P3	1/200x	5.75×10^4	Pos
P4	1/400x	2.87×10^4	Pos
P5	1/800x	1.43×10^4	Pos
P6	1/1600x	7.18×10^3	Pos
P7	1/3200x	3.59×10^3	Pos
P8	1/6400x	1.79×10^3	Neg
P9	1/12800x	8.98×10^2	Neg
P10	1/25600x	4.49×10^2	Neg

Pos: positivie result, Neg: negative result

2.1.2 Conclusion

- As shown in the result tables, GenBody COVID-19 Ag' concentration was detected 1/3200x and it is 3.59x 10^3 $TCID_{50}$/ml

2.2 Analytical Sensitivity / LoD

2.2.1 Protocols

- Material: SARS-CoV-2 Iisolate: USA-WA1/2020) Culture Fluid (Heat inactivated) (Zeptomatrix corp.)

No	Serial dilution
P12	1/500x
P13	1/1000x
P14	1/2000x
P15	1/3000x
P16	1/4000x
P17	1/5000x

- Method: serial dilution of material spiked in matrix
- No. of tests: single per sample
- Test Kit: GenBody COVID-19 Ag
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Result analysis

Smaple	Type / Serial dliution	$TCID_{50}$/ml	FMFOS25201
P12	1/500x	2.3 x 10^4	Pos
P13	1/1000x	1.15 x 10^4	Pos
P14	1/2000x	5.75 x 10^3	Pos
P15	1/3000x	3.83 x 10^3	Pos
P16	1/4000x	2.87 x 10^3	Pos
P17	1/5000x	2.30 x 10^3	Neg

Pos: positivie result, Neg: negative result

2.2.2 Conclusion

- As shown in the result tables, GenBody COVID-19 Ag' LoD was 1/4000x and it is 2.87x 10^3 $TCID_{50}$/ml

2.3 Analytical Specificity

2.4 Analytical Specificity(Interfering substances testing)

2.4.1 Protocols

- Material:

Sample name	Sample name	TCID50/ml
NC(Negative control)	NC(Negative control)	-
Low titer of P6	Low titer of Positive control	7.18×10^3

- Method: Material spiked in matrix
- No. of tests: single per sample
- Test Kit: GenBody COVID-19 Ag (Lot No.: FMFOS25201)
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Test guidance : Interference Testing in Clinical Chemistry ; Approved Guideline-Second Edition, EP07-A2, NCCLS

2.4.2 Results

Sample name	Compound	Concentration(mg/dL)	Only positive sample		Positive sample + Material		Negative sample + Material	
NC	Viral Transport Medium (VTM)	50%	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Whole blood	2%	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Mouth wash	10%	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Phenylephrine	100mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Acetylsalicylic acid	20 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Beclomethasone	500 ng/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Benzocaine	1 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Flunisolide	3 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Guaiacol glyceryl ether	20 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Menthol	10 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Oxymetazoline	10 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Tobramycin	40 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+

NC	Zanamivir	3.3 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	Oseltamivir phosphate	25 mg/ml	-	-	-	-	-	-
P6			+	+	+	+	+	+
NC	mucous	35%	-	-	-	-	-	-
P6			+	+	+	+	+	+

+: Positive signal -: Negative signal

2.4.3 Conclusion

No positive, smearing and/or negative interference due to each material test **was not observed**.

2.5 Cross-reactivity

2.5.1 Protocols

- Material:

Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS25201

- No. of tests: single per sample
- Test Kit: GenBody COVID-19 Ag
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Test result: There was cross-reactivity of SARS-coronavirus and no cross reactivity was observed for any of virus and bacterium tested etc.

2.5.2 Result

Organism	Results	Concentration
SARS-CoV	+	2.0ug/ml
Coronavirus Culture Fluid (NL63)	-	1.17×10^5 $TCID_{50}$/mL
Coronavirus Culture Fluid (229E)	-	1.51×10^6 $TCID_{50}$/mL
Coronavirus Culture Fluid (OC43)	-	5.01×10^5 $TCID_{50}$/mL
MERS-CoV Culture Fluid	-	1.70×10^5 $TCID_{50}$/mL
Human Adenovirus type 1	-	1.4×10^8 pfu/ml
Human Adenovirus type 3	-	2.0×10^5 pfu/ml
Human Adenovirus type 8	-	2.0×10^9 pfu/ml
Human Adenovirus type 18	-	4.0×10^6 pfu/ml
Human Adenovirus type 23	-	9.0×10^7 pfu/ml
Human Adenovirus type 7	-	6.0×10^7 pfu/ml
Human Adenovirus type 5	-	4.0×10^8 pfu/ml
Human Adenovirus type 11	-	3.0×10^6 pfu/ml
Human Coronavirus OC43	-	6.8×10^7 pfu/ml
Human Coronavirus 229E	-	1.0×10^6 pfu/ml
Human Parainfluenza virus type 1	-	2.8×10^6 pfu/ml
Human Parainfluenza virus type 2	-	2.0×10^8 pfu/ml

Human Parainfluenza virus type 3	-	6.0 x 10^7 pfu/ml
Human Parainfluenza virus type 4	-	4.6 x 10^8 pfu/ml
Human Rhinovirus type 14	-	9.8 x 10^7 pfu/ml
Human Rhinovirus type 42	-	4.2 x 10^5 pfu/ml
Human Rhinovirus type 1	-	4.0 x 10^6 pfu/ml
Human Metapneumovirus	-	1.4 x 10^5 pfu/ml
Respiratory syncytial virus-A culture fluid	-	1 x $10^{6.58}$ $TCID_{50}$/mL
Respiratory syncytial virus-B culture fluid	-	5.01 x 10^5 $TCID_{50}$/mL
Coronavirus Culture Fluid (NL63)	-	1.17 x 10^5 $TCID_{50}$/mL

2.5.3 Conclusion

Other pathogens cell should not be affected to its reactions excepted SARS-CoV.

2.6 Whole System Failure

2.6.1 Protocols

- Test purpose: To determine the variation for multiple results of samples (same concentration)
- Material: each sample spiked in matrix. Samples concentration belew under table.

Sample name	Sample name	TCID50/ml
NC(Negative control)	NC(Negative control)	-
Low titer of P6	Low titer of Positive control	7.18 x 10^3

- No. of Tests: singal per run, 100 tests
- Test Kit: GenBody COVID-19 Ag (Lot No.:FMOS25201)
- Protocol: Followed by GenBody COVID-19 Ag manual

2.6.2 Results

- Whole System Failure : Results was determined within intensity
- Whole system Faliure rate= 0%(False nagative detection number 0/100 tests)

Sample name	Tests(n)	False nagative (n)
NC	0	0
PC6	100	0

2.6.3 Conclusion

100 samples were detected at Whole system Failure test

2.7 Precision assay

2.7.1 Protocols

- Material:

Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS25201,FMFOS25202, FMFOS25203

Sample name	$TCID_{50}$/ml
NC (negative control)	-
P4	2.87×10^4
P5	1.43×10^4
P6	7.18×10^3

- No. of Tests: Triplicates per run, 2 run a day; 5 days
- Protocol: followed by the manual of GenBody COVID-19 Ag

2.7.2 Results

- Precision : Results was determined within intensity

Lot No. FMFOS25201										
Sample name	Day1		Day2		Day3		Day4		Day5	
Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
P4	+	+	+	+	+	+	+	+	+	+
P5	+	+	+	+	+	+	+	+	+	+
P6	+	+	+	+	+	+	+	+	+	+

Lot No. FMFOS25202										
Sample name	Day1		Day2		Day3		Day4		Day5	
Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
P4	+	+	+	+	+	+	+	+	+	+
P5	+	+	+	+	+	+	+	+	+	+
P6	+	+	+	+	+	+	+	+	+	+

Lot No. FMFOS25203					
Sample name	Day1	Day2	Day3	Day4	Day5

Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
P4	+	+	+	+	+	+	+	+	+	+
P5	+	+	+	+	+	+	+	+	+	+
P6	+	+	+	+	+	+	+	+	+	+

Positive signal: + Negative signal: -

2.8 Reproducibility / Inter-Operator

- Material

Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS25201,FMFOS25202, FMFOS25203

Sample name	$TCID_{50}$/ml
NC (negative control)	-
P4	2.87×10^4
P5	1.43×10^4
P6	7.18×10^3

- No. of Tests: Duplicates per run, 2 run a day; 5 days
- Protocol: followed by the manual of GenBody COVID-19 Ag

2.8.1 Test Result

- Results was determined within intensity

Day 1				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 2				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 3				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 4				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 5				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Positive Signal: + Negative signal: -

2.9 Reproducibility / Inter-site

2.9.1 Protocols

- Material:

Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS20201

Sample name	$TCID_{50}$/ml
NC (negative control)	-
P4	2.87×10^4
P5	1.43×10^4
P6	7.18×10^3

- No. of Tests: Duplicates per run, 2 run a day; 5 days
- Protocol: followed by the manual of GenBody COVID-19 Ag

2.9.2 Test Result

- Results was determined within intensity

Day 1				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 2				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 3				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 4				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Day 5				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
P4	+	+	+	+
P5	+	+	+	+
P6	+	+	+	+

Positive Signal: + Negative signal: -

2.10 Reproducibility / Total analysis

Item	Results
With-in run	Confirmed
With-in day	Confirmed
Between run	Confirmed
Inter-Operator	Confirmed
Inter-batch	Confirmed
Inter-site	Confirmed

3 Clinical Evaluation/Diagnostic sensitivity & specificity

3.1 Test Protocol

- Material : 130 clinical samples(30 positive specimens, 100 negative specimens/ see under each result)
- No. of Tests : Single test per sample
- Test Kit : GenBody COVID-19 Ag
- Protocol: Follow GenBody COVID-19 Ag manual
- Test guidance : User Protocol for Evalution Qualitative Test Performance ; Approved Guideline, EP12-A2, NCCLS
- Result analysis : Each target in positive samples were tested Real-Time PCR kit
- * User Protocol for Evalution Qualitative Test Performance ; Approved Guideline, EP12-A2, NCCLS

3.2 Test Result

		Other kit(Real-Time PCR)		Total
		Positive	Negative	
GenBody COVID-19 Ag	Positive	27	2	29
	Negative	3	98	101
Total		30	100	130

- Sensitivity = 90.0% (95% CI = 73.47% to 97.89%)
- Specificity = 98.0% (95% CI = 92.96% to 99.76%)

4 Performance claim in IFU

Sample type: *Nasopharyngeal swab and oropharyngeal swab from human*