
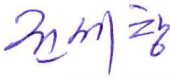

	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	1 / 10

Analytical Performance Characteristics Report of
 BIOCREDIT COVID-19 IgG/IgM Combo
 : Detection of neutralized antibody

Authorization	Dept. & Name	Signature	Date
Prepared by	R&D K. H. Yoon		2021.03.16
Reviwer	R&D S. C. Kwon		2021.03.16
Approved by	R&D K. M. Min		2021.03.16



	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	2 / 10

Table of contents

1. Purpose
2. Tested by & read by
3. Test date
4. Materials and Methods
 - 4.1 Materials
 - 4.2 Methods
5. Test result
 - 5.1. Interpretation of results
 - 5.2. Sensitivity criteria
 - 5.3. Test result
6. Conclusion
7. Reference
8. Attachments

	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	3 / 10

1. Purpose

To investigate whether BIOCREDIT COVID-19 IgG/IgM Combo can detect neutralized antibody.

2. Tested by & read by

- 1) Tested by: Kyu-hwa Yoon (R&D)
- 2) Read by: Se-chang Kwon (R&D)

3. Test date

Mar. 15. 2021

4. Materials and Methods

4.1 Materials

4.1.1. Test product

Table 1. Test product

Product	Lot No.	Mfg. date	Cat No
BIOCREDIT COVID-19 IgG/IgM Combo	H074002SD	2020.02.17	G62RHA25

4.1.2. Test materials


Table 2. Test specimen

Material	Name	Cat. No.	Manufacturer
COVID-19 Positive serum	SARS-CoV-2 Vaccinated donor Serum, 20days after 2nd vaccination	DV1224	TRINA BIOCREACTIVES AG
Negative Standard	SARS-CoV-2 normal serum	8500	ABO pharmaceuticals

4.1.3. Test equipment

Table 3. Test equipment

Equipment	Type	Equipment No.	Calibration date	Calibration valid date
-----------	------	---------------	------------------	------------------------

	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	4 / 10

Micropipette	2~20 μl	R-11-0002	2020.05.16	2021.05.15
	10~100 μl	R-11-0003	2020.05.16	2021.05.15
	20~200 μl	R-11-0004	2020.05.16	2021.05.15
	200~1000 μl	R-11-0005	2020.05.16	2021.05.15
Thermo-hydrometer	N/A	P-11-0058	2020.07.13	2021.07.12

4.2. Methods

4.2.1. Test condition

This test was conducted at RapiGen Biotechnology Research Institute, and the temperature and humidity conditions were verified using a thermo-hydrometer.

Table 4. Test condition

Test site	Temperature and humidity
RapiGen Biotechnology Research Institute	Minimum 17°C, 21% RH
	Maximum 20°C, 25% RH

4.2.2. Test method


To investigate whether BIOCREDIT COVID-19 IgG/IgM can detect neutralized antibody, We used serum from 10 donors collected 20 days after 2nd vaccination (Moderna SARS-CoV-2 vaccine).

- Add 10 μl (serum) of specimen into the sample well (S) of each device using pipette.
- Add 3 drops of assay diluent into the sample well (S) of the device.
- Read the result within 10~15 minutes.

5. Test result

5.1. Interpretation of results

- 1) Negative: The presence of only one red band at the control line (C) within the result window indicates a negative result.

	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	5 / 10



2) Positive: Two bands appear, one red control line (C) and one or two black test line (G or M) within the result window indicates a positive result.



3) Invalid: If the control line fails to appear within the result window or presence of only one black band at the test line (T), the result is considered invalid.



5.2. Sensitivity criteria

The test line intensity was evaluated by referring to the RapiGEN color chart (Figure 1).

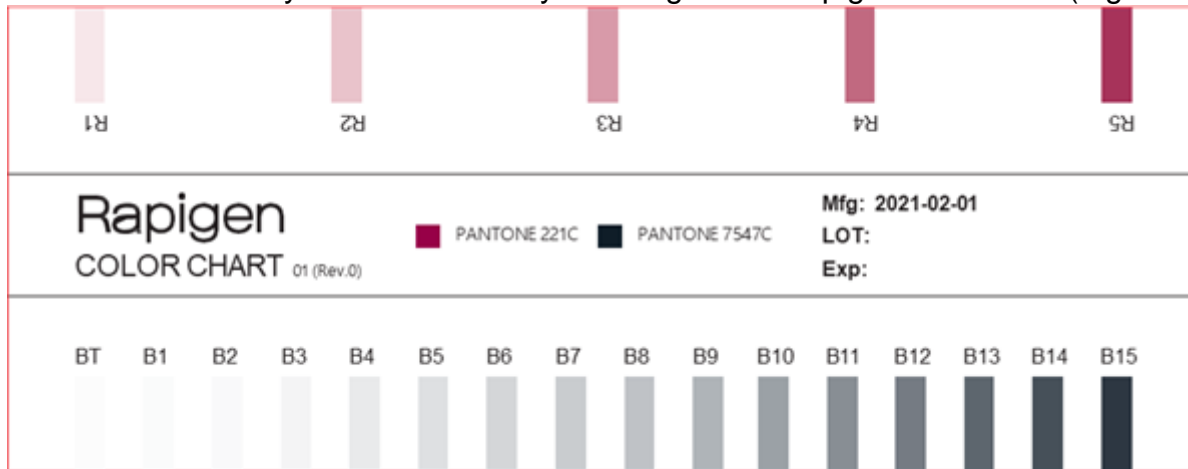


Figure 1. RapiGEN Color Chart. Strong positive (B11~B15); Medium positive (B6~B10); Weak positive (B1~B5); Negative (Black trace (BT) or Not detected (-)).

5.3. Test result

As a result, serums from 10 donors were detected by BIOCREDIT COVID-19 IgG/IgM Combo product (Table 5, 6).


	Analytical Performance Characteristics Report : Detection of neutralized antibody						Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo						Page	6 / 10

Table 5. Detection of neutralized antibody for COVID-19 IgG/IgM Combo (IgG)

Lot No	No.	Donor number									
		1	2	3	4	5	6	7	8	9	10
H074002SD	1	B15	B15	B15	B15	B15	B15	B15	B15	B15	B15
	2	B15	B15	B15	B15	B15	B15	B15	B15	B15	B15
Rate of positive		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Table 6. Detection of neutralized antibody for COVID-19 IgG/IgM Combo (IgM)


Lot No	No.	Donor number									
		1	2	3	4	5	6	7	8	9	10
H074001SD	1	B2	B5	B1	B2	B1	B2	B2	B4	B4	B7
	2	B2	B5	B1	B2	B1	B2	B2	B4	B4	B7
Rate of positive		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

6. Conclusions

As a result of test using serum and plasma samples from 10 donors who vaccinated with Moderna, it is expected that BIOCREDIT COVID-19 IgG/IgM Combo can detect neutralized antibodies.

7. References

- 10.1 Regulations on medical device licensing, notification and examination, KFDA, 2017
- 10.2 CLSI EP17
- 10.3 Guideline on COVID-19 *in vitro* diagnostic devices licensing and examination, KFDA, 2020

	Analytical Performance Characteristics Report : Detection of neutralized antibody	Doc. No.	AP-H074-DE-R00
	BIOCREDIT COVID-19 IgG/IgM Combo	Page	7 / 10


8. Attachments

1.1 SARS-CoV-2 vaccinated donor serum, 20days after 2nd vaccination CoA from TRINA


SARS-CoV-2 Vaccinated donor Serum, 20days after 2nd vaccination
 Trina Cal. No. DV1224
 Name of vaccine: Moderna SARS-CoV-2 vaccine
 Donors: No COVID-19 symptoms nor positive result before vaccination (based on self declaration. Donors' IgG has not been tested before vaccination)

No.	Lot No.	DOB	1st Vaccination Date	2nd Vaccination Date	Serum/plasma (matched) Collection Date	Days after 2nd vaccination for collection	Sars-COV2 IgG (Diasorin Liaison AU/ml) Cut-off: <15 AU/ml	Sars-COV2 IgG Interpretation	Sars-COV2 IgM (Diasorin Liaison INDEXI Cut-off: <1 INDEXI	Sars-COV2 IgM Interpretation	Volume
1	21CDV148767	21.08.1956	28.12.2020	26.01.2021	15.02.2021	20	>400	Positive	0.285	Negative	1 ml
2	21CDV148768	11.09.1949	28.12.2020	26.01.2021	15.02.2021	20	211	Positive	0.506	Negative	1 ml
3	21CDV148769	25.06.1974	28.12.2020	26.01.2021	15.02.2021	20	309	Positive	0.107	Negative	1 ml
4	21CDV148770	24.07.1970	28.12.2020	26.01.2021	15.02.2021	20	294	Positive	0.116	Negative	1 ml
5	21CDV148771	22.08.1956	28.12.2020	26.01.2021	15.02.2021	20	233	Positive	0.97	Negative	1 ml
6	21CDV148772	26.01.1989	28.12.2020	26.01.2021	15.02.2021	20	232	Positive	0.249	Negative	1 ml
7	21CDV148773	01.06.1960	28.12.2020	26.01.2021	15.02.2021	20	193	Positive	0.368	Negative	1 ml
8	21CDV148774	11.12.1950	28.12.2020	26.01.2021	15.02.2021	20	315	Positive	2.82	Positive	1 ml
9	21CDV148775	08.03.1974	28.12.2020	26.01.2021	15.02.2021	20	384	Positive	0.361	Positive	1 ml
10	21CDV148776	15.12.1986	28.12.2020	26.01.2021	15.02.2021	20	282	Positive	1.83	Positive	1 ml

The material has not been tested with viral markers, please handle with care!



TRINA BIOCREDITIVES AG
 Grabenstrasse 8
 CH-8606 Nänthikon
 trina@trina.bio.com
 F +41 44 905 20 10



TRINA BIOCREDITIVES AG
 Spiezstrasse 8
 8600 Maderiswil
 F +41 44 905 20 11
 www.trina.bio.com
 trina@trina.bio.com



**Analytical Performance Characteristics Report
: Detection of neutralized antibody**

Doc. No.

AP-H074-DE-R00

BIOCREDIT COVID-19 IgG/IgM Combo

Page

8 / 10

1.2 8500 normal serum CoA from ABO

		ABO INVOICE NUMBER, DETAILS ABO I 2021 01 0004		CUSTOM CODIFICATION 3002 9010 HUMAN SERUM, NON INFECTIOUS, NON ZOOLOGIC		Billing address: RAPIGEN TAX@RAPIGEN-INC.COM ; RAPIGEN@RAPIGEN-INC.COM 4F, 16, LS-ro 91beon-gil Dongtan-gu, Anyang-si Gyeonggi-do 14119 Republic of Korea								
				Total number of tubes Total volume, mL		BE 2 901.0								
						Total discounted amount, USD 1 232.93								
#	Item code	Item name	Quotation references	Quotation date	Order reference	Order date	Delivery date	Delivery note number	Unit price USD	Number of units	Total price before discount USD	Discount %	Discount amount USD	Total amount after discount USD
01	-	Normal serum 12 units, 251.0 to 341.0 mL per unit Total volume 2 901.0 mL	-	25-Jan-21	Email confirmation	25-Jan-21	02-Feb-21	-	0.50	2 901.0	1 450.50	15.00%	217.58	1 232.93
02	-	AmRoad International normal biomaterial specific packaging + Dry ice (+12°F / -90°C)	-	22-Jan-21	Email confirmation	26-Jan-21	03-Feb-21	-	50.00	1	50.00	0.00%	0.00	50.00
03	-	Shipment to Republic of Korea with RAPIGEN Prefix account #267 263 385	-	22-Jan-21	Email confirmation	26-Jan-21	02-Feb-21	-	400.00	0	0.00	0.00%	0.00	0.00
Purchaser		Mr. Youngju LEE +82 331 427 4677												
Consignee		Mrs. Da-Jung SOHN +82 31 427 4677												

invoice details

ABO PHARMACEUTICALS
7930 Arjons Drive, Suite A, San Diego, California 92126, United States of America



**Analytical Performance Characteristics Report
: Detection of neutralized antibody**

Doc. No.

AP-H074-DE-R00

BIOCREDIT COVID-19 IgG/IgM Combo

Page

9 / 10

Customer selection	Box #	#	Source ID	Internal ID	Date of unit collection	1.0 mL aliquots Stock volume mL	1.0 mL aliquots Price per mL USD	Full units Stock volume mL	Full units Price per L USD	Ethnicity	Gender	Age (years)	Country of Collection	Type of collection	Matrix	Method	EIA
341.0	1000	0004	ABDFCOL01	WH1781600614700	28-Nov-16	4	5.0	341.0	500.0	Caucasian	Male	33	Florida - USA	Blood donation, Single donor, single donation	Serum of the clot	Reagent Producer	FDA licensed screening test Abbott Prism
316.0	1000	0005	ABDFCOL01	WH1781600626400	06-Sep-16	5	5.0	316.0	500.0	Hispanic	Male	51	Florida - USA	Blood donation, Single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
306.0	21	0010	ABDFCOL01	WH1781600601100	29-Nov-16			306.0	500.0	African American	Female	42	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
254.0	21	0008	ABDFCOL01	WH1781600596400	10-Oct-16			254.0	500.0	African American	Male	23	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
266.0	21	0007	ABDFCOL01	WH1781600603000	10-Oct-16			266.0	500.0	Hispanic	Male	20	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
287.0	21	0006	ABDFCOL01	WH1781600604600	11-Oct-16			287.0	500.0	African American	Male	30	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
270.0	21	0005	ABDFCOL01	WH1781600446300	18-Aug-16			270.0	500.0	Hispanic	Male	38	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
269.0	21	0003	ABDFCOL01	WH1781600598100	11-Oct-16			269.0	500.0	Hispanic	Male	34	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
269.0	21	0004	ABDFCOL01	WH1781600748000	27-Oct-16			269.0	500.0	Caucasian	Female	32	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism
261.0	21	0002	ABDFCOL01	WH1781600739600	26-Oct-16			261.0	500.0	African American	Female	27	Florida - USA	Blood donation, single donor, single donation	Serum of the clot	Reagent Producer	Abbott Prism



Pending list & Certificate of Analysis 01

ABO human specimen inventory for Normal donation, Real Serum of the Clot

ABO PHARMACEUTICALS
7930 Arjons Drive, Suite A, San Diego, California 92126, United States of America



**Analytical Performance Characteristics Report
: Detection of neutralized antibody**

Doc. No.

AP-H074-DE-R00

BIOCREDIT COVID-19 IgG/IgM Combo

Page

10 / 10

EIA	EIA	ST5	PCR Multiplex	Blood grouping
FDA licensed screening test Abbott Prism	FDA licensed screening test Abbott Prism	FDA licensed screening test	FDA licensed screening test NGI Ultra Qual	FDA licensed test
Hbs Ag	Ab anti HCV	Ab anti Syphilis	Virus HIV, HBV, HCV	Blood Grouping
negative	negative	negative	negative	A+
negative	negative	negative	negative	O+
negative	negative	negative	negative	O-
negative	negative	negative	negative	O+
negative	negative	negative	negative	A+
negative	negative	negative	negative	A-
negative	negative	negative	negative	A-
negative	negative	negative	negative	O-
negative	negative	negative	negative	B+
negative	negative	negative	negative	O-

ABO PHARMACEUTICALS
7930 Arjons Drive, Suite A, San Diego, California 92126, United States of America