# SARS CoV-2 Testing Strategy in Korea

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# Situation in Korea

- Real time RT-PCR tests: >600,000

**Coronavirus Disease-19, Republic of Korea**

Central Disaster Management Headquarters | Central Disease Control Headquarters | • Korean • Chinese

About COVID-19 | Latest Updates | Media Resources | Public Advice | Notice

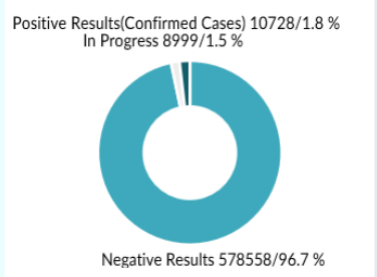
**Cases in Korea** (as of 12am on April 26, 2020, data aggregated from January 3)

| Confirmed Cases (accumulation) | Released from isolation (Released from Quarantine) | Isolated | Deceased |
|---|---|---|---|
| 10,728 | 8,717 | 1,769 | 242 |
| Daily Change + 10 | + 82 | - 74 | + 2 |

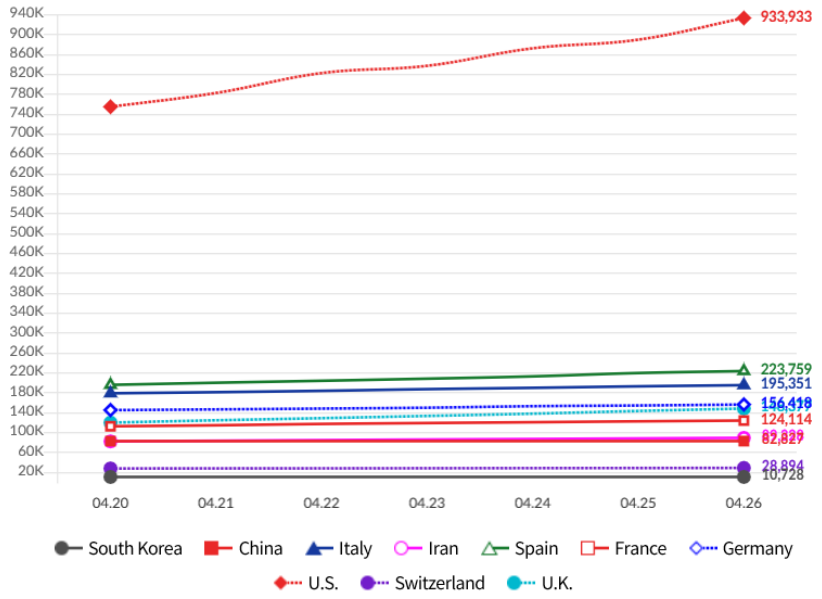
**Testing in Korea** (as of 12am on April 26, 2020, data aggregated from January 3)

| | |
|---|---|
| Tests Performed | 598,285 |
| Tests Concluded | 589,286 |
| * Positivity Rate | 1.8% |

* postitive tests / total number of tests concluded * 100%




**Weekly Updates for Countries with Major Outbreaks**



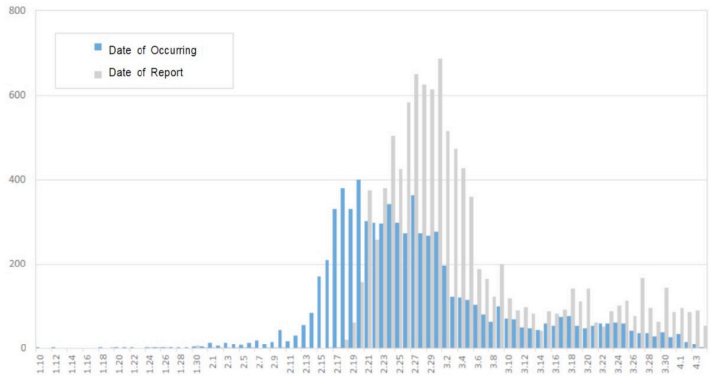

http://ncov.mohw.go.kr/en/

How Korea responded to a pandemic using ICT

# Flattening the curve on COVID-19

April 15, 2020

The Government of the Republic of Korea




< Average of 4.5 days of time lag report >

**Table 1** Companies that obtained emergency use approval

| Company (Date of Approval for Emergency Use) | Company Information |
|---|---|
| **KogeneBiotech (Feb.4)** | - Established in Mar. 2000 / SME<br>- (Business area) Diagnostic reagent development and genome analysis service |
| **Seegene (Feb.12)** | - Established in Sep. 2000/ SME (listed on KOSDAQ market)<br>- (Business area) Development of diagnostic reagents and automated software |
| **Solgent (Feb.27)** | - Established in Aug. 2000 / SME<br>- (Business area) Diagnostic reagent development and genome analysis service |
| **SD Bio-sensor (Feb.27)** | - Established in Dec. 2010 / SME<br>- (Business area) Development of diagnostic reagents and in vitro diagnosis system |
| **Biosewoom (Mar.13)** | - Established in Sep. 1997 / SME<br>- (Business area) Development of clinical diagnostic drugs including diagnostic reagents |

Infrastructure

# H1N1 Epidemic in 2009
# ; Multiplex PCR, real-time PCR

Flocked swab
(Copan, Bresica, Italy)

Real time PCR machines

Real time PCR tests were allowed
(2009, just few months before the epidemic)

## Multiplex reverse-transcriptase PCRs for respiratory viruses (2009)

- 제3부. 행위비급여

| | |
|---|---|
| CZ974 | 너. 인플루엔자바이러스 A & B [역전사이중중합효소연쇄반응] |
| CZ975 | 더. 파라인플루엔자바이러스 1,2,3 [역전사이중중합효소연쇄반응] |
| | 러. 호흡기바이러스 [다중역전사중합효소연쇄반응] |
| CZ981 | (1) 아데노바이러스 |
| CZ982 | (2) 호흡기합포체바이러스(RSV) |
| CZ983 | (3) 인플루엔자바이러스 A & B |
| CZ984 | (4) 파라인플루엔자바이러스 1,2,3 |
| CZ996 | 커. 인플루엔자바이러스 A&B [실시간 중합효소연쇄반응] |

(1) Adenovirus
(2) RSV
(3) Influenza A &B
(4) Parainflueza 1,2,3

Regulations

# MERS-CoV outbreak in 2015 ; Novel virus

그림 3-5-5. 메르스 정례 브리핑 화면


## CDC, NIH & Public Health Laboratories

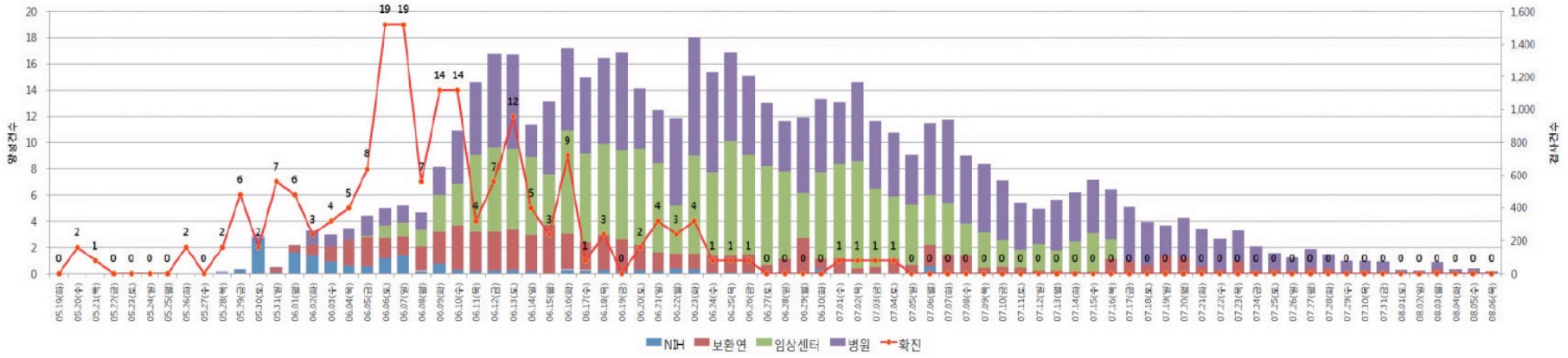
- Real time PCR kit
  - Distributed to 17 PHLs
- 50 tests were done from 2013 to 2015 (May)
- External Quality Control (twice)
- NIH participated EQC from Robert Koch Institute (Mar-2014)

## Medical Laboratories (2015)

- No tests could be performed for novel viruses at first
- “Hospital laboratories have no ability to test such a complicated test.”
- Local government authorities suggested to test for medical laboratories (7-Jun-2015)

# MERS in Korea (2015)
; Maximum testing (1,400 tests/day)

그림 3-4-6. 검사기관 종별 메르스 진단검사 건수 추이



Aftermath ; For the Next Outbreak

# Communications!

## CDC, NIH & Public Health Laboratories

- Organization
  - KCDC; diagnosis, prevention
  - KNIH; vaccine, therapeutic
- KCDC
  - Center for Laboratory control of Infectious Diseases
- Consultative body for diagnostic test
  - CDC
  - Public health laboratories
  - Laboratory Physicians

## Medical Laboratories

- TF of Korean Society of Laboratory Medicine
- Commercial reference laboratories
- Consultative body for CDC, local government and academics

# Charite Hospital in Germany (2020-Jan-13) ; Prof. Christian Drosten

Berlin, 13.01.2020

**Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR**

-Protocol and preliminary evaluation as of Jan 13, 2020-

Victor Corman, Tobias Bleicker, Sebastian Brünink, Christian Drosten
Charité Virology, Berlin, Germany

Olfert Landt, Tib-Molbiol, Berlin, Germany

Marion Koopmans
Erasmus MC, Rotterdam, The Netherlands

Maria Zambon
Public Health England, London

<MERS>

| Target region | Sensitivity |
|---|---|
| Upstream of the E protein gene (upE) | Highly sensitive (Screening) |
| Open reading frame 1a (ORF 1a) | Equal sensitive |
| Open reading frame 1b (ORF 1b) | Less sensitive |

<SARS-CoV-2: Wuhan-Hu-1>

*The Rising Heroes of the Coronavirus Era? Nations' Top Scientists*

Scientists in Europe are becoming household names, fulfilling societies' emotional and practical need for the truth.

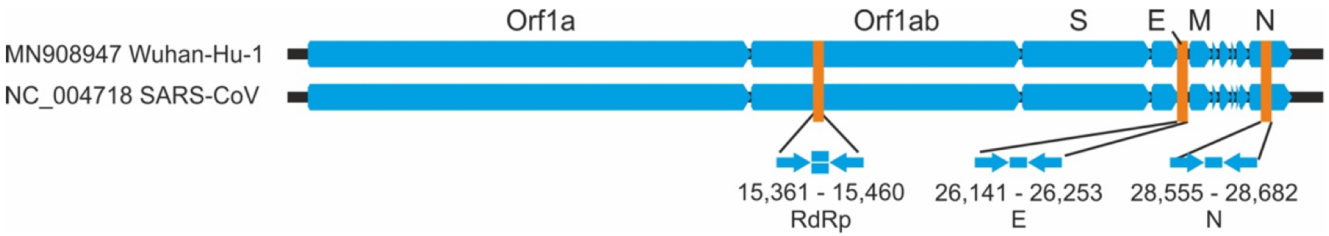
Dr. Christian Drosten, chief virologist at the Charité university research hospital in Berlin, researching the coronavirus in late January. Christophe Gateau/Picture Alliance, via Getty Images

By Matina Stevis-Gridneff

April 5, 2020

**All assays can use SARS-CoV genomic RNA as positive control. Synthetic control RNA for Wuhan virus will be provided shortly.**

**First line screening assay: E gene assay**
**Confirmatory assay: RdRp gene assay**
**Additional confirmatory assay: N gene assay**



# Novel Coronavirus in Wuhan (2019-2020)

## Ready for testing

### CDC & Laboratory Medicine

- Diagnostic kit
  - Emergence Use kits
    - 5 companies: Feb. 4th – Mar. 13th
  - Regulation
    - No antigen, antibody test allowed.
    - Evaluated by 3 medical laboratories
- Lab accreditation and external quality control
  - Nearly 100 laboratories
  - Testing Capacities
    - 20,000 tests per day or more


REUTERS

Business Markets World Politics TV More

WORLD NEWS MARCH 19, 2020 / 3:13 AM / A MONTH AGO

**Special Report: How Korea trounced U.S. in race to test people for coronavirus**

Chad Terhune, Dan Levine, Hyunjoo Jin, Jane Lanhee Lee 20 MIN READ

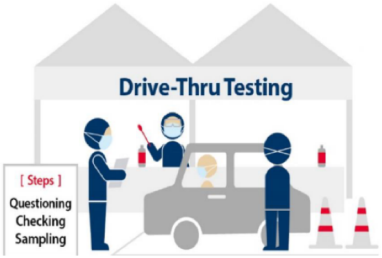
SEOUL - In late January, South Korean health officials summoned representatives from more than 20 medical companies from their lunar New Year celebrations to a conference room tucked inside Seoul's busy train station.

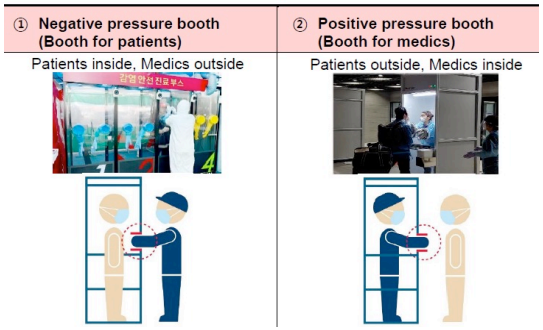
Health officer, Medical company, M.D.
; Seoul Station (Jan. 27th)

**Laboratory Accreditation System**
**: Laboratory Physicians**


**Quality Assurance**
**: KAQACL (1976)**

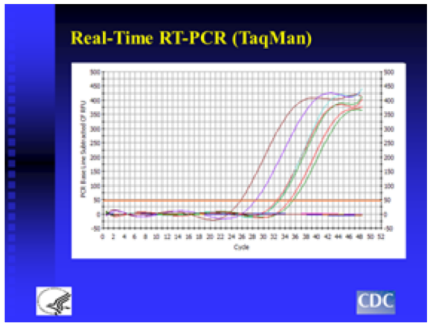
# Molecular test




- Sample collection
  - Negative pressure room; bottleneck
  - Drive-through (Flu-vaccination in USA), Walk-through
- Pooling for mass screening nursing homes, military recruits
  - Pooling of around 10 NPS specimens
  - Low costs, High speed
- K-bio companies

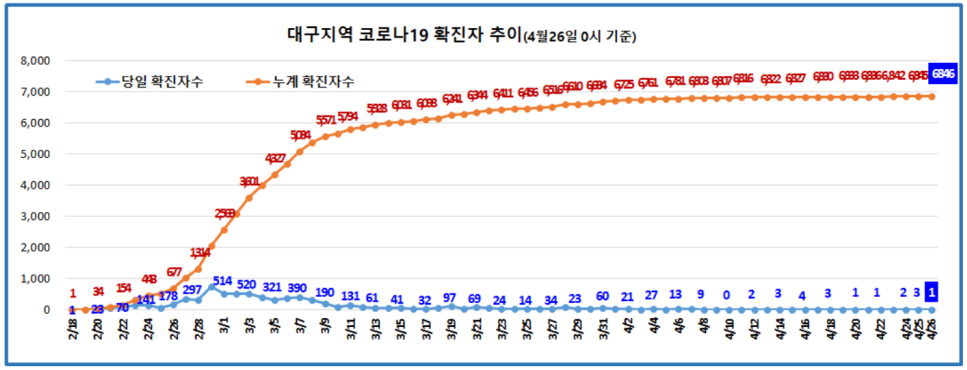
US CDC in 2003 (SARS)



# Molecular test

- Diagnostic is useful but it is not for cure
  - Saving persons and waiting for vaccines or therapeutics

- It looked impossible to contain the transmission when the number of patients surged in Daegu, but it seems to be successful till now.




*확진자 수는 질병관리본부 공식 발표자료에 의함

No. of patients in Daegu (>6,000)

# Summary

- “Detection, Isolation and Trace”
  - Minimize the transmission of SARS-CoV-2
  - Real time PCR testing is main diagnostic tools
- Cooperation and communication
  - Public health and Medicine
  - Medicine and Biotech companies
- Trained Personnel and Technologies are necessary
  - Real time PCR
  - Rapid real time PCR (future)

Korean Society for Laboratory Medicine (Laboratory Physicians)

Review Article
Diagnostic Genetics
Ann Lab Med 2016;36:203-208
http://dx.doi.org/10.3343/alm.2016.36.3.203
ISSN 2234-3806 · eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

## Korean Society for Laboratory Medicine Practice Guidelines for the Molecular Diagnosis of Middle East Respiratory Syndrome During an Outbreak in Korea in 2015

Chang-Seok Ki, M.D.[1,*], Hyukmin Lee, M.D.[2,*], Heungsup Sung, M.D.[3], Sinyoung Kim, M.D.[4], Moon-Woo Seong, M.D.[5], Dongeun Yong, M.D.[4], Jae-Seok Kim, M.D.[6], Mi-Kyung Lee, M.D.[7], Mi-Na Kim, M.D.[3], Jong-Rak Choi, M.D.[4], Jeong-Ho Kim, M.D.[4], and The Korean Society for Laboratory Medicine MERS-CoV Laboratory Response Task Force

Original Article
Clinical Microbiology
Ann Lab Med 2016;36:457-462
http://dx.doi.org/10.3343/alm.2016.36.5.457
ISSN 2234-3806 · eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

## Comparative Evaluation of Three Homogenization Methods for Isolating Middle East Respiratory Syndrome Coronavirus Nucleic Acids From Sputum Samples for Real-Time Reverse Transcription PCR

Heungsup Sung, M.D.[1], Dongeun Yong, M.D.[2], Chang-Seok Ki, M.D.[3], Jae-Seok Kim, M.D.[4], Moon-Woo Seong, M.D.[5], Hyukmin Lee, M.D.[6], and Mi-Na Kim, M.D.[1]

Original Article
Clinical Microbiology
Ann Lab Med 2016;36:450-456
http://dx.doi.org/10.3343/alm.2016.36.5.450
ISSN 2234-3806 · eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

## Analytical and Clinical Validation of Six Commercial Middle East Respiratory Syndrome Coronavirus RNA Detection Kits Based on Real-Time Reverse-Transcription PCR

Mi-Na Kim, M.D.[1], Young Jin Ko, M.D.[1], Moon-Woo Seong, M.D.[2], Jae-Seok Kim, M.D.[3], Bo-Moon Shin, M.D.[4], and Heungsup Sung, M.D.[1]

Original Article
General Laboratory Medicine
Ann Lab Med 2016;36:154-161
http://dx.doi.org/10.3343/alm.2016.36.2.154
ISSN 2234-3806 · eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

## Survey of Clinical Laboratory Practices for 2015 Middle East Respiratory Syndrome Coronavirus Outbreak in the Republic of Korea

Mi-Kyung Lee, M.D.[1], Sinyoung Kim, M.D.[2], Mi-Na Kim, M.D.[3], Oh Joo Kweon, M.D.[1], Yong Kwan Lim, M.D.[1], Chang-Seok Ki, M.D.[4], Jae-Seok Kim, M.D.[5], Moon-Woo Seong, M.D.[6], Heungsup Sung, M.D.[4], Dongeun Yong, M.D.[2], Hyukmin Lee, M.D.[7], Jong-Rak Choi, M.D.[2], Jeong-Ho Kim, M.D.[2]; MERS-CoV Laboratory Response Task Force of The Korean Society for Laboratory Medicine

Original Article
Clinical Microbiology
Ann Lab Med 2016;36:230-234
http://dx.doi.org/10.3343/alm.2016.36.3.230
ISSN 2234-3806 · eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

## External Quality Assessment of MERS-CoV Molecular Diagnostics During the 2015 Korean Outbreak

Moon-Woo Seong, M.D.[1], Seung Jun Lee, M.D.[1], Sung Im Cho, M.S.[1], Kyungphil Ko, M.T.[1], Mi-Na Kim, M.D.[2], Heungsub Sung, M.D.[2], Jae-Seok Kim, M.D.[3], Ji Soo Ahn, M.T.[1], Byung Su Yu, M.T.[1], Taek Soo Kim, M.D.[1], Eui Chong Kim, M.D.[1], and Sung Sup Park, M.D.[1]