DECLARATION OF CONFORMITY

Manufacturer: RapiGEN Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119,
Republic of Korea

European Representative: MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert, Germany

CE

Product : BIOCREDIT COVID-19 Ag

Catalog no.: G61RHA20

Classification: Neither listed in the annex II of the IVDD, nor self-testing device
This declaration of conformity is issued under the sole responsibility of the manufacturer.
EDMA code: 15.70.90.90.00; Other Other Virology Rapid Tests

Conformity Assessment Route: Self Declaration (according to annex III of IVDD)

We herewith declare that the above mentioned products meet the provisions of the council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied :ISO13485:2016, EN ISO14971:2012, EN13640:2002, EN13641:2002, EN13612:2002, EN ISO 15223-1:2016, ISO17511:2003, EN13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008, KGMP

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place, Date of Issue: Gyeonggi-Do, Republic of Korea, 9th September, 2020.

Signature:

Jae-Ku, Park
CEO/President
RapiGEN Inc.

Digitally signed by Botnaru Andrei
Date: 2021.04.26 11:54:02 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARAȚIE DE CONFORMITATE

Producător: RapiGEN Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119,
Republica Corea

Reprezentant European: MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert, Germany

CE

Produs: BIOCREDIT COVID-19 Ag

Nr. Catalog: G61RHA20

Clasificare: Nu este listat nici în anexa II a IVDD, nici ca dispozitiv de auto-testare.
Această declarație de conformitate este emisă sub responsabilitatea exclusivă a producătorului.
Cod EDMA 15.70.90.90.00; Alte alte teste rapide de virologie

Traseul de evaluare a conformității: Declarație pe proprie Răspundere (conform anexei III la IVDD)

Declarăm că produsele menționate mai sus respectă prevederile Directivei Consiliului 98/79/CE pentru dispozitivele medicale de diagnostic in vitro. Toată documentația justificativă este păstrată la sediul producătorului

Standarde aplicate :ISO13485:2016, EN ISO14971:2012, EN13640:2002, EN13641:2002, EN13612:2002, EN ISO 15223-1:2016, ISO17511:2003, EN13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008, KGMP

Această declarație de conformitate este emisă pe responsabilitatea exclusivă a producătorului.

Locul, Data Emiterii: Gyeonggi-Do, Republica Corea, 9 Septembrie, 2020.

Semnătură:

Jae-Ku, Park
CEO/President
RapiGEN Inc.

Clinical Performance Report

BIOCREDIT COVID-19 Ag

Authorization	Dept. & Name	Signature	Date
Prepared by	RA A. J. J. Kim		20. 8. 11
Reviwer	RA I. J. Cho		20. 8. 11
Approved by	Quality Assurance T. Y. Park		20. 8. 11

Summary Clinical study Report

BIOCREDIT COVID-19 Ag is a rapid lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antigen in human nasopharynx. Nasopharyngeal swab specimen is needed to perform the assay. Reading of the results is done visually i.e. subjectively read.

Performance evaluation (Total)

Total sensitivity and specificity are in the following.

BIOCREDIT COVID-19 Ag		**RT-PCR**		**Sensitivity (%)**	**Specificity (%)**
		Positive	**Negative**		
Ag	Positive	46	0	90.2% (46/51)	100% (136/136)
	Negative	5	136		
Total		51	136		

Sensitivity: 90.2% (46/51, 95% CI, 77.81% - 96.33%)

Specificity: 100% (136/136, 95% CI, 96.57% - 100%)

Positive predictive value (PPV): 100% (46/46, 95% CI, 90.40% - 100%)

Negative predictive value (NPV): 96.45% (136/141, 95% CI, 91.49% - 98.69%)

1) Clinical Evaluation 1

a. Test site: Seoul Asan Hospital(South Korea), Eunpyung St. Mary's Hospital(South Korea)

b. Test date: April 01, 2020

c. Specimen: 15 COVID-19 positive and 2 COVID-19 negative specimens

d. Test result: Summary of performance of BIOCREDIT COVID-19 Ag compare to PCR confirmed specimens

BIOCREDIT COVID-19 Ag		**RT-PCR**		**Sensitivity (%)**	**Specificity (%)**
		Positive	**Negative**		
Ag	Positive	12	0	80 (12/15)	100 (2/2)
	Negative	3	2		
Total		15	2		

Sensitivity: 80% (12/15, 95% CI, 51.37% - 94.69%)

Specificity: 100% (2/2, 95% CI, 19.79% - 100%)

2) Clinical Evaluation 2

a. Test site: Fundação Oswaldo Cruz, Brazil

b. Test date: June 18, 2020

c. Specimen: 11 COVID-19 positive and 109 COVID-19 negative specimens

d. Test result: Summary of performance of BIOCREDIT COVID-19 Ag compare to PCR confirmed specimens

BIOCREDIT COVID-19 Ag		RT-PCR		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Ag	Positive	10	0	90.9% (10/11)	100% (109/109)
	Negative	1	109		
Total		11	109		

Sensitivity: 90.9% (10/11, 95% CI, 57.18% - 99.52%)

Specificity: 100% (109/109, 95% CI, 95.76% - 100%)

3) Clinical Evaluation 3

a. Test site: Infectious Clinical Hospital No. 2 of the Moscow City Health Department, Russia
(Web site: https://www.ikb2.ru/english)

b. Test date: June 15~18, 2020

c. Specimen: 25 COVID-19 positive and 25 COVID-19 negative specimens

d. Test result: Summary of performance of BIOCREDIT COVID-19 Ag compare to PCR confirmed specimens

BIOCREDIT COVID-19 Ag		RT-PCR		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Ag	Positive	24	0	96 (24/25)	100 (25/25)
	Negative	1	25		
Total		25	25		

Sensitivity: 96% (24/25, 95% CI, 77.68% - 99.79%)

Specificity: 100% (25/25, 95% CI, 83.42% - 100%)

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No	Clinical Site	Test date
1	Catholic University, Eunpyung St. Mary's Hospital, South Korea	Apr 1, 2020
	Seoul Asan Hospital, South Korea	Apr 9, 2020

Retrospective clinical trial to evaluate clinical performance of BIOCREDIT COVID-19 Ag using clinical specimens of nasopharyngeal swap obtained from symptomatic patients confirmed by RT-PCR

Catholic University, Eunpyung St. Mary's Hospital, South Korea

Seoul Asan Hospital, South Korea

2.2 BIOCREDIT COVID-19 Ag Kit Mechanism

BIOCREDIT COVID-19 Ag kit mechanism is based on lateral flow immunochromatographic assay. The nitrocellulose membrane strip within the device contains test line pre-coated with anti-SARS-CoV-nucleocapside protein (NP) for capture of SARS-CoV-2. The captured SARS-CoV is also detected by mouse anti-SARS-CoV·NP-gold conjugate for visualization. When sample is added to device sample pad, it moves through the nitrocellulose membrane by capillary action and contact the immobilized antibody coated test region. Should the sample contain specific COVID-19 antigen, immunocomplex will form revealing visible colored conjugate. Control region contains colored conjugate regardless of test specimen composition.

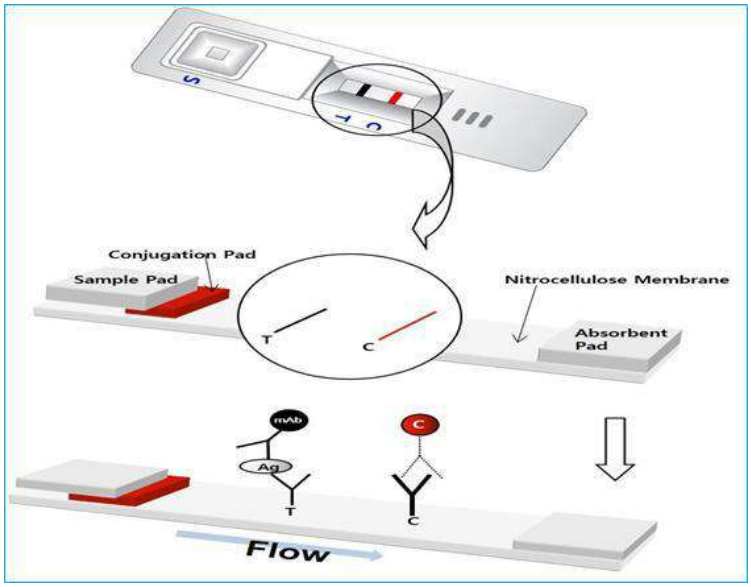

Figure 1. BIOCREDIT COVID-19 Ag kit mechanism

	No data	17 Mar. 2020	UTM	5	E:18.46, R:19.95 N:23.36	Pos.	w+	Pos.
A004	No data	28 Mar. 2020	UTM	1	E:20.35, R:21.93 N:23.99	Pos.	w+	Pos.
	No data	30 Mar. 2020	UTM	3	E:27.95, R:29.81 N:30.99	Pos.	w+	Pos.
	No data	03 Apr. 2020	UTM	7	E:29.99, R:31.69 N:32.26	Pos	w+	Pos.

7. Conclusion

1) 15 positive specimens which were confirmed by RT-PCR are tested with BIOCREDIT COVID-19 Ag kit, and all the specimens are identified as positive as well.
Relative Sensitivity (%) = 100 x (No. of specimens with positive results / No. of positive
specimen tested by RT-PCR)

2) 2 negative specimens collected by hospital are tested with BIOCREDIT COVID-19 Ag kit, and all the specimens are identified as negative as well.
Relative Specificity (%) = 100 x (No. of specimens with negative results/ No. of negative specimens)

Total sensitivity and specificity are in the following.

BIOCREDIT COVID-19 Ag		**RT-PCR**		**Sensitivity (%)**	**Specificity (%)**
		Positive	**Negative**		
Ag	Positive	12	0	80 (12/15)	100 (2/2)
	Negative	3	2		
Total		15	2		

8. Reference

- Gitlin N., Hepatitis B: Diagnosis, prevention and treatment. Clinical Chemistry, 1997,43:1500 - 1506

-Wang Y, Kang H, Liu X, Tong Z. Combination of RT-qPCR testing and clinical features for diagnosis of COVID-19 facilitates management of SARS-CoV-2 outbreak. J Med Virol. March 2020:jmv.25721. doi:10.1002/jmv.25721

-Wu F, Zhao S, Yu B, et al. A new coronavirus associated with human respiratory disease in China. Nature. 2020;579(7798):265-269. doi:10.1038/s41586-020-2008-3

- Korean Diagnostic Examination Medical Association, Laboratory Medicine Volume5, 2014, 68-91

- Ministry of Food and Drug Safety, High-risk virus diagnostic reagent (For immunological testing) Permission* screening guidelines, 2015