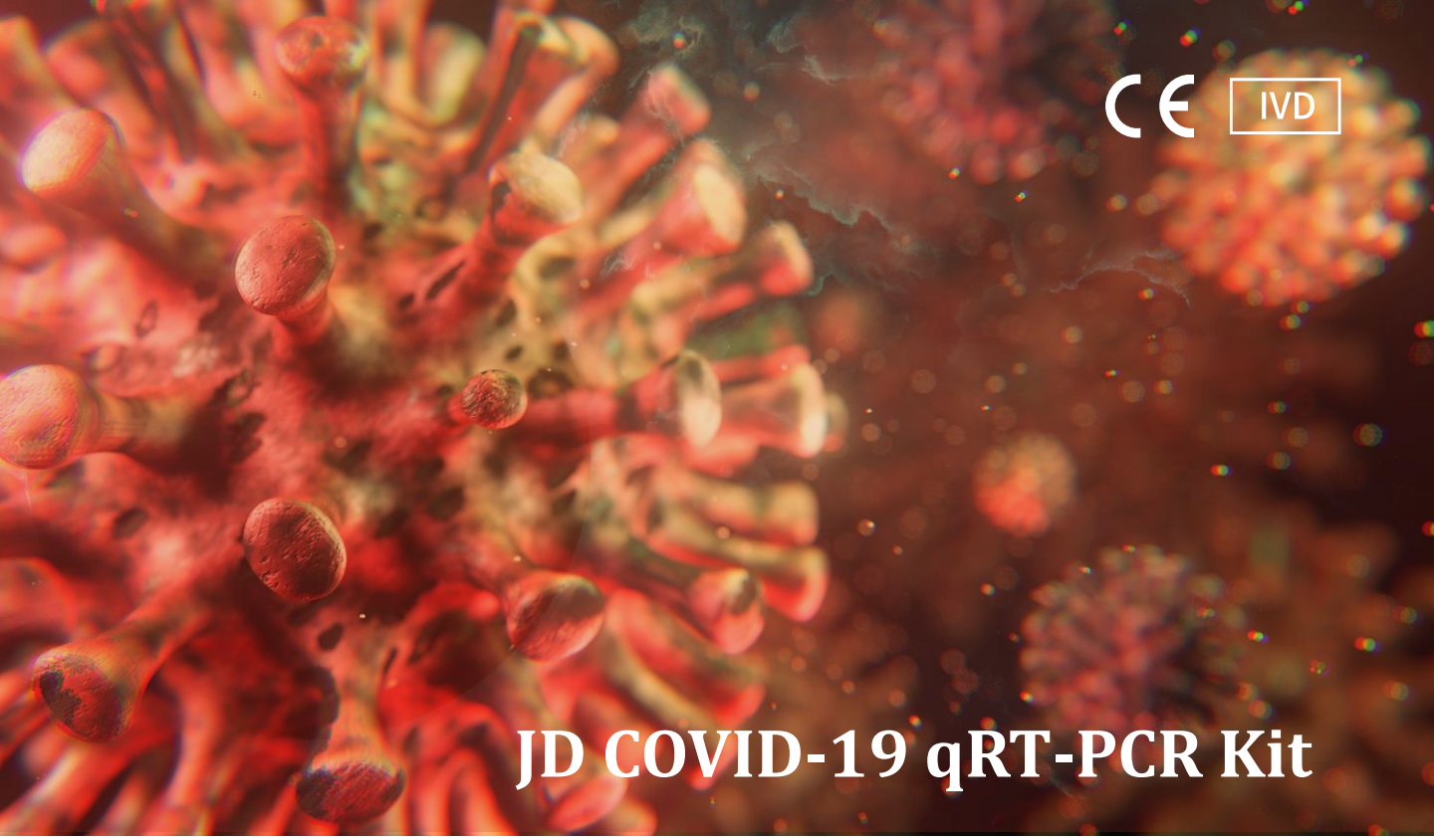
CE IVD

JD™ COVID-19 qRT-PCR Kit

Joonghun Pharmaceutical



CE IVD

JD COVID-19 qRT-PCR Kit

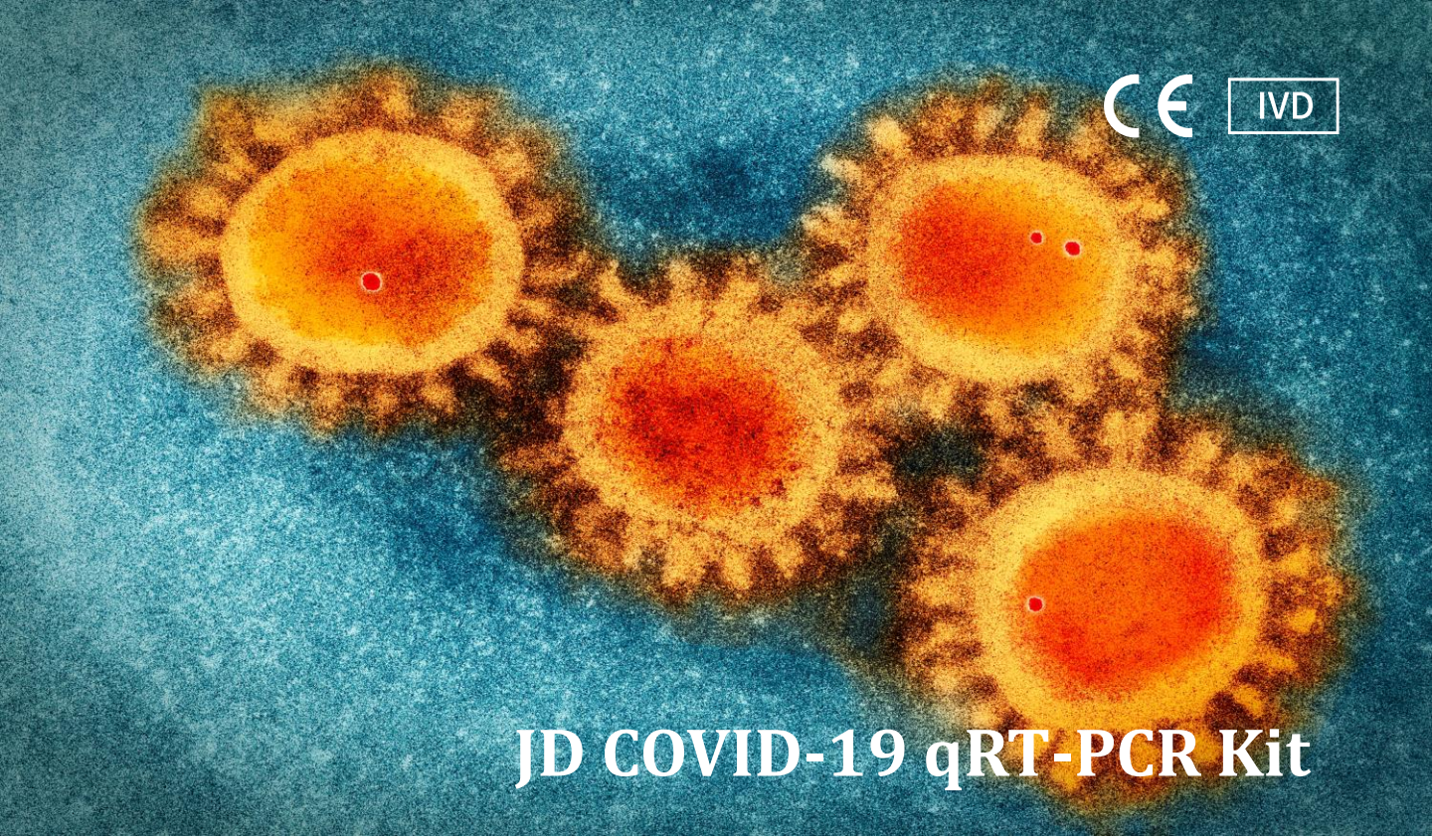
JD COVID-19 qRT-PCR Kit is used for *in vitro* diagnostics of novel coronavirus (SARS-CoV-2) in human oropharyngeal and nasopharyngeal swab and sputum samples. JD COVID-19 qRT-PCR Kit uses Real-time RT-PCR. SARS-CoV-2 is first transcribed into cDNA by reverse transcriptase, and then cDNA is used as a template for PCR amplification. Primer and fluorescent probe were set to the N gene site in reference to US FDA's "FAQs on Diagnostic Testing for SARS-CoV-2." JD COVID-19 qRT-PCR Kit can determine positive results through reaction of increased amount of fluorescent Taqman probe contained in the reagent, in real time.

Product Name	JD COVID-19 qRT-PCR Kit
Packaging Unit	96 tests/kit, box
Target Gene	N gene (SARS-CoV-2)
Running Time	1 hour 40 minutes
Storage	-20℃ or below
Shelf-life	1 year from manufacturing date
Clinical Trial Results *	Positive Predictive Value (PPV) = 100% (95% CI 88.78-100) Negative Predictive Value (NPV) = 100% (95% CI 90.00-100)
Manufacturing	GMP for Pharmaceuticals, GMP for Medical Devices, ISO 13485:2016
Highly Recommended Machine	Bio-Rad CFX96, Thermo Fisher Scientific AB7500, Roche LC96

* We performed clinical trial based on 31 positive and 35 negative clinical samples in accordance with FDA's Emergency Use Authorization clinical study guidelines

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

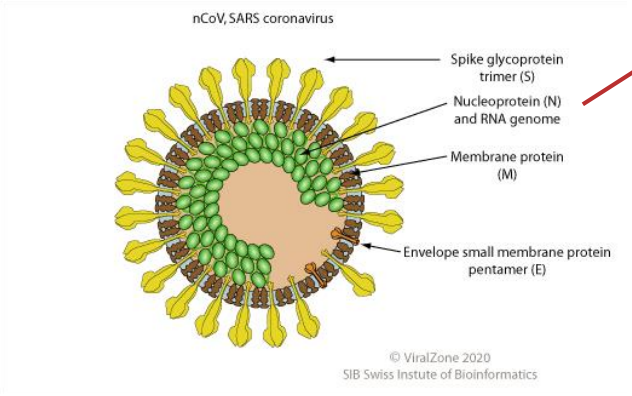
Joonghun Pharmaceutical



CE IVD

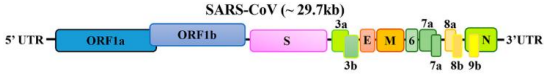
JD COVID-19 qRT-PCR Kit

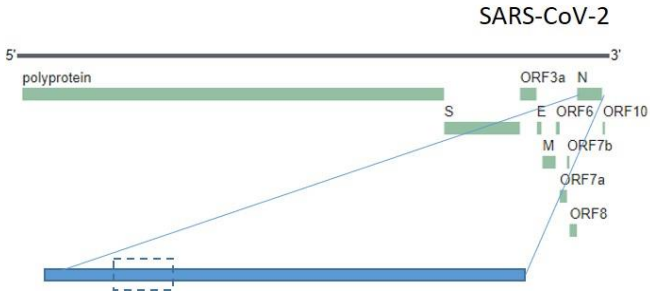
Target Gene



Target : N gene

US CDC recommends N gene of SARS-CoV-2 for Real-Time PCR





Amplifying the target gene regardless of mutation

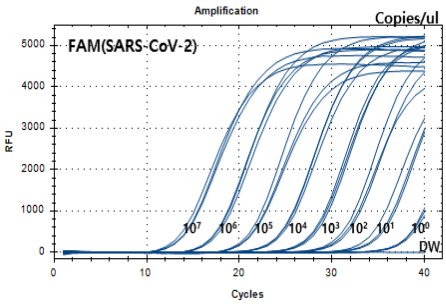
Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

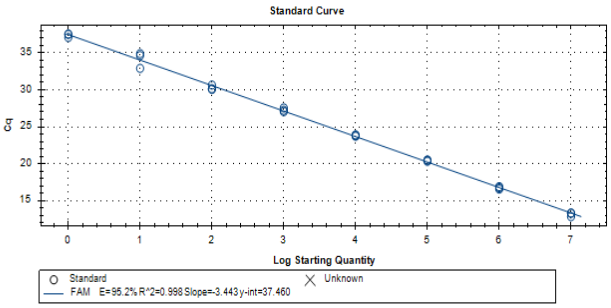
Joonghun Pharmaceutical

Sensitivity

Diluted SARS-CoV-2 was detected with high sensitivity, with linearity.

LOD: 5 copies/μl





• Rxn cycle

50℃	30min	
95℃	15min	
95℃	5s	40cycle
55℃	30s	
4℃	10s	

Lane		1	2	3	4	5	6	7	8	9
Name		Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Negative Control
Conc. (Copies/μℓ)		10^7	10^6	10^5	10^4	10^3	10^2	10^1	10^0	-
Result*		P	P	P	P	P	P	P	P	N
Ct values	1	13.32	16.76	20.35	23.81	27.56	30.07	34.63	37.52	-
	2	12.88	16.59	20.50	23.74	27.06	30.15	32.9	37.08	-
	3	13.34	16.91	20.51	23.91	27.23	30.65	34.89	37.50	-
Mean		13.18	16.75	20.45	23.82	27.28	30.29	34.14	37.37	-
STD		0.26	0.16	0.09	0.09	0.25	0.31	1.08	0.25	-
CV%		1.97	0.96	0.44	0.36	0.93	1.04	3.17	0.66	-

* P: Positive, N: Negative

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

Joonghun Pharmaceutical

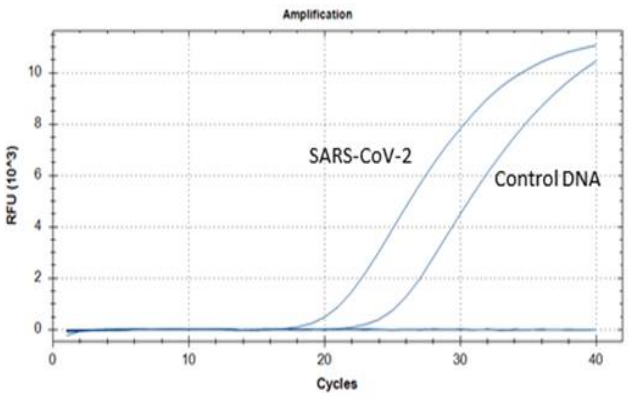
CE IVD

JD COVID-19 qRT-PCR Kit

Specificity

No.	Virus	Result *
1	SARS-CoV-2 (β coronavirus)	P
2	MERS-CoV (β coronavirus)	N
3	HCoV-NL63 (α coronavirus)	N
4	Human Influenza A (CA/04, H1N1)	N
5	Human Influenza H3N2	N
6	Human Influenza B (Vic)	N
7	PED(SM98) (α coronavirus)	N

* P: Positive, N: Negative



JD COVID-19 qRT-PCR Kit specifically detects SARS-CoV-2.

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
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Website www.joonghun.com

Joonghun Pharmaceutical

CE IVD

JD COVID-19 qRT-PCR Kit

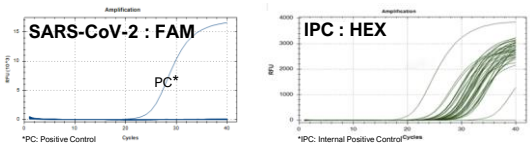
Instruction for Use

1. Preparation of reagent and extracted RNA
2. qRT-PCR

*** Real-time PCR Machine:** CFX96 (Bio-Rad)

Step	PCR Program (20μl reaction)		
	Temp	Time	Cycle
cDNA synthesis	50℃	30 min	1 cycle
Initial inactivation	95℃	15 min	1 cycle
Denaturation	95℃	5 sec	40 cycles
Elongation	55℃	30 sec	
Hold	4℃	10 sec	1 cycle

3. Reading



4. Data Analysis and Interpretation

Item	Fluorescent		Result
	FAM(SARS-CoV-2)	HEX(Human B2M)	
SAMPLE 1	+	+/- *	Positive
SAMPLE 2	-	+	Negative
SAMPLE 3	-	-	False Negative/Retest

* According to EUA summary (FDA), a high SARS-CoV-2 (target N gene) RNA load in the sample can lead to reduced or absent Internal Positive Control(IPC), thus making the test result positive.

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

Joonghun Pharmaceutical

Certificates

*refer to the appendix

Pharmaceutical GMP

의약품 제조 및 품질관리기준 적합판정서
(Certificate of GMP Compliance of a Manufacturer)

- 제조소의 명칭/업허가번호(Name of Manufacturer/License No.)
(주)중헌제약/2631
- 제조소의 소재지(Address of Manufacturer)
충청북도 청주시 흥덕구 옥산면 옥산산단로 28 공장동
- 제형 또는 제조 방법
(Dosage forms of Product(s) of Manufacturing operations : 붙임 참고)

위 제조소는 「약사법」 제38조, 「의약품 등의 안전에 관한 규칙」 제48조 및 의약품실사상호협력기구(PIC/S) 규정에 의한 의약품 제조 및 품질관리기준에 적합함을 판정합니다.
(We hereby certify that the above manufacturer complies with Good Manufacturing Practices of Pharaceutical Products(s) according to the Korea Pharaceutical Affairs Act and PIC/S GMP guides)

발급일자(Date of Issue) : 2019.11.06
유효기간(Date of Expiration) : 2022.04.16
비고 : 실사종료일 2019.04.17, 2019.06.19(추사제)

대전지방식품의약품안전청장

Medical Device GMP

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

GMP

대전지방식품의약품안전청장
DAEJEON REGIONAL FOOD AND DRUG ADMINISTRATION

KTR
한국화학융합시험연구원
KOREA TESTING & RESEARCH INSTITUTE

CE

promedt CONSULTING

Certificate
of EU product notification

Hereunto we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

Joonghun Pharmaceutical Co., Ltd
15, Gukhoe-daero 62-gil, Yeongdeungpo-gu
Seoul
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

30 April 2020

Dr. Michael Rinck
- Managing Director -

Enclosures
Annex I

ISO 13485

Certificate No : IMS 6001

MEDICAL DEVICE QUALITY
MANAGEMENT SYSTEMS CERTIFICATE

JOONGHUN PHARMACEUTICAL CO., LTD.

HEAD OFFICE 15, GUKHOE-DAERO 62-GIL, YEONGDEUNGPO-GU, SEOUL, 07236, KOREA
FACTORY 28, OKSANSANDAN-RO, OKSAN-MYEON, HEUNGDEOK-GU, CHEONGJU-SI, CHUNGCHEONGBUK-DO, 28101, KOREA

This is to certify that organization above has been assessed and registered by KTR-CC for the scope of supply described as follows:

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS
ISO 13485:2016

SCOPE OF SUPPLY :
DESIGN, DEVELOPMENT AND PRODUCTION OF
GRAFT/PROSTHESIS, BIOMATERIALS AND IVD REAGENTS FOR
INFECTIOUS DISEASE MARKER(JD COVID-19 qRT-PCR Kit)

Valid Until : FEBRUARY 27, 2022
Registered Date : FEBRUARY 28, 2019
Issued Date : MARCH 30, 2020

KTR CERTIFICATION CENTER
#501, 646-30, Hosu-ro, Bundang-gu, Goyang-si, Gyeonggi-do, Korea
Tel : 82-2-2093-3452/82-70-4010-4981 Web : www.ktrcc.or.kr
President

KTR-CC SINCE 1995
IAS ACCREDITED MSCB-156

This certificate remains the property of KTR-CC. This certificate is accredited by IAS which is IAF MLA joined corporation.
If not received further management audit within a given period, this certificate will be canceled.

KFDA CFS

Certificate of Free Sales

The Ministry of Food and Drug Safety, certifies that the following Firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is/are permitted to be freely sold in overseas markets.

JOONGHUN PHARMACEUTICAL Co.,Ltd.

Director of High-Tech Medical Devices Division
Department of Medical Device Evaluation
National Institute of Food and Drug Safety
Ministry of Food and Drug Safety

US FDA EUA

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

5/4/2020

Kyo San Ku
AKI Health LLC
651 N Broad St, Suite 205 #2405
Middletown, DE 19709
UNITED STATES

Dear Kyo San Ku:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA200652
Received: 5/4/2020
Applicant: Joonghun Pharmaceutical Co., Ltd.
Device: JD COVID-19 qRT-PCR Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

*US FDA EUA is in progress

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

Joonghun Pharmaceutical

CE IVD

JD COVID-19 qRT-PCR Kit

F&Q

MOQ	1,000 Kit (96,000 tests)
MSRP	Contact for pricing details
Payment Term	100% T/T advanced, non-refundable
Incoterms	FOB KOREA
Lead Time	Within 2-week basis after payment (Firm delivery date will be notified after payment)
Certificates	CFS by MFDS (KFDA) CE-IVD US FDA EUA (in process) GMP for Pharmaceuticals GMP for Medical Devices ISO 13485:2016
Storage	-20 °C or below
Shelf-life	1 year from manufacturing date
Weekly Manufacturing Capacity	15,000 Kit
Highly Recommended PCR Machine	Bio-Rad CFX96, Thermo Fisher Scientific AB7500, Roche LC96
Dimensions and Weight	1kit = 70mm x 63mm x 52mm / 30g 1 container = 764mm x 590mm x 535 mm / 31,430g (±10%)
Packaging	Thermal Insulation Container with Bio-Pharm Coolant (6 containers per 1,000 kits / 187,080g (±10%))
Check List for End Point	Precheck for Registration or Certificate for IVD importer in destination country And confirmation of BSL(Bio Safety Level 3) lab for end-user

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

Joonghun Pharmaceutical

Appendix 1, KMFDS Certificate of Free Sales

시정확인본 진본 2020-04-21 12:28:12 KST 정부사정확인센터

Document Number : 1KHK-WJ7L-OTSO-UQRJ

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2342, Fax: +82-43-719-1000

No. of Certificate : 20200044307 Date : 2020/04/21

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No. : 5480)

JOONGHUN PHARMACEUTICAL Co., Ltd.

28, Oksansandan-ro, Oksan-myeon, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do

Product-License No.	Classification
20-292	IVD reagents for infectious disease marker(Diagnosis of Saxually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), nucleic acid test [3] Product Name : JD COVID-19 qRT-PCR Kit

※Attached : List of Product Classification and Model

Director of High-Tech Medical Devices Division
Department of Medical Device Evaluation
National Institute of Food and Drug Safety Evaluation
Ministry of Food and Drug Safety

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

Appendix 2, CE

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

Joonghun Pharmaceutical Co., Ltd
15, Gukhoe-daero 62-gil, Yeongdeungpo-gu
Seoul
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

30 April 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

Appendix 2, CE, continued

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULTING

Joonghun Pharmaceutical Co., Ltd

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

Page 1 / 1 of Annex I

Internal Number	Registration Number (at the German CA/ DIMDI)	Product Category (EDMS)	EDMS Code Description	Classification Annex
JOO-01	DE/CA70/40838- 155295	16 90 90 01 90	Other Other Genetic Tests	III

30 April 2020

Dr. Michael Rinck
- Managing Director -

Appendix 3, US FDA Acknowledgment Letter

FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

5/4/2020

Kyo San Ku
AKI Health LLC
651 N Broad St, Suite 205 #2405
Middletown, DE 19709
UNITED STATES

Dear Kyo San Ku:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA200652
Received: 5/4/2020
Applicant: Joonghun Pharmaceutical Co., Ltd.
Device: JD COVID-19 qRT-PCR Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Appendix 4, Certificate of ISO13485

원본대조필 2020.04.10

Certificate No : IMS 6001

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS CERTIFICATE

JOONGHUN PHARMACEUTICAL CO., LTD.

HEAD-OFFICE: 15, GUKHOE-DAERO 62-GIL, YEONGDEUNGPO-GU, SEOUL, 07236, KOREA
FACTORY: 28, OKSANSANDAN-RO, OKSAN-MYEON, HEUNGDEOK-GU, CHEONGJU-SI, CHUNGCHEONGBUK-DO, 28101, KOREA

This is to certify that organization above has been assessed and registered by KTR-CC for the scope of supply described as follows:

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS

ISO 13485:2016

SCOPE OF SUPPLY :
DESIGN, DEVELOPMENT AND PRODUCTION OF GRAFT/PROSTHESIS, BIOMATERIALS AND IVD REAGENTS FOR INFECTIOUS DISEASE MARKER(JD COVID-19 qRT-PCR Kit)

Valid Until	: FEBRUARY	27. 2022
Registered Date	: FEBRUARY	28. 2019
Issued Date	: MARCH	30. 2020

KTR CERTIFICATION CENTER
#501, 646-30, Hosu-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea
Tel : 82-2-2093-3450/82-70-4010-4981 Web : www.ktrcc.or.kr

President

International Management System KTR-CC Certification Center
SINCE 1995

IAS ACCREDITED Management Systems Certification Body
MSCB-156

This certificate remains the property of KTR-CC
This certificate is accredited by IAS which is IAF MLA joined corporation.
If not received further management audit within a given period, this certificate will be canceled.

Appendix 5, Certificate of Medical Device GMP

원본대조필

인정번호(No.) :KTR-AABA-7907

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)

(주)중헌제약

Joonghun Pharmaceutical Co.,Ltd.

■ 대표자 (Representative)

윤석준 (Sukjoon Yoon)

■ 업체 소재지 (Company address of Applicant)

충청북도 청주시 흥덕구 옥산면 옥산산단로 28 , 28101

28 Oksansandanro, Chungjoosi, Choongchungbookdo 28101, Korea

■ 제조소명 (Name of Manufacturer)

제조자 : (주)중헌제약(Joonghun Pharmaceutical Co.,Ltd.)

■ 제조소 소재지 (Address of Manufacturer)

제조자 : 충청북도 청주시 흥덕구 옥산면 옥산산단로 28, 28101

28 Oksansandanro, Chungjoosi, Choongchungbookdo 28101, Korea

■ 품목군 (Category)

인체조직 또는 기능 대치품(Substitute of Human Tissue or Body Function)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2020. 03. 27

유효기간(Date of Expiration) : 2023. 03. 26

대전지방식품의약품안전청장
DAEJEON REGIONAL FOOD AND DRUG ADMINISTRATION

KTR

한국화학융합시험연구원장
KOREA TESTING & RESEARCH INSTITUTE

Appendix 6, Certificate of Pharmaceutical GMP

원본대조필

번호(No.) : MFDS-6-F-2631-1-2019-65

의약품 제조 및 품질관리기준 적합판정서
(Certificate of GMP Compliance of a Manufacturer)

• 제조소의 명칭/업허가번호(Name of Manufacturer/License No.)

(주)중헌제약/2631

• 제조소의 소재지(Address of Manufacturer)

충청북도 청주시 흥덕구 옥산면 옥산산단로 28 공장동

• 제형 또는 제조 방법
(Dosage forms of Product(s) of Manufacturing operations : 붙임 참고)

위 제조소는 「약사법」 제38조, 「의약품 등의 안전에 관한 규칙」 제48조 및 의약품실사상호협력기구(PIC/S) 규정에 의한 의약품 제조 및 품질관리기준에 적합함을 판정합니다.
(We hereby certify that the above manufacturer complies with Good Manufacturing Practices of Pharmaceutical Products(s) according to the Korea Pharmaceutical Affairs Act and PIC/S GMP guides)

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대전지방식품의약품안전청장

Headquarters 15, Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Republic of Korea, 07236
Manufacturing Facility 28 Oksansandan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea, 28101
Tel. +82 2 2138 8114
E-mail COVID-19TF@joonghun.com
Website www.joonghun.com

Joonghun Pharmaceutical