TEST REPORT

Clinical Performance

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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 %.