

Korean Coronavirus test method overview

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Embassy of the Netherlands, Seoul

Massive testing is the strategy of the Korean government to respond to the outbreak. The country did not block international travel except Wuhan and Hubei area. The government emphasizes that travel is essential for a country as it lives on international trade and export. Instead, the country tried to detect the infection in an early stage to minimize the spreading and enhance chances to have proper medical care. In early February, the government also obtained mobile phone records, credit card receipts and other private data of everyone who tested positive for the coronavirus, and used the information to track the spread of the virus, making much of the data available to the public.

The Korean CDC (Center for Disease Control) firstly used Pan-coronavirus detection method, which is comparing the gene sequence with all the known coronavirus gene information before domestic test kits were developed with the genetic data of the virus (2019-nCoV). On 20 January 2020, the first infected case was confirmed in Korea, the coronavirus testing Task Force in the Korea Society for Laboratory Medicine (KSLM) was formed to find the most optimal diagnostic method with the Korean CDC. They decided to use German molecular diagnostic method using target site with less risk of mutation. On 27 January, the Korean CDC disclosed information on the test methods so test kit makers were able to speed up development. 1200 laboratory medicine specialists worked together to make objective diagnostic protocol. KSLM has been aggregating positive samples and enhancing the test method including cycle threshold (Ct) figures. The estimated accuracy is 95-98% as there is rare false positive and false negative according to Korean CDC.

Korea Food and Drug Agency (KFDA) implemented the 'emergency use authorization' which was introduced after MERS outbreak in 2015. The first approval was done on 4 February after going through synthesized RNA virus and real virus testing by comparing results with both the Korean CDC and the KSLM testing. The test kit decreased the testing time to ¼ of the conventional Pan-coronavirus detection. As of last week, the KFDA approved five Korean test kits for molecular diagnosis (RT-PCR) instruments. The Korean test kit manufacturers are producing 10,000 units per week, which can test a quarter million population.

During the MERS outbreak in 2015, only the Korean CDC lab was able to test the infection. So Korean authorities with the lesson from 2015, promoted the private molecular diagnosis labs by verifying the capability with cross-checking the test results. South Korea now has 100 verified labs available to perform 15,000 to 25,000 tests per day now days. The labs are all operated by specialized Medical Doctors (MD) with RT-PCR Instruments. The labs are carefully analyzing samples gathered from 600 testing facilities (Mostly municipal healthcare centers operated by public MDs) nationwide including the drive-through testing for 50 locations which system are now used in Germany and Australia as well. The test procedure is as following:

- 1) Samples obtained from upper respiratory system using sterilized plastic swab. Lower respiratory system sample like sputum is recommended to be collected.
- 2) 3 layers shielded sample is transported to a negative pressure lab (BL3 level)
- 3) The samples are prepared for RT-PCR test. The test is done with method recommended by WHO: E gene PCR screening test, RdRp part of orf1b gene PCR is done for confirmatory test.
- 4) The test result (Positive, Negative or Invalid) near the cutoff line, will be reviewed by MD. If necessary, re-test or re-sampling is done.
- 5) Even if the result is negative, ones who has clear contact histories with the infected and who has severe symptom or prognosis of pneumonia will be also subjected to another test.

The PCR test takes 2-3 hours and total testing including lab preparation and transportation takes about 6 hours.

The Korean government is trying to provide the RT-PCR testkit and the experiences to other countries as sign of global cooperation against COVID-19. President Moon has offered the tools during G20 summit call last week. KOTRA (Korea Trade and Investment Promotion Agency) offices over the world are actively co-working with their host countries. According to the promotion materials, the RT-PCR testkit approved in Korea are compatible to international RT-PCR Instruments. Lately some countries including U.S. are asking for it. Seegene, Solgent, Kogene and Labgenomics have applied for EUA (Emergency Use Authorization) from US FDA and waiting for the approval as of 30 March. However, CLIA (Clinical Laboratory Improvement Amendments) certified labs in U.S. can use the testkit without FDA approval. So Los Angeles and other cities in U.S. sent purchasing order to Seegene. Seegene is producing kits for half million people per week. It exports to 45 countries including Italy, Spain, France, Germany and UAE. Israel is totally depending on its product for testing. Seegene has reportedly exported 50,000 test kits to the United Arab Emirates as well. Romania sent NATO aircraft to import the testkits from Korea. A Finnish hospital is sending test samples to Korea for coronavirus diagnosis due to lack of PCR instrument available in Finland. 18,000 samples will be sent to Korea via airplanes for next two weeks from April 1.

Figure 2. KFDA approved Korean RT-PCR Testkits

Number	Company	Product	Approval date
1	Kogene	PowerCheck™ 2019-nCoV RT PCR kit	4 Feb
2	Seegene	Allplex™ 2019-nCoV Assay	12 Feb
3	Solgent	DiaPlexQ™ N Coronavirus Detection Kit	27 Feb
4	SD Biosensor	STANDARD M nCoV RT Detection kit	27 Feb
5	BioSewoom	Real-Q 2019-nCoV Detection kit	13 Mar

* Beside the companies above, PCL, Labgenomics, Cancer Rop, Osang Healthcare obtained export license for the testkit.

Korean Authorities do not use rapid Testing using antigen/antibody detection as more accurate RT-PCR can perform almost enough number of testing in Korea.

Figure 1. Comparison Table of Testing Methods

	Molecular Testing	Rapid Testing	
		Antigen detection	Antibody detection
Detection mechanism	Genetic information of virus from respiratory samples (nasopharyngeal swab or sputum sample) Ex. RT-PCR	Antigen from blood sample	Antibody from blood sample
Detection term	Early symptom – End	Mid symptom	7-28 days after the first symptom
Sensitivity (Accuracy for the infected)	95% or above	50-70% (When using conventional antigen diagnosis)	95%
Specificity (Accuracy for the non-infected)	95% or above	50-70% (Affected by seasonal coronavirus)	? (Affected by seasonal coronavirus)
Detecting cases without symptom	Possible	Depending on quantity of antigen founded	Only possible in later stage of infection
Cost for testing	High	Low	Low
Purpose	Common testing	In large scale (100,000s) epidemic situation	epidemiological surveillance after infection
Use cases	All countries as recommended by WHO and U.S. CDC	Some provinces in China	Some provinces in China

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< Definition >

- 2019-nCoV: new type of Corona Virus founded in 2019, which causes coronavirus disease 2019, also known as SARS-CoV-2
- COVID-19: coronavirus disease 2019
- RT-PCR: Real-Time Polymerase Chain Reaction. Each virus has some unique genetic information within its gene sequence. PCR is a device to amplify the sequence using enzyme. Roche is the world leading manufacturer of the instrument. The instrument uses testkits/marker which reacts on target genes with primer so that the unique genetic info can be found.
- MERS: Middle East Respiratory Syndrome
- Antigen: a toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies.
- Antibody: a blood protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood.