1. Clinical Performance (Updated on December 24, 2020)

Study 1 Nasopharyngeal swab samples stored in VTM

Clinical performance evaluation of nasopharyngeal (NP) swab samples stored in viral transport media (VTM) was evaluated retrospectively by comparing the results obtained with the PCL COVID19 Ag Gold (REF: COV04S) and the results obtained with COVID-19 RT-PCR (Real-Q 2019-nCoV Detection Kit: FDA-EUA authorized (BioSewoom)). A total of 300 blinded frozen NP swab samples consisting of 150 positive and 150 negative NP swab specimens were tested to evaluate the sensitivity and specificity of the PCL COVID19 Ag Gold by five minimally trained operators in Chosun University Hospital under respective IRB approval. NP swabs specimens were collected from patients with COVID-19 suspected symptoms in Korea during the COVID-19 outbreak. All specimens were confirmed as positive or negative and validated with Ct value by the FDA-EUA authorized RT-PCR as a comparator method prior to the study. All samples were randomized and the operators were blinded from the sample information and performed the test following the instructions for use.

Specimen Provider/Specimen inclusion and exclusion criteria

Specimen provider inclusion criteria

- Patients suspected of respiratory infections due to symptoms such as coughing, phlegm, fever, etc. who have been identified with COVID-19 by RT-PCR method.

Specimen inclusion criteria

- Residual nasopharyngeal swab samples that will be discarded after the virus test and stored in VTM.
- Specimen guaranteed to be anonymized that have been completely removed personal identification
- Specimen stored frozen at -70°C in VTM.

Specimen provider exclusion criteria

- Patients with unknown COVID-19 infection

Specimen exclusion criteria

- Insufficient samples for testing
- Sample containing excessive amounts of blood
- Specimens suspected of microbial contamination
- Pooled sample
- Samples with broken containers or unlabeled samples
- Sample consisting of a different type of body fluid, not nasopharyngeal swab samples stored in VTM.

	No. of samples	Collection site	Testing site	RT-PCR test used for confirmation	No. of Operator
Positive*	150	CUH	CUH	Real-Q 2019-nCoV Detection Kit	5
Negative	150	CUH	CUH	Real-Q 2019-nCoV Detection Kit	5

° · CUH: Chosun University Hospital, Gwangju, Rep. of Korea – 5 OPERATORS

° Among 150 positive samples, 16 positive samples have Ct value >30

Clinical agreement Summary

PCL COVID19 Ag Gold	Comparator Method Real-Q 2019-nCoV Detection Kit		
	Positive	Negative	Total
Positive	128	0	128
Negative	22	150	172
Total	150*	150	300
Positive Percent Agreement (PPA)	85.33 % (95% CI: 78.79% - 90.11%)		
Negative Percent Agreement (NPA)	100 % (95% CI: 97.50% - 100%)		

* In samples with Ct<30, the positive percent agreement (PPA) achieved 95.52% (128/134).

Study 2 Fresh nasopharyngeal specimens

Clinical performance evaluation of fresh saliva and nasopharyngeal (NP) swab samples was evaluated prospectively by comparing the results obtained with the PCL COVID19 Ag Gold (REF: COV04S) and the results obtained with RT-PCR COVID-19 (PowerChek^{TM}2019-nCoV Real-time PCR Kit: FDA-EUA, MFDS-EUA authorized and CE marked test (Kogenebiotech)). The patients were sequentially enrolled and tested. The tests were performed by five minimally trained non-laboratory experience operators with IFU provided.

A total of 150 samples (105 saliva and 45 NP swab samples) including 45 positives (35 saliva positives and 10 NP swab positives) and 105 negatives (70 saliva negatives and 35 NP swab negatives) for the COVID-19 were used for the performance evaluation of the PCL COVID19 Ag Gold at Chosun University Hospital under respective IRB approval.

The fresh saliva samples (105 samples) were obtained from each patient for Ag test (extraction buffer). In case of fresh NP swab samples, 45 NP swab samples were obtained from each patient in parallel for both Ag test (extraction buffer) and RT-PCR confirmation test (VTM) according to the kit IFU, while the other 105 NP swab samples were obtained only for RT-PCR confirmation test (VTM).

Specimen Provider/Specimen inclusion and exclusion criteria

Specimen provider inclusion criteria

- Patients suspected of respiratory infections due to symptoms such as coughing, phlegm, fever, etc.

Specimen inclusion criteria

- Specimen guaranteed to be anonymized that have been completely removed personal identification
- Fresh NP swab samples and fresh saliva samples have been collected in extraction buffer or VTM based upon the test to be performed (Antigen or PCR).
- According to the Instructions for Use (IFU), fresh specimens were collected only in the provided extraction buffer for use with the PCL COVID19 Ag Gold.
- Saliva samples have been collected from individuals as follows:
    a. The fresh saliva sample was directly collected from the patient and utilized to the antigen's extraction buffer according to the Instructions for Use (IFU).
- NP swab samples have been collected from individuals as follows:
    a. Two separate specimens were obtained from each patient.
    b. The first specimen was a direct fresh swab sample transported utilizing the antigen's extraction buffer according to the Instructions for Use (IFU).
    c. Immediately following this, a second swab was obtained and transported in Viral Transport Media (VTM) for RT-PCR analysis according to the manufacturer's RT-PCR IFU.

Specimen provider exclusion criteria

- Patients with no confirmation result of COVID-19 infection

Specimen exclusion criteria

- Insufficient samples for testing
- Sample containing excessive amounts of blood
- Specimens suspected of microbial contamination
- Pooled sample
- Samples with broken containers or unlabeled samples
- Any sample consisting of a different type of body fluid other than nasopharyngeal and saliva specimens.
- Nasopharyngeal swab/saliva samples previously stored in VTM that are not a fresh sample.

Collection site	Testing site	Positive specimen tested by RT-PCR	Negative specimen tested by RT-PCR
		NP	NP
CUH	CUH	45	105

· NP: Nasopharyngeal swab specimens

· CUH: Chosun University Hospital, Gwangju, Rep. of Korea – 5 OPERATORS

· RT-PCR: PowerChek^{TM} 2019-nCoV Real-time PCR kit (Kogenebiotech)

Clinical agreement Summary

Saliva (Test results of paired specimen between Saliva and NP)

PCL COVID19 Ag Gold (saliva result)	Comparator Method PowerChek™2019-nCoV Real-time PCR Kit (NP swab result)		
	Positive	Negative	Total
Positive	33	0	33
Negative	2	70	72
Total	35	70	105
Positive Percent Agreement (PPA)	94.29 % (95% CI: 81.39% - 98.42%)		
Negative Percent Agreement (NPA)	100% (95% CI: 94.8% - 100%)		

Nasopharyngeal swab

PCL COVID19 Ag Gold (NP swab result)	Comparator Method PowerChek™2019-nCoV Real-time PCR Kit (NP swab result)		
	Positive	Negative	Total
Positive	9	0	9
Negative	1	35	36
Total	10	35	45
Positive Percent Agreement (PPA)	90 % (95% CI: 59.58% - 98.21%)		
Negative Percent Agreement (NPA)	100 % (95% CI: 90.11% - 100%)		

The clinical performance of the PCL COVID19 Ag Gold was evaluated in comparison with RT-PCR test using saliva and nasopharyngeal swab specimens. In saliva specimens, the positive percent agreement is 94.29% (95% CI: 81.39% - 98.42%) and the negative percent agreement is 100% (95% CI: 94.8% - 100%). In nasopharyngeal swab specimens, the positive percent agreement is 90 % (95% CI: 59.58% - 98.21%) and the negative percent agreement is 100 % (95% CI: 90.11% - 100%).

In addition to the clinical samples, a total of 20 contrived samples, including), 10 negatives samples, and 10 low positives (<2x LoD, $1.44X10^3$ $TCID_{50}$/ml) were prepared using the heat-inactivated SARS-CoV-2 virus (ZeptoMetrix #0810587CFHI, isolate USA-WA1/2020) spiked into the normal saliva (pooled human donors) in extraction buffer. All contrived samples were added to the clinical population and tested at the same study site by the same operators in a blinded and randomized fashion. All the samples were tested by five operators according to the IFU.

The near cut-off performance is summarized as follows:

Sample	Overall Agreement%
Negative	100% (10/10)
Low Positive (2x LoD)	100% (10/10)