Clinical Trial Report

A single-center, randomized, single-blind, retrospective, and confirmatory trial aimed to evaluate clinical performance of a study group (Ezplex® 2019-nCoV Real-time PCR Kit) which is devised for qualitative testing of SARS-CoV-2 virus using RNA extracted from oropharynx and nasopharynx specimens of patients suspected of coronavirus infection-19(COVID-19).

Study Protocol No.: GN-GCP-10

VERSION NO. 0.0

Document drafted on: March 18, 2020

Document completed on: March 18, 2020

의료법인 삼광의료재단

Revision History of Protocol Synopsys

Revision No.	Date of Revision	Description of Revision	Drafted by
00	Mar. 18, 2020	Initial Release	KIM, Hyeong-nyeon

Trial Overview

Protocol Title	A single-center, randomized, single-blind, retrospective, and confirmatory trial aimed to evaluate clinical performance of a study group (Ezplex® 2019-nCoV Real-time PCR Kit) which is devised for qualitative testing of SARS-CoV-2 virus using RNA extracted from oropharynx and nasopharynx swab specimens of patients suspected of coronavirus infection-19(COVID-19).
Trial Design	Cross-over, randomized, single-blind
Trial Objective	To assess the efficacy of the investigational device by evaluating clinical performance of Ezplex® 2019-nCoV Real-time PCR Kit which qualitatively detects the SARS-CoV-2 virus.
Subjects	Remaining specimens of patients who were referred to SM Lab, tested for SARS-CoV-2 virus with an existing test kit, and notified either positive or negative.

Category	Registered no. of specimens	No. of excluded specimens	No. of specimens used for the trial
Oropharynx swab	27	0	27
Nasopharynx swab	26	0	26

	Manufacturer	Device Name/Classification No. (Grade) / Model Name
Study Group	SML Genetree Co. Ltd.	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), nucleic acid test/D06080.01[3] Ezplex® 2019-nCoV Real-time PCR Kit
Control Group	Kogene Co. Ltd.	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), nucleic acid test/D06080.01[3] Powerchek™ 2019-nCoV Real-time PCR kit

Sponsor	AHN, Ji-hoon, Representative of SML Genetree
Address	SML Genetree Co. Ltd. (225, Baumoe-ro, Seocho-gu, Seoul)
Trial Period	March 16, 2020 – march 18, 2020
Participating Site	SM Lab (Molecular Biology Testing Team)
Address	Samgwang Bldg., 57, Baumoe-ro 41-gil, Seocho-gu, Seoul

Principal Investigator	Name	KIM, Hyeong-nyeon
	Department	SM Lab
	Title	Specialized Medical Doctor
Inclusion Criteria	1) Remaining specimens of patients who were referred to SM Lab, tested for SARS-CoV-2 virus with an approved testing kit, and notified either positive or negative. 2) Remaining specimens kept frozen under -20℃ and elapsed less than 2 months.	
Exclusion Criteria	1) Remaining specimens that have been thawed and kept long in room temperature (19-25°C) 2) Remaining specimens less than 1,000 ㎕, the minimum requirement. 3) Specimen containers are broken or contamination with other virus is suspected.	
Trial Methods	1. Primary Efficacy Assessment The results of the remaining specimen are compared with the results from the investigational device to evaluate the study group's clinical sensitivity. 2. Secondary Efficacy Assessment The results of the investigational device are compared with the control group device to evaluate the correlation of the study group device and control group device.	
Trial Results	26 nasopharynx specimens and 27 oropharynx specimens were collected according to the inclusion criteria, and a total of 53 specimens were tested with no exclusion. It was confirmed from the test results that both the sensitivity and specificity were 100%, and the Kappa value was 1.00 with the approved testing kit in terms of correlation.	

March 18, 2020

Principal Investigator: KIM, Hyeong-nyeon (signature/seal)

Table of Contents

1 Protocol Title

A single-center, randomized, single-blind, retrospective, and confirmatory trial aimed to evaluate clinical performance of a study group (Ezplex® 2019-nCoV Real-time PCR Kit) which is devised for qualitative testing of SARS-CoV-2 virus using RNA extracted from oropharynx and nasopharynx specimen of patients suspected of coronavirus infection-19(COVID-19).

2 Name and Address of the Participating Site

Category	Name	**Address**	**Phone Number**
Clinical Trial Institution	SM Lab	57, Baumoe-ro 41-gil, Seocho-gu, Seoul	+82-2-3497-5100

3 Names and Titles of Principal Investigator, Investigators, and Co-investigators

3.1 Principal Investigator and Investigators

	Name	**Department**	**Title**	**Contact Number**
Principal Investigator	KIM, Hyeong-nyeon	Testing HQ	Specialized Medical Doctor	+82-2-3497-5132
Investigator A	LEE, In-seob	Molecular Biology Testing Team	Team Head	+82-2-3497-5232
Investigator B	PARK, Joo-hyeon	Molecular Biology Testing Team	Team Staff	+82-2-3497-5232

3.2 Trial Statistics Personnel

Name	**Department**	**Title**	**Contact Number**
KIM, Hyeong-nyeon	SM Lab (Testing HQ)	Specialized Medical Doctor	+82-2-3497-5132

4 Name and Title of Investigational Medical Device Manager

	Name	**Department**	**Title**	**Contact Number**
Study Personnel	LEE, In-seob	Molecular Biology Testing Team	Team Head	+82-2-3497-5232

5 Name and Address of the Trial Sponsor

5.1 Trial Sponsor

Company	Name	Address	Phone Number
SML Genetree Co. Ltd.	AHN, Ji-hoon	225, Baumoe-ro, Seocho-gu, Seoul	+82-70-7425-3958

5.2 Monitoring Staff

Company	Name	Address	Phone Number
SML Genetree Co. Ltd.	LEE, Seung-Mok	225, Baumoe-ro, Seocho-gu, Seoul	+82-70-7425-3953

6 Inclusion/Exclusion Criteria for Trial Subjects and the Number of Target Subjects

6.1 Inclusion/Exclusion criteria for trial subjects

1) Inclusion criteria

- Remaining specimens of patients who were tested for SARS-CoV-2 virus with an approved testing kit* in SM Lab and notified either positive or negative.
- Remaining specimens kept frozen under -20℃.

2) Exclusion Criteria

- Remaining specimens that have been thawed and kept long in room temperature (19-25℃).
- Remaining specimens less than 1,000 ㎕, the minimum requirement.
- Specimen containers are broken or contamination with other virus is suspected.

*** Powerchek™ 2019-nCoV Real-time PCR kit (Kogene Biotech, KCDC Announcement No. 2020-105)**

6.2 The number of collected subjects

Specimen Type	Positive	Negative
Oropharynx Swab	5	22
Nasopharynx Swab	5	21

19. Trial Period

Test Period	March, 2020		
	16th	17th	18th
Clinical Observation and Trial Conduct			
Result Analysis and Statistical Processing			
Report Preparation			

8. Trial Process of the Investigational Device

8.1 Investigational Device Information

1. Device Name/Classification Number [Grade]: IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), nucleic acid test / D06080.01[3]
2. Type Name (Model Name) : Ezplex® 2019-nCoV Virus Real-time PCR Kit
3. Manufacturer: SML Genetree
4. Storage Condition: - 20 ℃
5. Measurement Principles

The device's measuring process mainly consisted of three steps:

① Specimen pretreatment

RNA is extracted from oropharynx and nasopharynx swab specimens

② PCR amplification

SARS-CoV-2 virus-specific primer and probe are used for PCR amplification and the amplified device is detected with the probe's fluorescence.

③ Result Analysis

The analysis program included in the device is used for analysis.

8.1 Preparation for the trial

1) The reagents should be stored at -20±2 ℃ and should avoid repeated thawing and freezing.
2) The reagents should be completed melted before use.
3) Since DNA degradation is likely to happen in case of positive control reagents, it is recommended to divide the reagents into small amounts for 1-2 tests and keep them frozen.
4) CFX96 Real-time PCR detection system (Import License 10-205) is a necessary machine for the testing. Therefore, it should be turned on before the test for booting and should be kept in an idle condition.

8.2 Trial Process

1) Refer to the below table and prepare master PCR mixes according to the number of samples to be tested (See Tables 1 and 2).

Table 1. When IC is separately included in the specimen extraction (Unit: uL)

Component	Volume
RQ Mixture	10
nCoV P+P	5
Total	15

Table 2. When IC is not separately included in the specimen extraction (Unit: uL)

Component	Volume
RQ Mixture	10
nCoV P+P	5
IC	0.1
Total	15

2) Divide 15uL of the master PCR mix into tubes and divide 5uL of ribonucleic acid (RNA) extracted from specimens and mix them well.
3) Both positive and negative control reagents will be tested together for the accuracy of the test.

4) Set the configurations of the machine as follows:

Step	Temperature / Time	Cycle
Hold	25 ℃ / 2 min	1 Cycle
	50 ℃ / 30 min	
	95 ℃ / 5 min	
Cycle	95 ℃ / 15 sec	40 cycles
	60 ℃ / 45 sec	

8.3 Result Analysis

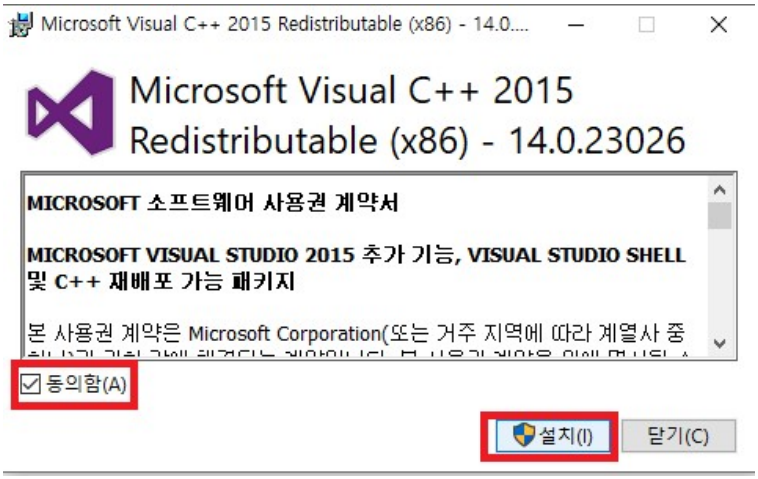
A. Amplification setup

After the test is finished, use the machine software (CFX manager) to set up the threshold values of fluorescence for each detection target as follows: '1000' for FAM, 500 for HEX, '150' for Cy5 and '100' for Cy5.5 (Quasar705).

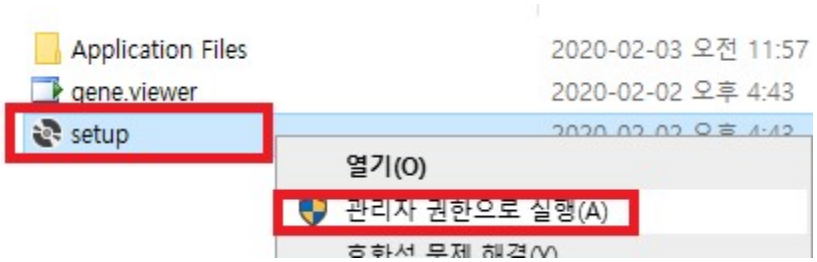
B. Software installation

(1) Files to be pre-installed

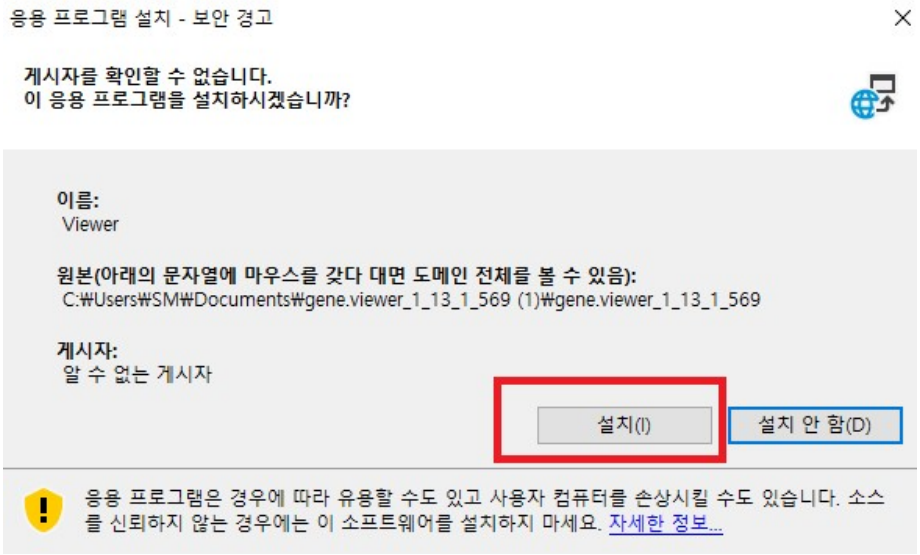
Before installing the analysis software, double-click the 'vc_redist.x86.exe' file as shown in the below image to install the 'Microsoft Visual C++ 2015 Redistributable(x86)' in the same folder.



(2) After installing the MS Visual C++ 2015, click 'Run as Administrator' for 'Setup.exe' file in the Setup folder.

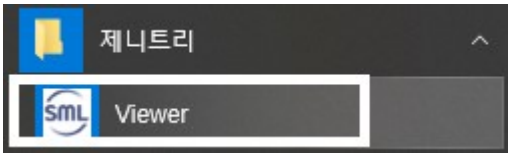


(3) After running the setup file, click the 'Install' button as shown in the below image and start installation.



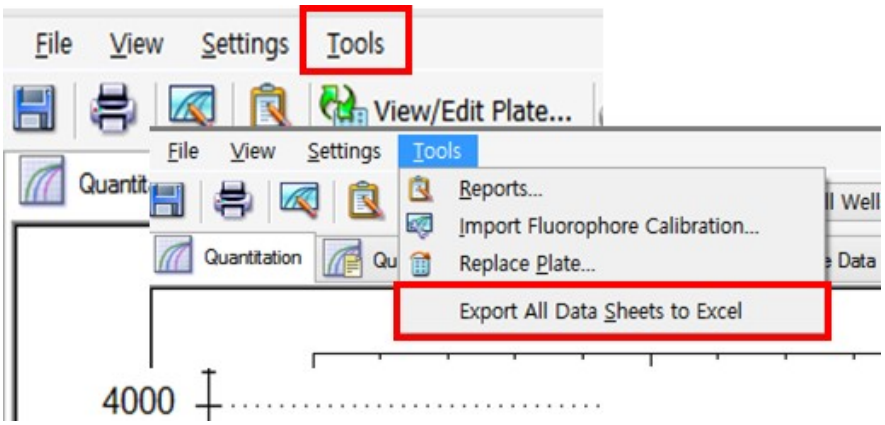
(4) After the installation is complete, the execution file can be seen from the Windows Start menu.

Note: If the program is not executed, install the 'Microsoft Visual C++ 2015 Redistributable X64 version and reinstall the analysis program (vc_redist.x64.exe).

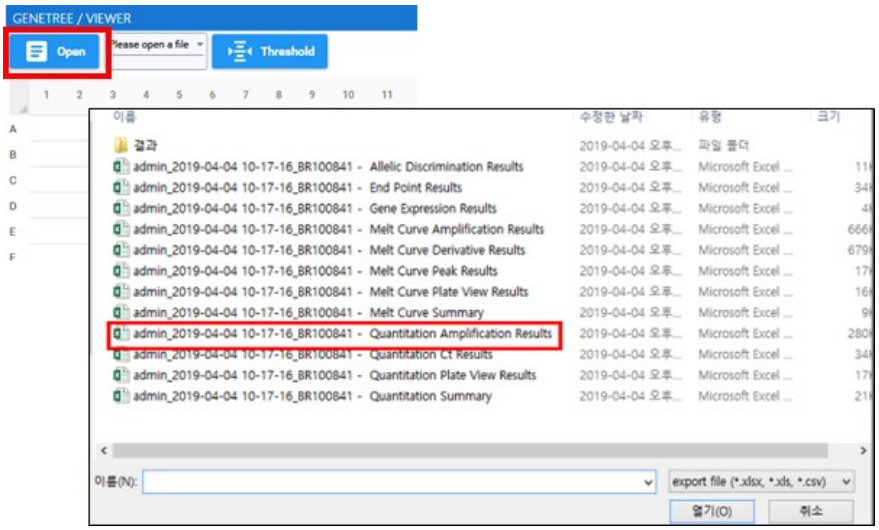


C. Software-enabled analysis

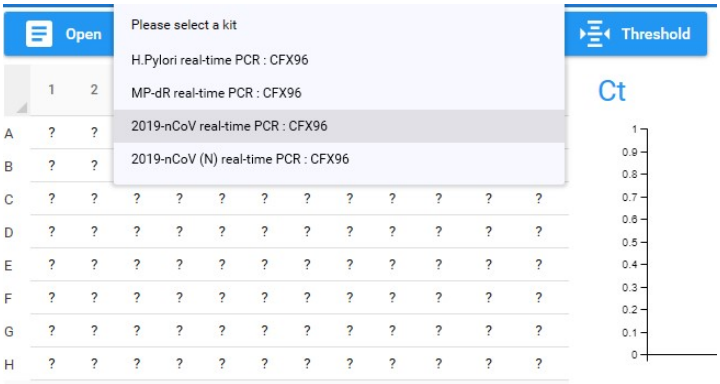
(1) Check that PCR test is complete and transfer the test data to an excel spreadsheet through 'Export All Data Sheets' in the 'Tools' menu of CFX96 Manager software (Create a folder and save the file in it).



2) Run the analysis software (Genetree Viewer), click 'Open' on the upper left to locate the folder where the transferred excel spreadsheet is saved and open the file with a file name ending in 'Quantitation Amplification Results.'



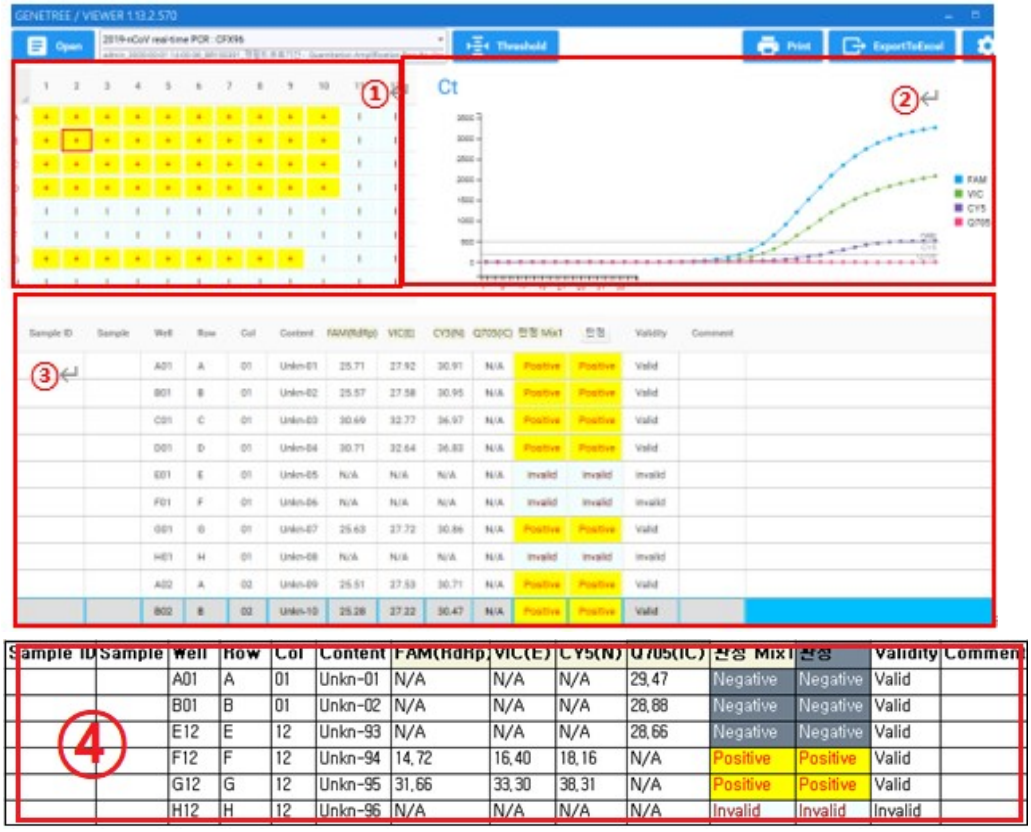
3) Click 'Please select a kit' on the upper part of the screen and select an appropriate kit (2019-nCoV real-time PCR:CFX96) for the experimented panel as shown in the below image.



4) As shown in the below image, test results for each well are displayed according to the selected kit.

Note : See the below table for detailed description of the result screen .

No.	Description
①	Positive/negative results for each well is indicated as '+' or '-,' respectively.
②	Ct and fluorescence values for each well's results are shown on a graph.
③	Ct values for each well's results are shown in numbers and qualitative results are displayed.
④	Analysis results are exported as an excel spreadsheet.



Sample ID	Sample	Well	Row	Col	Content	FAM(RdRp)	VIC(E)	CY5(N)	Q705(IC)	판정 Mix1	판정	Validity	Comment
		A01	A	01	Unkn-01	N/A	N/A	N/A	29,47	Negative	Negative	Valid	
		B01	B	01	Unkn-02	N/A	N/A	N/A	28,88	Negative	Negative	Valid	
		E12	E	12	Unkn-93	N/A	N/A	N/A	28,66	Negative	Negative	Valid	
		F12	F	12	Unkn-94	14,72	16,40	18,16	N/A	Positive	Positive	Valid	
		G12	G	12	Unkn-95	31,66	33,30	38,31	N/A	Positive	Positive	Valid	
		H12	H	12	Unkn-96	N/A	N/A	N/A	N/A	Invalid	Invalid	Invalid	

D. How to interpret the results

Results are determined by checking the Ct values according to the table below.

FAM (RdRp)	HEX (E)	Cy5 (N)	Quasar705 (IC)	Judgment*	Remarks
<40	<40	<40	Any	**Positive**	
<40	≥40 or Neg	<40	Any	**Inconclusive***	
<40	<40	≥40 or Neg	Any	**Inconclusive***	
≥40 or Neg	<40	<40	Any	**Inconclusive***	
<40	≥40 or Neg	≥40 or Neg	Any	**Negative****	
≥40 or Neg	<40	≥40 or Neg	Any	**Negative****	
≥40 or Neg	≥40 or Neg	<40	Any	**Negative****	
≥40 or Neg	≥40 or Neg	≥40 or Neg	<38	Negative	
≥40 or Neg	≥40 or Neg	≥40 or Neg	≥38 or Neg	Invalid	Retest after re-extraction

*** If positive results are confirmed for 2 or less genes from using this device, an additional test should be done by retesting with the same device or using another diagnostic method.**

**** If only one type of gene is detected regardless of genetic types, the result must be judged as negative.**

8.4 Severity

- Positive control should be included in the test, and the test result should be positive for all the test targets.
- D.W. which is used as negative control should be included in the test, and the test result should be negative in all kits. If any positive result is shown in the negative control well, a carry-over or contamination can be suspected and a retest should be performed.

9. Clinical Test Methods (Quantity of Use, Method of Use, Period of Use, Combination Therapies, etc.)

1. Specimen Handling

- Collected and tested specimen were remaining oropharynx and nasopharynx swab specimens of anonymized (coded with unique identifiers) patients referred to the participating site (SM Lab) that were confirmed either positive or negative of SARS-CoV-2 virus using the existing test kits (See Table 3).
- Approved medical devices (See Table 3) were used to extract ribonucleic acid (RNA) from all the remaining specimens.
- The principal investigator took the responsibility to have all the specimens coded with unique identifiers and randomized so that an investigator may not become aware of any personal information. The principal investigator delivered the uniquely identified and randomized specimens to the investigator B and instructed to perform the tests.

2. Clinical Test

- The investigator B received and tested the specimens using the medical devices allocated for the clinical trial (See Table 3) according to the dosage and administration. Then, the results were delivered to the investigator A for interpretation.
- The investigator A used an exclusive software (Genetree Viewer 1.13.2.570) for the investigational device to interpret the test results, recorded the results on the CRF and informed the principal investigator and no retest was required.

[Table 3]. Medical devices that were used together with the investigational device

Model Name	License Info	Manufacturer	Remarks
Powerchek™ 2019-nCoV Real-time PCR kit	Emergency Use Authorized device as per KCDC Announcement No. 2020-105	Kogene Biotech	Control group
CFX96 Real-time PCR	Import License 10 - 205	Bio-Rad	Study group equipment
Nextreactor NX-48	Gyeong-in Jesin14-66	Genolution	Extraction of ribonucleic acid

3. Result Analysis

- The principal investigator received the study group results from the investigator A and compared the results with the existing specimen results to assess clinical sensitivity and specificity according to Table 4. No sequencing was required due to discrepancy.

[Table 4]. Methods for result interpretation

Remaining specimen results	Investigational device results	Retest results	Sequencing results	Final Judgment
Positive	Positive	-	-	Positive
	Negative	-	Positive	False Negative
			Negative	Negative
	Invalid	Positive	-	Positive
		Negative	Positive	False Negative
			Negative	Negative
		Invalid	-	Invalid
Negative	Positive	-	-	False Positive
	Negative	-	-	Negative
	Invalid	Positive	-	False Positive
		Negative	-	Negative
		Invalid	-	Invalid

10 Clinical Trial Results

10.1 Summary of the clinical trial targets

1) A summary of the clinical trial targets can be in the table below.

Specimen Selection	Remaining specimens of patients who were referred to SM Lab, tested for SARS-CoV-2 virus with an existing test kit, and notified either positive or negative.
Number of Screened Specimen	53 cases
Number of Analytes	53 cases
Excluded Specimen	None
Final Number of Tested Specimen	53 cases

10.2 Statistical Analysis

10.2.1 Efficacy Assessment

1) Regarding efficacy parameters available for the assessment, ratios are presented for specimens that were positive before but judged negative with the investigational device or specimens that were negative before but judged positive with the investigational device

2) Original specimen results are compared with the results from the investigational device and presented in a table.

10.2.2 Safety Assessment

Mechanical issues or malfunction/defect and their percentages are suggested for the investigational device as well as other medical devices that were used together.

10.2.3 Analysis Sets

Analysis sets for this trial are defined as remaining oropharynx and nasopharynx swab specimens that satisfy the 'inclusion and exclusion criteria.'

10.2.4 Statistical Analysis Method

MedCalc Statistical Software version 14.8.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2014) was used for statistical analysis.

In order to assess clinical performance of the investigational device in comparison with the specimens' original results, clinical sensitivity and specificity were calculated. The Kappa value was also calculated to evaluate the correlation with a kit which was approved earlier.

10.3 Trial Results

10.3.1 The number of specimens that were judged positive or negative after testing.

Number of specimens for completed testing		
Specimen Type	**Positive**	**Negative**
Oropharynx swab	5	22
Nasopharynx swab	5	21

10.3.2 The number of specimens with discrepant results (positive/negative)

Category	Original result	Study Group Result	No. of discrepancy	Concordance (%)
Positive	10	10	0	100
Negative	43	43	0	100

10.3.3 Mechanical issues or malfunction/defects for medical devices used together with the investigational device.

There was no issue regarding degeneration of diagnosis reagents or malfunction/defects from the devices used in the course of conducting this trial.

10.3.4. Compliance with the inclusion/exclusion criteria

Category	No. of Specimen	Compliance with the inclusion/exclusion criteria
Positive	10	100 %
Negative	43	100 %

10.3.5. Test Results

1. Primary Efficacy Assessment Results

(1) Overall results

SARS-CoV-2 Virus		Control Group (Specimens and Sequencing Results)	
		Positive	**Negative**
Study Group	**Positive**	10	0
	Negative	0	43
Sensitivity (95% CI)		100 % (69.2 ~ 100 %)	
Specificity (95% CI)		100 % (91.8 ~ 100 %)	

(2). Results by Specimen Type

Oropharynx Swab		Control Group			Nasopharynx		Control Group		
		Positive	Negative	Total			Positive	Negative	Total
Study Group	Positive	5	0	5	Study Group	Positive	5	0	5
	Negative	0	22	22		Negative	0	21	21
	Total	5	22	27		Total	5	21	26
Sensitivity (95% CI)		100 % (47.8 ~ 100 %)			Sensitivity (95% CI)		100 % (47.8 ~ 100 %)		
Specificity (95% CI)		100 % (84.6 ~ 100 %)			Specificity (95% CI)		100 % (83.9 ~ 100 %)		

2. Secondary Efficacy Assessment Results

(1) Overall Results

SARS-CoV-2 Virus		Control Group (Specimens and Sequencing Results)	
		Positive	Negative
Study Group	Positive	10	0
	Negative	0	43
Positive Percent Agreement		100 % (69.2 ~ 100 %)	
Negative Percent Agreement		100 % (91.8 ~ 100 %)	
Kappa value		1.00	

(2) Results by Specimen Type

Oropharynx Swab		Control Group			Nasopharynx Swab		Control Group		
		Positive	Negative	Total			Positive	Negative	Total
Study Group	Positive	5	0	5	Study Group	Positive	5	0	5
	Negative	0	22	22		Negative	0	21	21
	Total	5	22	27		Total	5	21	26
Positive Percent Agreement		100 % (47.8 ~ 100 %)			Positive Percent Agreement		100 % (47.8 ~ 100 %)		
Negative Percent Agreement		100 % (84.6 ~ 100 %)			Negative Percent Agreement		100 % (83.9 ~ 100 %)		
Kappa value		1.00			Kappa value		1.00		

11. Conclusion

Clinical sensitivity and specificity of Ezplex® 2019-nCoV Real-time PCR Kit was evaluated in order to assess the device's clinical performance by testing remaining specimens of those that were tested with an already approved test kit and comparing the results. This device is for an in-vitro diagnostic test which uses oropharynx and nasopharynx swabs collected from people suspected of coronavirus infection to extract ribonucleic acid. Therefore, the device is judged to have no safety issues since it does not cause a direct harm on human body. 53 specimens that were involved in the trial all met the inclusion criteria and none were excluded.

According to the result of testing the study group device for the targeted SARS-CoV-2 Virus, a high clinical performance was confirmed from the study group. The high clinical performance of the study group was validated from 100% sensitivity and specificity of the study group that were determined from the collected specimens, 100% positive/negative percent agreement in terms of correlation, and the Kappa value of 100.

12. Annex

- Case Report Form

임상시험명	코로나바이러스감염증(COVID-19) 의심 환자에서의 비인두 및 구인두 도말 검체에서 추출한 핵산(RNA)을 이용하여 SARS-CoV-2 virus를 정성 검사하기 위한 시험군 (Ezplex® 2019-nCoV Real-time PCR Kit)의 임상적 성능을 평가하는 단일기관, 무작위배정, 단일 눈가림, 후향적 확증 임상시험

의뢰기관		㈜에스엠엘제니트리		시험기관		삼광의료재단	
No.	Sample Code	검체	대조군 결과	FAM (1,000)	HEX (500)	Cy5 (150)	Quasar750 (100)
1	SML-CV2-01	구인두	Positive	31.32	24.58	25.98	35.18
2	SML-CV2-02	구인두	Negative	N/A	N/A	N/A	33.51
3	SML-CV2-03	비인두	Positive	34.90	28.74	29.88	36.19
4	SML-CV2-04	비인두	Negative	N/A	N/A	N/A	32.99
5	SML-CV2-05	구인두	Negative	N/A	N/A	N/A	32.58
6	SML-CV2-06	구인두	Negative	N/A	N/A	N/A	32.30
7	SML-CV2-07	비인두	Negative	N/A	N/A	N/A	32.44
8	SML-CV2-08	비인두	Positive	25.27	23.16	22.19	34.36
9	SML-CV2-09	비인두	Negative	N/A	N/A	N/A	32.57
10	SML-CV2-10	비인두	Negative	N/A	N/A	N/A	32.70
11	SML-CV2-11	비인두	Negative	N/A	N/A	N/A	32.30
12	SML-CV2-12	비인두	Negative	N/A	N/A	N/A	32.64
13	SML-CV2-13	비인두	Negative	N/A	N/A	N/A	32.27
14	SML-CV2-14	구인두	Negative	N/A	N/A	N/A	32.07
15	SML-CV2-15	비인두	Negative	N/A	N/A	N/A	32.54
16	SML-CV2-16	구인두	Negative	N/A	N/A	N/A	32.63
17	SML-CV2-17	비인두	Positive	35.85	27.99	28.33	34.26
18	SML-CV2-18	구인두	Negative	N/A	N/A	N/A	34.27
19	SML-CV2-19	구인두	Positive	31.95	25.25	28.57	33.58
20	SML-CV2-20	구인두	Negative	N/A	N/A	N/A	33.44
21	SML-CV2-21	구인두	Negative	N/A	N/A	N/A	32.64
22	SML-CV2-22	비인두	Negative	N/A	N/A	N/A	32.23
23	SML-CV2-23	비인두	Negative	N/A	N/A	N/A	33.82
24	SML-CV2-24	구인두	Negative	N/A	N/A	N/A	33.19
25	SML-CV2-25	구인두	Negative	N/A	N/A	N/A	32.71
26	SML-CV2-26	비인두	Negative	N/A	N/A	N/A	32.20
27	SML-CV2-27	비인두	Negative	N/A	N/A	N/A	32.37
28	SML-CV2-28	비인두	Negative	N/A	N/A	N/A	32.22
29	SML-CV2-29	비인두	Negative	N/A	N/A	N/A	32.54
30	SML-CV2-30	구인두	Negative	N/A	N/A	N/A	32.42
31	SML-CV2-31	구인두	Negative	N/A	N/A	N/A	33.70
32	SML-CV2-32	비인두	Negative	N/A	N/A	N/A	32.01
33	SML-CV2-33	구인두	Negative	N/A	N/A	N/A	32.10
34	SML-CV2-34	구인두	Negative	N/A	N/A	N/A	31.20
35	SML-CV2-35	비인두	Negative	N/A	N/A	N/A	32.39
36	SML-CV2-36	비인두	Positive	35.25	30.77	30.99	32.34
37	SML-CV2-37	구인두	Negative	N/A	N/A	N/A	32.11
38	SML-CV2-38	구인두	Negative	N/A	N/A	N/A	32.72
39	SML-CV2-39	구인두	Positive	30.07	26.55	26.28	35.08
40	SML-CV2-40	비인두	Negative	N/A	N/A	N/A	32.78
41	SML-CV2-41	구인두	Negative	N/A	N/A	N/A	33.84
42	SML-CV2-42	비인두	Negative	N/A	N/A	N/A	32.62
43	SML-CV2-43	구인두	Negative	N/A	N/A	N/A	32.03
44	SML-CV2-44	구인두	Negative	N/A	N/A	N/A	32.50
45	SML-CV2-45	구인두	Positive	32.25	27.59	27.59	32.60
46	SML-CV2-46	구인두	Negative	N/A	N/A	N/A	32.05
47	SML-CV2-47	비인두	Negative	N/A	N/A	N/A	32.01
48	SML-CV2-48	비인두	Positive	27.09	24.57	23.40	32.64
49	SML-CV2-49	비인두	Negative	N/A	N/A	N/A	32.46
50	SML-CV2-50	구인두	Positive	28.11	27.03	25.74	32.91
51	SML-CV2-51	구인두	Negative	N/A	N/A	N/A	32.13
52	SML-CV2-52	구인두	Negative	N/A	N/A	N/A	32.60
53	SML-CV2-53	비인두	Negative	N/A	N/A	N/A	32.36

증례기록서의 모든 내용을 검토하였으며, 빠짐없이 정확히 기록하였음을 확인합니다.

임상시험 책임자 : 김 형 년 서명 : 김형년 (인)