

Stability Studies

Product:	GenBody COVID-19 Ag
Date:	2020-06-30

Prepared by / date	Reviewed by / date	Approved by / date
Researcher	R&D Director	QMR
Seo seul ki	Jedae Moon	Jung Young Choi
2020-06-30	2020-06-30	2020-06-30



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0. Revision history

Revision History		
Rev. 0	2020. 06. 02	Release of the stability for the GenBody COVID-19 Ag
Rev. 0.1	2020. 06. 30	Updated information of in-use stability and Robustness



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I. Stability test

1 Accelerated stability test

1.1 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	2.8 x 10 ⁴
P5	1.4 x 10 ⁴
P6	7.1 x 10 ³

- No. of test: triplicates per sample
- Incubation time: 1 month at 50°C
- Test kit: GenBody COVID-19 Ag
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Method: acceleration stability test is based on the assumption that the chemical reaction involved in the deterioration of materials follows the *Arrhenius* formula. This formula implies that the 10°C of temperature increasment or decreasement in a homogenous process affects the approximately two times of increasment or decreasement of the biochemical reaction;

1) $AAF^* = Q_{10}^{[(AAT-AT)/10]} = 2.0^{[(50-25)/10]} = 5.6568542... \approx 5.6569$

*Acceleration aging factor (AAF)

2) Expiration date/AAF= 730 days/ 5.6569 = 129.0459...days. \approx 130 days

- Q₁₀= 2.0
- Ambient temperature (AT) = 25°C
- Acceleration test temperature (ATT) = 50°C
- Storage temperature: 15°C (product storage middle temperature)
- This indicates 130 days incubation at 50°C is considered to be equal to 2 year incubation at 25°C.

- Accelerated stability

Three lots of GenBody COVID-19 Ag were tested. The assay was performed by instructions for use.

*D: day

Lot	Specimen	Repeat	0 D*	7 D	14 D	21 D	28 D
Lot FMFOS25201	NC	1	-	-	-	-	-
		2	-	-	-	-	-
		3	-	-	-	-	-



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	P4	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P5	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P6	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
Lot FMFOS25202	NC	1	-	-	-	-	-
		2	-	-	-	-	-
		3	-	-	-	-	-
	P4	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P5	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P6	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
Lot FMFOS25203	NC	1	-	-	-	-	-
		2	-	-	-	-	-
		3	-	-	-	-	-
	P4	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P5	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+
	P6	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+



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2 Real-time stability test

2.1 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	2.8 x 10 ⁴
P5	1.4 x 10 ⁴
P6	7.1 x 10 ³

- No. of test: triplicates per sample
- Incubation time: 1 month at room temperature (2 to 30°C)
- Test kit: GenBody COVID-19 Ag
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Real-time stability

Three lots of GenBody COVID-19 Ag were tested. The assay was performed by instructions for use. All kits were stored at the closed original condition at room temperature (2 to 30°C).

- Test period
Evaluation of the kit was performed for 1 month. For each assay, the whole test kit reagents were used.
- Designation of the result:
+: positive, -: negative
- Result analysis
The stability data of kit at room temperature (2 to 30°C) are summarized in Table 1 (3 lots at 2 °C), Table 2 (3 lots at room temperature), and Table 3 (3 lots at 30°C).

*M, month

Lot	Specimen	Repeat	0 M*	1 M							
Lot FMFOS25201 (2°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							



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	P6	1	+	+							
		2	+	+							
		3	+	+							
Lot FMFOS25202 (2°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							
2		+	+								
3		+	+								
3		+	+								
Lot FMFOS25203 (2°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							

Lot	Specimen	Repeat	0 M	1 M							
Lot FMFOS25201 (room- Temperature)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							
Lot FMFOS25202 (room-	NC	1	-	-							
		2	-	-							
		3	-	-							

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Temperature)	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							
Lot FMFOS25203 (room- Temperature)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							

Lot	specimen	Repeat	0 M	1 M							
Lot FMFOS25201 (30°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							
Lot FMFOS25202 (30°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							



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		3	+	+							
Lot FMFOS25203 (30°C)	NC	1	-	-							
		2	-	-							
		3	-	-							
	P4	1	+	+							
		2	+	+							
		3	+	+							
	P5	1	+	+							
		2	+	+							
		3	+	+							
	P6	1	+	+							
		2	+	+							
		3	+	+							



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3 In-use stability of device

3.1 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	2.8 x 10 ⁴
P5	1.4 x 10 ⁴
P6	7.1 x 10 ³

- No. of test: triplicates per sample
- Incubation time: for 7 days
- Test kit: GenBody COVID-19 Ag
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- In-use Stability

One lot of GenBody COVID-19 Ag was tested. The assay was performed by the instructions for use. All kit were stored in closed original condition at 2 °C, room-temperature, and 35°C.

- Designation of the result:
+: positive, -: negative
- Result analysis

*D, day

Lot	Specimen	Repeat	1 D*	2 D	3 D	4 D	5 D	6 D	7 D
Lot FMFOS25201	NC (room temperature)	1	-	-	-	-	-	-	-
		2	-	-	-	-	-	-	-
		3	-	-	-	-	-	-	-
	NC (1°C)	1	-	-	-	-	-	-	-
		2	-	-	-	-	-	-	-
		3	-	-	-	-	-	-	-
	NC (35°C)	1	-	-	-	-	-	-	-
		2	-	-	-	-	-	-	-
		3	-	-	-	-	-	-	-
	PC4 (room temperature)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC4 (1°C)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
PC4	1	+	+	+	+	+	+	+	



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	(35°C)	2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC5 (room temperature)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC5 (1°C)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC5 (35°C)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC6 (room temperature)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC6 (1°C)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+
	PC6 (35°C)	1	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+

4 In-use stability of assay solution

4.1 Protocols

- Material

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

Sample name	TCID ₅₀ /ml
NC (negative control)	-
P4	2.8 x 10 ⁴
P5	1.4 x 10 ⁴
P6	7.1 x 10 ³

- No. of test: triplicates per sample
- Incubation time: for 7 days
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- In-use Stability

One lot of GenBody COVID-19 Ag was tested. All kits were stored in closed original condition at 2°C, room-temperature, and 35°C.

- Designation of result:
+: positive, -: negative

Technical File

- Result analysis

*D, day

Lot	Specimen	Repeat	1 D	2 D	3 D	4 D	5 D	6 D	7 D	
Lot FMFOS25201	NC (room temperature)	1	-	-	-	-	-	-	-	
		2	-	-	-	-	-	-	-	
		3	-	-	-	-	-	-	-	
	NC (1°C)	1	-	-	-	-	-	-	-	-
		2	-	-	-	-	-	-	-	-
		3	-	-	-	-	-	-	-	-
	NC (35°C)	1	-	-	-	-	-	-	-	-
		2	-	-	-	-	-	-	-	-
		3	-	-	-	-	-	-	-	-
	PC4 (room temperature)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC4 (1°C)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC4 (35°C)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC5 (room temperature)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC5 (1°C)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC5 (35°C)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
	PC6 (room temperature)	1	+	+	+	+	+	+	+	+
		2	+	+	+	+	+	+	+	+
		3	+	+	+	+	+	+	+	+
PC6 (1°C)	1	+	+	+	+	+	+	+	+	
	2	+	+	+	+	+	+	+	+	
	3	+	+	+	+	+	+	+	+	
PC6 (35°C)	1	+	+	+	+	+	+	+	+	
	2	+	+	+	+	+	+	+	+	
	3	+	+	+	+	+	+	+	+	

5 In-use stability of specimen(storage at 4°C)

5.1 Protocols

- Material



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Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS2521

Sample name	TCID ₅₀ /ml
NC (negative control)	-
P6	7.1 x 10 ³

- No. of test: triplicates per sample
- storage time: for 2 days
- Test kit: GenBody COVID-19 Ag
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- In-use Stability
One lot of GenBody COVID-19 Ag was tested. The assay was performed by the instructions for use. All specimens were stored in closed original condition at 4 °C.
- Designation of the result:
+: positive, -: negative
- Result analysis

*D, day

Lot	Specimen	Repeat	1 D*	2 D
Lot FMFOS25201	NC	1	-	-
		2	-	-
		3	-	-
	PC6	1	+	+
		2	+	+
		3	+	+

6 In-use stability of specimen(Freeze-Thaw(F-T) test)

6.1 Protocols

- Material

Product name	GenBody COVID-19 Ag
Manufacturer	GenBody Inc.
Cat. No/ Lot. No	COVAG025/ FMFOS2521

Sample name	TCID ₅₀ /ml
NC (negative control)	-
P6	7.1 x 10 ³

- No. of test: triplicates per sample

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- storage time: for 5 days
- Test kit: GenBody COVID-19 Ag
- Instrument: *not applicable*
- Protocol: followed by the manual of GenBody COVID-19 Ag
- In-use Stability
 - Sample is stored in -20°C. for 1 day. Then incubated at room temperature for 10~15 min.
- Designation of the result:
 - +: positive, -: negative
- Result analysis

		*D, day					
Lot	Specimen	Repeat	1 D*	2 D	3 D	4 D	5 D
Lot FMFOS25201	NC	1	-	-	-	-	-
		2	-	-	-	-	-
		3	-	-	-	-	-
	PC6	1	+	+	+	+	+
		2	+	+	+	+	+
		3	+	+	+	+	+

7 Shipping Stability

- Material

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

Sample name	TCID ₅₀ /ml
NC (negative control)	-
P4	2.8 x 10 ⁴
P5	1.4 x 10 ⁴
P6	7.1 x 10 ³
- No. of test : triplicates per sample
- Instrument: not applicable
- Protocol: followed by the manual of GenBody COVID-19 Ag
- Shipping & delivery condition: the packaged kits were shipped to Jeju Island (Korea) by air transportation. After arriving Jeju, the distributor shipped back the kits to GenBody Headquater (HQ).
- Designation of result:
 - Pos: positive, Neg: negative

Technical File

- Result analysis

The stability of transportation was determined over 1 week in the packaged condition.

*C, control line; **T, test line

Condition of transportation		Test 1		Test 2		Test 3	
		C*	T**	C	T	C	T
Negative control	NC	Pos	Neg	Pos	Neg	Pos	Neg
Positive control	PC3	Pos	Pos	Pos	Pos	Pos	Pos
		Pos	Pos	Pos	Pos	Pos	Pos
	PC4	Pos	Pos	Pos	Pos	Pos	Pos
		Pos	Pos	Pos	Pos	Pos	Pos
	PC5	Pos	Pos	Pos	Pos	Pos	Pos
		Pos	Pos	Pos	Pos	Pos	Pos

Contents of study	Storage temperature	Duration
Real-time stability	Room temperature	This test is still ongoing. All the testing will be completed at 2022.
Accelerated stability	50℃	Accelerated testing.
Shelf life	Room temperature, 2℃, 35℃	Pass
In-use stability	-	Pass
Shipping stability	-	Pass

III. Conclusion

Stability studies of GenBody COVID-19 Ag

Contents of study		Conclusion
Stability	Real-Time Stability	12 months, on-going
	Accelerated Stability	On-going
	In-use Stability	Pass
	Shipping Stability	Pass
Shelf life		Pass