에스디바이오센서 코비드-19 제품 & 사업화 소개

박 해 준

부사장, 에스디바이오센서

BIOPLUS INTERPHEX KOREA

BIOPLUS INTERPHEX KOREA

Table of Contents

Introduction

SD BIOSENSOR was established in 2010. Since then, there has been a continuous growth in the number of innovative products, production facilities and sales. Currently, 158 diagnostic assays are available selling globally to more than 500 distributors.

Headquarter
Suwon, Korea

- Foundation date : Dec, 2010
- No. of employees : 418
- Division : R&D, Sales, Marketing, RA, Administrative Department

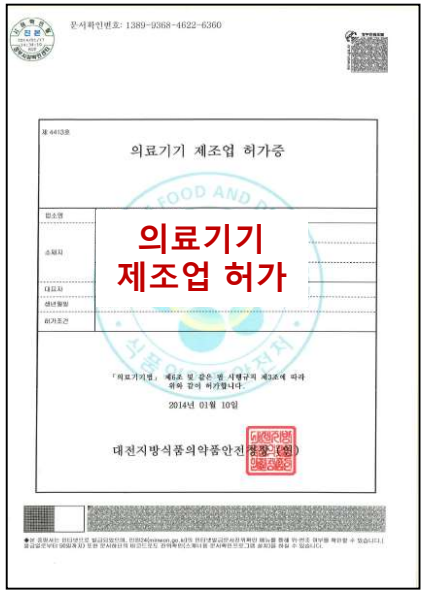
Factory
O-song, Korea

- Foundation date : Aug, 2013
- Total area : 18,115m^2
- Production capacity : 60 million rapid tests / month
- Division : Production, QA, QC, warehouse
- Automation production : RDT, FIA, RT-PCR, Glucose strips

Headquarter & Factory
India

- Foundation date : Sep, 2012
- Total area : 13,106 m^2
- Production capacity : 29 million tests/ month
- Division : R&D, Sales, Marketing, RA, Administrative Department, Production, QA, QC, warehouse
- Automation production : RDT, FIA, RT-PCR

Quality Control | Certificates



	List of related standard
1	EN ISO 13485:2016 (규격)
2	IVD 98/79/EC Directives
3	KGMP (MFDS Regulation)
4	Directive 2002/95/EC (RoHS)

	List of MDSAP
1	FDA QSR (CFR Title 21 – Food and Drugs: Parts 820) 미국
2	RDC 16/2013 – ANVISA GMP 브라질
3	Canadian Medical Device Regulations (MDR) SOR/98-282 캐나다
4	Therapeutic Goods (Medical Devices) Regulations 2002 호주
5	MHLW Ministerial Ordinance No. 169 일본

SD BIOSENSOR

We devote ourselves to improves human health by developing innovative products.

1999~2013

2009.08 **World 1st**
- Influenza A (H1N1pdm09)

2003.07
- SARS Antibody, Antigen

1999.02
- Standard Diagnostics, Inc.(SD) establishment by Dr. Cho

2014~2019

2019.08 **The Global Fund ERPD Approved**
- HIV/Syphilis Combo

2019.04 **UNICEF long term supply agreement signed**
- Arbo Panel I (Zika, Dengue, Chikungunya, Yellow fever)

2016.09
- Zika IgG/IgM

2015.04 **World 1st**
- MERS-CoV Antigen

2014.12 **WHO EUAL**
- Ebola *Zaire* Antigen

2020~

FDA EUA in progress
- Q COVID-19 Ag rapid
- Q COVID-19 IgM/IgG Combo rapid
- Q COVID-19 IgM/IgG Plus rapid
- F COVID-19 Ag FIA

2020.08
- M nCoV real-time detection kit **KFDA Approved**

2020.06
- E COVID-19 Total Ab ELISA
- Q HIV 1/2 Ab 3-Line **WHO PQ Approved**

2020.05 **WHO PQ Approved**
- Q HIV/Syphilis diagnosis kit

2020.04 **FDA EUA Approved**
- M nCoV Real-time detection kit

2020.03
- Q HCV Ab **WHO PQ approved**
- Q Malaria Ag **WHO PQ approved**

CE registration
- Q COVID-19 Ag rapid
- Q COVID-19 IgM/IgG Combo rapid
- F COVID-19 Ag FIA
- F COVID-19 IgM/IgG Combo FIA

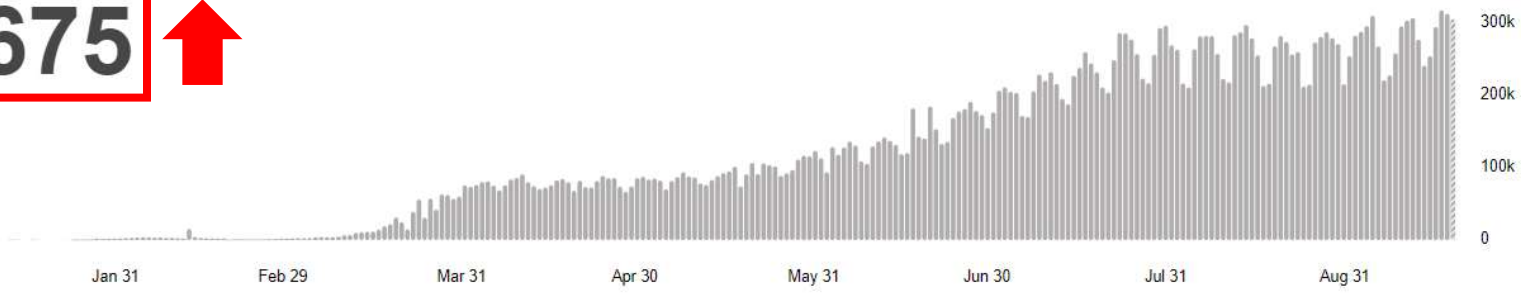
2020.02 **CE registration /KFDA EUA Approved**
- M nCoV Real-time detection kit

I. About SARS-CoV-2

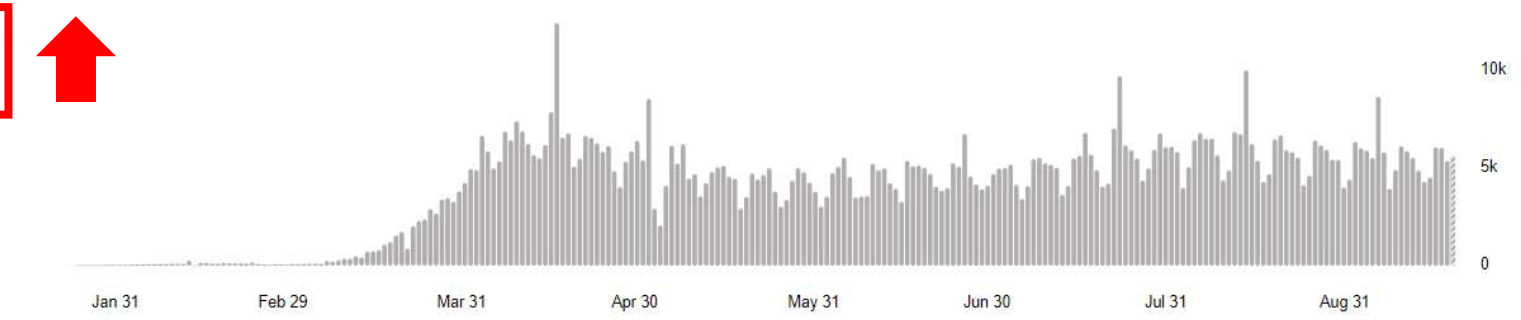
WHO Coronavirus Disease (COVID-19) Dashboard

Global Situation

30,675,675
confirmed cases



954,417
deaths



Source: World Health Organization
Data may be incomplete for the current day or week.

Data last updated: 2020.09.20 1:08pm CEST Overview

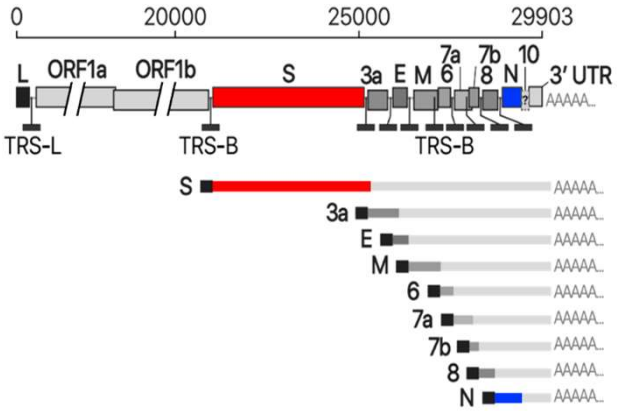
Reference: https://covid19.who.int/

Confirmed cases and deaths are continuously increasing.

General features of SARS-CoV-2

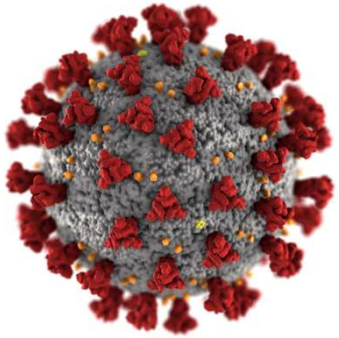
Genome

- Coronavirus carry the largest genomes among all RNA virus families.
- Positive-sense, single-stranded RNA genome of ~30 kb
- **The genomic RNA is protected by nucleocapsid protein**.

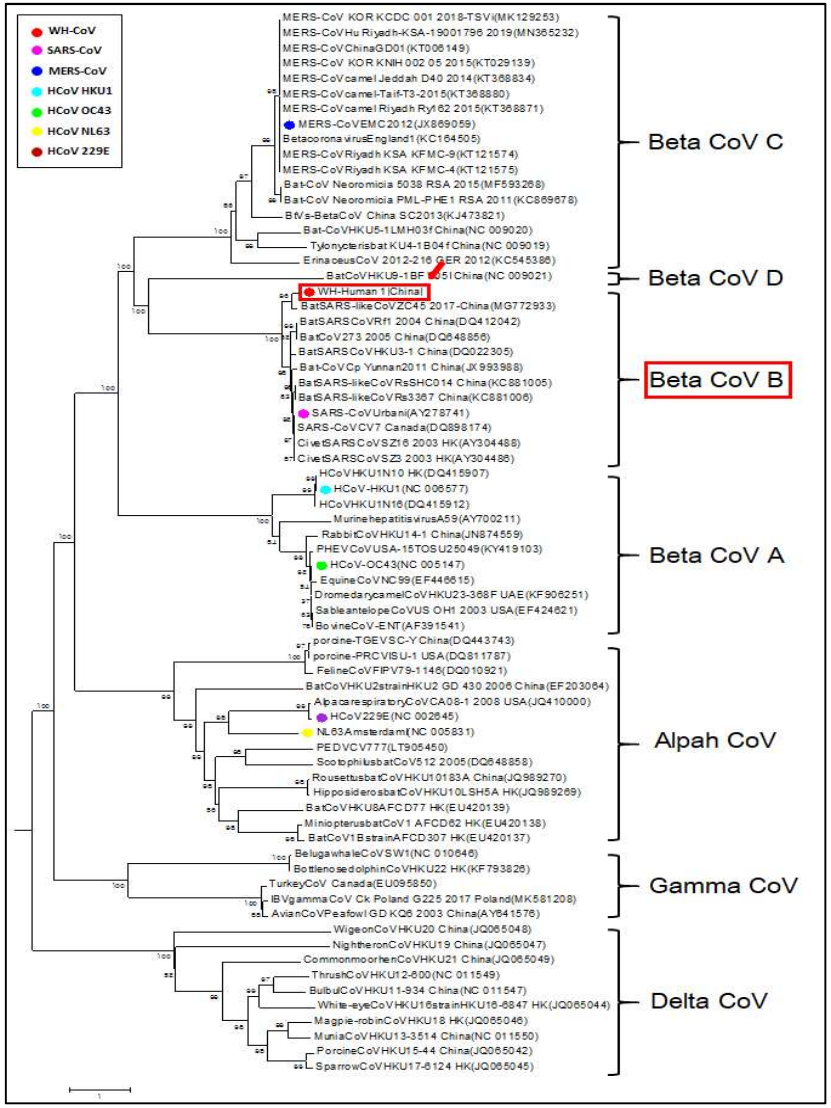


Virion

- Genomic RNA is packaged by the structural proteins to assemble virions. (Diameter : 75 - 160 nm)
- There are **4 structural proteins** and several accessory proteins.
  - **Nucleocapsid protein**
  - **Spike protein**
  - **Membrane protein**
  - **Envelope protein**



Phylogenetic Systematics of SARS-CoV-2



Source : Korean CDC

- **Corona Virus**
  - **Alpha, Beta**
  - **Gamma, Delta**

- **Beta coronavirus is divided into A~D lineages**

  A: OC43, HKU1

  B: SARS-CoV (Severe acute respiratory syndrome coronavirus)

  C: MERS-CoV (Middle East respiratory syndrome coronavirus)

- **SARS-CoV-2**: a member of the subgenus *Sarbecovirus*

  (**Beta-CoV lineage B**)

Virus Classification			Cellular receptor	Symptoms
Genus	**subgroup**	**Strain**		
α	1b	Human CoV-229E	Human Aminopeptidase N	Mild respiratory tract infections
		Human CoV-NL63	ACE2	
β	2a	Human CoV-HKU1	9-O-Acetylated sialic acid	
		Human CoV-OC43	9-O-Acetylated sialic acid	
	2b	SARS-CoV	ACE2	**Severe** acute respiratory syndrome
		SARS-CoV-2	ACE2	
	2c	MERS-CoV	DPP4	

II. SARS-CoV-2 Specimen

SARS-CoV-2 Specimen

- **Type of specimen**

Both specimens should be collected from lower and upper respiratory tract

No.	Types of specimen		Container
1	Lower respiratory tract	Sputum (not mandatory)	**Container** Sterilized tube (50 ㎖) **Volume** >3㎖
2	Upper respiratory tract	Nasopharyngeal swab Oropharyngeal swab	**Container** Both NP and OP swabs should be collected to the same medium containing viral transport media (VTM)

Table. Types of sample for COVID-19

- **How to collect 'Upper respiratory tract specimen'**

1. Nasopharyngeal swab can be collected by scratching the nasopharynx through the nostril.

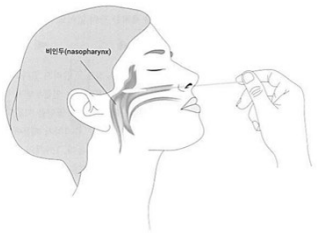


Figure. How to collect the NP swab

2. Oropharyngeal swab can be collected by scratching the pharynx having your tongue down.

Figure. How to collect the OP swab

✓ **Collect the NP and OP swabs in one VTM.**

Storage of Specimen

Table 1. Specimens to be collected from symptomatic patients
Guidance on specimen collection (adapted from reference 5)

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
(Endo)tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	
Sputum	sterile container	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	Ensure the material is from the lower respiratory tract
Tissue from biopsy or autopsy including from lung	sterile container with saline	4 °C	≤24 hours: 4 °C >24 hours: –70 °C	
Serum (2 samples acute and convalescent possibly 2-4 weeks after acute phase)	Serum separator tubes (adults: collect 3-5 ml whole blood)	4 °C	≤5 days: 4 °C >5 days: –70 °C	Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later
Whole blood	collection tube	4 °C	≤5 days: 4 °C >5 days: –70 °C	For antigen detection particularly in the first week of illness
Urine	urine collection container	4 °C	≤5 days: 4 °C >5 days: –70 °C	

Reference: WHO/2019-nCoV

III. STANDARD M nCoV 1-Step RT-PCR Protocol

Prior to Real-Time PCR

1. Specimen pretreatment

- **NP and OP swabs**

  extract the nucleic acids by re-suspending from the VTM or PBS

- **Sputum**

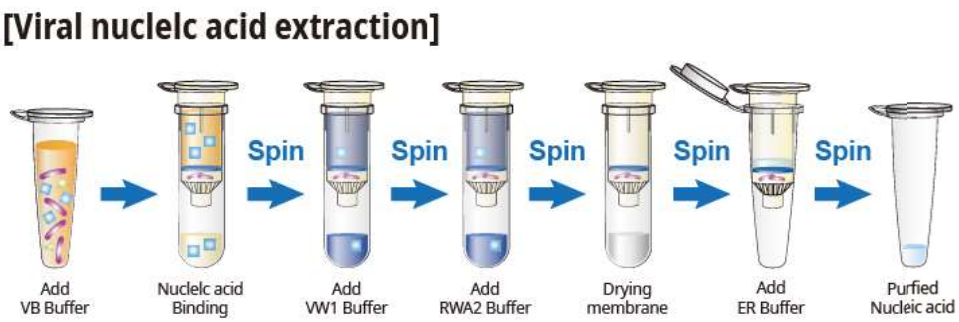
  Add the same amount of 2X sputum lysis buffer and shake the incubation for 30 minutes

2. Extraction of nucleic acids

Commercially available viral RNA extract reagents or automation instruments can be used.

Follow the instructions given by the manufacturer.

Recommended kit: **STANDARD™ M SPIN-X Viral RNA Extraction Kit (Cat. no. 11SPN10)**



*** Setting values might be different depending on sites (hospitals)**

Test method recommend by WHO

Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases

Interim guidance
17 January 2020

WHO/2019-nCoV/laboratory/2020.3

World Health Organization

putting on a disposable particulate respirator, always check the seal/fitness. Be aware that the presence of facial hair (e.g. beard) may prevent a proper respirator fit for the wearer. In some countries, a powered air-purifying respirator (PAPR) is utilized instead of a respirator.

- Eye protection (i.e. goggles or a face shield).
- Clean, long-sleeved gown and gloves. If gowns are not fluid resistant, a waterproof apron should be used for procedures where it is expected that fluid might penetrate the gown

• Perform procedures in an adequately ventilated room: at a minimum natural ventilation with at least 160l/s/patient air flow, or negative pressure rooms with at least 12 air changes per hour and controlled direction of air flow when using mechanical ventilation
• Limit the number of persons present in the room to the minimum required for the patient's care and support; and
• Follow WHO guidance for steps of donning and doffing PPE. Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal.
• Waste management and decontamination procedures: Ensure that all materials used is disposed appropriately. Disinfection of work areas and decontamination of possible spills of blood or infectious body fluids should follow validated procedures, usually with chlorine-based solutions.

Specifics for transport of samples to laboratory:
• Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
• Follow the requirements in the national or international regulations for the transport of dangerous goods (infectious

5.Testing of 2019-nCoV in reference laboratories

2019-nCoV testing for patients that meet the suspected case definition

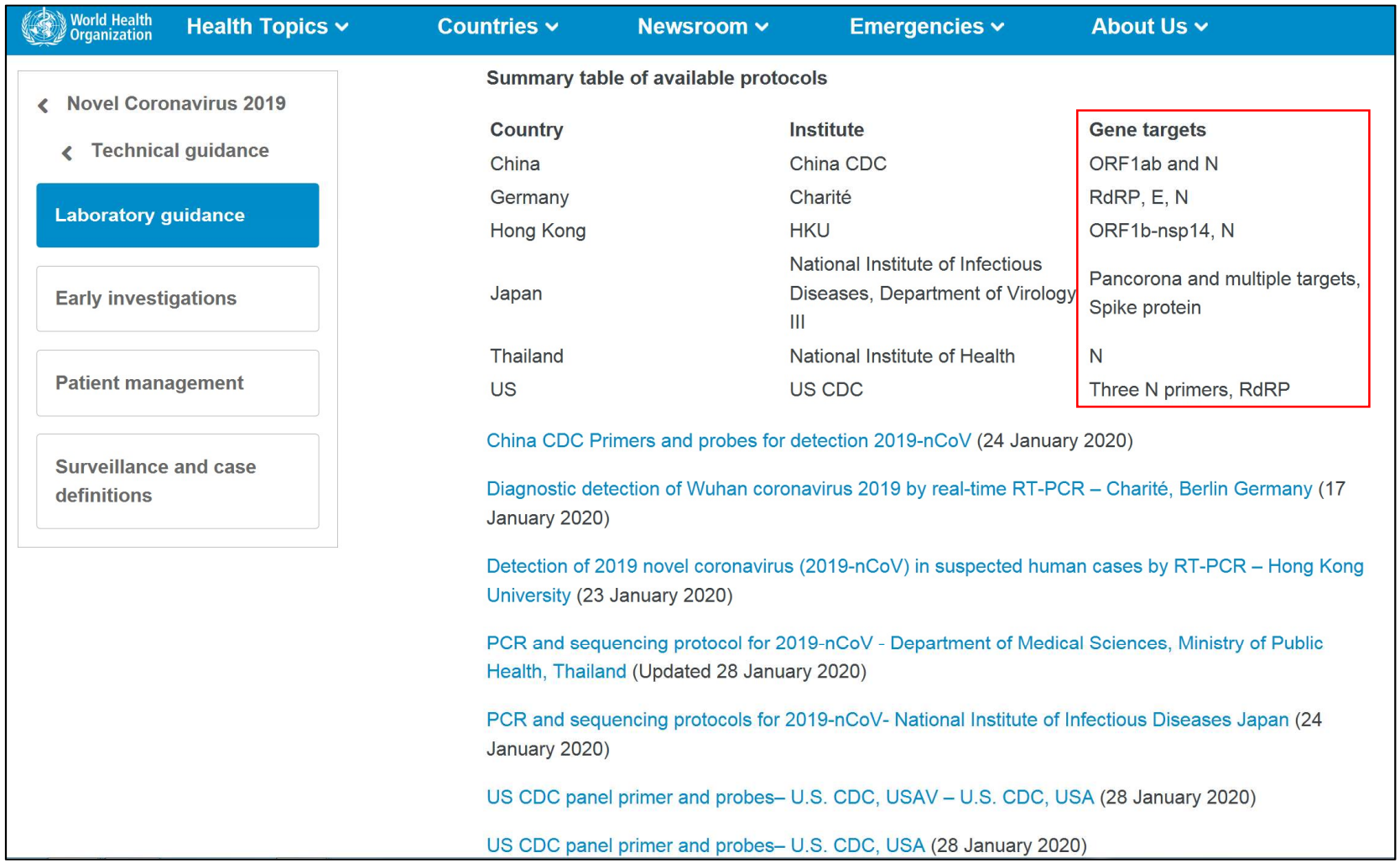
Patients that meet the case definition for suspected 2019-nCoV should be screened for the virus with PCR (details below). If case management requires, screen also for other common causes of respiratory illness according to local guidelines (1,5,7). As coinfections can occur, all patients that meet the case definition should be tested for 2019-nCoV regardless of whether a conventional respiratory pathogen is found. If testing does not occur in an expert/reference laboratory it is encouraged to send the sample for confirmation to a regional, national or international reference laboratory with pan-coronavirus or specific 2019-nCoV detection capacity. WHO can assist Member States to identify laboratories able to provide this support.

Nucleic acid amplification tests for 2019-nCoV

As sequence information from the 2019-nCoV has recently been made available, PCR assays can be designed to detect these sequences. PCR assay design optimization can be a complicated process, and a useful option is to contact the experienced laboratories publicizing their assays and request access to their assay chemistries.

✓ **WHO recommended rRT-PCR for SARS-CoV-2 Laboratory testing.**

WHO recommend primers/probes



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Novel Coronavirus 2019

Technical guidance

Laboratory guidance

Early investigations

Patient management

Surveillance and case definitions

Summary table of available protocols

Country	Institute	Gene targets
China	China CDC	ORF1ab and N
Germany	Charité	RdRP, E, N
Hong Kong	HKU	ORF1b-nsp14, N
Japan	National Institute of Infectious Diseases, Department of Virology III	Pancorona and multiple targets, Spike protein
Thailand	National Institute of Health	N
US	US CDC	Three N primers, RdRP

China CDC Primers and probes for detection 2019-nCoV (24 January 2020)

Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR – Charité, Berlin Germany (17 January 2020)

Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (23 January 2020)

PCR and sequencing protocol for 2019-nCoV - Department of Medical Sciences, Ministry of Public Health, Thailand (Updated 28 January 2020)

PCR and sequencing protocols for 2019-nCoV- National Institute of Infectious Diseases Japan (24 January 2020)

US CDC panel primer and probes– U.S. CDC, USAV – U.S. CDC, USA (28 January 2020)

US CDC panel primer and probes– U.S. CDC, USA (28 January 2020)

KCDC recommend primers/probes

2019-nCoV 검출 real-time RT-PCR 프로토콜(KCDC v1.5)

(질병관리본부 감염병분석센터)

WHO 발표('20.1.17. updated)한 검출법으로 설정한 프로토콜임

I Primer 및 Proe 정보

□ 염기서열 정보

Primer & Probe	Sequence (5'-3')	Target gene
RdRP_SARSr-F2	GTGARATGGTCATGTGTGGCGG	RdRP
RdRP_SARSr-R1	CARATGTTAAASACACTATTAGCATA	
RdRP_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BHQ	
E_Sarbeco_F1	ACAGGTACGTTAATAGTTAATAGCGT	E gene
E_Sarbeco_R2	ATATTGCAGCAGTACGCACACA	
E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BHQ	

* WHO 권고한 BBQ → BHQ로 변경하여 조건 설정함

Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR – Charité, Berlin Germany (17 January 2020)

Assay/ Use	Oligonucleotide ID	Sequence (5'–3')	Comment
RdRP gene	RdRP_SARSr-F2	GTGARATGGTCATGTGTGGCGG	use 600 nM per reaction
	RdRP_SARSr-R1	CARATGTTAAASACACTATTAGCATA	use 800 nM per reaction
	RdRP_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe, will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs use 100 nM per reaction and mix with P2
E gene	E_Sarbeco_F1	ACAGGTACGTTAATAGTTAATAGCGT	use 400 nM per reaction
	E_Sarbeco_R2	ATATTGCAGCAGTACGCACACA	use 400 nM per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	use 200 nM per reaction

* RdRp primer/probe2 : nCoV specific detection
** E primer/probe : Beta CoV specific detection

IV. STANDARD M nCoV Real-time Detection kit

Principle of STANDARD M nCoV Real-time Detection Kit

- **측정원리**

① Based on TaqMan probe real-time fluorescent PCR technology

② Fluorescence intensity increases in proportion to the amount of RNA which amplified in each cycle of PCR

③ Reading device detects the fluorescence color and checks the result

- **Target별 형광**

Detection target	Reporter
ORF1ab (RdRP) gene	FAM
E gene	JOE (VIC 또는 HEX)
Internal reference	CY5

Kit Contents

	Kit Contents (96T/kit)	Quantity
1	**2019-nCoV Reaction Solution**	750㎕/vial x 2
2	**RTase Mix**	630㎕/vial x 1
3	**2019-nCoV Positive control**	600㎕/vial x 1
4	**Negative control**	600㎕L/vial x 1
5	**Internal control**	525㎕/vial x 1
6	**ROX***	55㎕/vial x 1
7	**Instructions for Use**	1

- Purpose: COVID-19 RNA detection
- Nucleic acid amplification reaction
- Test time: 90~ mins
- **Sensitivity 100%**
- **Specificity 100%**

Cat. no.: 11NCO10

96 Tests/Kit

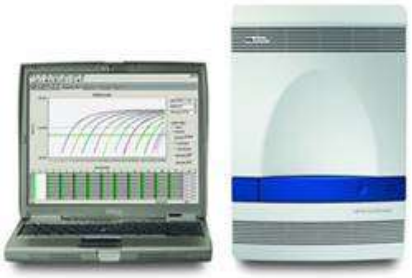
Storage: -25°C ~ -15°C

Stability: 12 months

A Wide Range of Instrument Compatibility

Instrument Compatibility | instruments mainly used in laboratories

CFX 96
Bio-Rad



ABI 7500/7500 Fast
Applied Biosystems

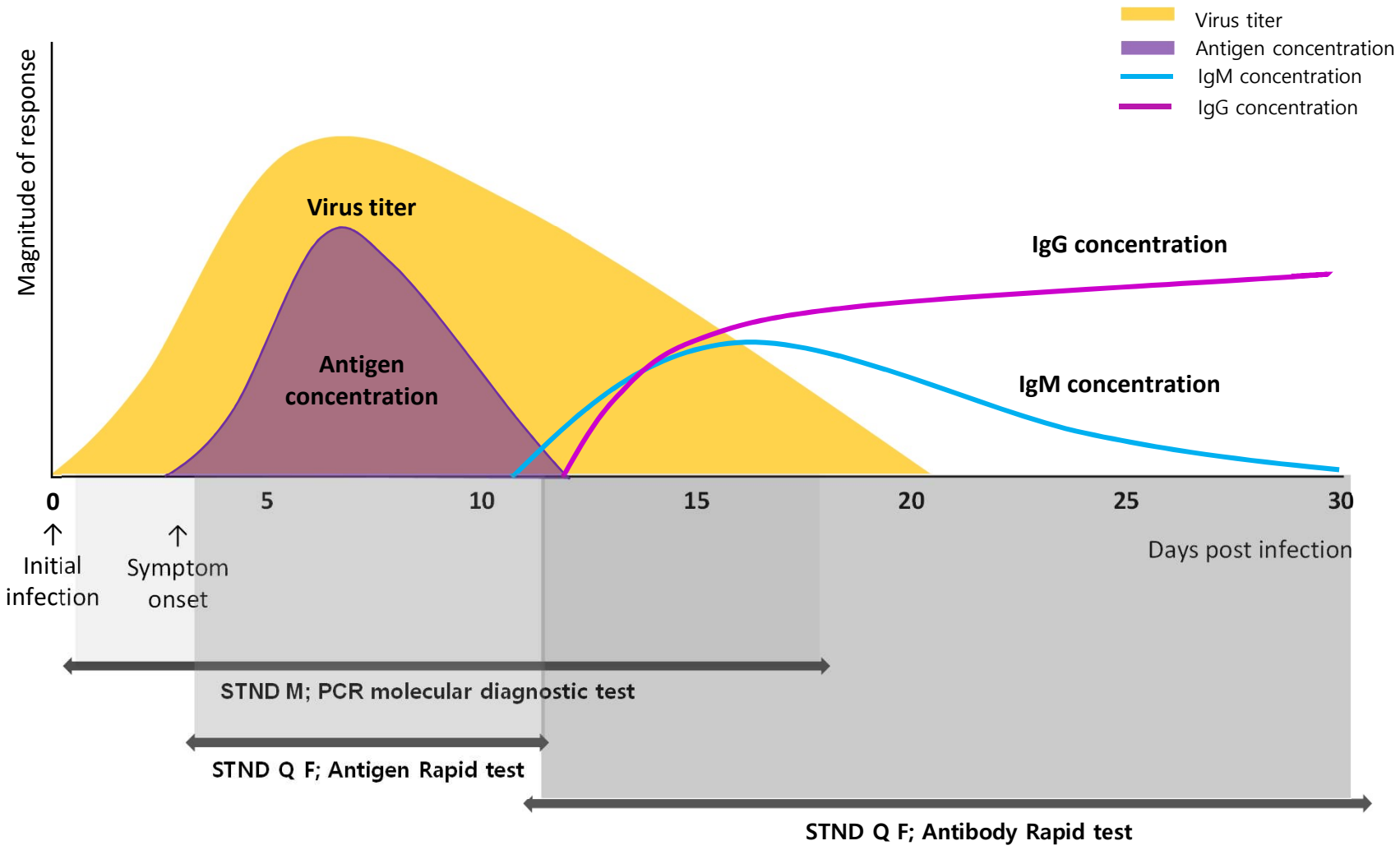
LightCycler 480
Roche

STANDARD M nCoV Real-Time Detection kit

Competitors

V. COVID-19 products

Total solution for COVID-19



Reference :
1. Chen J, Lau YF, Lamirande EW, Paddock CD, Bartlett JH, Zaki SR, Subbarao K. Cellular immune responses to severe acute respiratory syndrome coronavirus (SARS-CoV) infection in senescent BALB/c mice: CD4+ T cells are important in control of SARS-CoV infection. J Virol. 2010 Feb;84(3):1289-301. doi: 10.1128/JVI.01281-09. Epub 2009 Nov 11.
2. Hsueh PR, Huang LM, Chen PJ, Kao CL, Yang PC. Chronological evolution of IgM, IgA, IgG and neutralisation antibodies after infection with SARS-associated coronavirus. Clin Microbiol Infect. 2004 Dec;10(12):1062-6.

COVID-19 representative products

STANDARD M
nCoV Real-Time Detection kit CE

- **Detection:** COVID-19 RNA
- **Test time:** within 60~90 mins
- **Sensitivity:** 100%
- **Specificity:** 100%

FDA EUA Approved
Korea EUA Approved

STANDARD F
COVID-19 Ag FIA CE

- **Detection:** COVID-19 antigen
- **Test time:** within 30 mins
- **Sensitivity:** 100%
- **Specificity:** 100%

STANDARD F
COVID-19 IgM IgG Combo FIA CE

- **Detection:** COVID-19 antibody
- **Test time:** within 15 mins
- **Sensitivity:** 94.41%
- **Specificity:** 90.62%

STANDARD M
STANDARD F
STANDARD E
STANDARD Q
COVID-19 TOTAL SOLUTION

STANDARD E
COVID-19 Total Ab ELISA CE

- **Detection:** COVID-19 antibody
- **Sensitivity:** 100%
- **Specificity:** 98%

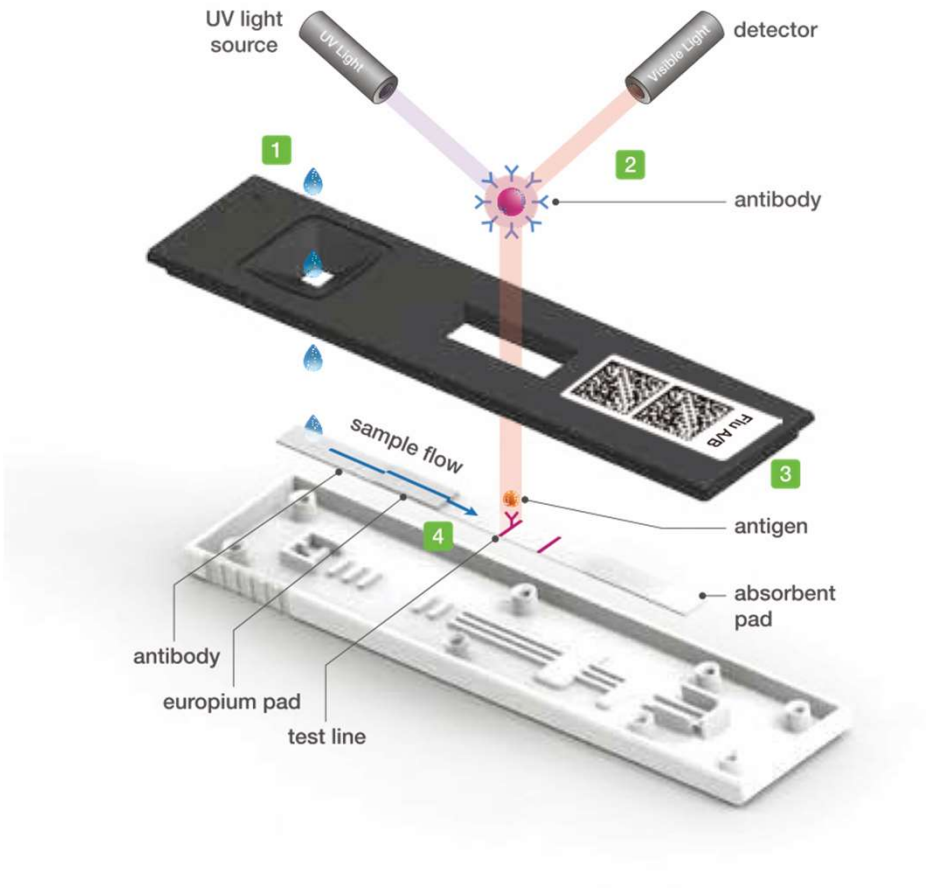
STANDARD Q
COVID-19 Ag CE

- **Detection:** COVID-19 antigen
- **Test time:** within 30 mins
- **Sensitivity:** 89%
- **Specificity:** 100%

STANDARD Q
COVID-19 IgM IgG Combo CE

- **Detection:** COVID-19 antibody
- **Test time:** within 10 mins
- **Sensitivity:** 94.5%
- **Specificity:** 95.7%

Principle of STANDARD F test – Instrument detection



- Fluorescent Immunoassay(FIA) is a different type of immunoassay based on **nitrocellulose membrane**.
- ***The fluorescent beads*** enable **highly sensitive detection** of the target analytes, antigens and antibodies than traditional immunochromatographic test.
- Simple lateral flow assay with a powerful but low cost analyzer like a **STANDARD F** improves assay performance.

STANDARD F Fluorescent Immunoassay | Available NOW

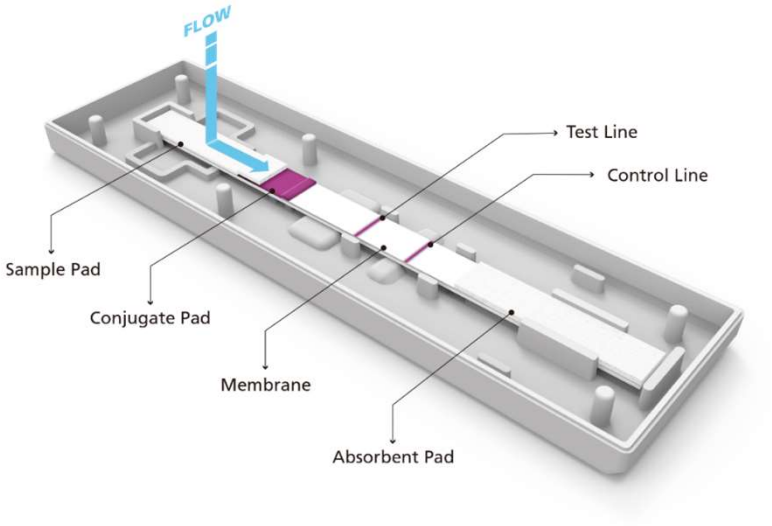
Products

- Quantitative: Inflammation, Hormone etc.
- Qualitative: Respiratory, Vector borne, Blood borne etc.

Benefits

- High sensitivity using fluorescent immunoassay
- Fast detection
- Data recognition through no-coding 2D barcode system
- Automatically print a patient's name
- LIS/HIS connection is available
- Expandable (Various kinds of products can be measured with one analyzer)
- F2400 : 70 tests/hour

Principle of STANDARD Q Rapid test – Eye test



1. **The Sample Pad**
   - Receives the test samples
   - Distributes the sample into the strip uniformly
   - Contains chemicals to modify sample composition
   - May act as a filter
2. **The Conjugate Pad**
   - Holds the detector reagent in a dry state
   - Does not interfere with detector reagent stability
   - Releases the detector reagent quickly, consistently, and quantitatively
   - Provides uniform transfer of detector reagent to the membrane
3. **The Membrane**
   - The surface used to hold capture reagents(e.g., antibodies)
   - The surface upon which immunocomplexes form(i.e., signals)
   - Controls overall flow rate of the system
   - Composed of nitrocellulose
4. **The Absorbent Pad**
   - Serves as the sink for the sample
   - Determines the total sample volume that can be processed
   - Typically not chemically altered

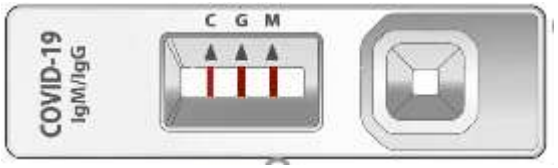
STANDARD Q Rapid Test | Available NOW

Products

Vector borne, Blood borne, Respiratory, Gastrointestinal, Hemorrhagic fever

Vector borne	Blood borne	Respiratory
• Malaria P.f Ag WHO PQ	• HIV/Syphilis Combo	• COVID-19 Ag
• Malaria P.f/P.v Ag WHO PQ	• HIV 1/2 Ab (3line)*	• COVID-19 IgM/IgG
• Malaria P.f/Pan Ag WHO PQ	• HIV 1/2 Ab (4line)	• Influenza A&B* 1st
• Dengue Duo	• Syphilis Ab	• Strep A
• Dengue NS1 Ag	• HCV Ab* WHO PQ	• RSV Ag*
• Dengue IgM/IgG	• HBsAg*	• *Legionella* Ag*
• Chikungunya IgM/IgG	• Anti-HBs*	• *S. pneumoniae* Ag*
• Zika IgM 1st	• HAV IgM	• MERS-CoV Ag 1st
• Yellow fever IgM		• TB MPT64 Ag
• Dengue/Chikungunya Trio		• Adeno Respi Ag
• Zika/Dengue Fast Trio		
• ZIKV/DENV/CHIKV Fast Quad		
• Arbo Panel I (Z/D/C/Y) 1st		
• Tsutsugamushi IgM/IgG		
• Leptospira IgM/IgG		
• Malaria/CRP Duo		

Gastrointestinal	Hemorrhagic fever
• Rotavirus Ag*	• Ebola Zaire Ag
• Rota/Adeno Ag*	
• Norovirus Ag	
• *H. pylori* Ab	
• *H. pylori* Ag	



Benefits

- **Fast detection of disease using very small specimen**
- **Simple and easy to use**
- **High sensitivity and specificity with low cost**
- **No instrument is needed.**
- **Superb development ability to cope with new infectious diseases quickly**
- **Continuous aid from international funds to combat infectious disease in low income countries**

VI. Global business strategy

1.Registration

SD BIOSENSOR

Registration

KCDC - EUA

MFDS

CE

US FDA EUA

WHO PQ EUL

Registration

COVID-19 products

품목	진행사항
STANDARD M nCoV Real-time Detection Kit	2020.02 **CE registration** 2020.02 **KCDC EUA approved** 2020.02 **Export license** 2020.04 **FDA EUA approved** 2020.08 **KFDA 제조허가 완료**
STANDARD Q COVID-19 Ag test	2020.03 **CE registration** 2020.03 **Export license** **US FDA EUA in progress**
STANDARD Q COVID-19 IgM/IgG Combo	2020.03 **CE registration** **US FDA EUA in progress**
STANDARD F COVID-19 Ag test	2020.03 **CE registration** 2020.03 **Export license**
STANDARD F COVID-19 IgM/IgG Combo	2020.04 **CE registration** 2020.04 **Export license**

2. Global Distributor

SD BIOSENSOR

Global Sales Networks

Based in South Korea, 3 subsidiaries in India, Indonesia and China.
More than **517** distribution partners in more than **126** countries.
≈ **123 million tests** of COVID-19 products has been sold (2020.09).

North/Central America
- HAITI
- HONDURAS
- JAMAICA
- MEXICO
- PANAMA
- TRINIDAD&TOBAGO
- USA

Europe
- AUSTRIA
- BOSNIA
- BULGARIA
- CROATIA
- CYPRUS
- CZECH
- DENMARK
- FINLAND
- FRANCE
- GERMANY
- GREECE
- ICELAND
- IRELAND
- ITALY
- KOSOVO
- LATVIA
- NETHERLANDS
- POLAND
- PORTUGAL
- ROMANIA
- SLOVAKIA
- SLOVENIA
- SPAIN
- SWITZERLAND
- UK

CIS
- AZERBAIJAN
- GEORGIA
- KAZAKHSTAN
- RUSSIA
- TAJIKISTAN

Asia Pacific
- AUSTRAILIA
- BANGLADESH
- CHINA
- INDIA
- INDONESIA
- JAPAN
- LAOS
- MALAYSIA
- MONGOLIA
- MYANMAR
- VIETNAM
- NEPAL
- NEW ZEALAND
- PAKISTAN
- PHILIPPINES
- SINGAPORE
- SOUTH KOREA
- SRI LANKA
- TAIWAN
- THAILAND
- TIMOR

South America
- BOLIVIA
- BRAZIL
- CHILE
- COLOMBIA
- ECUADOR
- PARAGUAY
- PERU
- URUGUAY

Africa
- ALGERIA
- BENIN
- BURKINA FASO
- BURUNDI
- CAMEROON
- CAR
- CHAD
- CONGO
- CÔTE D'LVOIRE
- DRC
- ETHIOPIA
- GHANA
- GUINEA
- KENYA
- LIBERIA
- MADAGASCAR
- MALAWI
- MALI
- MOROCCO
- MOZAMBIQUE
- NAMIBIA
- NIGERIA
- RWANDA
- SENEGAL
- SOUTH SUDAN
- SUDAN
- TANZANIA
- TOGO
- TUNISIA
- UGANDA
- ZAMBIA
- ZIMBABWE

Middle East
- AFGHANISTAN
- EGYPT
- IRAN
- IRAQ
- ISRAEL
- JORDAN
- LEBANON
- LIBYA
- QATAR
- SAUDI ARABIA
- TURKEY
- UAE
- YEMEN

3. 국제 기구

SD BIOSENSOR

International organization

FIND

BGMF

WHO

CHAI

UNITAID

PAHO

Etc..

Sales performance

SD BIOSENSOR

Sales performance

FEMA

CNN, one of global broadcasting systems in United States, reported that FEMA (Federal Emergency Management Agency) awarded a contract to SD BIOSENSOR last week to provide coronavirus test kits.

US to receive 750,000 coronavirus tests from South Korea

A member of the Brooklyn Hospital Center COVID-19 testing team calls in the next patient in line, Thursday, March 26, 2020, in the Brooklyn borough of New York.

Washington (CNN) — The United States is turning to South Korea -- a country with an aggressive testing regime that President Donald Trump previously downplayed -- to bring approximately 750,000 more coronavirus tests to the US, according to the Federal Emergency Management Agency.

FEMA, an agency within the US Department of Homeland Security, awarded contracts to manufacturers in South Korea last week to provide approximately 750,000 tests, according to a FEMA spokesperson and federal records.

Over the weekend, the first shipment of 150,000 tests were delivered to the US by SolGent. The next shipment of 600,000 tests will arrive by April 15. They are being provided by two South Korea-based companies, SD Biosensor and Osang Healthcare.

Brazil

STANDARD Q COVID-19 Ag test is being used in Brazil Drive-through to detect COVID-19.

photo & video by local distributor of SD BIOSENSOR

Sales performance

India

ICMR (Indian Council of Medical Research) approved the use of Antigen test of SD BIOSENSOR in terms of early detection of COVID-19 with high specificity. SD BIOSENSOR's STANDARD Q COVID-19 Ag test becomes the first of its kind to get ICMR validation.

ICMR gives nod to antigen-based testing kit for faster diagnosis

Sushmi Dey | TNN | Updated: Jun 16, 2020, 11:46 IST

A- A+

ANI photo.

NEW DELHI: The government's apex research body, Indian Council of Medical Research (ICMR), has recommended use of the first antigen-based testing kit for Covid-19 to enable faster diagnosis at lower rates and without laboratory examinations of samples.

The antigen test — developed by private biotechnology firm SD Biosensor — has also been validated by AIIMS, New Delhi, apart from ICMR and can detect presence of SARS CoV 2 in swab collected from the nose alone.

The test can detect presence of molecules of the pathogen that triggers immune response in Covid-19 infected persons. Maximum duration for interpreting a positive or negative test is 30 minutes through the antigen based kit.

"In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q Covid-19 Ag detection assay as a point of care diagnostic assay for testing...," ICMR said in an advisory recommending the antigen test in combination with the gold standard RT-PCR test.

While no confirmatory tests are required for samples testing positive, ICMR said those who test negative should undergo a RT-PCR test to rule out infection.

Last month, the US Food and Drug Administration also approved an antigen-based test, noting it is a new type of diagnostic test. "Each category of diagnostic test has its own unique role in the fight against this virus. PCR tests can be incredibly accurate, but running the tests and analysing the results can take time. One of the

influenza-like illness (ILI) in containment zones or hotspots and asymptomatic direct and high-risk contacts with co-morbidities of confirmed cases.

In hospitals, the kits are to be used for all symptomatic ILI patients, asymptomatic patients who are hospitalised or seeking hospitalisation for chemotherapy and transplants or those who are over 65 years with co-morbidities.

In view of rising demand for testing, ICMR has also asked other manufacturers, who have antigen detection assays, to come forward for validation.

Reference : times of India

Worldwide covid-19 product donation

Georgia

5,000 tests of STANDARD Q COVID-19 Ag/Ab Total Test

The Ministry of Health Procures 117 000 Rapid Tests under the World Bank Emergency COVID-19 Response Project

News

The Ministry of Health Procures 117 000 Rapid Tests under the World Bank Emergency COVID-19 Response Project

08 July, 2020

The Ministry of Health Procures 117 000 Rapid Tests under the World Bank Emergency COVID-19 Response Project

좋아요 0개 공

Within the framework of the World Bank Emergency COVID-19 Response Project, the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia procured 117 000 rapid tests. 50 000 antigen tests were procured from Korean company „BIOSENSOR" and 67 000 antibody tests from the company „Green lab/Biogene".

As stated by Acting Head of Administration of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia, Tinatin Khardziani the tests will be used with the purpose of epidemiological control among international truck drivers and will be distributed among various medical facilities for testing concrete selected target groups.

"Within the World Bank Emergency COVID-19 Response Project 50 000 Korean antigen tests and 67 000 antibody tests registered by Green lab were procured. I would like to mention, that the company „BIOSENSOR "donated 5000 antigen/antibody tests to the Ministry and I would like to express deep gratitude towards them", - stated Tinatin Khardziani.

Zimbabwe

10,000 tests of STANDARD Q COVID-19 Ag/Ab Total Test

Ministry of Information and Publicity Zimbabwe @Mi... · 7월 15일

His Excellency President @edmnangagwa this afternoon received Covid19 and Cyclone Idai humanitarian aid from several companies at State House. Among those who donated are Angel of Hope, Zundine Trading, Multichoice Zimbabwe, Cure Chem, PPC Zimbabwe and Nkatazo Company.

hoice Zimbabwe chairman Peter Van Deventer (right) presented disp on gowns to President Mnangagwa in Harare yesterday

After post-COVID-19,

STANDARD M10

SD BIOSENSOR

STANDARD M10 | molecular diagnosis

“Versatile POC MDx Platform”

⇒ **NA extraction + Amplification in one platform**

Simple & Fast

Sample in → Result out (**15min – 30min**)

Multiplex

Maximum **12 targets** including control

Various Menus

SARS-CoV-2, **Flu/SARS-CoV-2**

Modular & Scalable

Scalable configuration for customized throughput

All-in-one Cartridge

Nucleic acid extraction / amplification

Modular system

1 Console + Multiple Analyzer

SD BIOSENSOR

Thank You

SD BIOSENSOR, Inc.

Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
sales@sdbiosensor.com | www.sdbiosensor.com

WELLS BIO

The world's best life-caring companion

WELLS BIO

1. Introduce

WELLS BIO, INC

01 체외진단 개발 분야

WELLS BIO

“ 고민감도 종합 진단 솔루션 개발 WELLS BIO”

Access Bio

- 설립: 2002년 ~
- 연간 RDT 생산량: 1억~1억 3천만 테스트
- 주요 제품: 말라리아 RDT, 호흡기 RDT
- WHO인증 말라리아 RDT 성능 세계 1위
- 국제 말라리아 RDT 시장 점유율 세계 1위

면역 진단

전략적 파트너쉽: 안정적 수익 확보

TOP 성능 RDT 기술 확보 + 대량 생산 시스템 구축

고성능 HIV RDT 출시 및 WHO 인증 > 공공시장 진출

대규모 RDT OEM 계약

분자 진단

차별화된 기술 + 상품화 전략: 성장 동력

국가별 맞춤 진단 키트 개발 > 국가기관 공급
글로벌 기업과의 협업 > 선진 민간시장 진출

높은 정확도(고민감도, 특이도)의
고유 원천 기술 플랫폼(SBS) 확보

센서 진단

차세대 종합 진단 솔루션: 시장 혁신

기술 융합을 통한 고민감도 현장 센서 개발

한 플랫폼으로 다수 질병을 진단하는
ONE STEP 진단 플랫폼 개발

“ 고민감도의 현장 진단 PORTABLE 진단 시약 개발”

02 시설 현황 및 제품 현황

시설현황

마곡 R&D 센터

- 소재: 서울특별시 강서구 마곡동
- 연구 개발 (분자진단, 센서, RDT)
- ISO 13485 인증 완료
- GMP 인증 완료

고령 생산 공장

- 소재: 경상북도 고령
- 생산 (RDT, 센서)
  - ✓RDT 생산 CAPACITY
    : 연간 2억 테스트 (~2020)
  - ✓자동화 생산 시설
- ISO 13485 인증 완료
- GMP 인증 완료

주요 제품 및 인증 현황

	면역진단	분자진단	바이오센서
제품 포트폴리오	• HIV RDT • DENGUE RDT • FLU RDT 등 8종	• HPV 14종 동시 진단 • STD 12종 동시진단 • ZIKA, DENGUE 등 6종	• G6PD Biosensor • Biosensor 1 등 4종
인증 현황	• 국내허가 11 개 • 수출허가 13 개 • CE 18 개	• 국내허가 11 개 • 수출허가 9 개 • CE 7 개	• 국내허가 13 개 • 수출허가 6 개 • CE 11 개

1. Molecular Diagnostics

유전자 기반의 진단방법: 유전자 추출+PCR 증폭+형광 검출

01 Molecular Diagnostics

분자진단 이란?

샘플 채취 › 유전자 채취 › 유전자 증폭 › 유전자 진단 › 질병유무확인

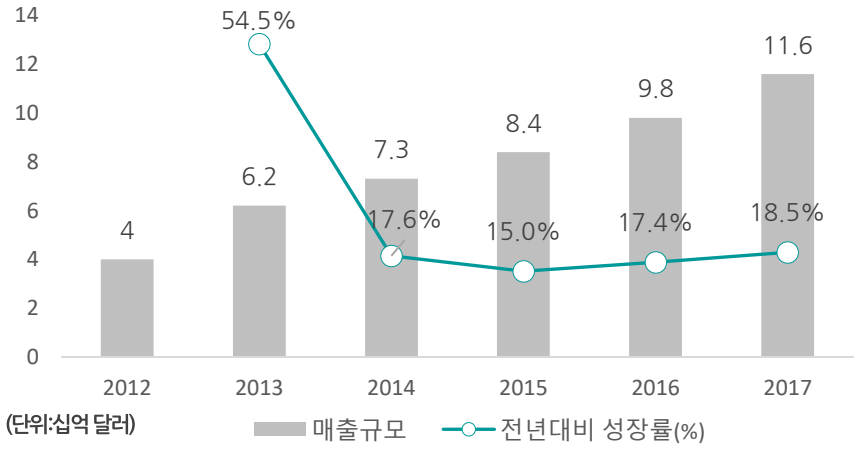
진단 시약

정밀 진단 가능

조기 진단 가능

개인 맞춤 치료 및 조기 치료 가능

분자진단 시장 규모 및 전망



Ref.: S&T Market Report, Vol.40, 2015.03 체외진단기기 시장동향

- 전세계 분자진단 시장규모: USD116억 (2017년)
- 성장률: CAGR 15.2% ('12~'17년)

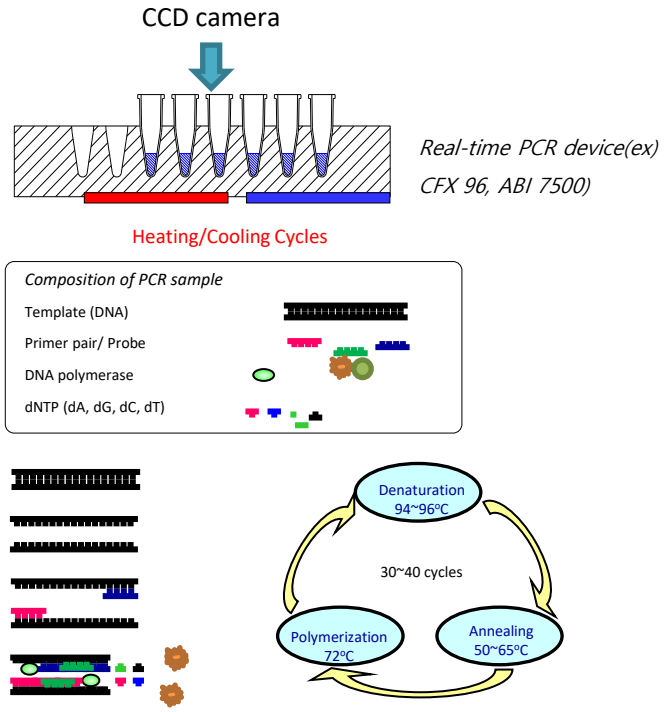
분자진단 시장의 급속한 성장
> 높은 성장률/ 큰 시장규모

Ref.: Molecular Diagnostics Market by Application (Infectious Disease (Hepatitis, HIV), Oncology, Genetic Testing), Technology (PCR, DNA Sequencing & NGS), End User (Hospital/Academic Laboratory), Product & Service (Reagent, Software) - Global Forecast to 2023

02 About Molecular Diagnosis/PCR

RT-PCR

- *PCR* (Polymerase Chain Reaction) is a method for amplifying target nucleic acid sequences, that has a wide spectrum of applications in life science R&D and diagnosis.
- Our RT-PCR technology is based on '*Thermal Cycling and TaqMan probe*' process consisting of denaturation (94~96°C), annealing (50~65°C), and polymerization (72°C) process.
- About 30 to 40 thermal cycles that typically take about 1 to 2 hours, are repeated to achieve amplification of a factor of several millions or higher.

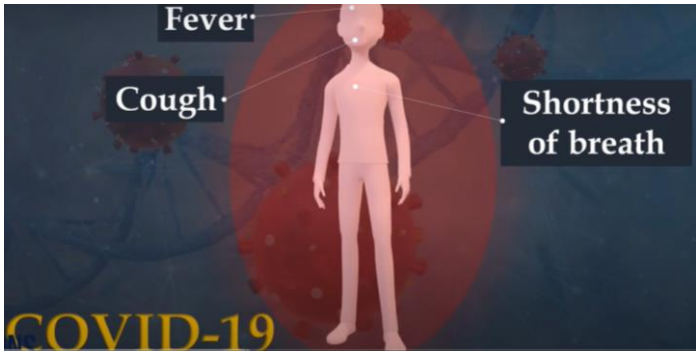


03 About COVID-19 Test

Major Specifications of careGENE™ COVID-19 Diagnostics

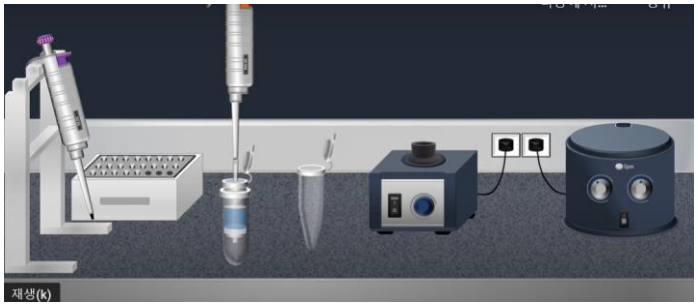
VIDEO

Symptom

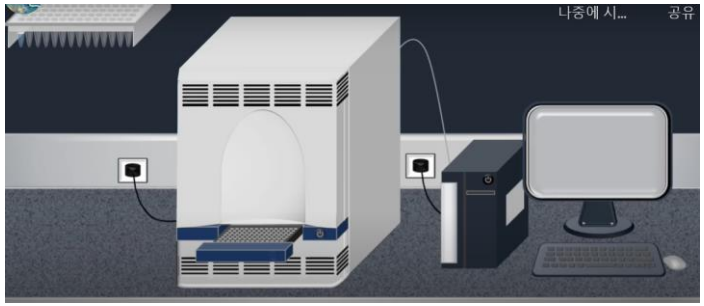


Sample collection

RNA extraction



Real-Time PCR Analysis



04 About COVID-19 Test

Total solution of RT-PCR with careGENE™ COVID-19

Automated sample preparation Instrument

KingFisher Flex®
& Extraction Kit

Processing volume range
- PCR plate (20–100 µL*), skirted
- 20–200 µL: 96-well plate
- 50–1,000 µL: 96 deep-well plate
- 200–5,000 µL: 24 deep-well plate

Samples per run: 24 or 96

Run time: 35~60minutes

RT-PCR reagent

careGENE™ COVID-19

PCR reagent
Automatic mix and dispensing

Liquid Handler
S2 Pipettor

Preparation: Reservoir to 96 plate
Program: Tablet PC

Dispensing time:
2~3 min/4x96 well plate

RT-PCR

QuantStudio® 5

Sample capacity (wells): 96 or 384

Optical detection
96 wells: 6 decoupled filters
384 wells: 5 coupled filters

Run time: <30-minute

Sensitivity
Detect differences as small as 1.5-fold in target quantities in single-plex reaction

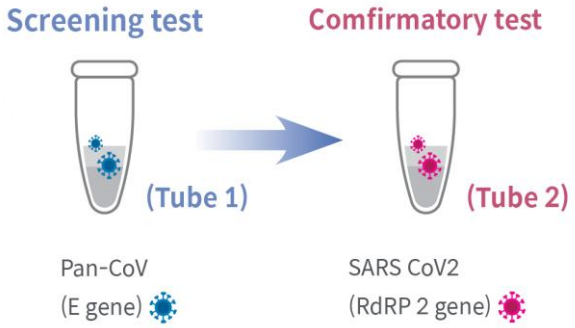
Average Processing Time: 100T per hour

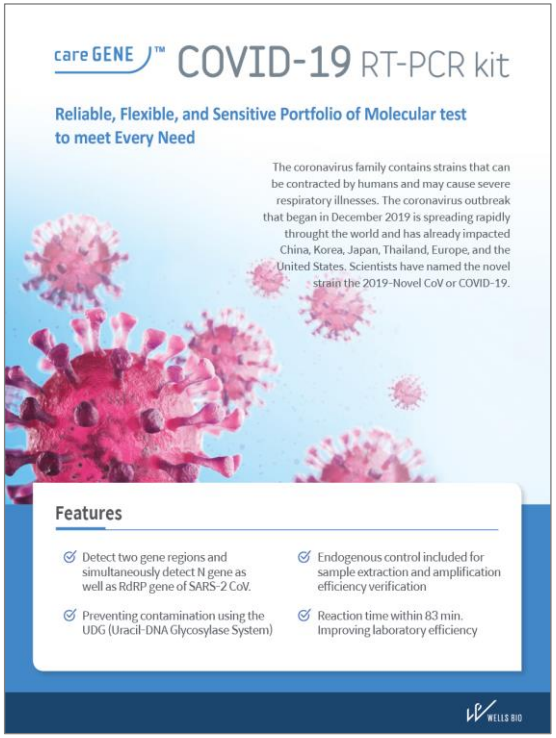
05 COVID-19 RT-PCR Development

한국화학연구원과 신종코로나 분자진단키트 공동개발: 검체 제공

2020.01월 말 신종코로나 분자진단키트 공동 개발 1종 완료(질병관리 본부 ver.)

N-CoV RT-PCR kit





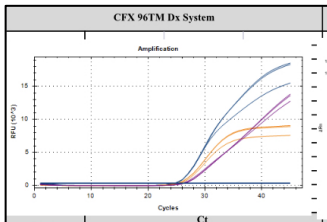
2020.02월 말 신종코로나 멀티플렉스 분자진단키트 개발 완료(MFDS, FDA 제출)

COVID-19 RT-PCR kit

Fig 1. Excellent results with real specimen

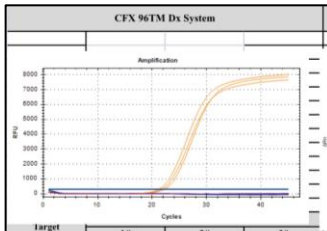
- ✓ **Positive – Superior Sensitivity 10 copies/uL, Used 10㎕ RNA sample**
- ✓ **Negative – Non-Specific reaction, No Abnormal Signal**

Positive Sample



CFX 96TM Dx System				Applied Biosystems 7500 Real-Time PCR Instrument System			
Target	Ct			Target	Ct		
	1#	2#	3#		1#	2#	3#
ROX (IC)	25.19	24.9	24.95	ROX (IC)	25.85	25.89	25.29
FAM (N-gene)	24.35	24.41	24.33	FAM (N-gene)	25.40	24.71	23.20
Cy5 (R-gene)	25.76	26.13	26.07	Cy5 (R-gene)	26.23	25.71	23.68

Negative Sample



CFX 96TM Dx System				Applied Biosystems 7500 Real-Time PCR Instrument System			
Target				Target			
	1#	2#	3#		1#	2#	3#
ROX (IC)	21.74	22.21	21.21	ROX (IC)	20.324	20.041	20.787
FAM (N-gene)	N/A	N/A	N/A	FAM (N-gene)	N/A	N/A	N/A
Cy5 (R-gene)	N/A	N/A	N/A	Cy5 (R-gene)	N/A	N/A	N/A

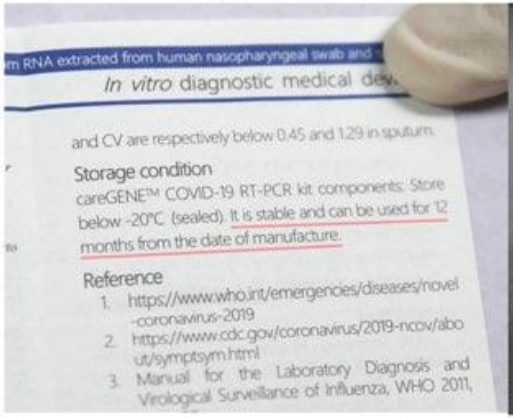
Fig 2. About Kit Components

careGENE™ COVID-19 RT-PCR kit Products

Manufacture date : 2020.05.18

Components

Storage condition



Storage Room

Fig 3. GMP Facillity

WELLS BIO

WELLS BIO GMP facility

www.wellsbio.net

WELLS BIO

Dispensing process for molecular diagnostics products

(COVID-19 RT-PCR kit , N-CoV RT-PCR kit)

WELLS BIO

2020/01/22 정보 확보-Primer design 논문 참고(NCBI, Sequence)

2020/01/27 질병관리 본부 소집 미팅 공동 대응 요청/ 질본 프로토콜 공개/ 긴급사용승인 예정

2019-nCoV 검출 real-time RT-PCR 프로토콜(KCDC v1.5)

(질병관리본부 감염병분석센터)

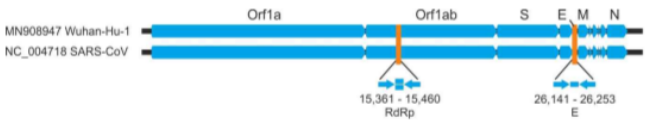
WHO 발표('20.1.17. updated)한 검출법으로 설정한 프로토콜임

I Primer 및 Proe 정보

□ 염기서열 정보

Primer & Probe	Sequence (5'-3')	Target gene
RdRP_SARSr-F2	GTGARATGGTCATGTGTGGCGG	RdRP
RdRP_SARSr-R1	CARATGTTAAASACACTATTAGCATA	
RdRP_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BHQ	
E_Sarbeco_F1	ACAGGTACGTTAATAGTTAATAGCGT	E gene
E_Sarbeco_R2	ATATTGCAGCAGTACGCACACA	
E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BHQ	

* WHO 권고한 BBQ → BHQ로 변경하여 조건 설정함



□ 결과 해석(판정)

- 2019-nCoV 특이검출용(RdRp-nCoV): RdRP_SARSr_F2 + R1 +P2
- Beta CoV 검출용(E_Sarbeco): E_Sarbeco_F1 + R2 + P1

II 시약 조성 및 PCR 조건

□ Primer 및 prober 조성

- Primer 농도: stock 10pmol/㎕ → 1㎕
- Probe 농도: stock 10pmol/㎕ → 0.5㎕

□ 시약 조성(AgPath-ID™ One-Step RT-PCR, ThermoFisher, AM100

○ Mixture for RT-PCR

Component		Volume
RT-PCR master mix (AgePath-ID)	2X RT-PCR Buffer	12.5 ㎕
	Primers (F/R)	2.0 ㎕
	TaqMan probe	0.5 ㎕
	25X RT-PCR Enzyme Mix	1.0 ㎕
RNA sample		5.0 ㎕
RNase free water		4.0 ㎕
Total volume per reaction		25.0 ㎕

□ Real-time RT-PCR 조건

Step	stage	Cycles	Temperature	time
Reverse transcription	1	1	50 ℃	30 min
RT-inactivation / initial denaturation	2	1	94 ℃	10 min
Amplification	3	40	95 ℃	15 sec
			60 ℃	1 min

* Applied Biosystems ABI 7500 Fast

07 Molecular Diagnostics/ COVID-19 RT-PCR

- 2020/01/28 긴급사용승인 공고
- 2020/01/30~2월28일 긴급사용승인 접수
- 2020/05월30일 긴급사용승인 평가 마감

1월30일~2월 초에 접수한 회사에 대한 평가는 빨리 진행 함.

그 이후에는 평가가 매우 느리게 진행됨.

결국 개발 속도가 매우 중요한 상황이였음.

신종 감염병을 개발을 신속히 하기 위한 전제 조건

- 전체 서열 공개
- 신종바이러스 특이적인 유전자 부위의 특정
- 다양한 환자에서의 in-silico reactivity 확인이 매우 중요
- 유사 바이러스와의 교차 반응성에 대한 검증

Prepare the genomic sequences of the organisms that may show the cross-activity with the careGENE™ COVID-19 RT-PCR kit on the NCBI GENOME website (https://www.ncbi.nlm.nih.gov/genome).

3.1.1. Access the NCBI GENOME website and enter the organism name you want to identify the cross-reactivity.

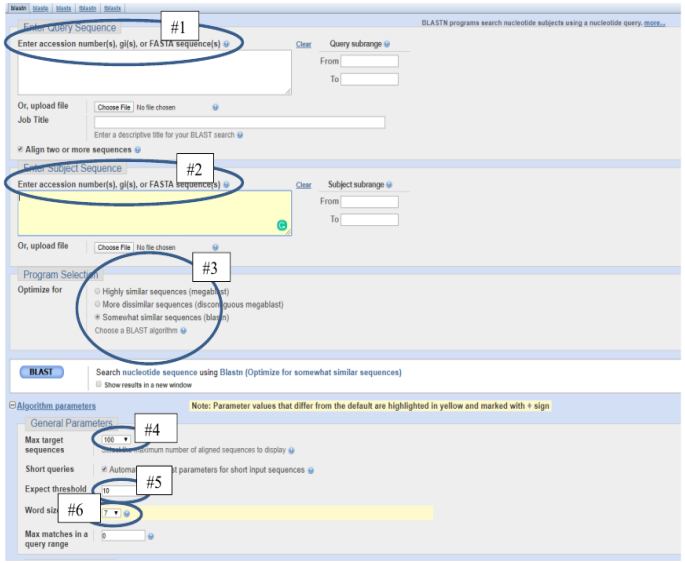
3.1.2. Identify and copy the Accession number.

3.2. In silico assay using the BLASTN.

3.2.1. Access “the Align two or more sequences” on the NCBI BLASTN website

(https://blast.ncbi.nlm.nih.gov/Blast.cgi?PAGE_TYPE=BlastSearch&BLAST_SPEC=blast2seq&LINK_LOC=align2seq)

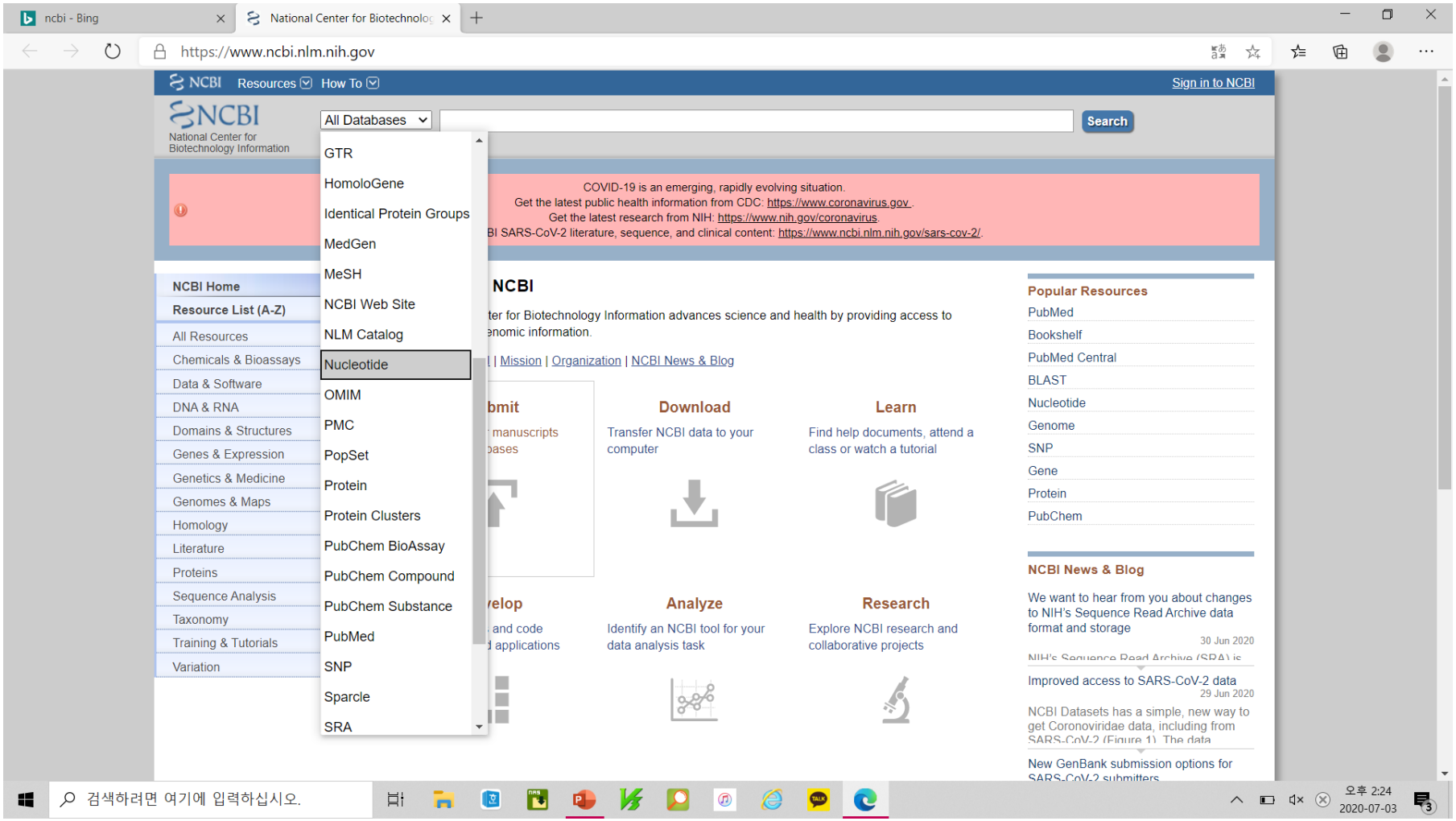
3.2.2. Enter the Accession number in the “Enter Query Sequence” window (Figure 1. #1).



신종 감염병에 대해서는 다양한 환자 검체와 교차반응 물질을 사전에 구하기 힘들기 때문에 in-silico 결과를 통한 예측이 매우 중요함

FDA에서도 In silico 자료를 매우 중요하게 다룸

09 Molecular Diagnostics/ COVID-19 RT-PCR



10 Lists of Molecular Diagnostic test

주력 제품

- careGENE™ HPV-H/ HPV-M kit
- careGENE™ STD-12 detection kit
- careGENE™ COVID-19 RT-PCR kit
- careGENE™ N-CoV RT-PCR kit
- careGENE™ Zika Virus RT-PCR kit

개발 진행중인 제품

- careGENE™ HIV-1 (Group M / Group O), HIV-2 RNA
- careGENE™ HCV RNA
- careGENE™ HBV DNA
- careGENE™ HTLV
- careGENE™ Syphillis TP DNA
- careGENE™ PAN Malaria DNA
- careGENE™ MERS RT-PCR kit
- careGENE™ ZIK/DEN/CHK/YFV RT-PCR kit
- careGENE™ Pneumonia-12 RT-PCR kit
- careGENE™ TB-NTM RT-PCR kit
- careGENE™ STFS RT-PCR kit
- careGENE™ Scrub Typus RT-PCR kit
- careGENE™ Dengue Virus genotyping kit

2. RDT(면역진단 키트)

항원 항체의 결합성을 이용한 반응

01 면역진단: 사업전략

웰스바이오 면역진단 사업부 핵심 경쟁력

대규모 OEM 생산
> 안정적 수익 확보

Access Bio와의 대규모 생산, 판매 협업

Access Bio

말라리아 RDT

정부출연연구소와의 협력
> 다양한 개발 포트폴리오 확보

항체 개발, Assay 디자인 개발로
포트폴리오 다각화

KRICT 한국화학연구원 Korea Research Institute of Chemical Technology

메르스 RDT, 신종코로나 RDT 등

careUS™ 공공, 민간 시장 판매
> 대규모 매출 확대

핵심원천 기술(HST) 기반
고품질 RDT 개발, 판매를 통한 매출 확대

HIV RDT, Dengue RDT, Flu RDT, 등

초민감도 현장 솔루션 (TRF) 개발
> 미래 성장 동력 확보

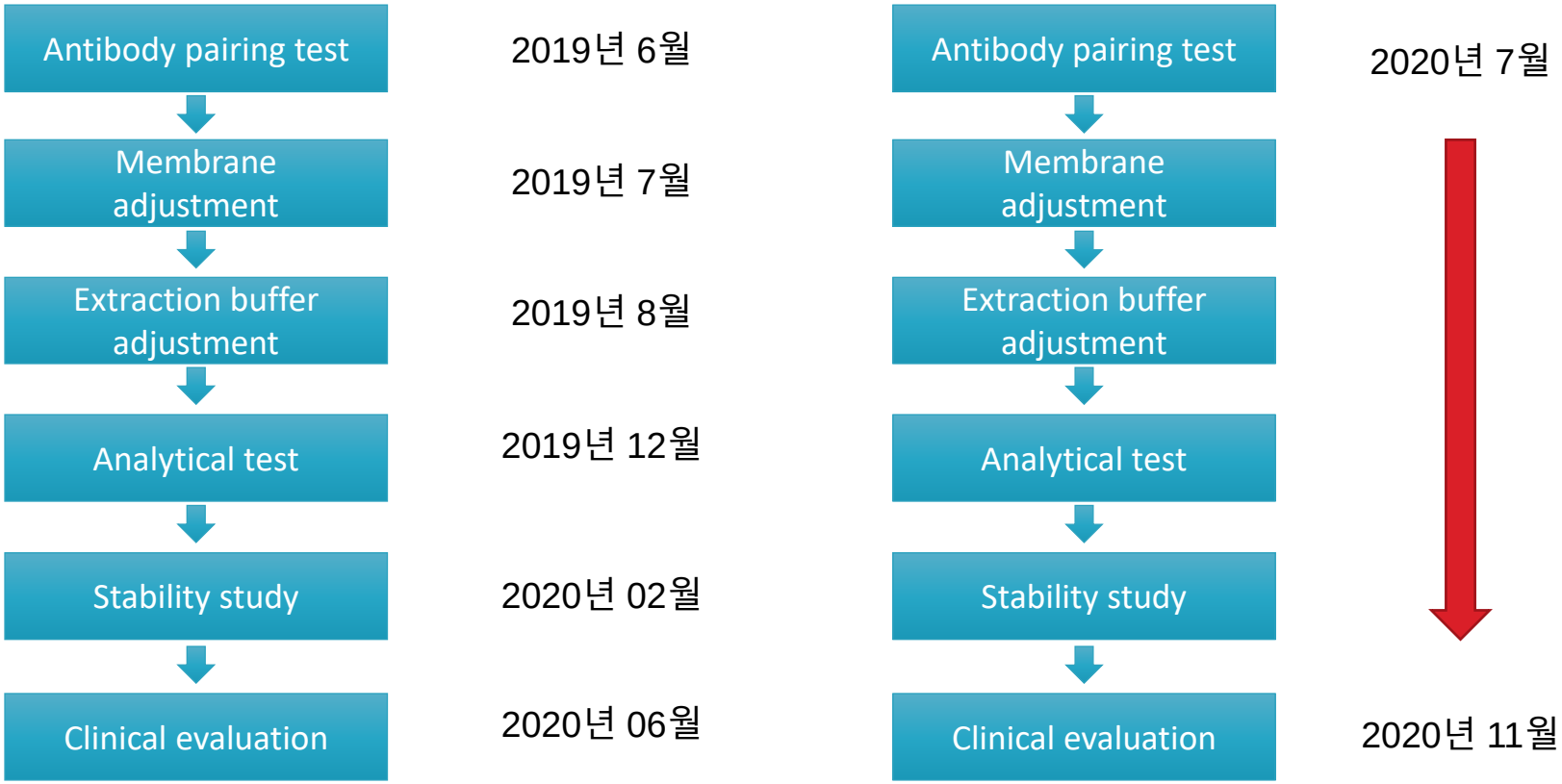
나노기술 융복합 솔루션 개발로
차세대 플랫폼 기술 확보

클라미디아 RDT, 심부전, 심근경색 RDT 등

주요 제품: 말라리아 진단 키트, HIV 진단 키트, 뎅기 진단 키트, Flu 진단 키트 등

메르스 항원진단 키트 | COVID-19 항원진단 키트

- **MERS-CoV RDT kit 개발 순서도**



메르스 항원진단 키트 성능

- **MERS-CoV RDT LOD test(mAb for S protein or mAb for NP protein)**

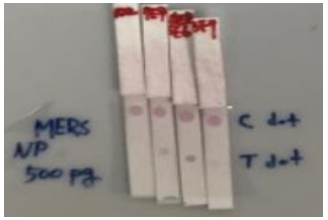
1'st Limit of detection(S protein)

Recombinant antigen concentration (ng/mL)	1,000	500	250	125	62.5	31.25	**15.625**	7.8125	Negative (Buffer)
Visible	2+	1+	W~1+	W+	W+	VW~W+	**VW+**	Trace	Negative
Lite-G value	215	156	103	87	77	65	**51**	38	15

* Lite-G cut-off : 40

기존 세계 최고 수준: BIONOTE (LOD: 1*10^6 TCID$_{50}$, 1.5 ng/ mL)
(논문 참고: JCM, Development and Validation of a Rapid Immunochromatographic Assay for Detection of Middle East Respiratory syndrome Coronavirus Antigen in Dromedary Camels, April 2015 Volume 53 Number 4)-Table 2~4 참고

2'st Limit of detection(NP protein)
: up to 500 pg/mL



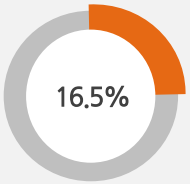
04 면역진단: COVID-19 IgM/IgG kit

COVID-19 RDT 시장 현황

COVID-19 RDT 시장 규모

출처: Global Market Insights

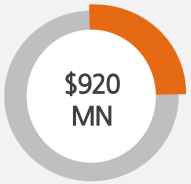
CAGR (2020-26)



비 인두
면봉 세그먼트

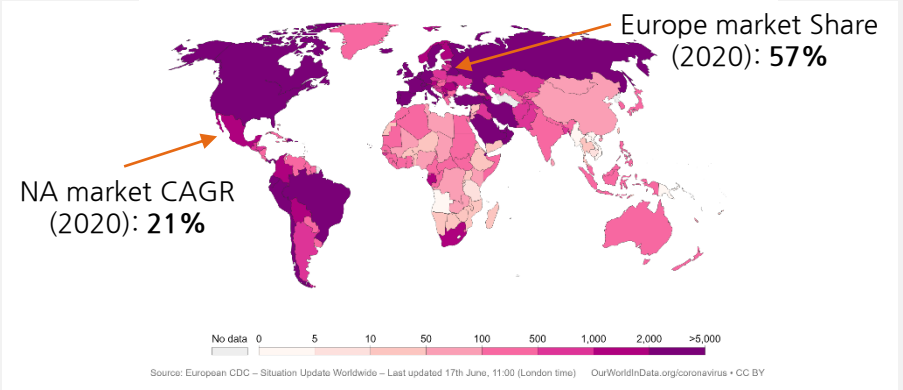
Market Value (2020)

병원
세그먼트



구 인두
면봉 세그먼트

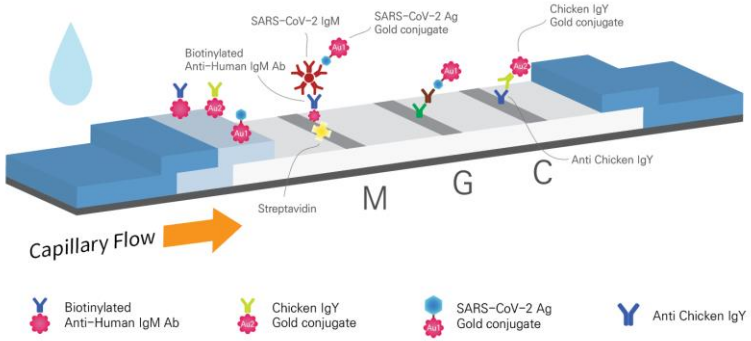
전세계 COVID-19 감염자 현황, 백만명당 (2020.6.17)



출처: European Centre for Disease Prevention and Control (ECDC)

코로나 진단키트

careUS™
COVID-19 IgM/IgG



신종코로나 항체 키트

검사 기술 면역크로마토그래피법을 사용한 코로나 IgM/IgG 항체의 정성검사

05 면역진단: COVID-19 IgM/IgG kit

COVID-19 RDT 검사 예

1일 4일 5일 7일

06 면역진단: COVID-19 IgM/IgG kit

COVID-19 RDT 검사 예

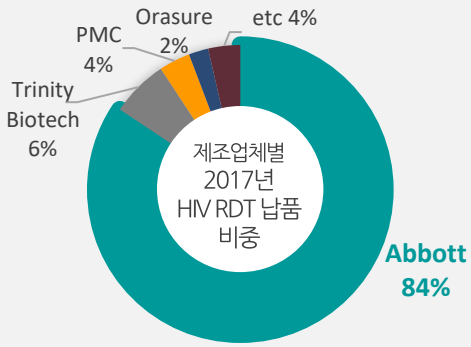
20명에 대한 항체 검사 결과

07 면역진단: HIV RDT (1)

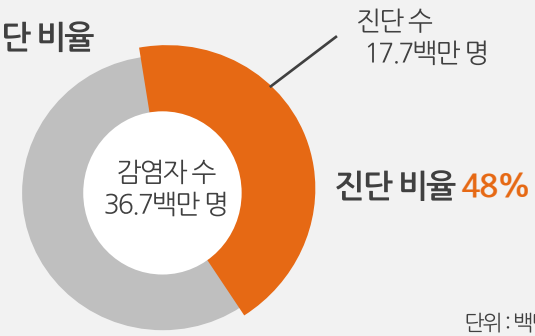
HIV RDT 시장 현황

HIV RDT 시장 규모

공공시장 조달규모
연간 102 million tests



전세계 HIV 진단 비율



단위 : 백만 명

HIV RDT 공공 시장의 독점 해제 필요성 대두

출처: The Global Fund, WHO

진단 비율의 확대 필요성 대두 > 자가진단 제품의 수요 절실

출처 : UNAIDS and partners launch initiative to improve HIV diagnostics

웰스바이오 사업전략

공공시장 제품

careUS™
HIV 1/2 RDT

자가진단 제품

CareStart™
EZ HIV RDT

공공시장대체 원가 절감, 품질 개선된 제품으로 기존 RDT공공 시장을 대체

신규 시장 확장 편리성, 안정성을 보완한 자가진단 올인원 제품으로 시장 확장

08 면역진단: HIV RDT (2)

careUS™ HIV RDT

careUS™ HIV RDT

HST Technology

우수한 성능 검증

- 글로벌 TOP 성능 확보

Sensitivity	100%
Specificity	100%

실험 기관: German Red Cross & the Institute of Tropical Medicine

대량 생산 시스템 구축

- 자동 대량 생산 시스템 구축 완료 (고령 생산공장)
- 연간 생산 Capacity 2억 테스트
- ISO, GMP 인증 완료

WHO 인허가

- 품질 시스템 수립 완료
- WHO Pre Qualification 진행 중

프로젝트 추진사항

- 임상 완료: 우수한 성능 검증 완료 (2017년)

→

- 생산 시스템 구축 (기계 설비구축/안정화)
- WHO 제품 인허가
- 품질/생산 시스템 확립

→

- 국가 입찰 참여 및 본격 생산 착수 추진

09 면역진단: HIV RDT (3)

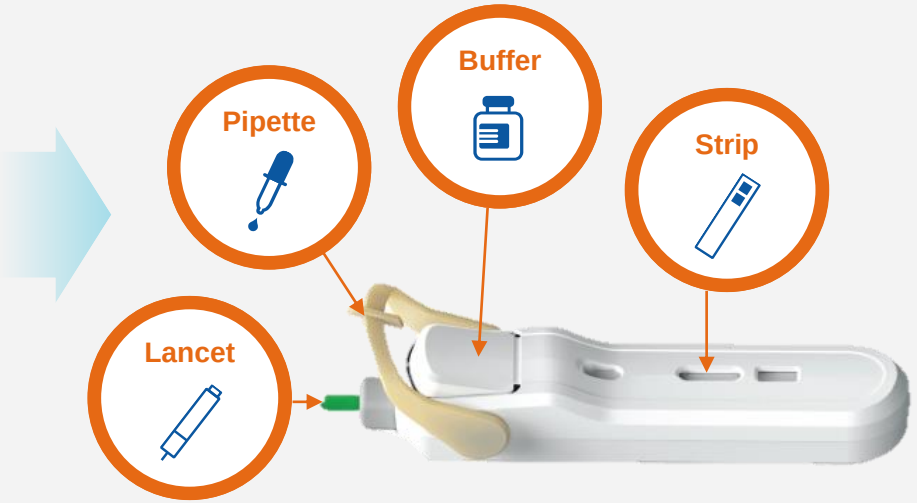
HIV RDT 자가진단 키트

자가진단 키트의 시장확대

WELLS BIO
스트립 개발/생산
공공 시장 판매

\+

atomo diagnostics
Device 개발
민간 시장 판매

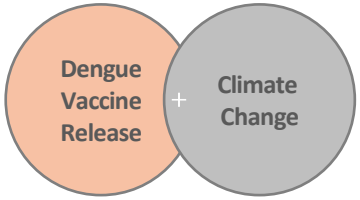


정책적 수요	가격 경쟁력 확보	패키지 마케팅
▪ WHO 90-90-90 정책에 따라 자가 진단을 적극 장려 중 ▪ WHO PQ 진행 추진	▪ 웰스바이오 대량 생산 시스템을 활용한 획기적 원가 절감 기대	▪ 일반 RDT와의 package 상품 판매를 통한 시너지 효과 기대

10 면역진단: 덴기 RDT

고민감도 제품 개발을 통한 덴기 진단 시장 혁신

덴기 진단의 수요 증가



덴기 감염 국가 30년 간 10배 증가

스리랑카, 인도, 베트남 등 아시아 지역을 중심으로 발생 빈도 증가

기존 제품의 한계

Evaluation of commercially available dengue NS1 rapid tests

	A	B
Sensitivity(%)	61.6	62.4
Specificity(%)	100.0	100.0

Source: BMC Infection Diseases

현 출시 제품들의 민감도 문제가 이슈화

고민감도의 덴기 키트의 절실한 필요

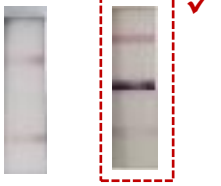
신기술 개발을 통한 기존 시장 대체

개발 목표

기존 제품 대비 X10~100 folds

콜라보레이션 +엑세스바이오

제품 경쟁력



Competitor 웰스바이오

11 면역진단: TRF

TRF 기술

TRF (시분할 형광분석) 기술

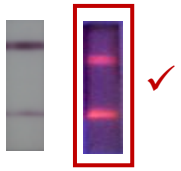
Europium Nanoparticle 활용한 시분할 형광분석 원천 기술

- 초 고민감도 (Ultra High Sensitivity) 현장 솔루션 실현
- 특허 미국, 중국 포함 10개 등록 완료

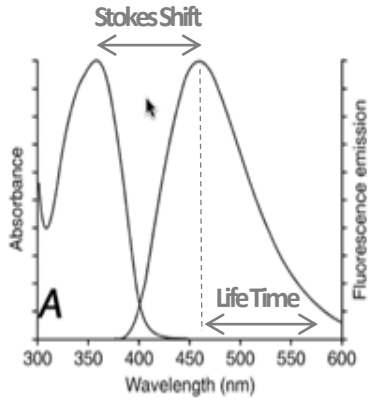
민감도의 획기적인 향상
기존 대비 50배~100배 향상

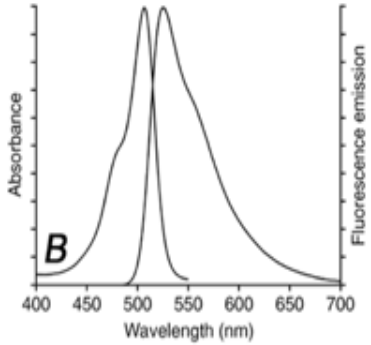
+

RDT의 현장 진단 용이성



기존 RDT TRF RDT





제품 포지셔닝

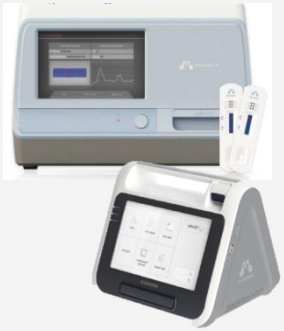
UHS POCT Solution의 차별적 Value Positioning

- 감염성 질병 조기 진단
- 필요 검체량 최소화
- 측방 유도 면역 진단 (Lateral Flow Immunoassay)
  All-in-One 바이오 센서 개발로 사용자 편리성 극대화

제품 확대 전략

개선 효과가 높은 감염성 질병 > 심혈관계 질환 Marker 조기 상품화

- 패혈증 (PCT)
- 장염 (Rota/Adeno)
- 심근경색 (hsCRP, Troponin-I)
- 심부전 (NT-proBNP)
- 혈전증 (D-Dimer) 등



3. 바이오센서

BT+IT 융합을 통한 종합진단 솔루션 구축

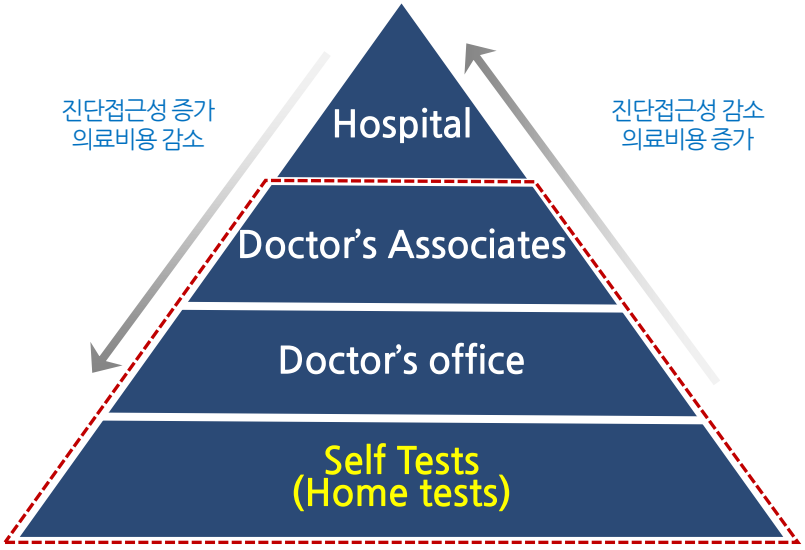
01 바이오센서의 진단법

사업전략

의료 환경 변화

- 인구 고령화 및 환자 편의성 요구 증가
- 삶의 질 향상 추구에 따른 개인 건강관리 중시
- 조기진단 및 조기치료 선호

의료기기의 IT화 & 스마트화



진단 시장 트렌드 및 사업전략

원격 의료 시스템 | 개인 맞춤 의료 시스템 | 실시간 의료 정보 통합

WELLS BIO

스크리닝 정책 납품 > 시장 진출 확대

- 전기센서, 광학센서 멀티진단 플랫폼 기술 확보
- 신생아 스크리닝 진단
- 말라리아 퇴치 + 동반진단

G6PD 바이오센서, POCT S1 등

차세대 네트워크 센서 > 미래 성장동력

- 융복합 네트워크 탑재 플랫폼 기술 확보
- 미래 의료환경 구축 (실시간 의료 정보 통합, 개인 맞춤 의료시스템 등)에 기여

차세대 Immuno-POCT 기반 기술 확보

02 바이오센서 제품 포트폴리오

플랫폼 기술 및 제품 포트폴리오

멀티진단 플랫폼 기술 개발 및 제품 확장

HAND-HELD-G6PD

- G6PD
- Hemo globin

careSTART™
G6PD Biosensor

HAND-HELD

신생아 진단 패키지

- G6PD
- Hemo globin
- Bili rubin

careSTART™
POCTS1

CARTRIDGE

당뇨 진단 패키지

- Hb A1c
- CRP
- ACR

CareU™
Analyzer 100

- 개발 완료
- 개발 중

진단 포트폴리오 확장

- Vitamin D
- Vitamin B12
- Lipid Profile
- Next Generation G6PD
- PKU

03 바이오센서

G6PD 결핍증

G6PD 결핍은 사전 진단이 반드시 필요한 유전성 질병

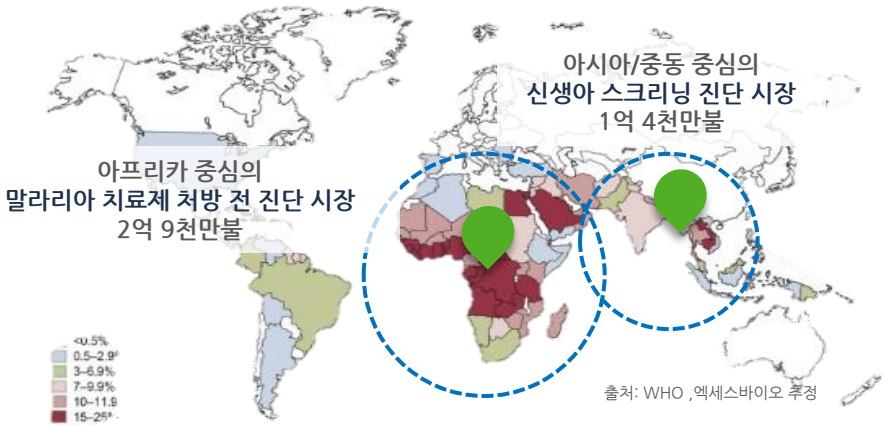
말라리아 퇴치를 위한 필수 진단

✓ 말라리아 치료제와 동반 진단 시장 형성

유전성 질병 스크리닝 시장 개척

✓ 신생아 스크리닝 프로그램 참여

G6PD 결핍현황 및 시장규모



출처: WHO ,엑세스바이오 추정

"말라리아 퇴치를 위한 국제기구와의 협력"

말라리아 퇴치를 위한 필수 동반 진단

세계 최초의 유일한 G6PD 바이오센서

WHO와 긴밀한 협의를 통한 공공시장 형성

> 국제 기금을 G6PD 바이오센서에 배정 방안 검토 중

+ WHO Pre Qualification 진행 중

04 바이오센서: 신생아 스크리닝 정책 참여

시장 진출 현황

아프리카, 전국민 스크리닝 프로그램 참여 추진

웰스바이오		우간다 MOH
G6PD 바이오센서 독점공급		국가 스크리닝 정책

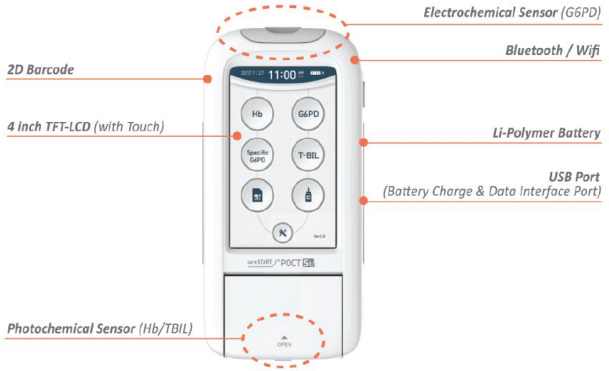
- 전국민/신생아 스크리닝 전략적 협력 체결 (2018.01)
- 소아과 협회 주관 임상 진행 중

우간다에서의 성공적인 레퍼런스 확보 ▶ 주변국가로의 확장 추진

- 베트남 : 210만불 규모의 5개년 장기 공급계약 체결
- 요르단, 쿠웨이트, 카타르, UAE, 싱가폴, 홍콩, 태국 등과의 판매 협의 논의

시장 확장 계획: 신생아 진단 패키지 POCT S1

멀티 센서 출시를 통한 판매 확대



careSTART™ POCT S1

- 멀티 POCT 진단 센서
- 신생아 진단 패키지 구성
  > G6PD, 헤모글로빈, 빌리루빈 등 확장 탑재

원격 현장 진단 + 실시간 의료 정보 통합

Possible Use of Raloxifene as a Broad-spectrum Antiviral Medication

정 귀 완

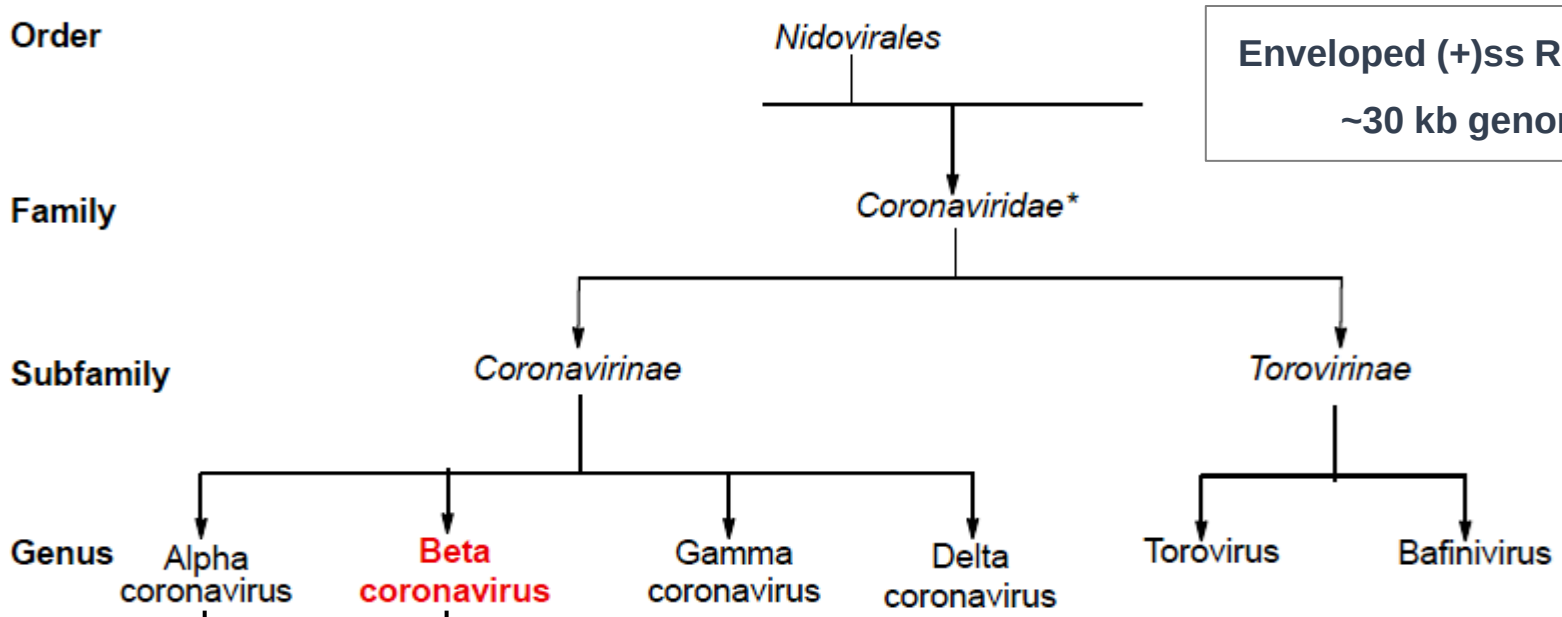
수석연구원, 경기도경제과학진흥원

Table of Contents

Introduction

- Project overview & Screening methods -

Human coronavirus infectious disease



Enveloped (+)ss RNA virus

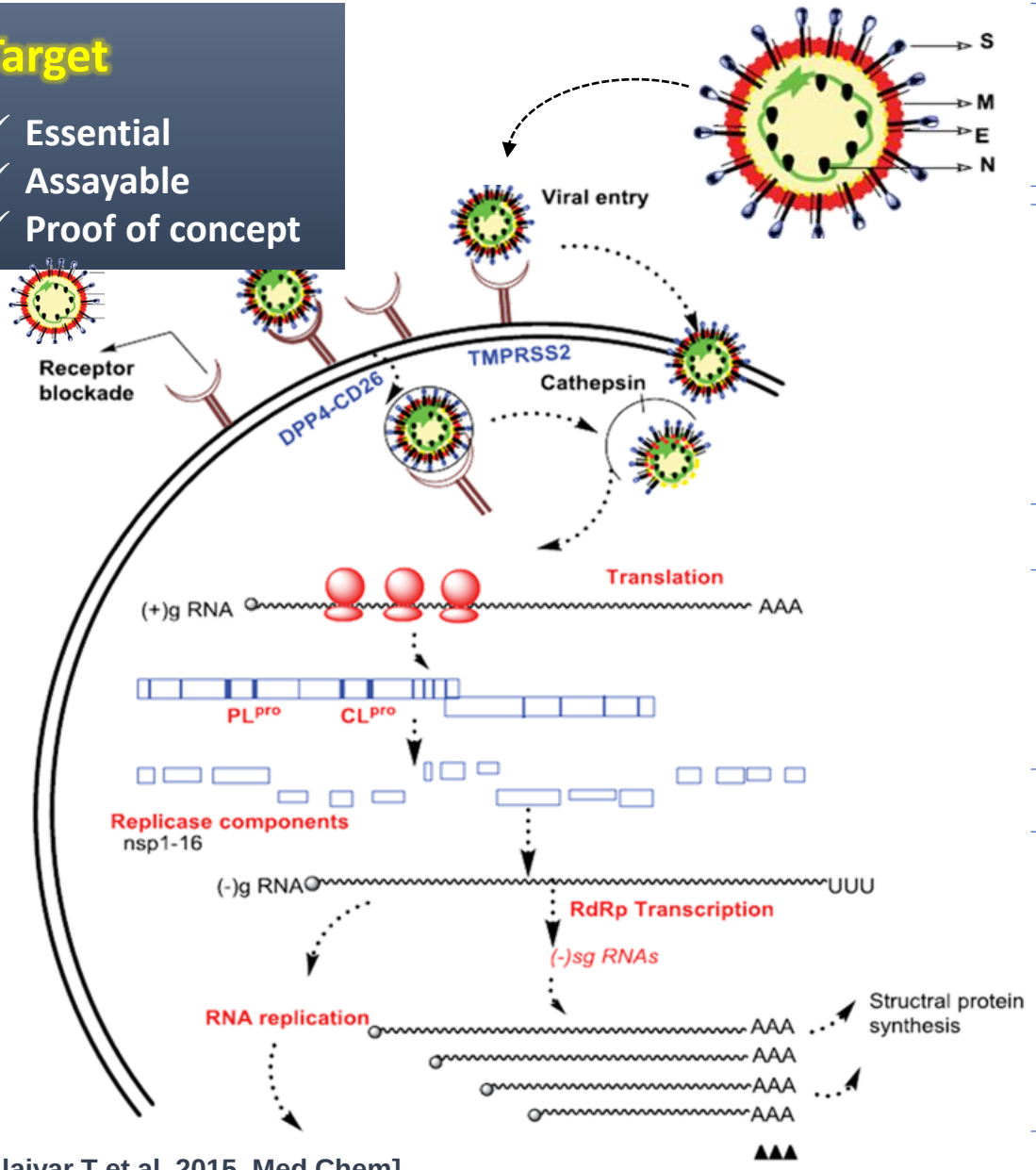
~30 kb genome

※'20.9.22 현재

Antiviral targets

Target

- ✓ Essential
- ✓ Assayable
- ✓ Proof of concept



[Pillaiyar T et al. 2015. Med Chem]

vaccines or neutralizing AB

Entry targets

I) Spike protein (RBD, Fusion intermediates)

II) Receptors: DPP4/CD26

III) Surface proteases: TMPRSS2

IV) Endosomal proteases

Polyprotein processing targets

I) Papain-like protease (PL^{pro})

II) 3C-like protease ($3CL^{pro}$)

Replicase targets

I) ADP-ribose-1'-phosphatase (nsp3)

II) RNA-dependent and RNA polymerase (nsp12)

III) Helicase (nsp13)

IV) Hexanuclease (nsp14)

V) Endoribonuclease (nsp15)

VI) 2'-O-methyltransferase

Assay & Chemical library

BIOPLUS · INTERPHEX KOREA

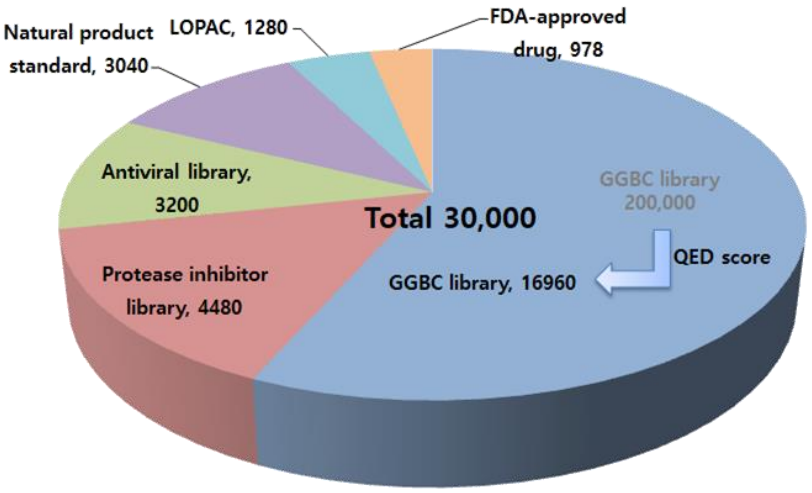
Assay

- ✓ Proved
- ✓ Convenient
- ✓ HTS-amenable

Library

- ✓ Druggable
- ✓ Focused
- ✓ Diverse

Target	Function	HTS	Secondary screening (Validation)
Spike-DPP4	Viral entry	Pseudovirus Luminescence	Alpha assay Fluorescence ELISA Absorbance
3CLpro	Proteolysis	FRET Fluorescence	Biosensor assay Luminescence
PLpro	Proteolysis Immune evasion	Peptide cleavage Fluorescence	FRET Fluorescence
Interferon pathway	Innate immunity	Reporter assay Luminescence	Westernblot qRT-PCR



바이오센터 약물 스크리닝 인프라

소재은행 319,367종

Disease-related compound libraries

수요자 맞춤 소재 라이브러리 제공

표준품 4,085종

- 천연물 유래 표준품 : 3,751종
- 천연물표준품(플라보노이드) : 211종
- 배당체 : 123종

추출물 99,634종

식물추출물 22,785종

- 해외소재추출물 17,881종
- 자생식물추출물 3,700종
- 생약추출물 504종
- 뷰티소재은행 700종

바이오소재 76,849종

- 방선균추출물 74,449종
- 미생물추출물(미소박테리아) 576종
- 해양추출물 1,824종

유기화합물 215,648종

Drug Likeness & Diversity

- 저분자량 : 20,000종
- 구조다양성 : 75,000종
- 신규 조합화학 합성물 : 60,485종
- 유효 약효 골격 화합물 : 17,249종
- Soluble Diversity : 2,240종

Targeted Libraries

- CNS : 20,000종
- GPCR : 8,359종
- Kinase : 856종
- Antiviral : 3,200종
- Cysteine Protease : 2,240종

Drug repositioning Libraries

- LOPAC : 1,280종
- FDA승인약물 : 1,412종
- 임상진입약물 : 1,920종
- Enzo Library : 1,407종

타겟별 시험 서비스 항목 HTS/HCS 검색계

골다공증
1. Alkaline phosphatase assay
2. Osteoclastogenesis assay
3. AR-s assay(MC3T3-E1)

미백
1. Melanin contents assay*
2. Cell free mushroom tyrosinase assay
3. Cell extracts tyrosinase assay

주름
1. Elastase assay
2. Collagenase inhibition assay
3. Collagen synthesis assay

근섬유화증
rpS6 phosphorylation assay

소양증
Trypsin-induced Ca^{2+} assay

지방간
GPR119 agonist assay

고요산혈증
Xanthine oxidase assay

혈행개선
PDE5 inhibition assay

신경계질환
1. Acetylcholine esterase assay
2. β-amyloid aggregation assay
3. Neurite outgrowth assay
4. Neuronal protection assay

통증
TRPA1 calcium assay

항산화
1. ABTS assay
2. DPPH assay
3. NRF2-Keap1 inhibition

안질환
Eye goblet protection assay

천식/호흡기질환
1. β2-Adrenergic receptor agonist
2. Cys LTR1 antagonist*
3. Phosphodiesterase enzyme assay
4. GSNO reductase assay
5. CRE luciferase assay
6. Inflammasome/IL-1β

암
1. Reporter gene (TCF/LEF, p53)
2. Kinase (IRAK4, EGFR…) assay
3. IDO-1 enzyme assay
4. Cytotoxicity (CCK-8, MTS)
5. Tankylase-1 assay
6. NAMPT inhibitor screening

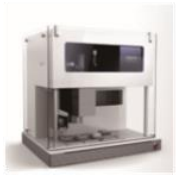
염증/과민면역반응
1. NFκB translocation assay
2. Heme oxygenase 1 assay
3. IL-6, IL-8, TNFα, NO
4. COX-2 inhibition assay
5. Nrf-2 translocation assay
6. β-Hexosaminidase assay

* 2차 검색계

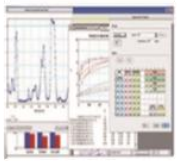
HTS system

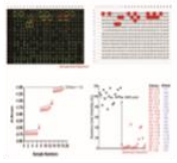
Flexstation

Envision



3D cell-based HTS system





Liquid handler

Biomek FX

JANUS MDT

96, 384 well plate Cherry pick & Transfer Cell-based assay
Protein(Target)-based assay

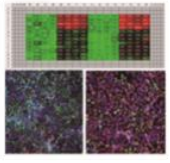
HCS system

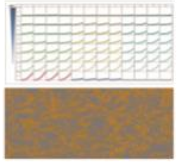
ImageXpress

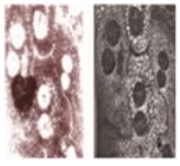
Incucyte

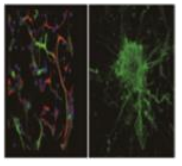
Nanolive

Confocal

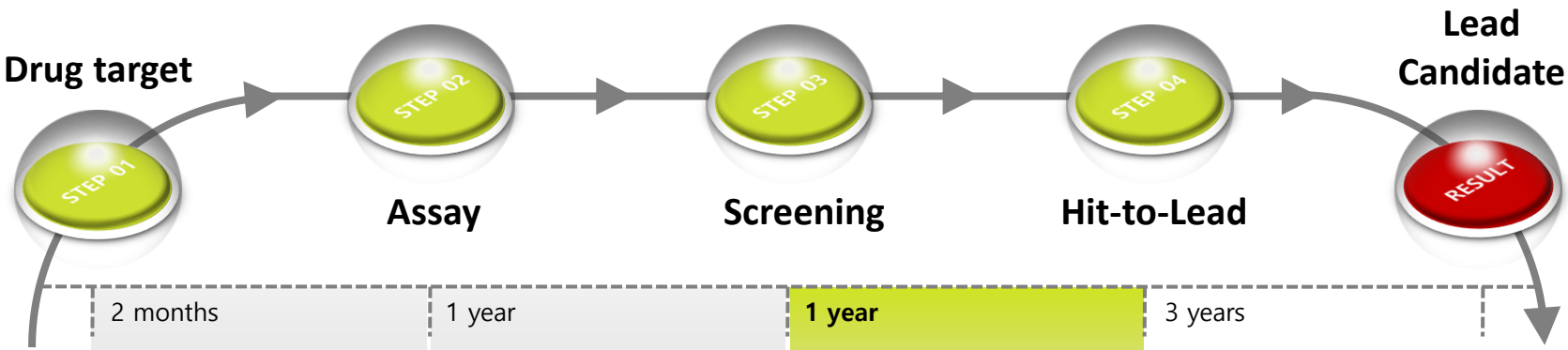








바이오센터 신약 발굴 사업 범위



2 months

Evaluation
- Market size ?
- Pipeline search
- Novel target ?
- First-in-class ?

Druggability
- Disease linkage
- Mechanistic rationale
- Proof of concept

Project planning

1 year

Assay choice & Development
- Cell- or target-based
- Label-free or fluor/lumi
- Enzyme reaction or PPI

Validation & Adaptation
- Convenience: homogenous
- Accuracy: minimal variance
- Robustness: Z factor
- High throughput

1 year

HTS

Confirmation

DRC/cytotoxicity

Hit selection

2nd screening

3 years

SAR
- Efficacy/Potency
- Selectivity index

SPR
- Stability
- Permeability
- Metabolic stability

PK/PD
- In vitro/in vivo efficacy
- PK
- ADME-Tox
- Safety

Mode of Action
- Pathway analysis
- Omics profiling
- Target deconvolution

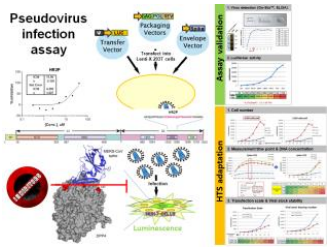
Tech transfer Follow-up

Research process for anti-MERS-CoV compounds

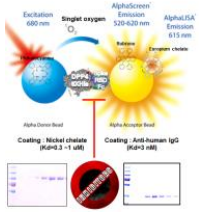
BIOPLUS · INTERPHEX KOREA

Assay development → HTS → 2nd screening (MERS-CoV) → Hit/Lead optimization → In-depth study → Animal study

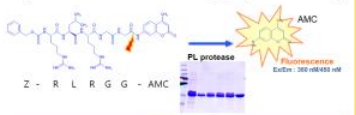
Pseudovirus infection assay

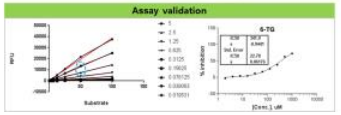


AlphaScreen®

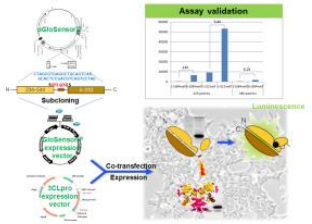


PL protease inhibitor screening (Peptide cleavage)

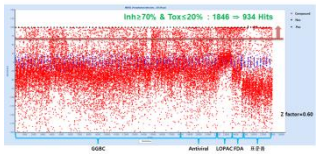




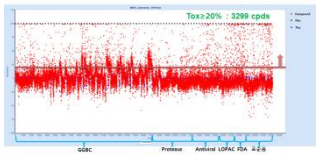
3CL protease inhibitor screening (Biosensor)



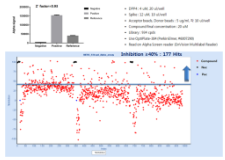
Pseudovirus (Total)



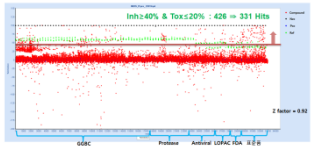
Cytotoxicity (Total)



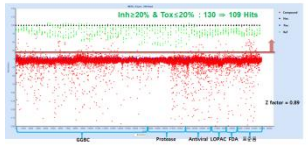
AlphaScreen® (HTS)



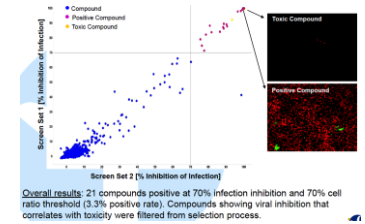
PLpro HTS



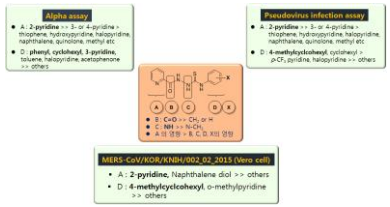
3CLpro HTS

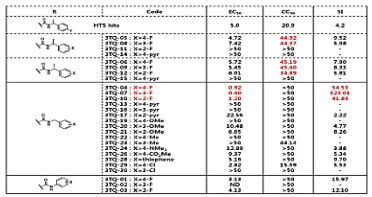


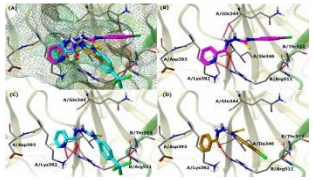
- ***Synthetic chemical & commercial sources***
  - Enzyme-based assay
  - Cell-based assay
  - MERS-CoV inhibition assay
  - SAR & docking study



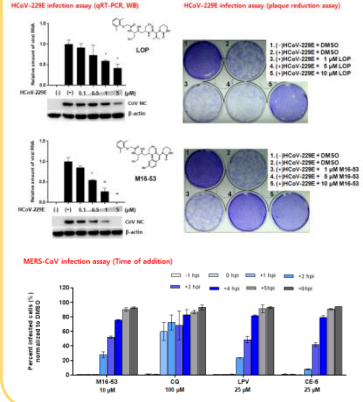
Overall results: 21 compounds positive at 70% infection inhibition and 70% cell ratio threshold (3.3% positive rate). Compounds showing viral inhibition that correlates with toxicity were filtered from selection process.



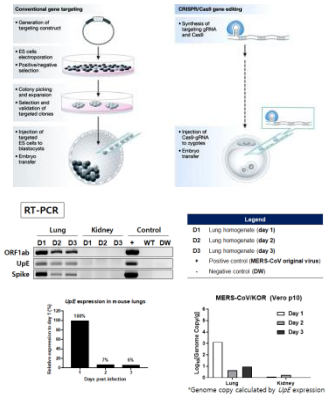


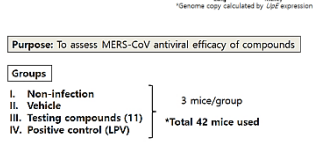


- ***Other coronavirus***
  - SARS-CoV
  - HCoV-229E
  - HCoV-OC43
- ***Other assays***
  - IF & qRT-PCR
  - CPE assay
  - Plaque reduction assay
  - ELISA
  - Time of addition
  - SPR
- ***Phychem studies***
  - Solubility
  - Permeability
- ***Metabolism***
  - Metabolic stability (Hu,Ms)
  - PK profile (iv, ip)



- ***Oral acute toxicity (Ms)***
- ***DPP4 knock-in mouse infection study***





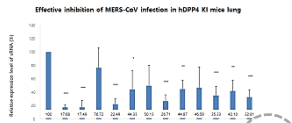
Purpose: To assess MERS-CoV antiviral efficacy of compounds

Groups

I. Non-infection
II. Vehicle
III. Testing compounds (11)
IV. Positive control (LPV)

3 mice/group
*Total 42 mice used

Scheme



Developing innate immune modulators

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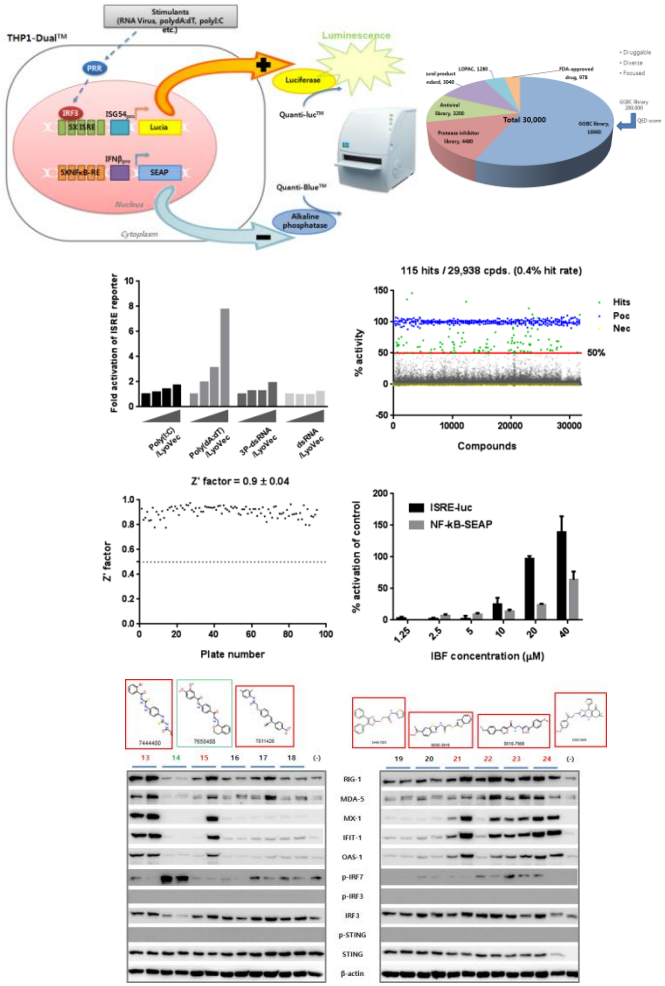
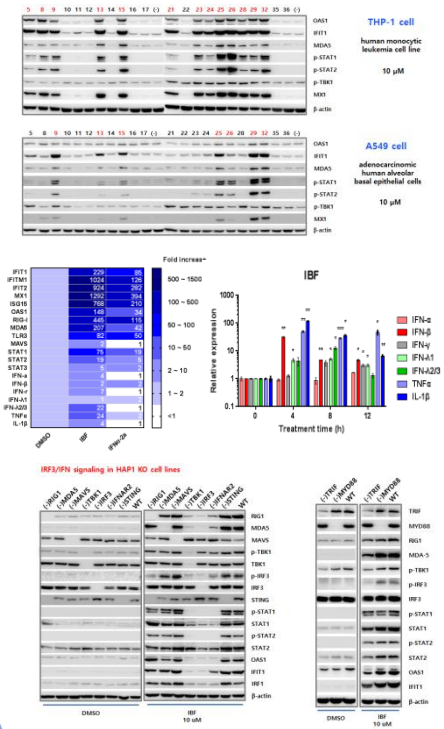
Screening system → **HTS** → **2nd screening (MERS-CoV)** → **Antiviral assay** → **MOA study**

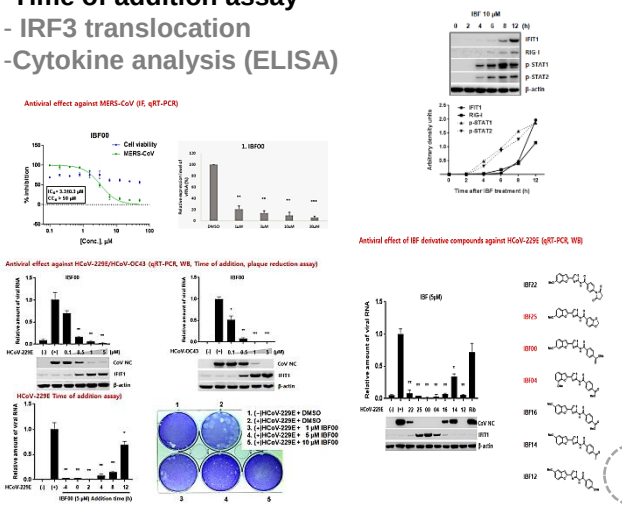


- ***Synthetic chemical & commercial sources***
  - IFN expression analysis
  - ISG expression analysis (HEK293, THP-1, A549, MRC-5, Huh7, HeLa, HAP1 etc.)
  - MERS-CoV inhibition assay

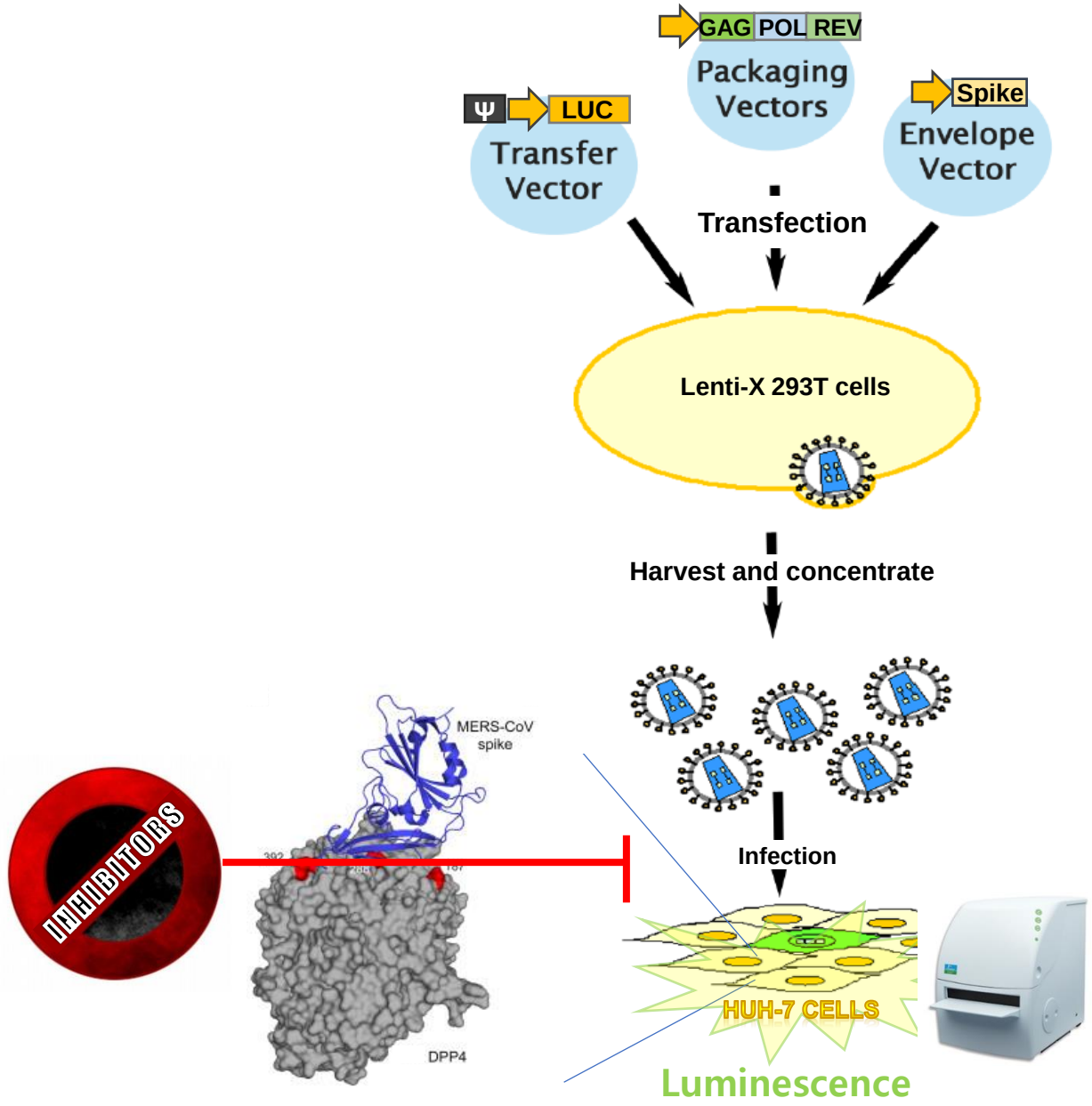


- ***Other viruses***
  - Coronavirus (MERS-CoV, SARS-CoV, HCoV-229E, HCoV-OC43
  - Respiratory syncytial virus
  - Influenza A virus
  - Zika virus
  - Dengue virus

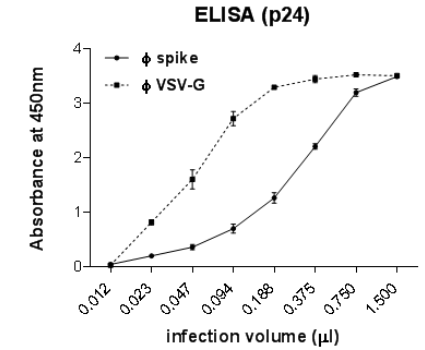
- ***Other assays***
  - Reporter assay
  - Immunofluorescence
  - Westernblot (IRF3/ IFN signaling,CoV)
  - qRT-PCR (ISGs, Cytokines)
  - CPE assay
  - Plaque reduction assay
  - Time of addition assay
  - IRF3 translocation
  - Cytokine analysis (ELISA)

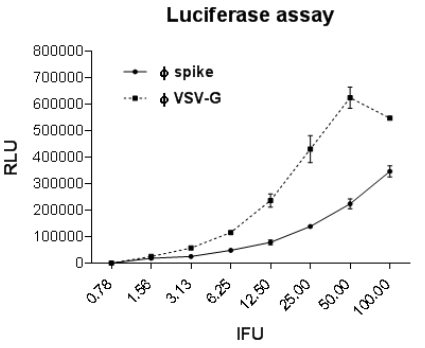


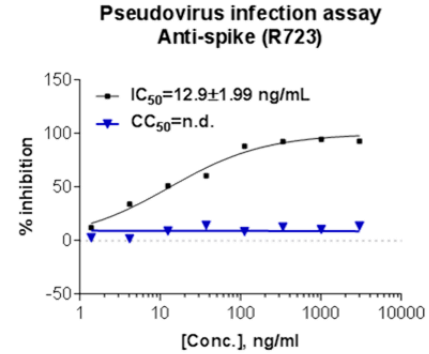
Pseudovirus assay



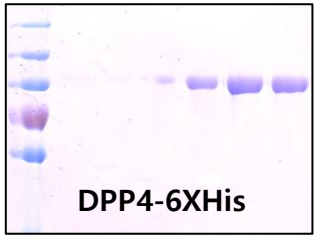
Assay validation

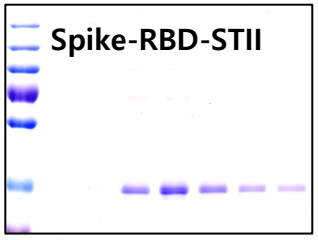


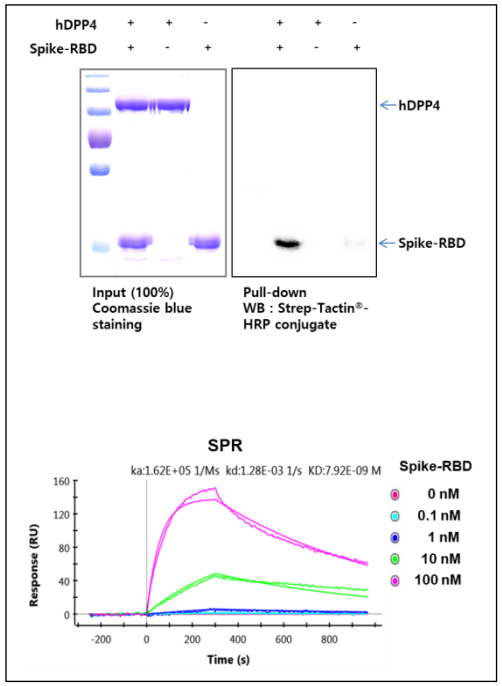


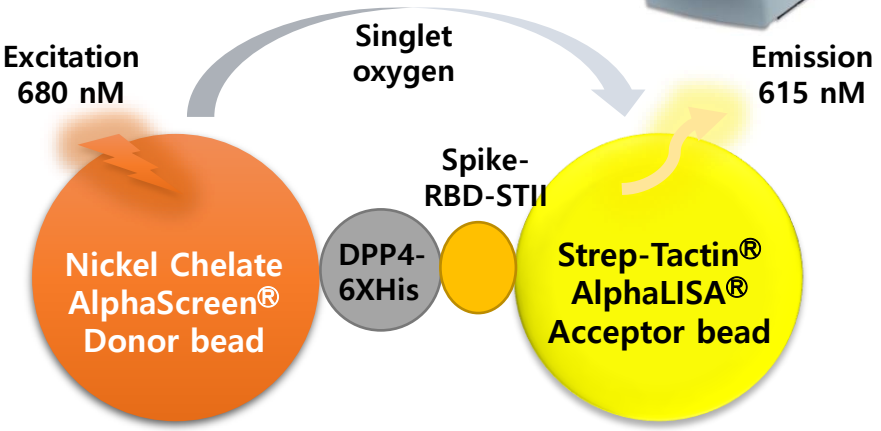


Alpha assay (Secondary screen)

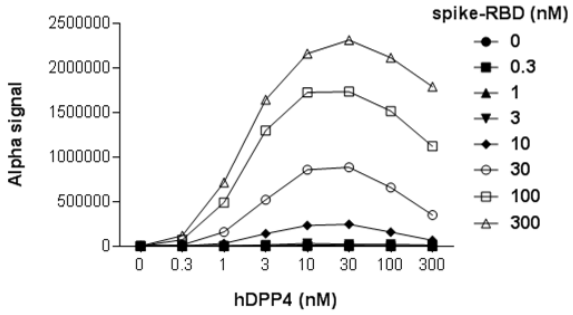


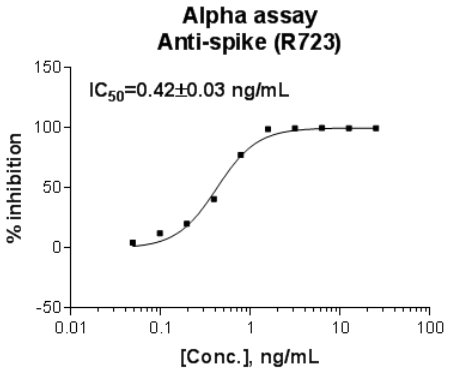


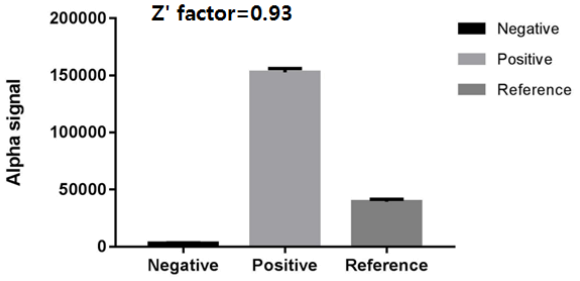




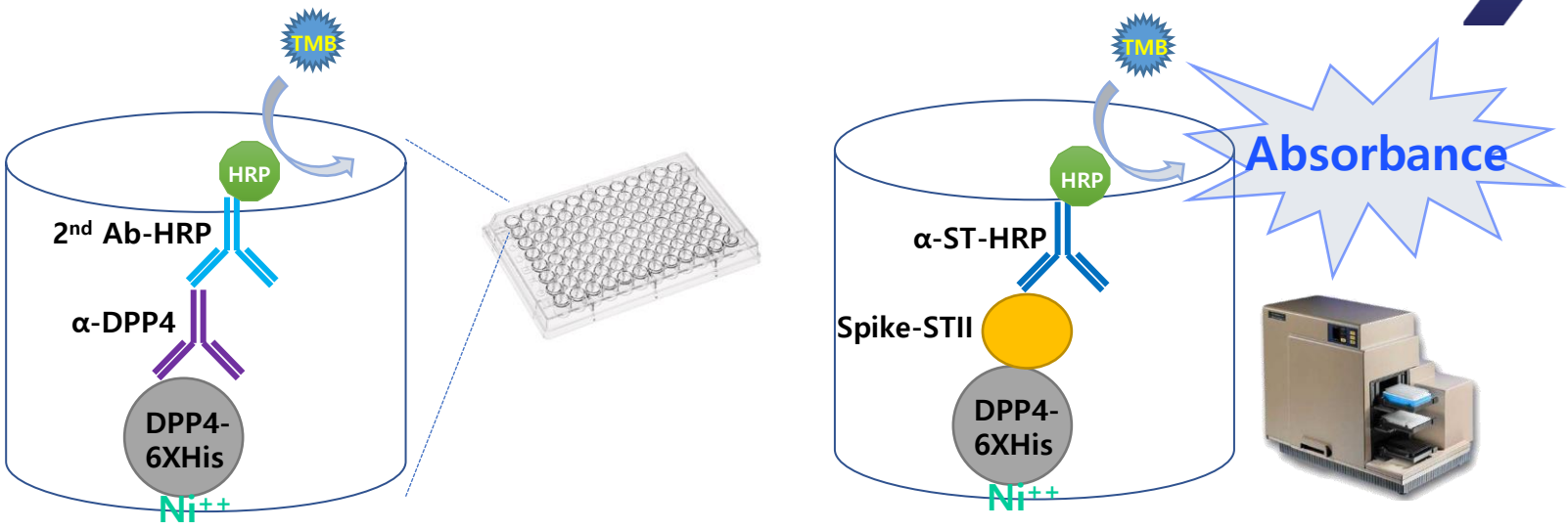
Assay validation



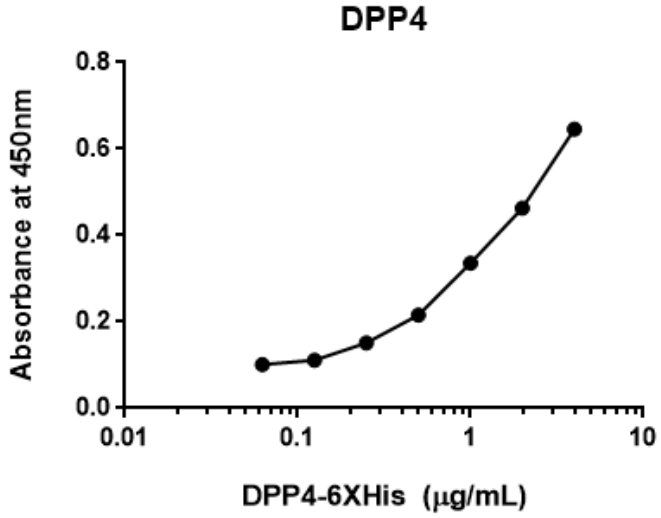


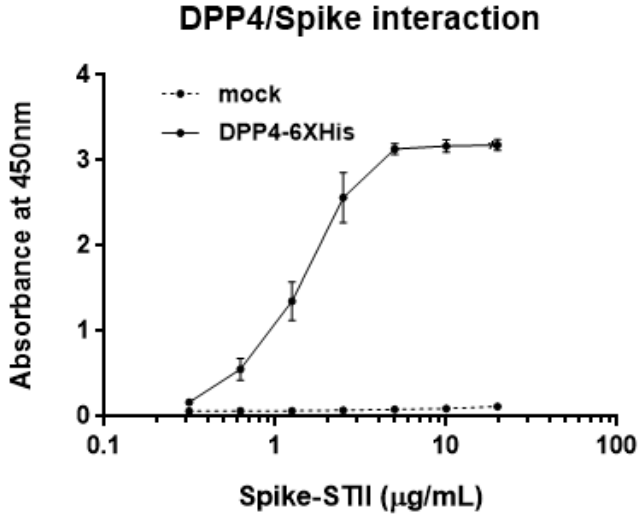


ELISA



Assay validation





Phenotypic MERS-CoV infection assay (1)

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MERS-CoV infection assay

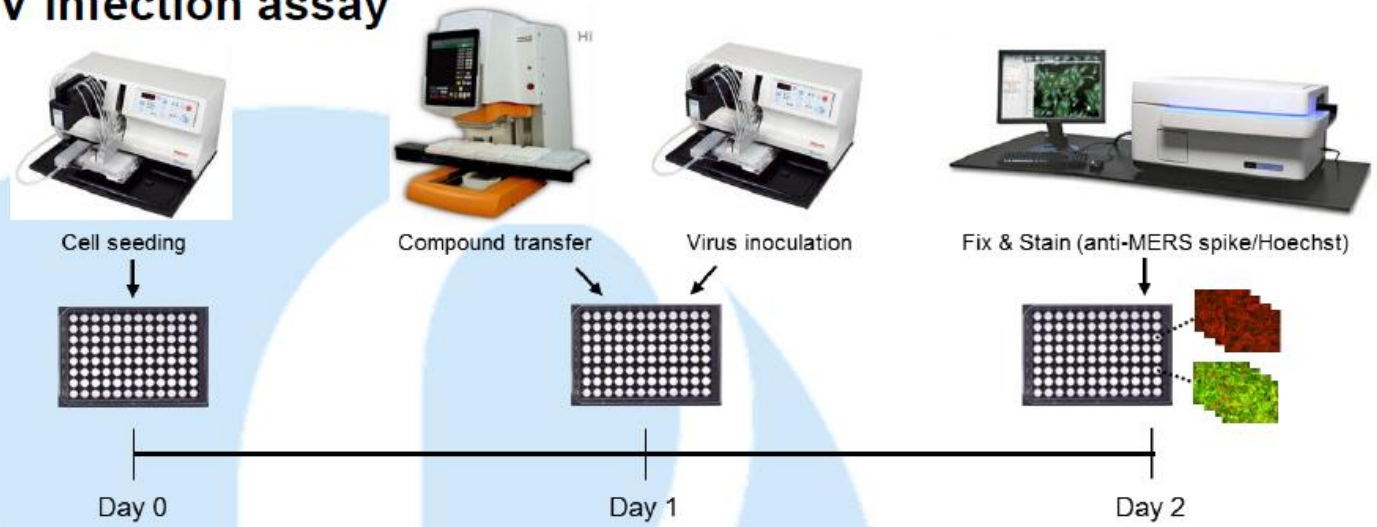
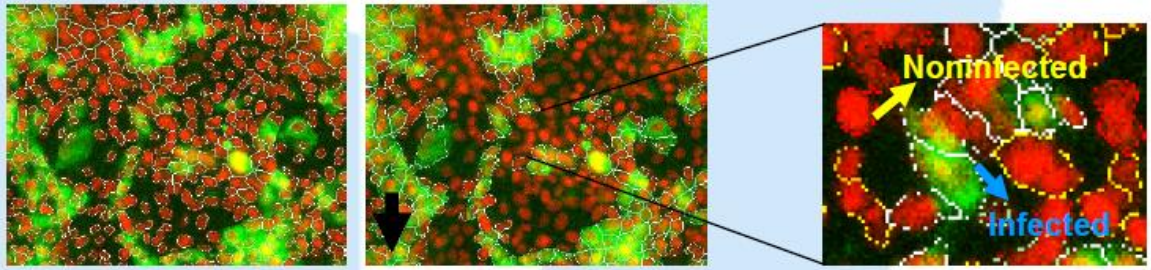


Image analysis using IM platform: Blue & Green Ch, 20X Objective, 5 images/well

Nuclei masking (Hoechst 33342)

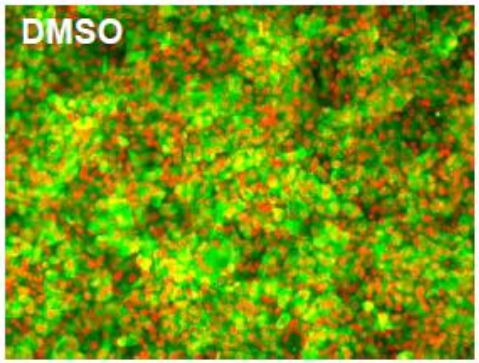
Infected cell masking (AlexaFluor488)

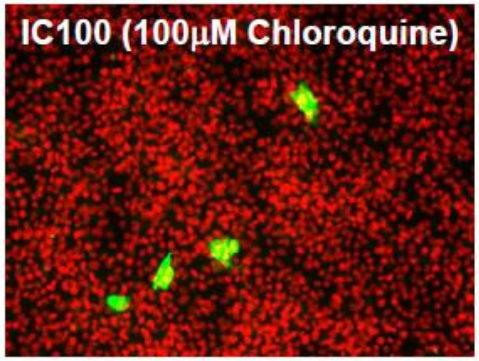


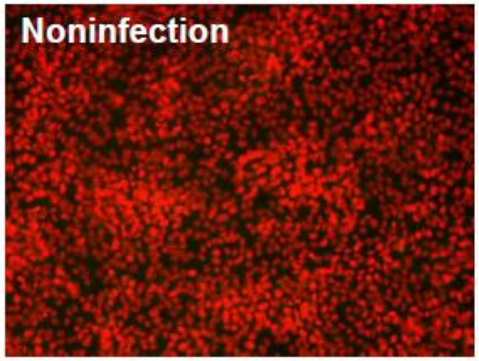
Sample data analysis

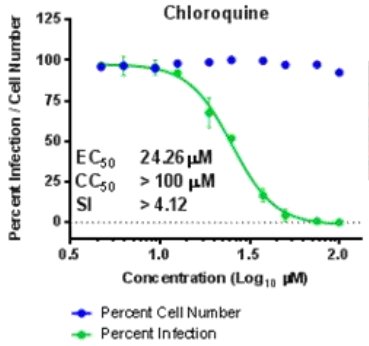
Total nuclei/cell number: 1192
Total cells infected: 441
Percentage of infected cells: 37%

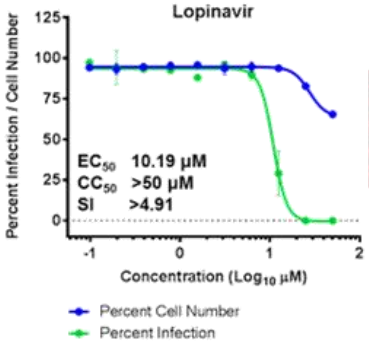
Phenotypic MERS-CoV infection assay (2)

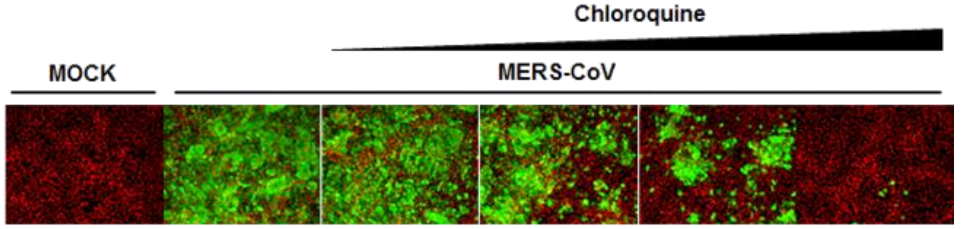


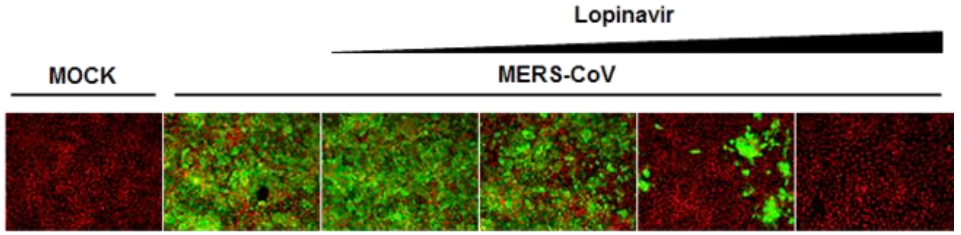












Drug repositioning

- HTS & anti-CoV activity -

HTS (Drug repositioning)

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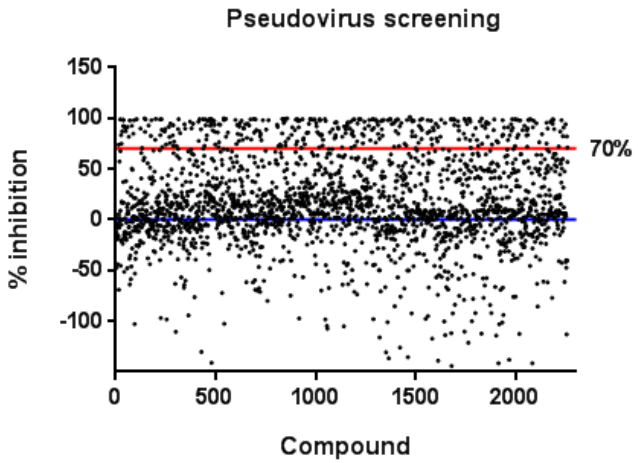
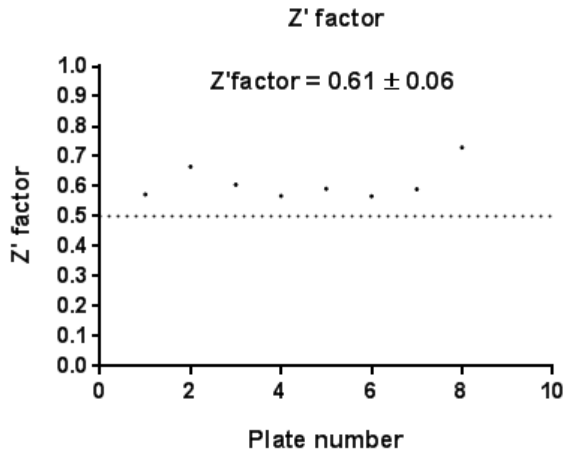
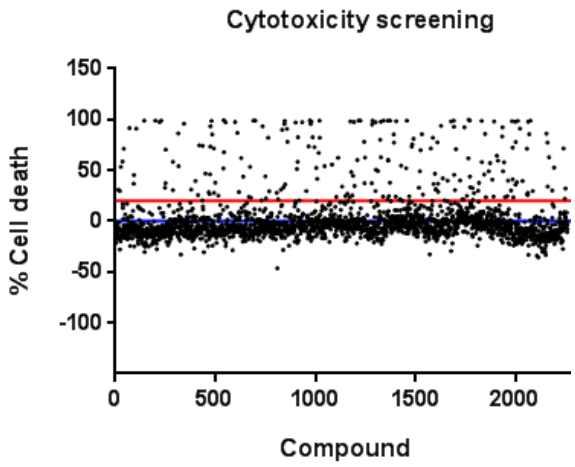
LOPAC library 1,280종

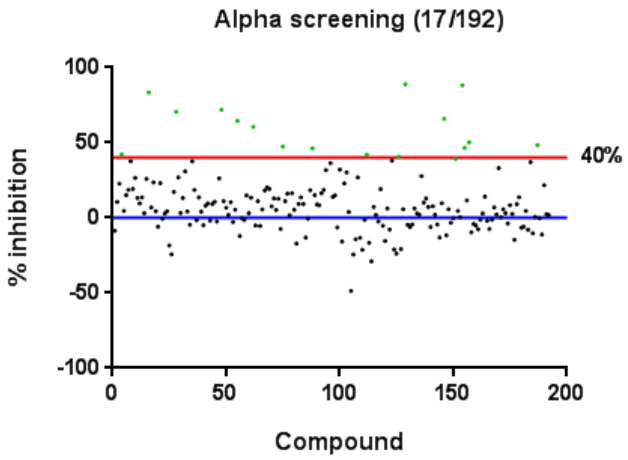
FDA-approved library 978종

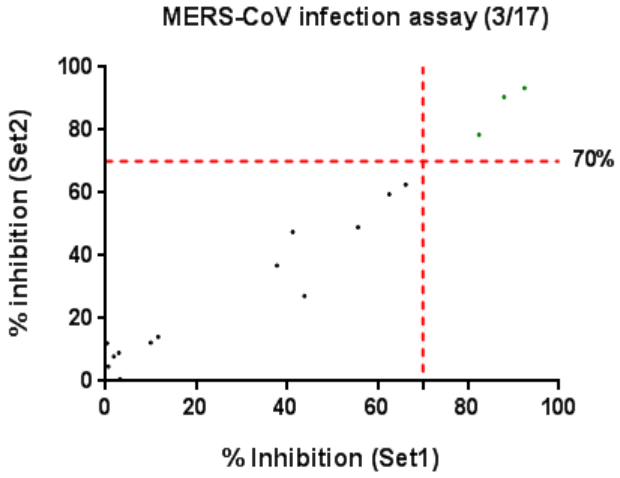
총 2,258종 화합물





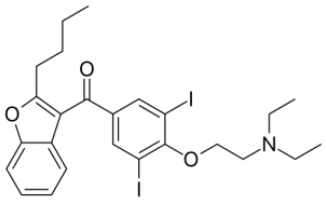






3 known drug Hits

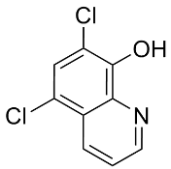
Amiodarone



부정맥 치료제

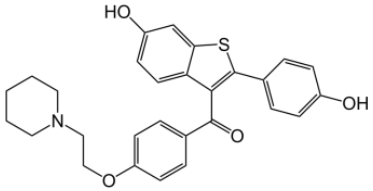
In vitro : 에볼라, C형간염

Chloroxine



항균제로서 감염성 설사, 염증성 장질환, 편모충증 치료제

Raloxifene



선택적 에스트로겐 수용체 조절제 (SERMs)로서
전이성 유방암 및 골다공증 예방/치료제

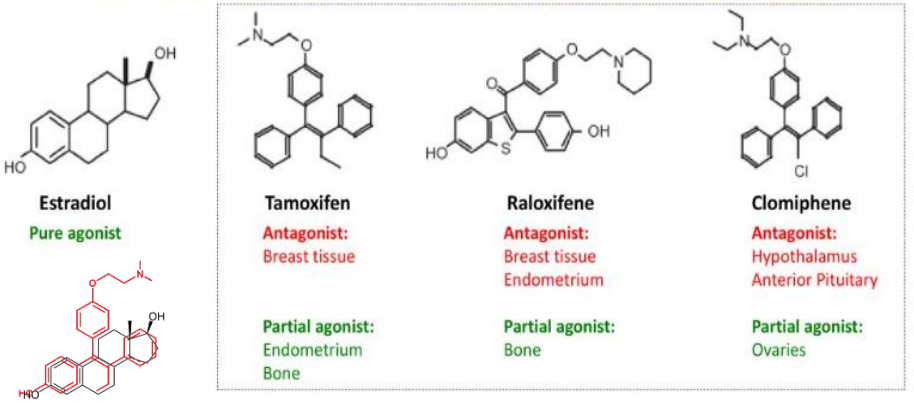
In vitro/임상 : C형간염, 인플루엔자, 에볼라 등

Raloxifene, a SERM for osteoporosis

Selective Estrogen Receptor Modulators (SERMs)

SERMs are ER ligands that exhibit **mixed agonist/antagonist** activity in a **tissue-specific fashion**

- SERMs act as ER antagonists in some tissues and ER partial agonists in others
- Allows the effects of estrogen to be specifically **inhibited** in certain target tissues without the adverse effects associated with loss of estrogen signaling in other tissues



Estradiol
Pure agonist

Tamoxifen
Antagonist:
Breast tissue

Partial agonist:
Endometrium
Bone

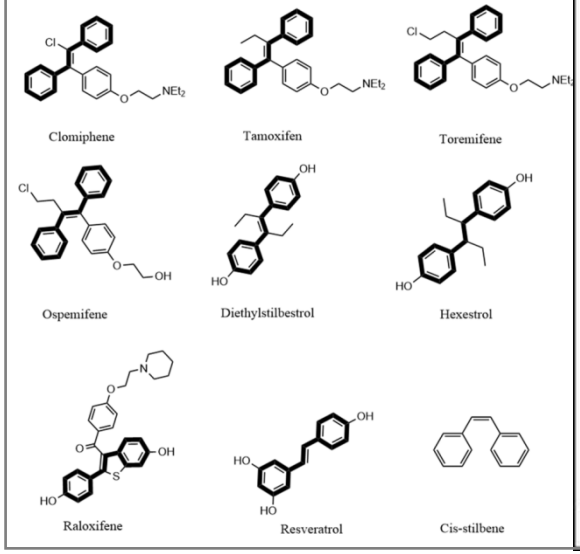
Raloxifene
Antagonist:
Breast tissue
Endometrium

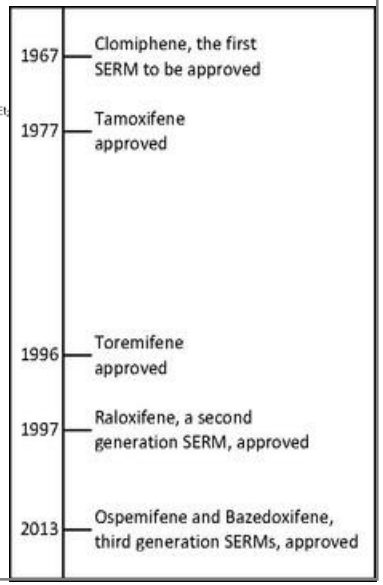
Partial agonist:
Bone

Clomiphene
Antagonist:
Hypothalamus
Anterior Pituitary

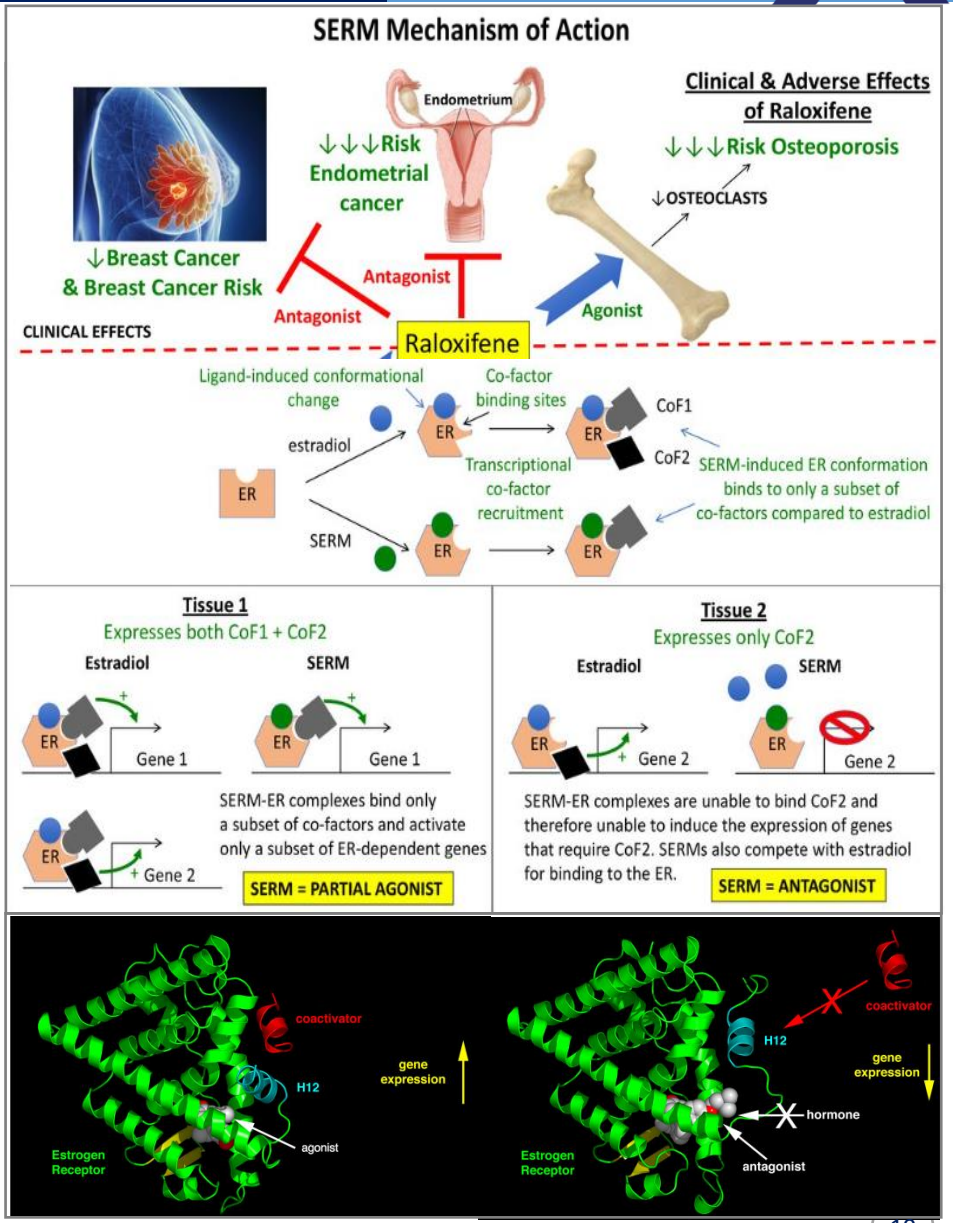
Partial agonist:
Ovaries

Stilbene type arrangement





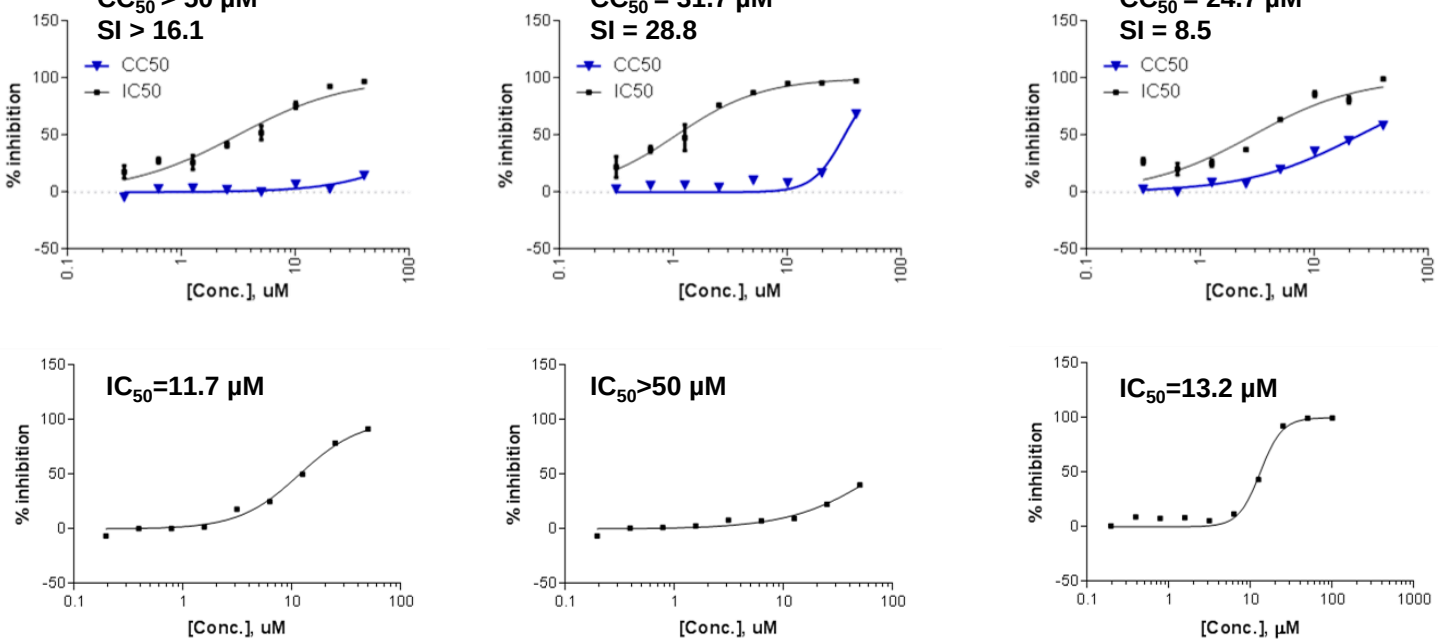
SERM Mechanism of Action



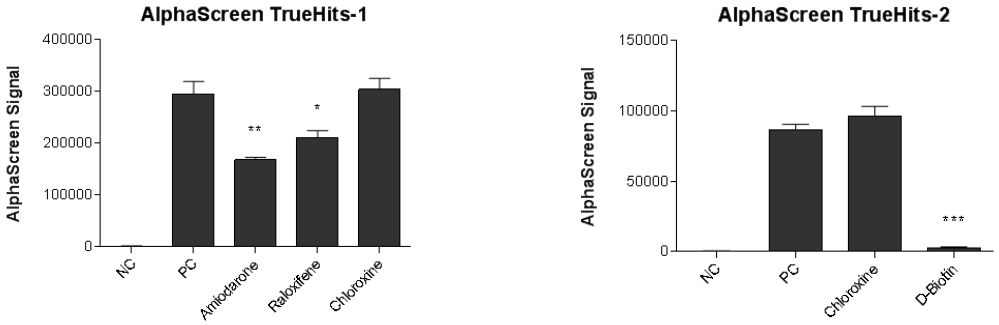
[Citation: https://slideplayer.com/slide/17324629/]

Hit validation (Screening assays)

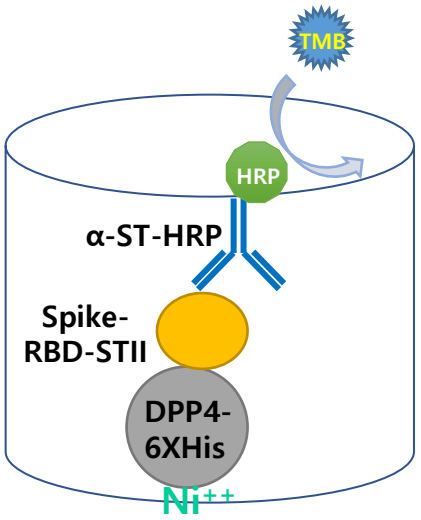
	Amiodarone	Raloxifene	Chloroxine
Pseudovirus	IC_{50} = 3.1 μM CC_{50} > 50 μM SI > 16.1	IC_{50} = 1.1 μM CC_{50} = 31.7 μM SI = 28.8	IC_{50} = 2.9 μM CC_{50} = 24.7 μM SI = 8.5
Alpha assay	IC_{50}=11.7 μM	IC_{50}>50 μM	IC_{50}=13.2 μM



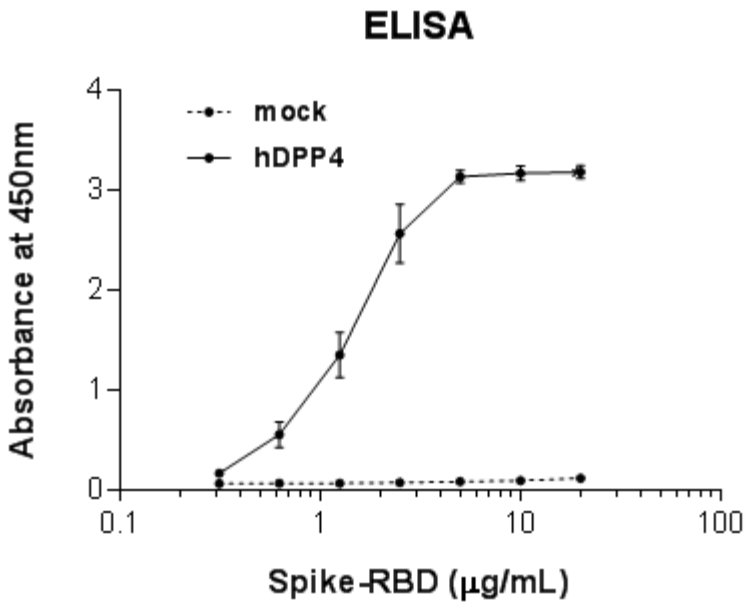
Alpha assay (TrueHits)



Hit validation (ELISA)

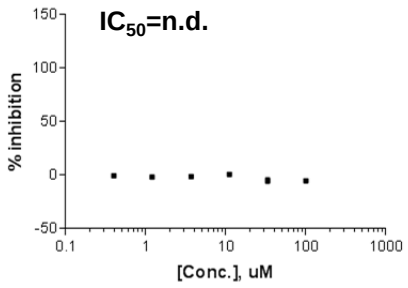


Measure A_{405}

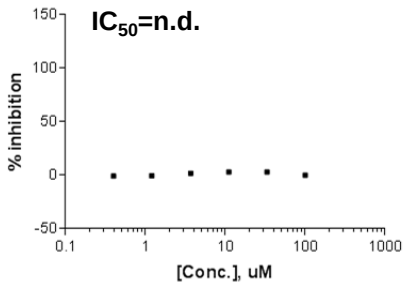


ELISA

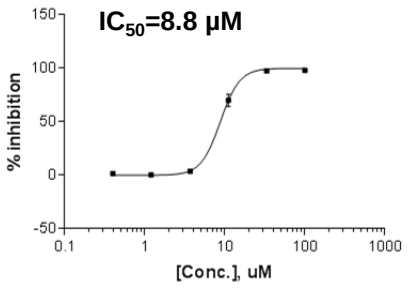
Amiodarone



Raloxifene



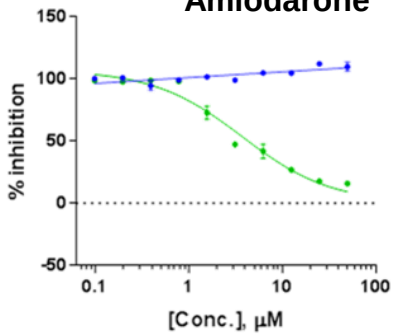
Chloroxine



Antiviral effect (MERS-CoV)

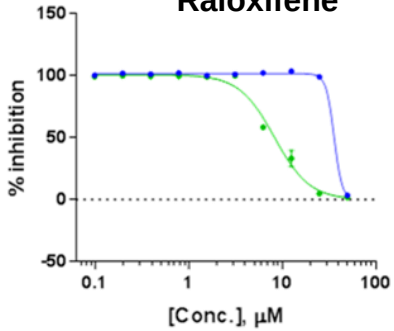
MERS-CoV (IF)

Amiodarone



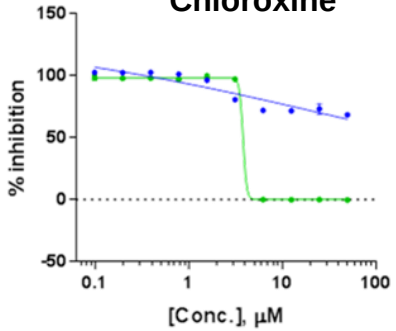
IC_{50} = 4.3 μM
CC_{50} > 50 μM

Raloxifene



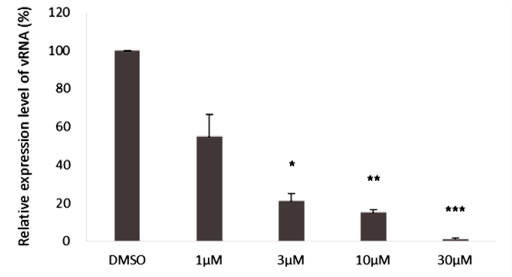
IC_{50} = 8.2 μM
CC_{50} > 44.22 μM

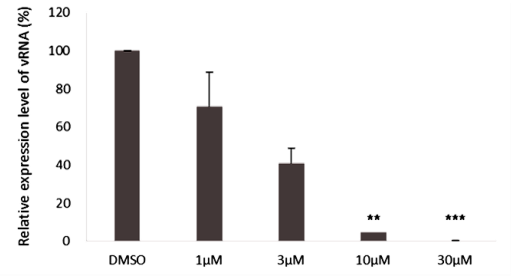
Chloroxine

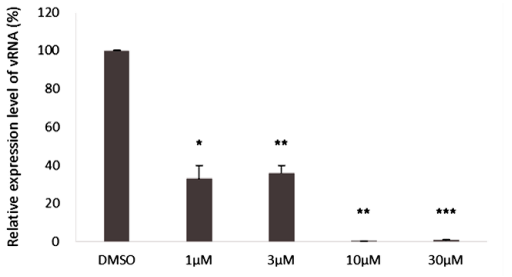


IC_{50} = 3.7 μM
CC_{50} > 50 μM

MERS-CoV (qRT-PCR)

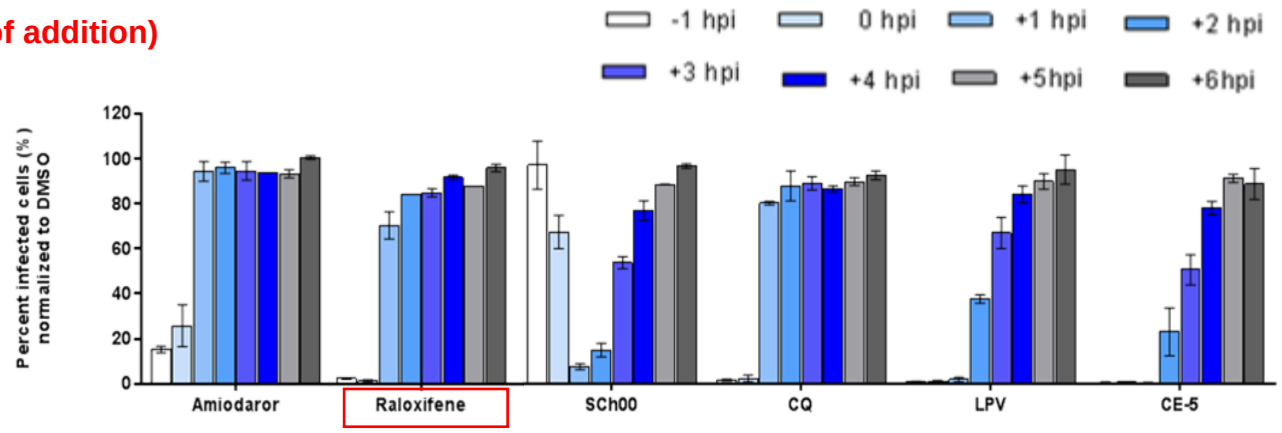




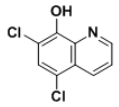
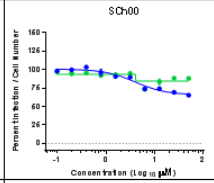
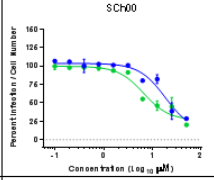
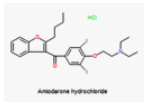
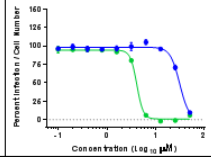
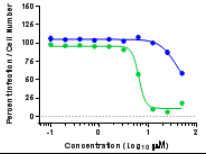
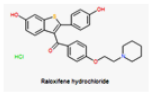
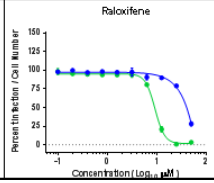
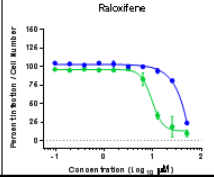


Antiviral effect (MERS-CoV, SARS-CoV)

MERS-CoV (Time of addition)



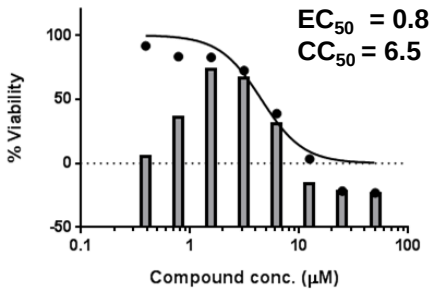
SARS-CoV (IF)

Chemical Name	Structure	M.W	SARS-CoV (HK39849) VeroE6				SARS-CoV (HK39849) Vero			
			EC50 (μM)	CC50 (μM)	SI	DRC	EC50 (μM)	CC50 (μM)	SI	DRC
Chloroxine		214.00	>50	>50	1.00		13.73	21.25	1.55	
Amiodarone		681.77	3.97	31.71	7.99		6.74	41.52	6.16	
Raloxifene		510.04	8.90	>50	5.62		10.64	49.20	4.62	

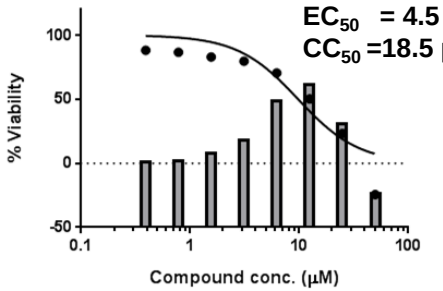
Antiviral effect (HCoV-229E/OC43)

HCoV-229E (CPE)

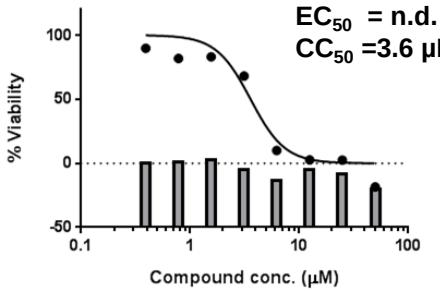
Amiodarone



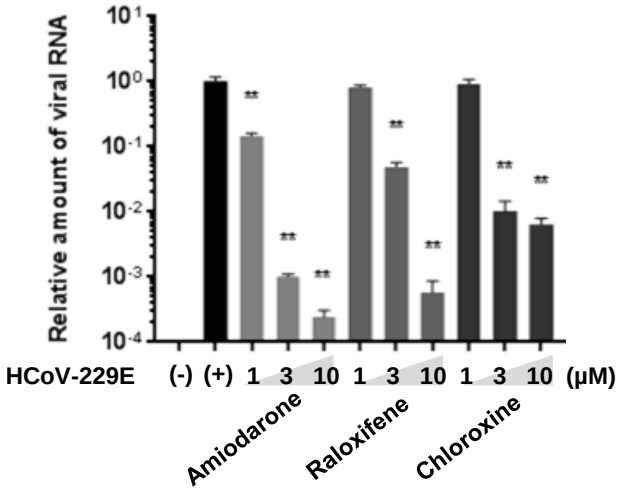
Raloxifene

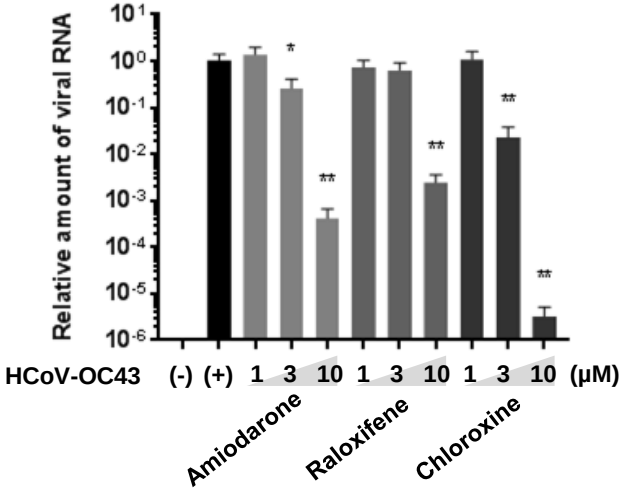


Chloroxine



HCoV-229E/HCoV-OC43 (qRT-PCR)

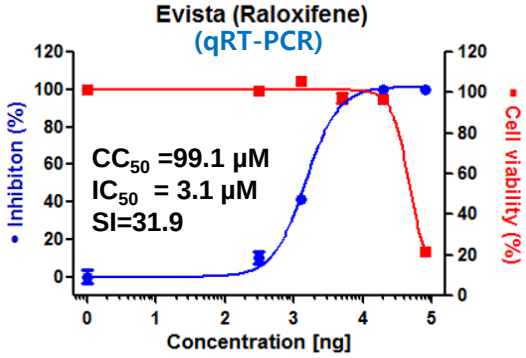


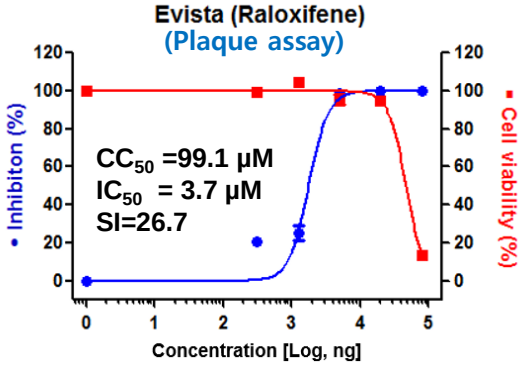


Antiviral effect (SARS-CoV-2)

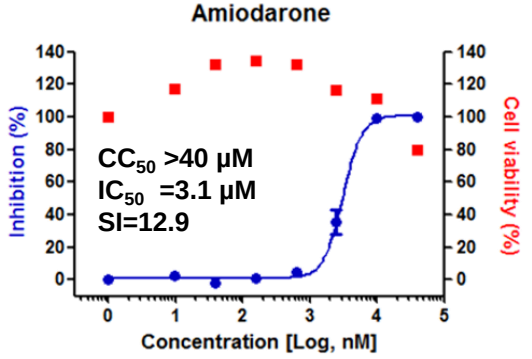
Drugs	CC_{50}	qRT-PCR		Plaque assay	
		IC_{50}	SI	IC_{50}	SI
Raloxifene	99.1 μM	3.1 μM	31.9	3.7 μM	26.7
Amiodarone	>40 μM	3.1 μM	12.9	-	-
Chloroxine	-	-	-	-	-
Remdesivir	>40 μM	7.7 μM	5.2	-	-

SARS-CoV-2 infection assay (qRT-PCR, Plaque assay)

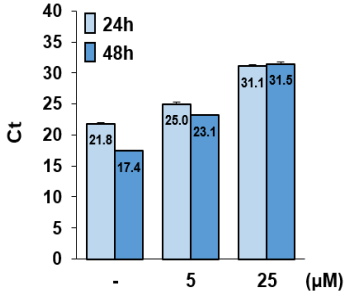


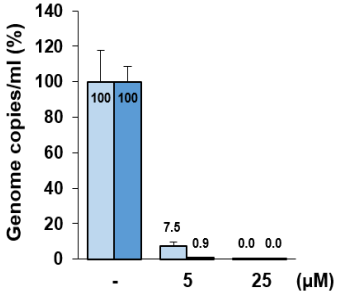


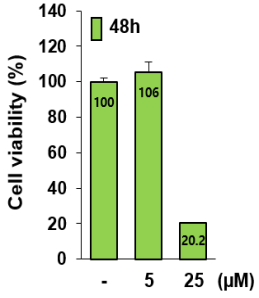
SARS-CoV-2 (qRT-PCR)

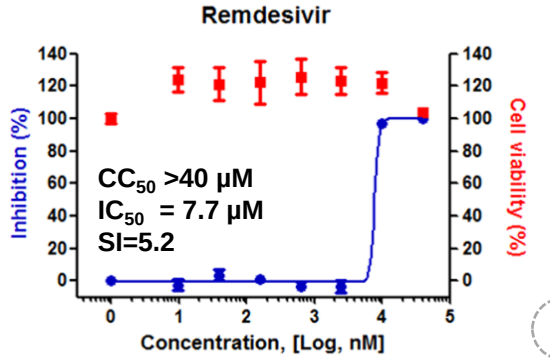


SARS-CoV-2 (Raloxifene, qRT-PCR)





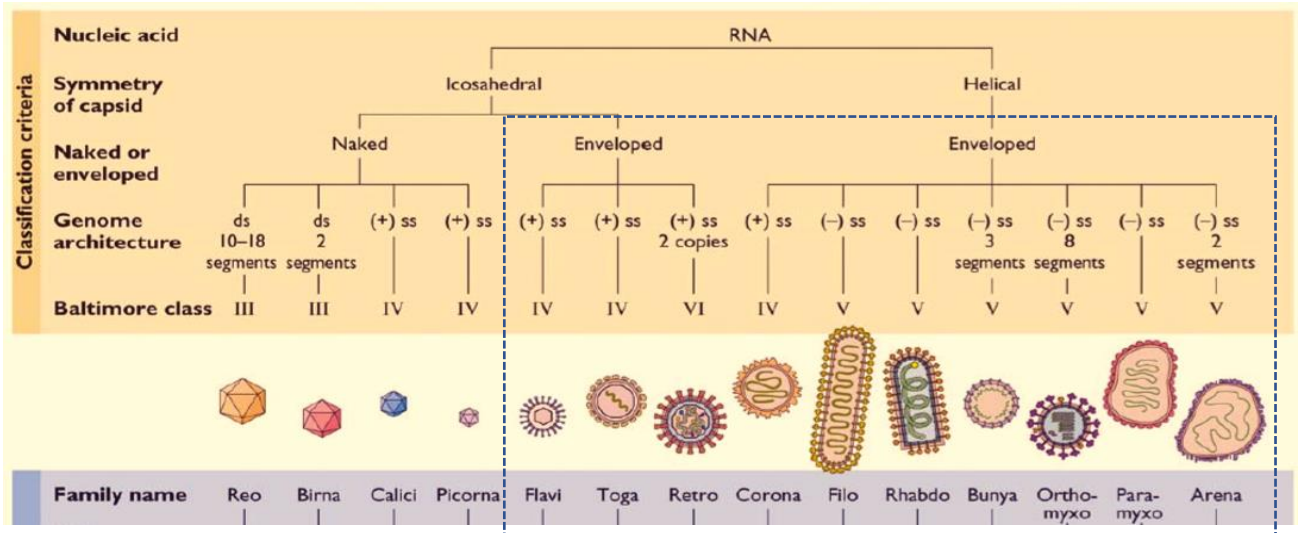




Mode of Action

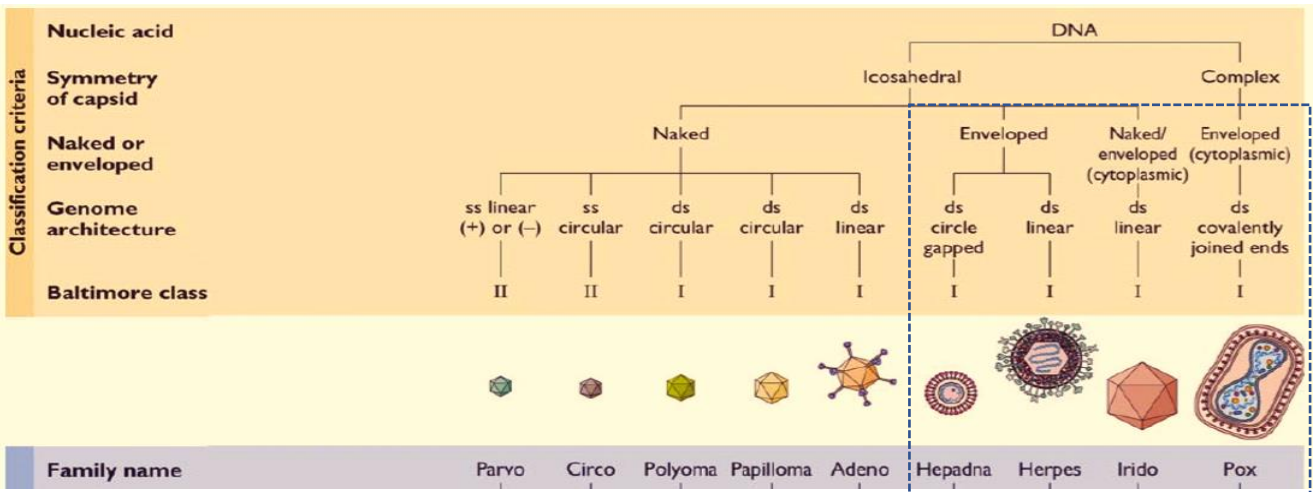
- Reviewing literature over 20 years -

Enveloped virus-specific antiviral effect



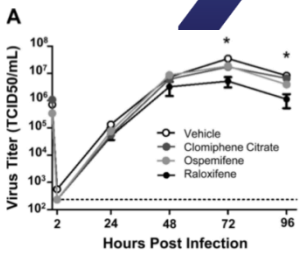
HCV SFV HIV EBOV IAV
DV SINV
ZIKV
YFV

"CoVs"

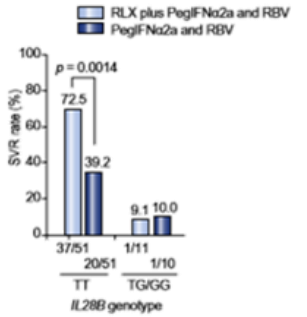


HBV HSV VACV

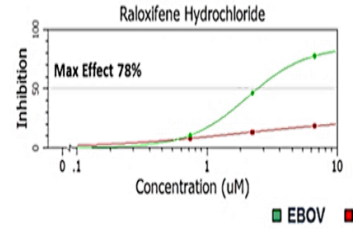
IAV



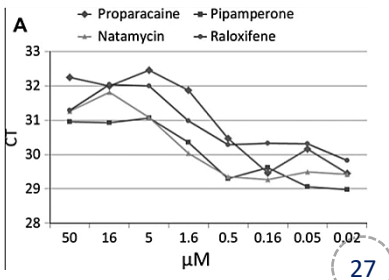
HCV



EBOV



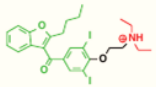
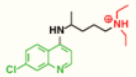
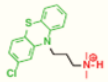
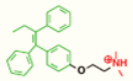
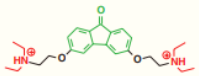
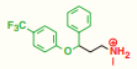
HBV

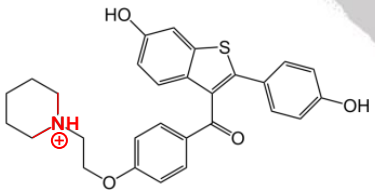


MoA1 : Lysosomotropic chemical property

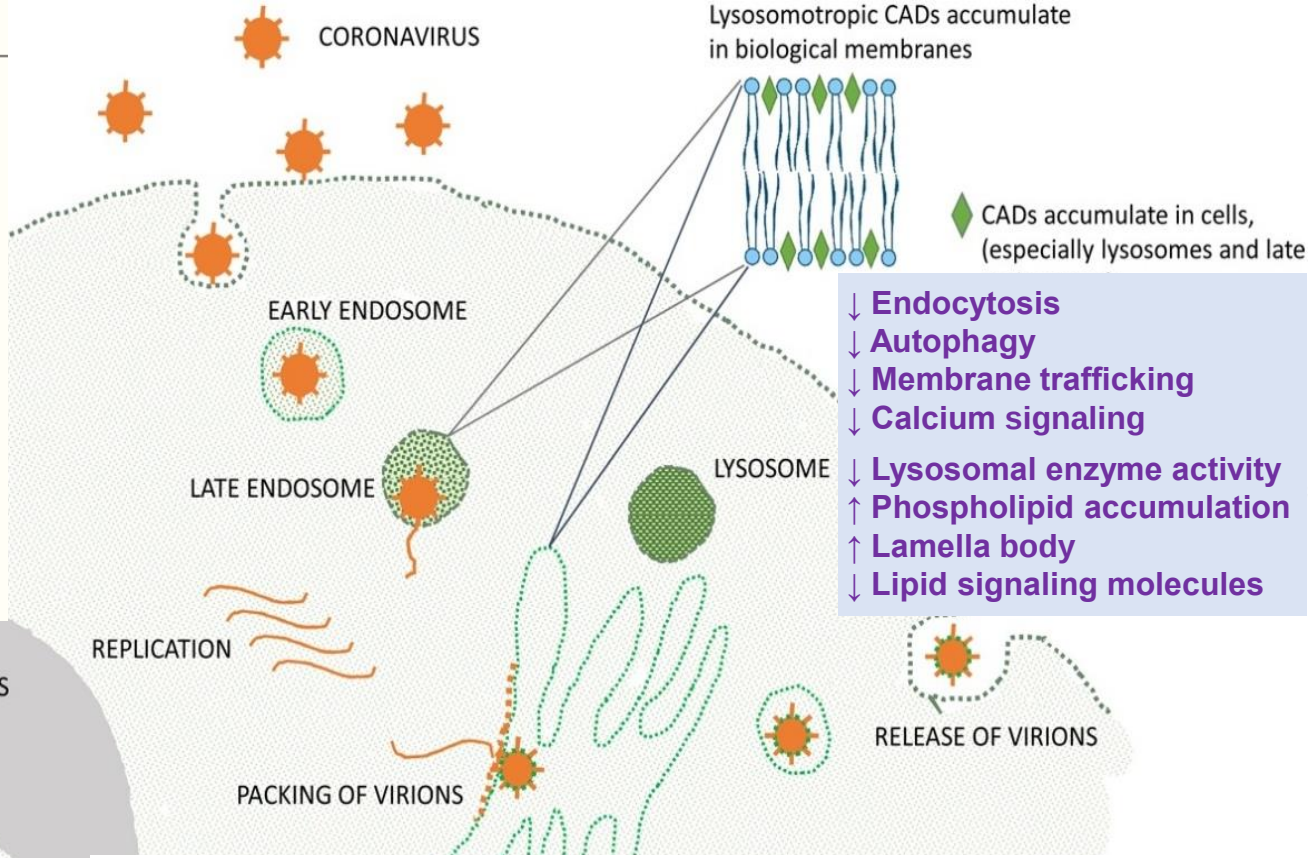
Lysosomotropic drugs or CADs (Cationic amphiphilic drugs)

LE/Lys Accumulation ↑ | **LE/Lys pH ↑** | **Surface (-)charge ↓**

Drugs	Categories	Structure
Amiodarone	Antiarrythmic	
Chloroquine	Antimalarial	
Chlorpromazine	Antipsychotic	
Tamoxifen	Antiestrogenic	
Tilorone	Antiviral	
Fluoxetine	Antidepressant	



[Raloxifene] pKa=8.89, LogP=5.45



257 cases of 15 CADs under global clinical trial for COVID-19

Muehlbacher M, Tripal P, Roas F, Kornhuber J. Identification of drugs inducing phospholipidosis by novel in vitro data. ChemMedChem. 2012;7(11):1925-1934.
Salata C, Calistri A, Parolin C, Baritussio A, Palù G. Antiviral activity of cationic amphiphilic drugs. Expert Rev Anti Infect Ther. 2017;15(5):483-492.
Breiden B, Sandhoff K. Emerging mechanisms of drug-induced phospholipidosis. *Biol Chem*. 2019;401(1):31-46. doi:10.1515/hsz-2019-0270
Norinder U, Tuck A, Norgren K, Munic Kos V. Existing highly accumulating lysosomotropic drugs with potential for repurposing to target COVID-19. Biomed Pharmacother. 2020;130:110582.
Fan H, Du X, Zhang J, et al. Selective inhibition of Ebola entry with selective estrogen receptor modulators by disrupting the endolysosomal calcium. *Sci Rep*. 2017;7:41226. Published 2017 Jan 24.

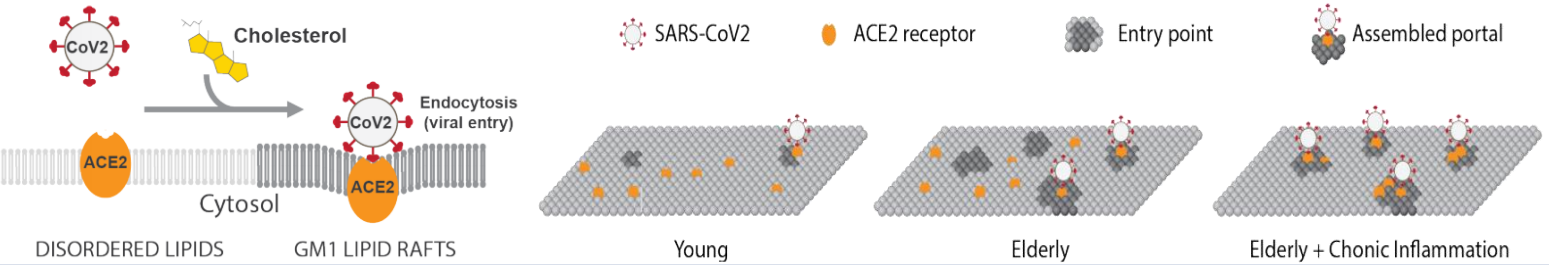
Selected readings

MoA2 : Cholesterol lowering effect

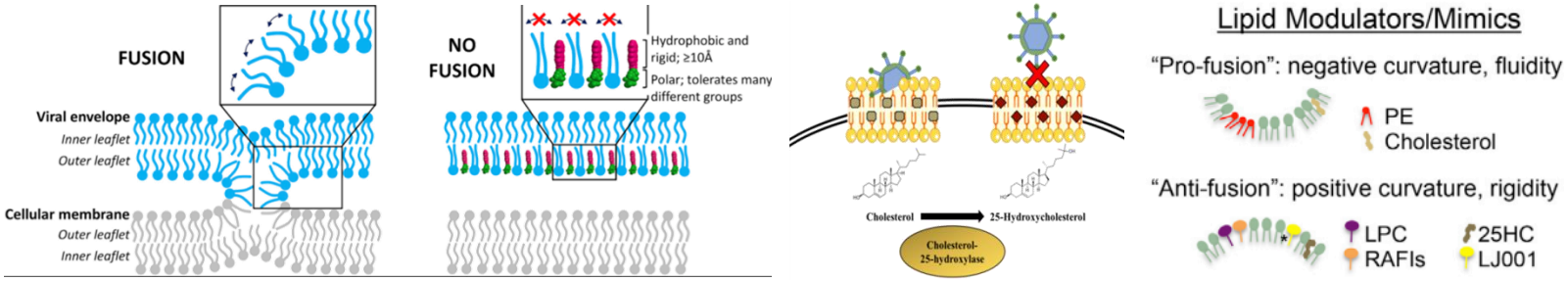
BIOPLUS · INTERPHEX KOREA

Cholesterol trafficking ↓ | Cholesterol biosynthesis ↓ | LDL-C ↓, TG ↓, HDL-C ↑

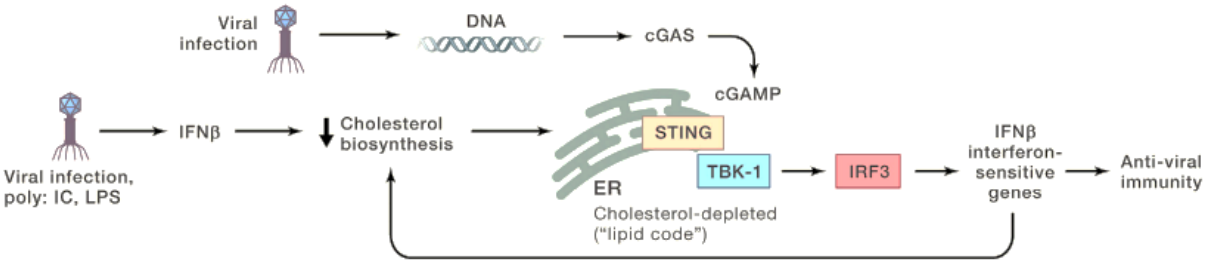
Lipid Raft ↓



Membrane Fluidity ↓



Innate Immune Response ↑



Atorvastatin
Rosuvastatin
Simvastatin
Ulinastatin

10 cases of 4 statins under global clinical trial for COVID-19

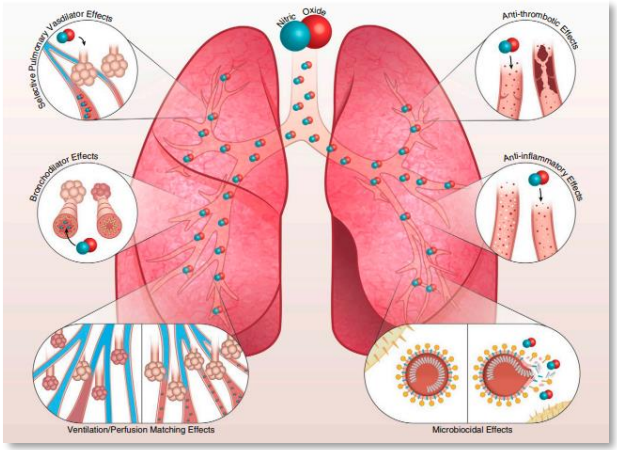
Selected readings

T., L., Does cholesterol play a role in COVID-19? *News-Medical* 2020
O'Neill LA. How Low Cholesterol Is Good for Anti-viral Immunity. *Cell*. 2015;163(7):1572-1574
Schoggins JW, Randall G. Lipids in innate antiviral defense. *Cell Host Microbe*. 2013;14(4):379-385.
Saitta A, Morabito N, Frisina N, et al. Cardiovascular effects of raloxifene hydrochloride. *Cardiovasc Drug Rev*. 2001;19(1):57-74.
Lu Y, Liu DX, Tam JP. Lipid rafts are involved in SARS-CoV entry into Vero E6 cells. *Biochem Biophys Res Commun*. 2008;369(2):344-349.
Kauffman RF, Bensch WR, Roudebush RE, et al. Hypocholesterolemic activity of raloxifene (LY139481): pharmacological characterization as a selective estrogen receptor modulator. *J Pharmacol Exp Ther*. 1997;280(1):146-153.
Fernández-Suárez ME, Escolà-Gil JC, Pastor O, et al. Clinically used selective estrogen receptor modulators affect different steps of macrophage-specific reverse cholesterol transport. *Sci Rep*. 2016;6:32105. Published 2016 Sep 7.
Dayspring T, Qu Y, Keech C. Effects of raloxifene on lipid and lipoprotein levels in postmenopausal osteoporotic women with and without hypertriglyceridemia. *Metabolism*. 2006;55(7):972-979.
Piperi C, Kalofoutis C, Lagogianni I, Troupis G, Kalofoutis A. Comparison of raloxifene and atorvastatin effects on serum lipids composition of healthy post-menopausal women. *Mol Cell Biochem*. 2004;261(1-2):71-75.
Wages PA, Kim HH, Korade Z, Porter NA. Identification and characterization of prescription drugs that change levels of 7-dehydrocholesterol and desmosterol. *J Lipid Res*. 2018;59(10):1916-1926.
Glende J, Schwegmann-Wessels C, Al-Falah M, et al. Importance of cholesterol-rich membrane microdomains in the interaction of the S protein of SARS-coronavirus with the cellular receptor angiotensin-converting enzyme 2. *Virology*. 2008;381(2):215-221.
Wang H, Yuan Z, Pavel MA, Hansen SB. The role of high cholesterol in age-related COVID19 lethality. Preprint. *bioRxiv*. 2020;2020.05.09.086249. Published 2020 May 29.
Li GM, Li YG, Yamate M, Li SM, Ikuta K. Lipid rafts play an important role in the early stage of severe acute respiratory syndrome-coronavirus life cycle. *Microbes Infect*. 2007;9(1):96-102.

MoA3 : On-target metabolic modulation

BIOPLUS · INTERPHEX KOREA

eNOS, NO ↑

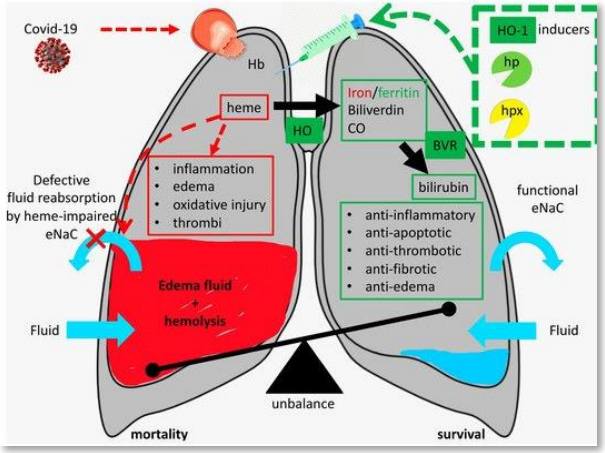


- Pulmonary vasodilation
- Bronchodilation
- V/Q matching
- Anti-thrombosis
- Anti-inflammation
- Anti-viral

NO

"Inhaled NO"
~10 cases of clinical trials for COVID-19

p38 MAPK, HO ↑



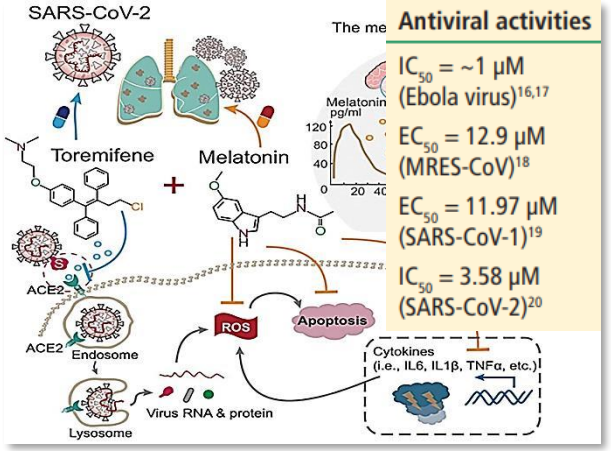
- Anti-inflammation
- Anti-thrombosis
- Anti-oxidation
- Anti-fibrosis
- Anti-edema
- Cardio & Neuroprotective

CO

Bilirubin

Raloxifene !
Why not ?

SERMs & Estrogen



- Upper airway
  - Nasal mucus
  - Hyaluronic acid
  - Cellular immunity
- Bronchial epithelium
  - Antiviral mucus

Estrogen

Estrogen, Tamoxifen, and Toremifene under clinical trials for COVID-19

Selected readings

Alvarez RA, Berra L, Gladwin MT. Home Nitric Oxide Therapy for COVID-19. *Am J Respir Crit Care Med*. 2020;202(1):16-20.
Saitta A, Morabito N, Frisina N, et al. Cardiovascular effects of raloxifene hydrochloride. *Cardiovasc Drug Rev*. 2001;19(1):57-74.
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Summary

<Summary>

1. We have carried out a R&D project to discover DAAs or immune modulators for MERS-CoV.

2. Three drugs (raloxifene, amiodarone and chloroxine) were repurposed to anti-CoV drugs.

3. Raloxifene was the most promising one in terms of efficacy and safety.

4. Its MoAs include lysosomotropism, cholesterol reduction and on-target estrogenic effects.

<On-going>

1. Animal experiments (hamster and hACE2 TG mouse)

2. Clinical study sponsored by Gyeonggi-do

3. Korea-EU collaborative research on Raloxifene

Perspectives

<EU finding>

07 September, 2020
Brussels 9° C

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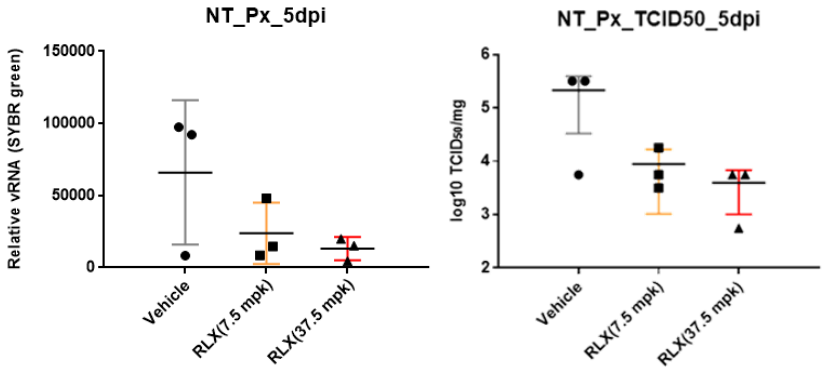
EU researchers: Registered generic drug could cure Covid-19

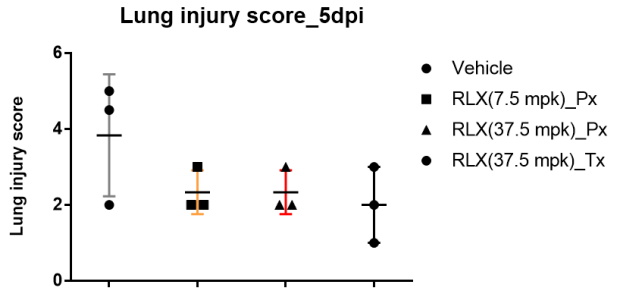
The medicine Raloxifene is used for treatment and prevention of osteoporosis

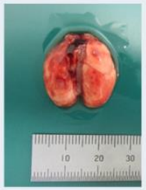
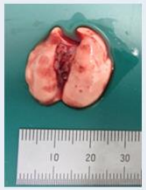
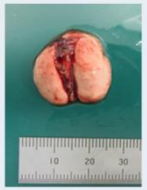
The consortium has already virtually tested 400 000 molecules on its supercomputers and 7 000 molecules were preselected and further tested “in vitro”. Out of them, 100 were selected and 40 resulted as active against the virus.

Raloxifene emerged as the most promising molecule. Researchers found that it could be effective in blocking the replication of the virus in cells, and could thus hold up the progression of the disease, in particular in cases of early detection or in asymptomatic cases. High patient tolerability, safety and highly established toxicological profile are among the other advantages of the drug.

<Animal study>





구분	비감염군	감염, 위약 투여군	감염, 랄록시펜 7.5 mpk 투여군 (예방모델)	감염, 랄록시펜 37.5 mpk 투여군 (예방모델)	감염, 랄록시펜 37.5 mpk 투여군 (치료모델)
평균점수	0	3.8±1.6	2.3±0.5	2.3±0.5	2±1
대표사진	 폐손상 점수: 0	 폐손상 점수: 5	 폐손상 점수: 2	 폐손상 점수: 2	 폐손상 점수: 2

Acknowledgement

GBSA 경기도경제과학진흥원

Assay development, HTS, in vitro & cell-based assay for HCoV

정귀완, 박선미, 양정은, 송명진, 이경빈, 최동화

Institut Pasteur Korea

Phenotypic screening & cell-based assay for MERS-CoV and SARS-CoV

류왕식, 김승택, 김진희, 이지혜, 고미현, 전상은, 민지영, 장소영

질병관리본부 국립보건연구원

Cell based- & animal study for SARS-CoV-2

이주연, 김경창, 김령의

국 방 과 학 연 구 소 Agency for Defense Development

Animal study for SARS-CoV-2

유치호

코로나19 예방 DNA 백신 GX-19의 개발

서유석

전무 ㈜ 제넥신

BIOPLUS INTERPHEX KOREA

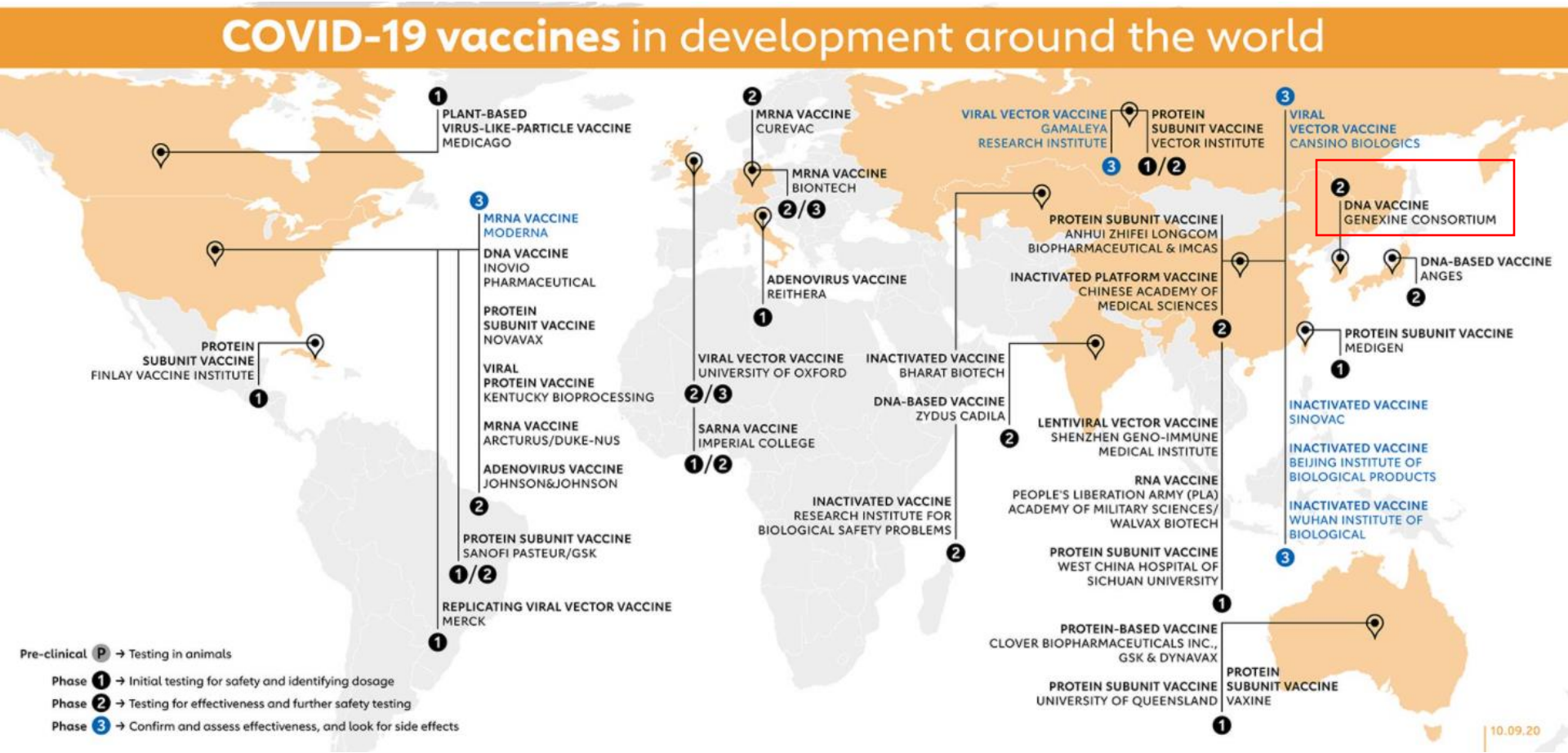
코로나 19 백신 개발의 필요성

- 미국의 지난 2020년 2분기 경제성장율은 -32.9% 기록 (연률 환산, 미국 상무부)
- 2020년 2분기 한국의 경제성장율은 외환 이후 최악인 -3.3% (OECD)
- 통제정책, 사회적 거리 두기로 경기 저하 뿐이나, 불안감, 우울증 등 사회적 문제 대두
- 치료제 사용 후, 면역반응이 충분히 생성되지 않을 경우, 재감염의 우려가 있음
- 궁극적으로 전 국민, 전 인류를 대상으로 백신 필요

Table 2-1 World Economic outlook projections (IMF, April 20, 2020)

		Projections	
	2019	2020	2021
World Output	**2.9**	**−3.0**	**5.8**
Advanced Economies	**1.7**	**−6.1**	**4.5**
United States	2.3	−5.9	4.7
Euro Area	1.2	−7.5	4.7
Germany	0.6	−7.0	5.2
France	1.3	−7.2	4.5
Italy	0.3	−9.1	4.8
Spain	2.0	−8.0	4.3
Japan	0.7	−5.2	3.0
United Kingdom	1.4	−6.5	4.0
Canada	1.6	−6.2	4.2
Other Advanced Economies[2]	1.7	−4.6	4.5
Emerging Market and Developing Economies	**3.7**	**−1.0**	**6.6**
Emerging and Developing Asia	5.5	1.0	8.5
China	6.1	1.2	9.2
India[3]	4.2	1.9	7.4
ASEAN-5[4]	4.8	−0.6	7.8
Emerging and Developing Europe	2.1	−5.2	4.2
Russia	1.3	−5.5	3.5
Latin America and the Caribbean	0.1	−5.2	3.4
Brazil	1.1	−5.3	2.9
Mexico	−0.1	−6.6	3.0
Middle East and Central Asia	1.2	−2.8	4.0
Saudi Arabia	0.3	−2.3	2.9
Sub-Saharan Africa	3.1	−1.6	4.1
Nigeria	2.2	−3.4	2.4
South Africa	0.2	−5.8	4.0
Memorandum			
European Union[5]	1.7	−7.1	4.8
Low-Income Developing Countries	5.1	0.4	5.6
Middle East and North Africa	0.3	−3.3	4.2
World Growth Based on Market Exchange Rates	2.4	−4.2	5.4
World Trade Volume (goods and services)	**0.9**	**−11.0**	**8.4**
Imports			
Advanced Economies	1.5	−11.5	7.5
Emerging Market and Developing Economies	−0.8	−8.2	9.1
Exports			
Advanced Economies	1.2	−12.8	7.4
Emerging Market and Developing Economies	0.8	−9.6	11.0

코로나 19 백신 개발 현황 (GAVI, Sep 9, 2020)



코로나19 DNA 백신 개발 현황

- 9월 3일자 WHO “Draft landscape of COVID-19 candidate vaccines”에 의하면 총 34개 백신이 임상단계, 142개 백신은 전임상 단계에 있음
- 임상단계의 DNA 백신은 INOVIO의 INO-4800을 포함하여 4개의 후보물질이 있음
- GX-19는 전달 기기로 Electroporator (EP) 및 무바늘분사식투여기 (Needle-free Jet Injector)를 사용하여 비교 임상연구를 수행하고 있음

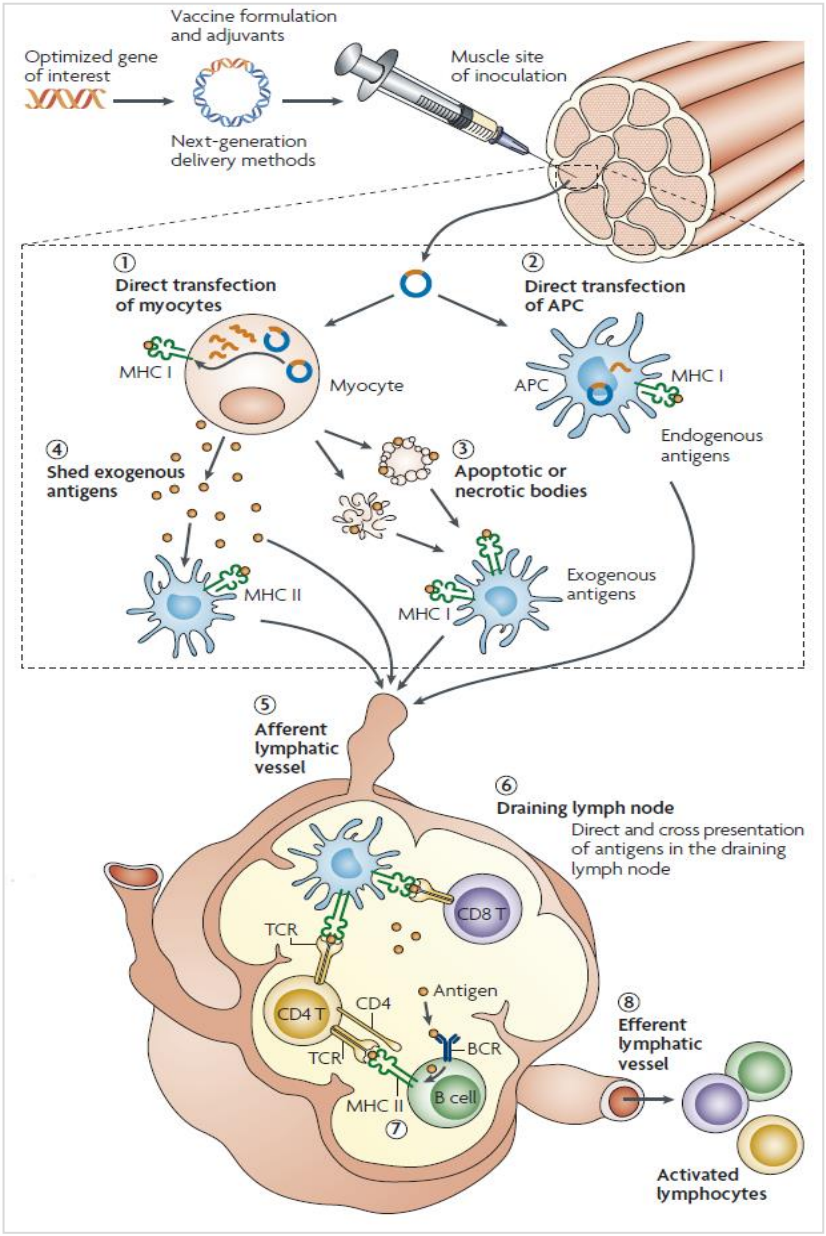
DRAFT landscape of COVID-19 candidate vaccines – 3 September 2020

34 candidate vaccines in clinical evaluation

Inovio Pharmaceuticals/ International Vaccine Institute	DNA	DNA plasmid vaccine with electroporation	2	0, 28 days	ID	NCT04447781 NCT04336410
Osaka University/ AnGes/ Takara Bio	DNA	DNA plasmid vaccine + Adjuvant	2	0, 14 days	IM	NCT04463472 NCT04527081
Cadila Healthcare Limited	DNA	DNA plasmid vaccine	3	0, 28, 56 days	ID	CTRI/2020/07/026352
Genexine Consortium	DNA	DNA Vaccine (GX-19)	2	0, 28 days	IM	NCT04445389

출처 : WHO

DNA 백신



GX-19 DNA Vaccine의 면역반응 유도 기전

- 인체(근육)에 투여되면 플라스미드 DNA(7,453 bp)로부터 S 항원(1,223 아미노산) 발현
- APC에 항원이 Presentation 되어 CD8+ T세포 반응 및 CD4+ T세포의 helping에 의해 항체반응 유도
- 강력한 세포면역반응에 의해 감염된 세포를 파괴하여 COVID-19을 예방함

DNA Vaccine의 장점

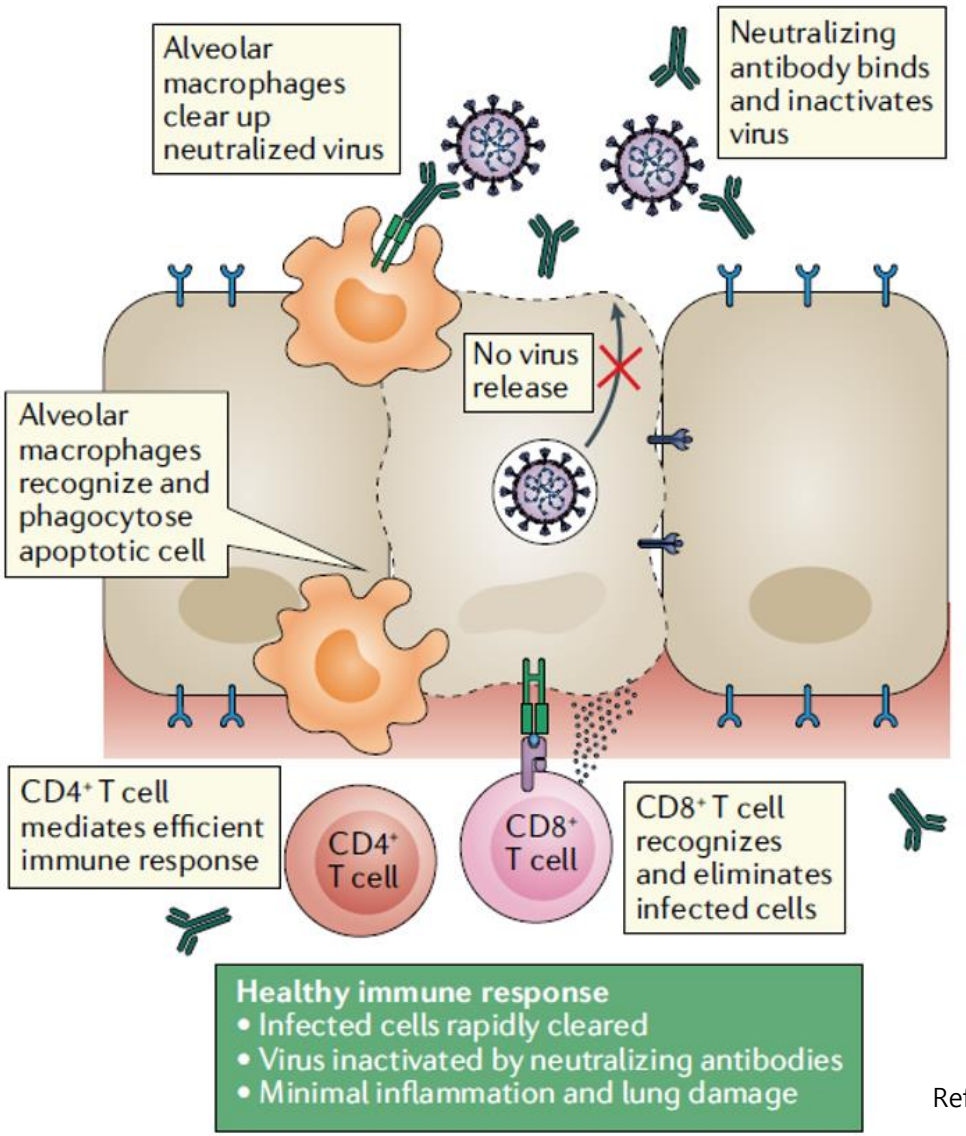
- 후보물질을 신속히 디자인하고 제작할 수 있음
- 생산공정이 간단하고, 신속한 생산이 가능함
- 460여건의 임상에서 안전성 확인
- 항체반응과 (Th1-biased) 세포면역반응을 동시에 유도
- 물질자체로 면역증강 활성 있음

DNA 백신과 RNA 백신의 비교

장단점 항목	RNA 백신	DNA 백신
생산	in vitro (숙주세포 없이 생산)	대장균을 숙주세포로 사용
단위 핵산분자 당 항원의 발현	많음	이론적으로 한 개 DNA에서 많은 RNA가 만들어지므로 RNA백신보다 발현항원 많음
염색체에 삽입 위험	없음	이론적으로 가능하나 실제적으로 일어나지 않음
세포 내 항원 발현을 위한 조건	Endosome을 벗어나야 함	핵 (Nucleus)안으로 들어가야 함
제형화 및 전달방법의 최적화	해결 필요 (여러 방법이 시도되고 있음)	해결 필요 (다양한 해결방안이 도출됨)
독성	더 많은 임상에서 검증 필요	이미 많은 임상에서 안전함이 확인 (상대적으로 많은 데이터가 축적됨)
생산비용	상대적으로 비쌈	상대적으로 저렴함

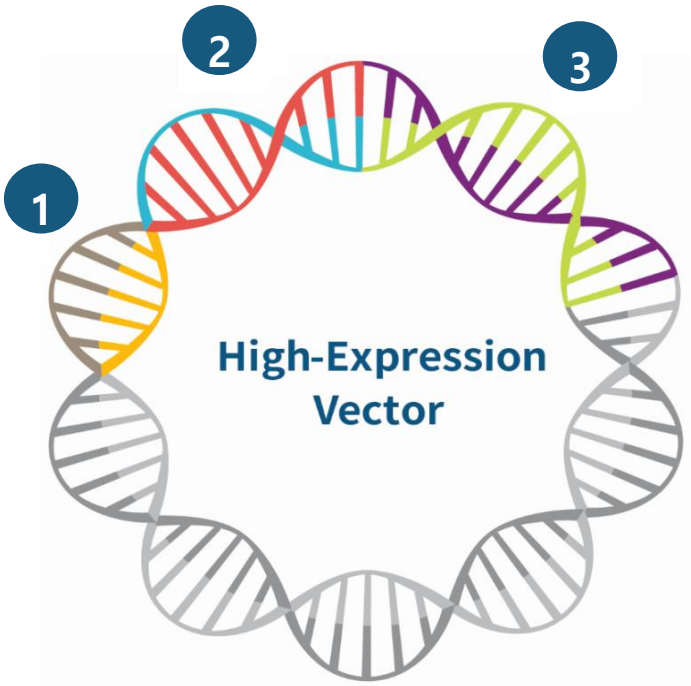
Reference : Liu MA. Vaccines (Basel). 2019 Apr 24;7(2). pii: E37. doi: 10.3390

중화항체 반응과 T 세포 면역반응



Reference : Nat Rev Immunol. 2020 Apr 28 : 1–12.

제넥신의 DNA 백신 플랫폼 기술



1

신호전달 서열

항원(단백질)의 발현을 증가시키고, 세포 밖 분비를 촉진하여 면역반응을 증진함

2

항원 엔지니어링

코돈 최적화를 통한 발현 증가,
가장 빈번히 발견되는 바이러스 유전자 사용,
Multimer가 형성되도록 디자인

3

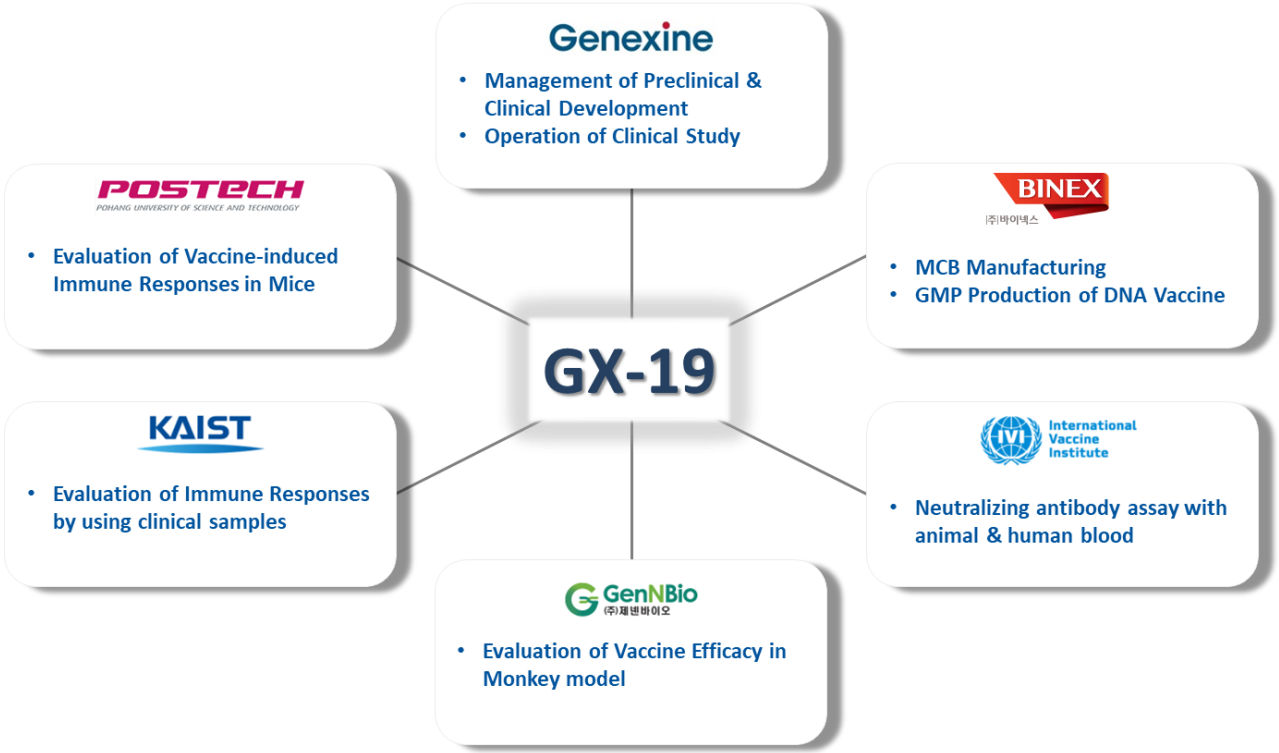
면역증강유전자 도입(필요시)

면역증강을 위해 플라스미드 내, 사이토카인 등 아주번트 유전자를 추가

본 기술이 적용된 다양한 DNA 백신이 임상에서 300명이상의 사람에 투여되어 안전성 및 효능이 검증되었음

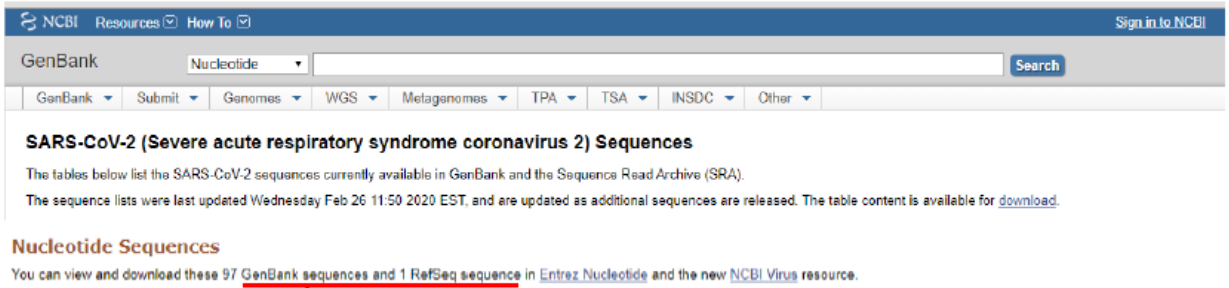
코로나19 백신개발을 위한 컨소시움 구성

- 제넥신 : 개발계획 수립, 전임상 및 임상개발 주도
- 바이넥스 : 세포주은행 및 임상시험용 의약품 생산
- 국제백신연구소 : 사람과 동물에서 중화항체반응 분석
- 제넨바이오 : 소동물 및 영장류 실험 진행
- 카이스트 : 임상에서 피험자 샘플의 면역반응 분석
- 포스텍 : 소동물에서 백신의 기전 및 후보물질 개선에 관한 연구



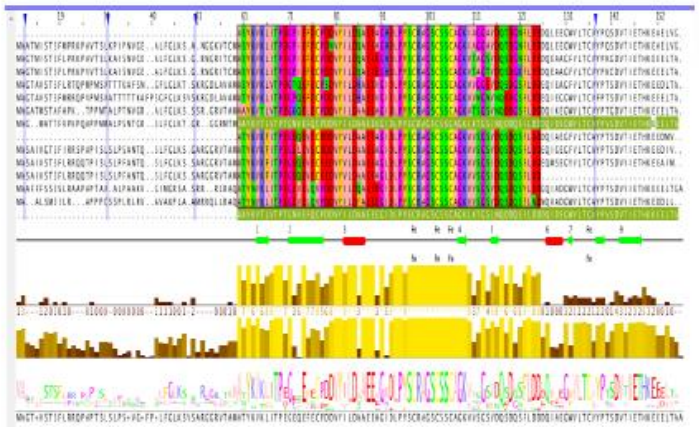
코로나19 DNA 백신 후보물질 제작

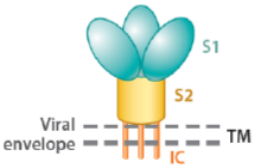
BIOPLUS · INTERPHEX KOREA



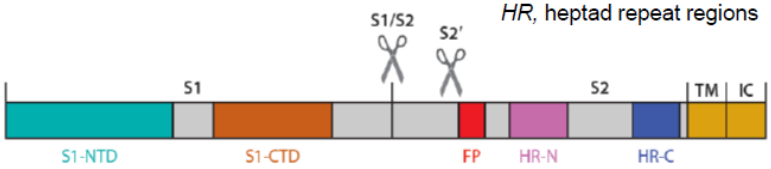
45 GenBank sequences

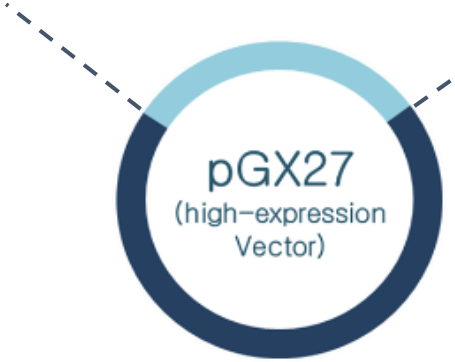
Jalview
A workbench for multiple sequence alignment and analysis





FP, fusion peptide
HR, heptad repeat regions

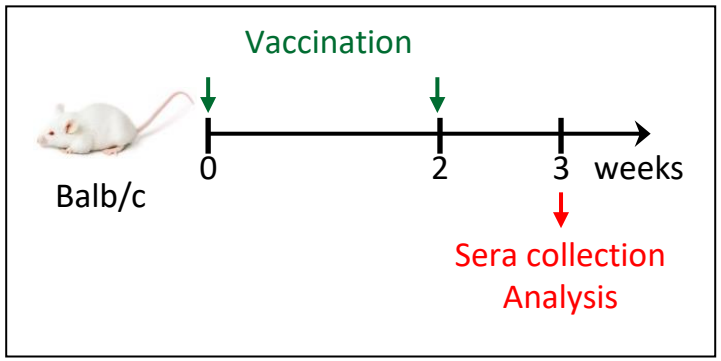


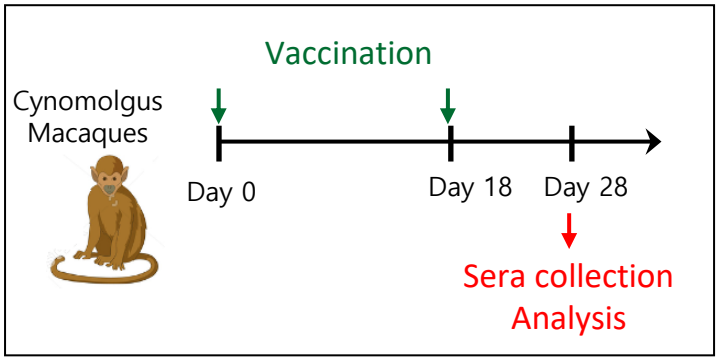


GX-19

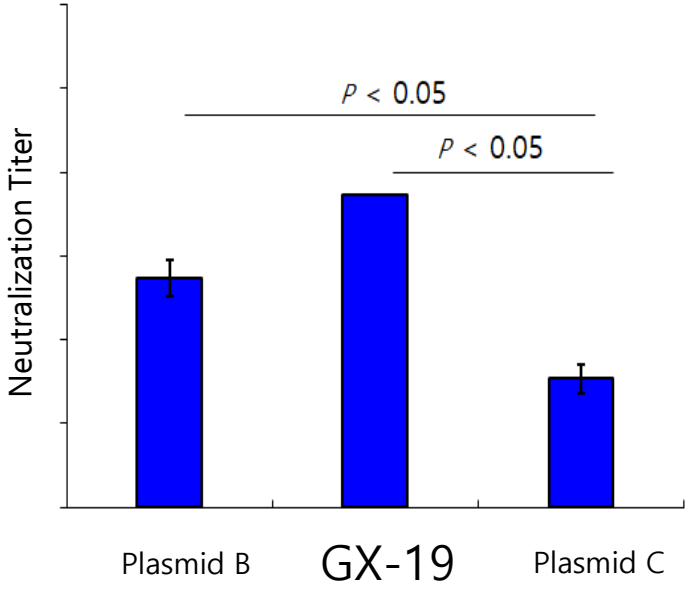
- 45개의 코로나19 바이러스 유전자를 검색하여 가장 많은 빈도로 발견되는 서열 적용
- 코로나19 스파이크 유전자를 자체 고발현 벡터 (pGX27)에 삽입하여 제작함

소동물 및 원숭이에서 GX-19의 면역원성 확인

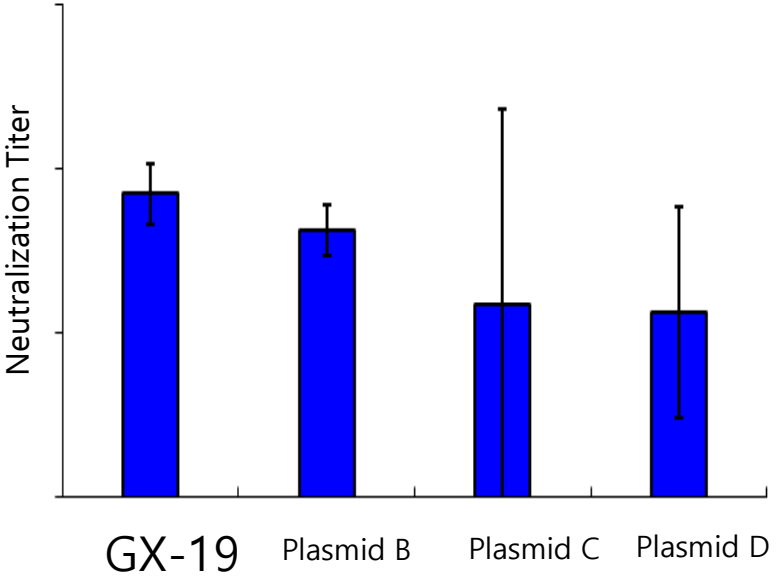




PRNT (Plaque reduction neutralization test)

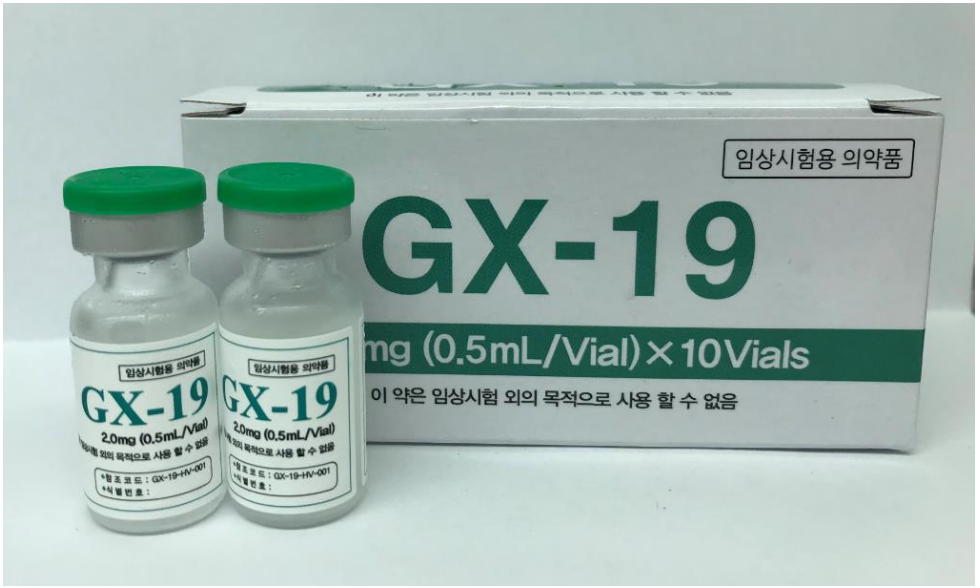


PRNT (Plaque reduction neutralization test)



코로나19 DNA 백신 GX-19 소개

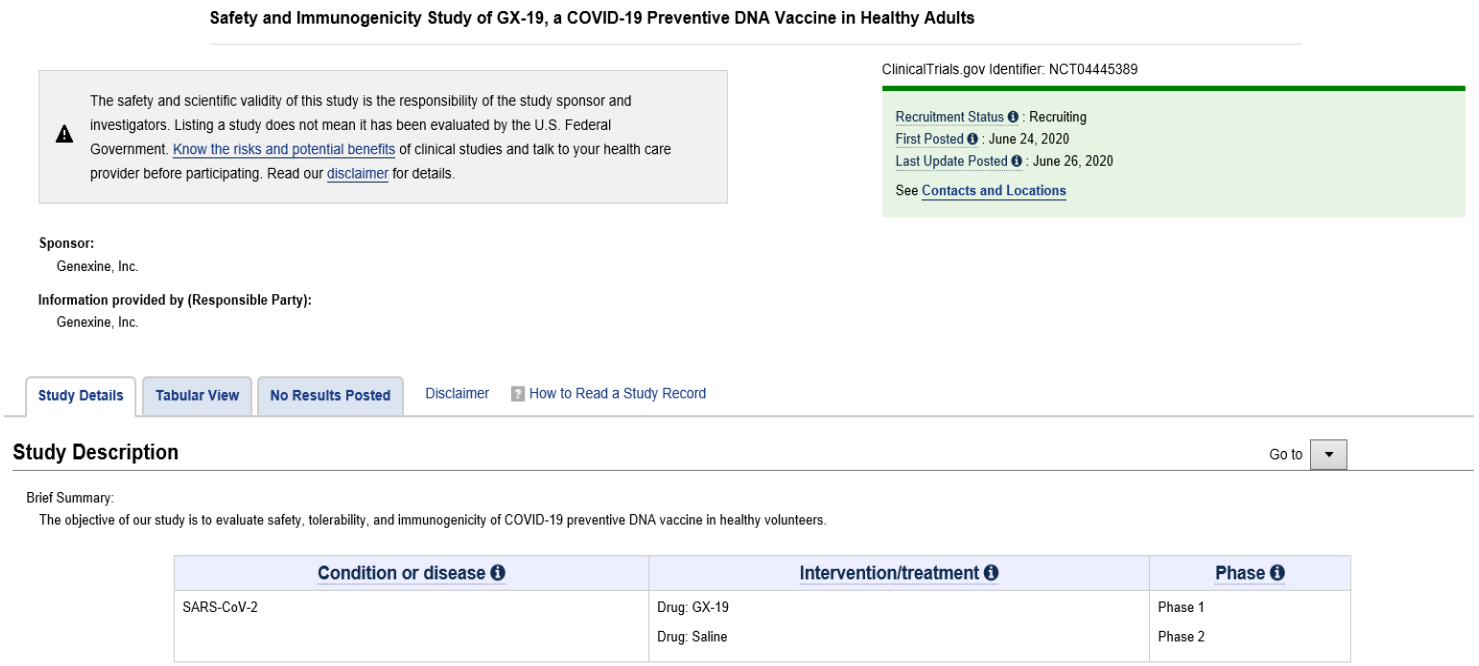
- 정의 : GX-19는 코로나19의 스파이크 (Spike) 단백질 항원 유전자를 함유한 플라스미드 DNA
- 기전 : 인체에 투여되면 플라스미드 DNA로 부터 스파이크 항원발현, 항원에 대한 면역반응 유도
  → COVID-19 예방
- 투여형태: 주사제 형태, 근육투여
- 개발단계 : 현재 한국 식약처로 부터 임상 1/2a 상을 승인 받아 임상 진행 중
  *투여기기 : EP 및 무바늘분사식투여기



코로나19 DNA 백신 GX-19 개발 경과

BIOPLUS · INTERPHEX KOREA

- 2020년 3월, GX-19 개발 컨소시움 (제넥신, 바이넥스, 국제백신연구, 제넨바이오, 카이스트, 포스텍) 결성 및 개발 착수
- 2020년 4월, 소동물 및 영장류에서 결합항체 반응 및 세포성 면역반응 확인
- 2020년 5월, 소동물 및 영장류에서 중화항체 반응 확인, 임상시험용 의약품 생산 완료, 식약처 임상1/2a상 신청
- 2020년 6월, 식약처 임상시험 (IND) 승인, 피험자 투여 개시
- 2020년 7월, 식약처 무바늘분사식투여기를 적용한 GX-19 임상 승인



Safety and Immunogenicity Study of GX-19, a COVID-19 Preventive DNA Vaccine in Healthy Adults

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04445389

Recruitment Status : Recruiting
First Posted : June 24, 2020
Last Update Posted : June 26, 2020
See Contacts and Locations

Sponsor:
Genexine, Inc.

Information provided by (Responsible Party):
Genexine, Inc.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:
The objective of our study is to evaluate safety, tolerability, and immunogenicity of COVID-19 preventive DNA vaccine in healthy volunteers.

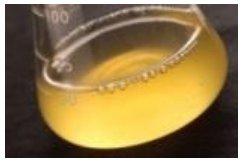
Condition or disease	Intervention/treatment	Phase
SARS-CoV-2	Drug: GX-19	Phase 1
	Drug: Saline	Phase 2

GX-19 제조 과정

- GX-19 플라스미드가 함유된 생산세포주를 사용하여 종배양 시작
- 종 배양액을 발효기(Fermenter)에 접종하여 본 배양 후, 대장균 세포를 수확
- 알칼리용액에 의한 세포 파쇄
- 음이온교환 크로마토그래피를 이용한 불순물의 제거
- 적합한 완충용액으로 교환한 후 바이알에 충진

생산세포주은행

GX-19 함유
대장균의 종배양



GX-19 함유
대장균의 본배양

대장균의 수확
및 파쇄

크로마토그래피
방법을 통한 정제
(불순물 제거)

제형화

바이알에 충전

GX-19 백신의 장점

- 산학연, 각 분야 전문가 집단에 의한 개발 (후보물질선정, 개발진행에서 시너지 발휘)
- 자궁경부암 치료 DNA 백신 등, 안전성 및 효능이 입증된 플랫폼 기술을 사용
- 개선된 공정을 적용 (수율이 높고, 대량생산이 가능 → 생산원가 절감)
- DNA 백신의 효능을 높이는 Delivery method 적용

nature COMMUNICATIONS

ARTICLE

Received 9 May 2014 | Accepted 19 Sep 2014 | Published 30 Oct 2014 DOI: 10.1038/ncomms6317 OPEN

Clearance of persistent HPV infection and cervical lesion by therapeutic DNA vaccine in CIN3 patients

Tae Jin Kim[1,*], Hyun-Tak Jin[2,*], Soo-Young Hur[3], Hyun Gul Yang[4], Yong Bok Seo[4], Sung Ran Hong[5], Chang-Woo Lee[6], Suhyeon Kim[6], Jung-Won Woo[2], Ki Seok Park[2], Youn-Young Hwang[2], Jaehan Park[2], In-Ho Lee[1], Kyung-Taek Lim[1], Ki-Heon Lee[1], Mi Seon Jeong[7], Charles D. Surh[4,8], You Suk Suh[2], Jong Sup Park[3] & Young Chul Sung[2,4]

Published OnlineFirst November 14, 2019; DOI: 10.1158/1078-0432.CCR-19-1513

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

A Phase II, Prospective, Randomized, Multicenter, Open-Label Study of GX-188E, an HPV DNA Vaccine, in Patients with Cervical Intraepithelial Neoplasia 3 AC

Youn Jin Choi[1,2], Soo Young Hur[1,2], Tae-Jin Kim[3], Sung Ran Hong[3], Jae Kwan Lee[4], Chi-Heum Cho[5], Ki Seok Park[6], Jung Won Woo[6], Young Chul Sung[7], You Suk Suh[6], and Jong Sup Park[1,6]

플랫폼 기술이 적용된 DNA백신 제품의 임상 논문

향 후 GX-19 개발 계획

- 2020년 연내 임상1/2a상을 통한 안전성 및 면역원성 확인 → 경쟁제품과 비교 우위 확보
- 2021년 상반기 임상 2b/3 상 개시, 글로벌 네트워크를 통한 다국가 임상 진행
- 2021년 말 까지 대량 생산 및 비축 계획

- GX-19 개발착수
- 임상에서 안전성 및 면역반응 확인

- 임상에서 효능 검증
- GX-19 대량생산 및 비축

- GX-19 제품 허가
- 국민 대상 접종
- 코로나19 퇴치

제넥신의 글로벌 파트너쉽

Companies for Joint Venture

Companies for Equity Investment

Companies for Clinical Research Collaboration

코로나백신 개발이 기업에 준 긍정적인 영향

- 시스템 구축

  : 값싸고 대량생산할 수 있는 제조공정의 개발

  : 팬데믹에 대응할 수 있는 전임상개발/임상개발 시스템 구축

  : 오픈 이노베이션을 위한 네트워크 구축

- 내부역량 강화

  : “신속 개발” 경험 축적

  : 플랫폼 기술을 활용한 허가역량 구축

- 플랫폼 기술의 적응증 범위 확장 (치료 백신에서 예방 백신까지)

- 해외 임상을 위한 글로벌 파트너쉽 강화

감사합니다

Genexine, Inc.
Korea Bio Park, Bldg. B,
700 Daewangpangyo-ro, Bundang Gu, Seongnam
Si, Gyunggi Do, 463-400 Korea

Contact
IR/PR
jykim@genexine.com
+82-31-628-3242