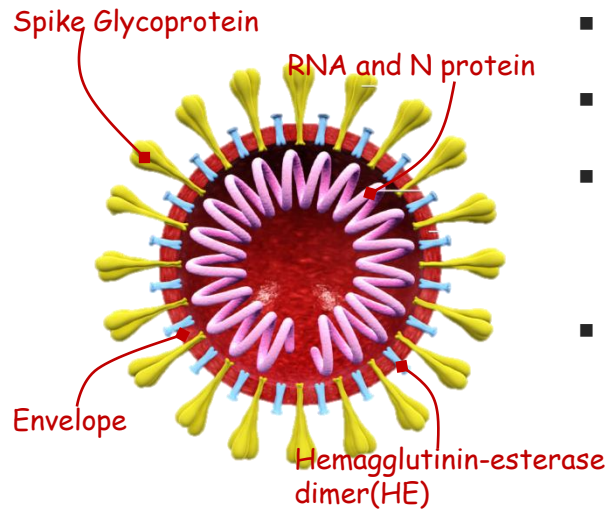


Allplex™ 2019-nCoV Assay

- 2020.02
- Seegene Inc., Marketing team

Coronavirus?



- Appearance like “Corona”, meaning crown or halo in Latin.
- Infect the upper respiratory and gastrointestinal track
- Cause a significant proportion of all common colds, primarily in the winter and early spring.
- 7 strains of human coronavirus are known

Genera	Strain
Alpha CoV - 1a	HCoV-229E, HCoV NL63
Beta CoV -2a	HCoV-OC43, HCoV-HKU1
Beta CoV -2b	SARS-CoV, COVID-19 <i>Sarbecovirus</i>
Beta CoV -2c	HCoV-EMC/2012 (MERS)

- HCoV-229E, -NL63, -OC43 and -HKU1 continually circulate and cause respiratory infection in the human population
- Coronavirus outbreaks of relatively high mortality
 - 2003 SARS, 2012 MESR and 2019 **COVID-19 (1,669/69,195)**

Coronavirus outbreaks



- **Origin** Bat
- **Outbreak** 2002.11-2003.07
- **Symptom**
Fever, headache, cough, shortness of breath & diarrhea
- **Transmission** Aerosol
- **Incubation period** 2-7d
- **775 death / 8273 infection**¹⁾



- **Carmel**
- **2012.11-**
- **Cough, shortness of breath, chills, nausea**
- **Coughs and sneezes**
- **-14d**
- **845 / 2,449** ²⁾



- **Unknown**
- **2019.12-**
- **Fever, cough, shortness of breath, sore throat, diarrhea, Pneumonia**
- **Cough and sneeze**
- **2-14d**
- **1,669 / 69,195** ³⁾
- **No specific medication and vaccine**

1) Nov 2002-July, 2003 2) 2012-June, 2019 3) Dec 2019-16 Feb 2020

1. Coronavirus?

2.

3.

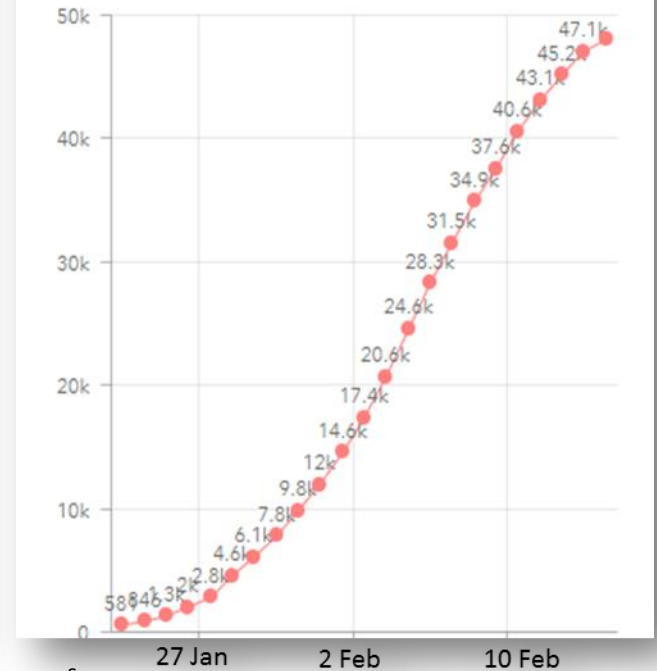
4.

COVID-19 spreading

COVID-19 has killed more people in 6 weeks than SARS did in 8 months



Cumulative laboratory-confirmed cases



Source :
<http://who.maps.arcgis.com/apps/opsdashboard/index.html#/c88e37cfc43b4ed3baf977d77e4a0667>

Doubling time is 6.4 days¹⁾, shorter than SARS (9 days)

Laboratory-confirmed 69,195 cases

Cases from 29 countries

Death 1,669 from 5 countries (China, Hong Kong, Japan, Philippines, France)

(16 Feb 2020 updates)

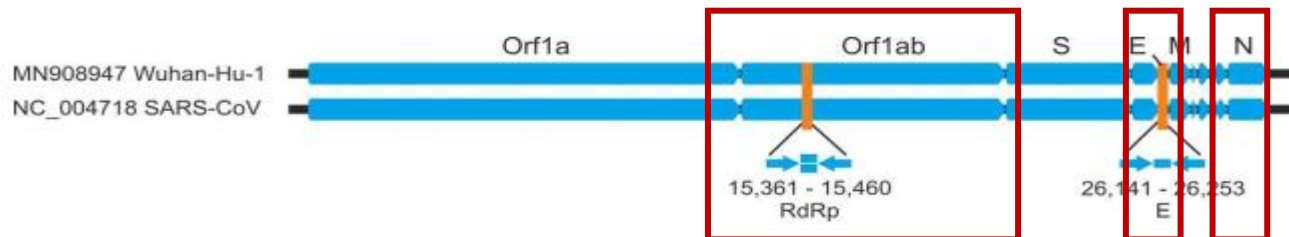
1) The Lancet. Wu, Joseph T.; Leung, Kathy; Leung, Gabriel M. (2020).

Diagnosis

- The only way to diagnosis of COVID-19

- Reference protocol **PCR**

Institute	Gene targets
China CDC (China)	ORF1ab, N
Charité (Germany) – WHO collaboration lab	RdRP, E
HKU (Hong Kong)	ORF1b, N
National institute of Health (Thailand)	N
US CDC	3 N primers



- **E gene** : *Sarbecovirus* screening (SARS and COVID-19)
- **RdRP or N gene** : COVID-19 ID

Allplex™ 2019-nCoV Assay

[Specification]

- **Target** E gene, N gene and RdRP gene
- **1 tube test**
- **TAT(PCR)** 1hr 50min
- **Specimen** Nasopharyngeal aspirate, sputum
nasopharyngeal/throat swab and bronchoalveolar lavage
- **Size** 50 rxns (RP10244Y), 100 rxns (RP10243X)
- **Instruments**

Extraction only : SEEPREP32/SGPrep32/EasyMAG

Extraction and PCR setup : NIMBUS/STARlet

Amplification : CFX96 IVD/CFX96 Dx

- **Data Analysis software** Seegene Viewer
- **Sensitivity** 100 copies/rxn for all targets
- **CE-IVD and emergency approval by KCDC**





Allplex™ 2019-nCoV Assay

[Analytes]

Fluorophore	Analyte
FAM	E gene (<i>Sarbecovirus</i>)
HEX	IC
Cal Red 610	RdRP gene (COVID-19)
Quasar 670	N gene (COVID-19)

[Cut-off]

Ct value	Result
≤ 40	Valid
> 40 or N/A	Invalid

- Re-test is required if Ct value of IC is >40.

[Interpretation]

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
IC (HEX)	+/-	+/-	+/-	+/-	+/-	+	-
E gene (FAM)	+	+/-	-	+/-	+	-	-
RdRP gene (Cal Red 610)	+	-	+	+	-	-	-
N gene (Quasar 670)	+	+	+	-	-	-	-
Result Interpretation	2019-nCoV Detected	Inconclusive Result*			2019-nCoV Not Detected, sarbecovirus Detected	Negative	Invalid

* Re-test with more concentrated NA or sequencing is recommended

Advantages of Seegene's

1. Reliable results

- Adapted **3 target genes** based on international recommended criteria
- Screening of *Sarbecovirus* with E gene
- Double check for **COVID-19** with N and RdRP gene
- Emergency approval by KCDC

2. High-Capacity

- Increase the throughput with **1 tube test** and **STARlet/NIMBUS** system
- **270 samples** loadable per day (8 hrs) with a STARlet

3. Ease of use

- **3 targets** in a tube
- Automation with STARlet/NIMBUS
- SEEPREP32 for **small scale** and **separation test**
- Auto-analysis with Seegene Viewer





Advantages of Seegene's

	Allplex™ 2019-nCoV	LightMix® Modular Wuhan CoV RdRP-gene
Company	Seegene (Korea)	Tib molbiol (Germany)
Target	E, RdRP, N	RdRP
TAT	1hr 50min	Unknown
Test #	1 tube/sample	2 tube/sample
Specimen type	Nasopharyngeal aspirate, sputum, bronchoalveolar lavage, Nasopharyngeal, throat swab	Tracheal aspirate, bronchoalveolar lavage
Size	50/100T	96T
Regulation	CE-IVD, KCDC Emergency approval	RUO

BGI biotechnology in China developed RT-PCR kit for detecting 2019-nCoV collaboration with China CDC.

For syndromic/co-infection test

Allplex™ Respiratory Panel 1

- Influenza A virus (Flu A)
- Influenza A-H1 (Flu A-H1)
- Influenza A-H1pdm09 (Flu A-H1pdm09)
- Influenza A-H3 (Flu A-H3)
- Influenza B virus (Flu B)
- Respiratory syncytial virus A (RSV A)
- Respiratory syncytial virus B (RSV B)
- Internal Control (IC)

Allplex™ Respiratory Panel 1A

Allplex™ Respiratory Panel 3

- Bocavirus 1/2/3/4 (HBoV)
- Coronavirus 229E (229E)
- Coronavirus NL63 (NL63)
- Coronavirus OC43 (OC43)
- Rhinovirus (HRV)
- Internal Control (IC)

Allplex™ Respiratory Panel 2

- Adenovirus (AdV)
- Enterovirus (HEV)
- Metapneumovirus (MPV)
- Parainfluenza virus 1 (PIV 1)
- Parainfluenza virus 2 (PIV 2)
- Parainfluenza virus 3 (PIV 3)
- Parainfluenza virus 4 (PIV 4)
- Internal Control (IC)

Allplex™ PneumoBacter Assay

- *Bordetella parapertussis* (BPP)
- *Bordetella pertussis* (BP)
- *Chlamydophila pneumoniae* (CP)
- *Haemophilus influenzae* (HI)
- *Legionella pneumophila* (LP)
- *Mycoplasma pneumoniae* (MP)
- *Streptococcus pneumoniae* (SP)
- Internal Control (IC)