



RapiGEN INC.

3~4F, 16,LS-ro 91 beon-gil, Dongan-gu,Anyang-si, Gyeonggi-do 14119, Republic of Korea

Tel: +82-31-427-4677 Fax:+82-31-427-4678 Website: www.rapigen-inc.com

Clinical Evaluation Summary

BIOCREDIT COVID-19 Ag

Revision Date: June 4, 2020

RapiGEN INCORPORATION
Park Jaekun

Jaekun Park. President

Confidential Statement

This document contains information that is proprietary confidential or exempt from disclosure. If you are not the intended recipient, please note that any other dissemination, distribution, use or copying of this document is strictly prohibited. This document may not be passed on to the third parties without the express agreement of the RapiGEN Inc.



RapiGEN INC.

3~4F, 16,LS-ro 91 beon-gil, Dongan-gu,Anyang-si, Gyeonggi-do 14119, Republic of Korea

Tel: +82-31-427-4677 Fax:+82-31-427-4678 Website: www.rapigen-inc.com

1. Introduction

Performance characteristic for the BIOCREREDIT COVID-19 Ag for rapid detection of SARS-CoV-2 antigens was established in multi institutes, retrospective, single-blinded and randomized study conducted at trial sites in Korea.

2. Test Objective

This report aims to evaluate the clinical performance of BIOCREREDIT COVID-19 Ag in comparison with Real-Time PCR.

3. Study Method

This studies were performed according to instruction for use of BIOCREREDIT COVID-19 Ag with specimens confirmed by Real-Time PCR.

4. Test Result

1) Clinical Evaluation 1

- a. Test site: Eunpyeong St. Mary's Hospital, Seoul, Korea
- b. Test date: Apr. 1, 2020
- c. Specimen: 3 COVID-19 positive and 3 COVID-19 negative specimens
- d. Test result: Summary of performance of BIOCREREDIT COVID-19 Ag compare to PCR confirmed specimens

Eunpyeong St. Mary's Hospital		PCR		
		Positive	Negative	Total
BIOCREREDIT COVID-19 Ag	Positive	3	0	3
	Negative	0	3	3
	Total	3	3	6
Sensitivity		100%		
Specificity		100%		

2) Clinical Evaluation 2

- a. Test site: Asan Medical Center, Seoul, Korea
- b. Test date: Apr. 9, 2020



RapiGEN INC.

3~4F, 16,LS-ro 91 beon-gil, Dongan-gu,Anyang-si, Gyeonggi-do 14119, Republic of Korea

Tel: +82-31-427-4677 Fax:+82-31-427-4678 Website: www.rapigen-inc.com

- c. Specimen: 11 COVID-19 positive
- d. Test result: Summary of performance of BIOCREREDIT COVID-19 Ag compare to PCR confirmed specimens

Asan Medical Center		PCR		
		Positive	Negative	Total
BIOCREREDIT COVID-19 Ag	Positive	9	0	9
	Negative	2	0	2
	Total	11	0	11
Sensitivity		82%		

3) Clinical Evaluation 3

- a. Test site: Asan Medical Center, Seoul, Korea
- b. Test date: May. 25, 2020
- c. Specimen: 44 COVID-19 positive and 56 COVID-19 negative specimens
- d. Test result: Summary of performance of BIOCREREDIT COVID-19 Ag compare to PCR confirmed specimens

Asan Medical Center		PCR		
		Positive	Negative	Total
BIOCREREDIT COVID-19 Ag	Positive	11	1	12
	Negative	0	46	46
	Total	11	47	58
Sensitivity		100%		
Specificity		98%		



RapiGEN INC.

3~4F, 16,LS-ro 91 beon-gil, Dongan-gu,Anyang-si, Gyeonggi-do 14119, Republic of Korea

Tel: +82-31-427-4677 Fax:+82-31-427-4678Website: www.rapigen-inc.com

5. Conclusion

Total sensitivity and specificity are in the following.

Total		PCR		
		Positive	Negative	Total
BIOCREDIT COVID-19 Ag	Positive	23	1	24
	Negative	2	49	51
	Total	25	50	75
Sensitivity		92%		
Specificity		98%		