Clin. Lab. 2025;71:1-4

ORIGINAL ARTICLE

Clinical Usefulness of the Loop-Mediated Isothermal Amplification Assay for SARS-CoV-2 Detection

Soyoon Hwang [1, *], Han Wook Park [2, *], Ki Tae Kwon [1], Eunkyung Nam [1], Sohyun Bae [3], Yoonjung Kim [3], Hyun-Ha Chang [3], Shin-Woo Kim [3], Nan Young Lee [4], Yu Kyung Kim [4], Won Kee Lee [5], Hyung Soo Han [6 - 9]

[*] *These authors contributed equally to this work as first authors*
[1] *Division of Infectious Diseases, Department of Internal Medicine, Kyungpook National University Chilgok Hospital, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[2] *Department of Medicine, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[3] *Division of Infectious Diseases, Department of Internal Medicine, Kyungpook National University Hospital, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[4] *Department of Clinical Pathology, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[5] *Department of Medical Informatics, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[6] *Department of Physiology, School of Medicine, Kyungpook National University, Daegu, Republic of Korea*
[7] *Clinical Omics Institute, Kyungpook National University, Daegu, Republic of Korea*
[8] *Department of Biomedical Science, Graduate School, Kyungpook National University, Daegu, Republic of Korea*
[9] *BK21 Four Program School of Medicine, Kyungpook National University, Daegu, Republic of Korea*

SUMMARY

Background: **Loop-mediated isothermal amplification (LAMP) is a molecular diagnostic method known for its rapid processing and operational simplicity due to its isothermal amplification process. While LAMP has demonstrated comparable diagnostic accuracy to PCR in certain applications, its performance may vary depending on assay design and implementation. This study aimed to evaluate the diagnostic performance of the MmaxSure™ assay (MmaxSure™; Mmonitor, Daegu, South Korea) in detecting SARS-CoV-2, comparing it with the STANDARD™ M nCoV Real-Time Detection Kit (STANDARD; SD BioSensor, Suwon, South Korea) using nasopharyngeal and oropharyngeal swab specimens.**

Methods: **A total of 333 specimens were included in the analysis, consisting of 113 positive and 220 negative nasopharyngeal and oropharyngeal swab samples. All specimens were tested using the MmaxSure™ assay, and the results were compared to those obtained using the STANDARD™ M nCoV Real-Time Detection Kit. The diagnostic performance of the MmaxSure™ assay was evaluated in terms of positive percent agreement (PPA), negative percent agreement (NPA), and Cohen's kappa index for inter-assay agreement. Sensitivity, specificity, and limit of detection (LOD) for SARS-CoV-2 variants were also determined.**

Results: **The MmaxSure™ assay demonstrated a 100% PPA and a 100% NPA with the STANDARD™ M nCoV Real-Time Detection Kit. The Cohen's kappa index was 1.0, indicating perfect agreement between the two diagnostic methods. The MmaxSure™ assay exhibited a high sensitivity, detecting SARS-CoV-2 variants at a LOD of 2 - 4 copies/μL, without cross-reactivity with other pathogens.**

Conclusions: **The MmaxSure™ Fast SARS-CoV-2 Detection Kit, based on LAMP technology, exhibited a high level of diagnostic accuracy in detecting SARS-CoV-2. Its rapid turnaround time and minimal equipment requirements suggest its potential suitability for point-of-care applications. However, further prospective studies with a broader range of clinical specimens and real-world validation are needed to confirm its diagnostic utility across diverse settings.**

(Clin. Lab. 2025;71:xx-xx. DOI: 10.7754/Clin.Lab.2025.250327)

Manuscript accepted April 30, 2025

Correspondence:
Ki Tae Kwon, MD, PhD
Division of Infectious Diseases
Department of Internal Medicine
Kyungpook National University Chilgok Hospital
807 Hokuk-ro, Buk-gu
41404, Daegu
Republic of Korea

Phone: +82 532002616
Fax: +82 532002027
Email: ktkwon@knu.ac.kr

Supplementary Data

Table S1. Verification of cross-reactivity and interference of the MmaxSure™ Fast SARS-CoV-2 Detection Kit.

A)

Pathogen	Source	Concentration	Result	
			RdRp	N
Human coronavirus 229E	KBPV-VR-9	8.0×10^9 PFU/mL	negative	negative
Human coronavirus OC43	KBPV-VR-8	6.0×10^7 PFU/mL	negative	negative
Human coronavirus HKU1	VR-3262SD	5.4×10^5 copies/µL	negative	negative
Human coronavirus NL63	KBPV-VR-88	4.0×10^5 PFU/mL	negative	negative
SARS-coronavirus	IDT-10006620	2.0×10^6 copies/µL	negative	positive
MERS-coronavirus	VR-3248SD	7.2×10^5 copies/µL	negative	negative
Respiratory syncytial virus A	KBPV-VR-41	1.2×10^6 PFU/mL	negative	negative
Respiratory syncytial virus B	KBPV-VR-42	4.0×10^5 PFU/mL	negative	negative
Influenza A (H1N1)	KBPV-VR-76	4.0×10^5 PFU/mL	negative	negative
Influenza A (H3N2)	KBPV-VR-85	1.0×10^7 PFU/mL	negative	negative
Influenza B	KBPV-VR-34	1.0×10^7 PFU/mL	negative	negative
Adenovirus	KBPV-VR-57	4.8×10^8 PFU/mL	negative	negative
Human metapneumovirus (hMPV)	KBPV-VR-87	3.0×10^5 PFU/mL	negative	negative
Parainfluenza virus 1	KBPV-VR-44	4.0×10^9 PFU/mL	negative	negative
Parainfluenza virus 2	KBPV-VR-45	2.0×10^{10} PFU/mL	negative	negative
Parainfluenza virus 3	KBPV-VR-46	4.0×10^8 PFU/mL	negative	negative
Parainfluenza virus 4A	KBPV-VR-69	2.0×10^5 PFU/mL	negative	negative
Enterovirus	KBPV-VR-55	8.0×10^{10} PFU/mL	negative	negative
Rhinovirus	KBPV-VR-81	8.0×10^8 PFU/mL	negative	negative
Human bocavirus	VR-3251SD	6.4×10^5 copies/µL	negative	negative
Haemophilus influenzae	NCCP-16498	1.0×10^6 CFU/mL	negative	negative
Legionella pneumophila	NCCP-16509	1.0×10^6 CFU/mL	negative	negative
Mycobacterium tuberculosis	ATCC-25618D	7.3×10^5 copies/mL	negative	negative
Streptococcus pneumoniae	KCCM-40410	1.0×10^6 CFU/mL	negative	negative
Streptococcus pyogenes	KCCM-11817	1.0×10^6 CFU/mL	negative	negative
Mycoplasma pneumoniae	ATCC-15531	1.0×10^6 CFU/mL	negative	negative
Escherichia coli	CP011	1.0×10^9 CFU/µg	negative	negative

B)

Interfering substance	Concentration	Result	
		RdRp	N
Mucin	2.5 mg/mL	negative	negative
Blood (human)	10% (v/v)	negative	negative
Mupirocin	6.6 mg/mL	negative	negative
Tobramycin	4.0 µg/mL	negative	negative
Zanamivir	3.3 mg/mL	negative	negative
Oxymetazoline	15% (v/v)	negative	negative
Menthol	0.8 g/mL	negative	negative
Nasal spray	15% (v/v)	negative	negative
Biotin	3.5 µg/mL	negative	negative
Human anti-mouse antibody	290 ng/mL	negative	negative
Human genomic DNA	100 ng/µL, 50 ng/µL, 25 ng/µL	negative	negative
Conjugated bilirubin	0.05 mg/mL	negative	negative
Lipid	15% (v/v)	negative	negative
Heparin	3,000 U/L	negative	negative
Sodium citrate	3.2% (w/v)	negative	negative
EDTA	18 mg/mL	negative	negative
Albumin	0.24 g/mL	negative	negative
Hemoglobin	40 mg/mL	negative	negative

RdRp - RNA-dependent RNA polymerase, N - nucleocapsid protein.

Table S2. Inclusivity test for the detection of SARS-CoV-2 variants by the MmaxSure™ Fast SARS-CoV-2 Detection Kit.

SARS-CoV-2 variants of concern (WHO classification)	Source	Result		
		RdRp	N	LoD (copies/µL)
B.1.1.7	NCCP 43381	positive	positive	4
B.1.617.2	NCCP 43390	positive	positive	4
B.1.1.529 (BA.1)	NCCP 43408	positive	positive	4
B.1.1.529 (BA.2)	NCCP 43412	positive	positive	4
B.1.1.529 (BA.4)	NCCP 43425	positive	positive	4
B.1.1.529 (BA.5)	NCCP 43426	positive	positive	4
B.1.1.529 (BA.2.75)	NCCP 43417	positive	positive	4

RdRp - RNA-dependent RNA polymerase, N - nucleocapsid protein, LoD - limit of detection.

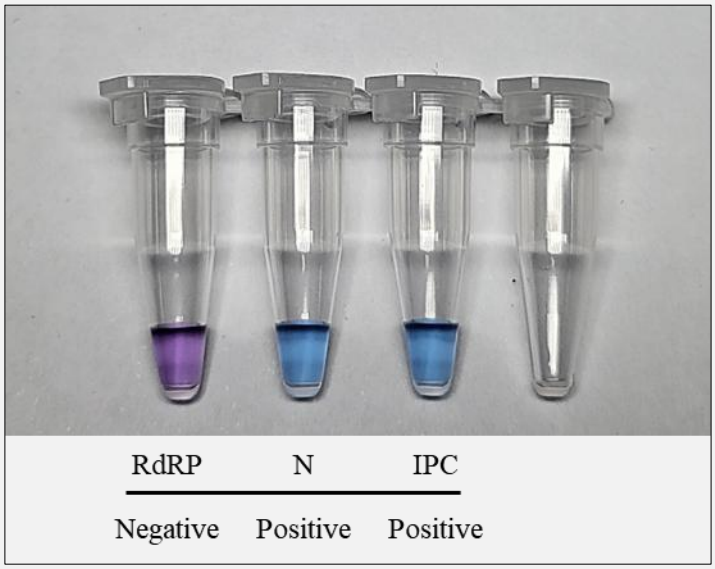

Figure S1. Visual results of the MmaxSure™ Fast SARS-CoV-2 Detection Kit for negative and positive samples.

RdRp - RNA-dependent RNA polymerase, N - nucleocapsid protein, IPC - internal positive control.