

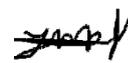
TEST REPORT

Clinical Performance

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WRITTEN BY: Youngmin Kim



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REVIEWED BY: Byeongchan An



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APPROVED BY: Misook Park



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MiCo BioMed

116 Gongdan 1-ro, Anseong-Si, Gyeonggi-Do, 456-781, Korea

Phone: +82-31-8056-5940, Fax: +82-31-8056-5518

1. Purpose

It is for design validation of clinical performance requirements according to the intended use of VERI-Q COVID-19 Ag Rapid Test.

2. General Information

The diagnostic accuracy of the VERI-Q COVID-19 Ag Rapid Test was evaluated for clinical sensitivity and clinical specificity by comparing results with RT-PCR, a standard diagnostic method. The diagnostic accuracy was assessed through samples of patients diagnosed positive or negative for COVID-19.

3. Investigators and Investigational Institutions

The clinical performance test of the VERI-Q COVID-19 Ag Rapid Test was performed CHUNG-ANG UNIVERSITY Hospital

3.1 Investigators: Lee Mi-kyoung

3.2 Test institution: CHUNG-ANG UNIVERSITY Hospital

3.3 Address: 102, Heukseok-ro, Heukseok-dong, Dongjak-gu, Seoul, 06973, Republic of Korea

4. Selection and Exclusion Criteria

4.1 Selection criteria for positive specimens

- 1) Nasopharyngeal swab specimens of patient who were diagnosed with COVID-19
- 2) COVID-19 positive specimens were confirmed by RT-PCR test
- 3) Uncontaminated specimens

4.2 Selection criteria for negative specimens

- 1) Nasopharyngeal swabs specimens without COVID-19 detected through RT-PCR test

4.3 Exclusion criteria

- 1) Specimens and nucleic acids that have not been anonymized by personnel or related to the clinical trial
- 2) Specimens and nucleic acids that cannot be compared with the control reagents
- 3) Specimens that cannot extract nucleic acids or are not stored according to the specified storage conditions

5. Samples Collection

Samples derived from patients confirmed by RT-PCR test were used. 50 positive samples with COVID-19 positive confirmed by RT-PCR test and 150 negative samples with COVID-19 negative confirmed by RT-PCR test were used in the study.

6. Statistical Analysis

The clinical sensitivity and specificity were analyzed by comparing the RT-PCR test and test medical device.

7. Result

		Standard Method (RT-PCR)		Total
		Positive	Negative	
Test Device	Positive	48	0	48
	Negative	2	150	152
Total		50	150	200

- PPA: 96 % (CI: 86.3 % ~ 99.9 %)
- NPA: 100.0 % (CI: 92.6 % ~ 100.0 %)
- Overall percent Agreement: 99.0% (CI: 96.43 % ~ 99.98 %)

8. Conclusion

As a result of evaluating the clinical sensitivity and specificity of the VERI-Q COVID-19 Ag Rapid Test, clinical validation was confirmed with a PPA of 96 % and a NPA of 100 %.