

## South Korea's Response to COVID-19

### I. Executive Summary

SARS-CoV-2 and the disease it causes, coronavirus disease 2019 (COVID-19), have created an unprecedented global public health emergency. In early April 2020, numerous sources around the world declared South Korea's response strategy had successfully "flattened the curve" of COVID-19.<sup>1</sup> As South Korea's experience may be informative for future considerations, the U.S. Food and Drug Administration (FDA) reviewed information, including reports in the press and information made publicly available by the South Korean government about their COVID-19 response strategy. This report describes the approach used by the South Korean government to address COVID-19, particularly regarding development, authorization, and use of diagnostic tests. FDA recognizes different approaches may work for different countries, and this report does not make recommendations for what approaches could or should be adopted in the United States (U.S.) for emerging infectious diseases.

South Korea's approach is based on lessons they learned from a deadly outbreak of Middle Eastern Respiratory Syndrome (MERS) in 2015 and steps they took before the COVID-19 pandemic hit. First, the government invested in commercial development of diagnostic testing technology.<sup>2</sup> Since 2017, the Ministry of Science and Information and Communications Technology (MSIT) has invested almost 27 billion South Korean won (approximately 25 million U.S. dollars) in infectious disease diagnosis technology.<sup>3</sup> As a result of these investments, a subset of South Korean commercial manufacturers were well positioned to develop and manufacture tests quickly. Second, the government designed an emergency use authorization (EUA) pathway modeled on the system used in the U.S.<sup>4</sup> Third, the South Korea legislature amended the Infectious Disease Prevention and Control Act (IDPCA) of Korea in 2015 to allow relevant authorities to collect personal data on confirmed and suspected cases of infection during an infectious disease emergency.<sup>5</sup>

When COVID-19 hit, South Korea prioritized the early detection of SARS-CoV-2 through diagnostic testing.<sup>6</sup> The KDCA developed its own test and made it available in late January 2020 without an EUA. At the same time, KDCA met with commercial test developers, many of whom the government had invested in prior to the outbreak, to encourage them to develop and submit EUA requests for molecular diagnostic tests. KDCA issued a public notification soliciting such EUA requests and stating the

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<sup>1</sup> J. Park and E. Chung, "Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea," *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

<sup>2</sup> "How We Fought COVID-19: A Perspective from Science & ICT," MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>3</sup> *Id.*

<sup>4</sup> In South Korea, the EUA process is overseen by the Korea Centers for Disease Control and Prevention (KDCA; counterpart to the U.S. Centers for Disease Control and Prevention (CDC)) and the Ministry of Food and Drug Safety (MFDS; counterpart to the U.S. Food and Drug Administration (FDA)).

<sup>5</sup> IDCPA, Act No. 9847, Article 6(2), Korean Law Translation Center (amended December 2015), available at: [https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=1](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=1).

<sup>6</sup> "All About Korea's Response to COVID-19," Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

submission requirements.<sup>7</sup> The government also informed private test developers that the government would absorb the financial risk of developing SARS-CoV-2 diagnostic tests by guaranteeing to purchase minimum quantities of tests, once authorized for use.<sup>8</sup> These types of steps to de-risk and incentivize product development, although later taken for vaccine development, were not taken early on for test development by the U.S. government.

Consistent with South Korea’s practices for prior outbreaks, the KDCA established a testing capability in selected laboratories to conduct clinical studies to evaluate commercial manufacturer tests seeking an EUA. As a result, test developers did not have to find their own clinical specimens or viral material to validate their tests, which likely shortened the length of time needed to complete validation studies to support EUA applications and increased the government’s confidence in test accuracy. KDCA provided data from test developers and the government-sponsored evaluation to the MFDS, South Korea’s equivalent to the FDA, for review. MFDS issued its first EUA for a COVID-19 diagnostic test on February 4, 2020,<sup>9</sup> followed by four additional EUAs by mid-March 2020, all for commercial tests.

The FDA also issued the first EUA for a SARS-CoV-2 molecular diagnostic test on February 4, 2020; this first EUA was issued to CDC.<sup>10</sup> In South Korea, the KDCA’s test was introduced a few days earlier without an EUA. At that time, FDA accepted EUA requests from “all comers,” including laboratories, yet FDA did not receive any additional complete EUA requests until the end of February 2020. In order to increase access to testing, on February 29, 2020, FDA implemented a flexible policy for laboratories offering their own tests prior to EUA issuance but after notifying FDA. In contrast, South Korea’s response to the pandemic did not include tests from non-commercial developers. From February 29 through mid-March 2020, almost 50 laboratories began testing in the U.S. after notifying FDA, and one laboratory and four commercial manufacturers introduced tests under EUAs. FDA did not receive EUA requests from any of the manufacturers that had tests authorized by MFDS until several weeks later because they were serving the needs of the South Korean market.

South Korea developed a coordinated, nationwide testing program that relied upon a few dozen authorized tests manufactured in high volumes through public-private partnerships. To do this, South Korea initially accepted EUA requests from commercial manufacturers for only one month whereas the U.S. accepted EUA requests from laboratories and commercial manufacturers alike for months, accumulating a volume in excess of 2,000 EUA requests. At the end of November 2020, South Korea had

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<sup>7</sup> “Approval of emergency use of new coronavirus gene test reagents: Notification of application for evaluation,” Infectious Disease Diagnosis Management Division (January 28, 2020).

<sup>8</sup> “COVID-19 and Korea’s Response (Video),” Ministry of Foreign Affairs (October 27, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/view.do?seq=37&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq=0&itm\\_seq\\_1=0&itm\\_seq\\_2=0&company\\_cd=&company\\_nm=&page=1&titleNm=](http://www.mofa.go.kr/eng/brd/m_22591/view.do?seq=37&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq=0&itm_seq_1=0&itm_seq_2=0&company_cd=&company_nm=&page=1&titleNm=)

<sup>9</sup> “Latest COVID-19 News: Emergency Use of COVID-19 test kit authorized, COVID-19 tests also conducted at medical institutions,” MFDS (February 4, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_64/view.do?seq=14&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_64/view.do?seq=14&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1).

<sup>10</sup> Letter from RADM Hinton (FDA) to Robert Redfield (CDC) dated February 4, 2020.

authorized approximately two dozen diagnostic tests,<sup>11</sup> whereas the U.S. had authorized over 200,<sup>12</sup> in addition to receiving over 400 notifications from laboratories offering their diagnostic tests prior to EUA issuance. South Korea chose not to rely on, or accept EUA requests for, diagnostic tests developed by laboratories as part of their national strategy.<sup>13</sup>

South Korea used testing results to support a larger contact tracing program built on information technology systems, which collect and analyze personal data such as credit card transactions and CCTV footage for up to 14 days, in addition to test results.<sup>14</sup> Under the program, all suspected and probable cases of COVID-19 are subject to 14-day self-quarantine, and the violation rate has been less than 0.2 percent.<sup>15</sup> This contact tracing program, along with mask wearing, social distancing, selective, temporary business closures, and an effective communications strategy, helped contain the spread of COVID-19 in South Korea.<sup>16</sup>

## II. Background

SARS-CoV-2 and the disease it causes, COVID-19, have created an unprecedented public health emergency. An outbreak of pneumonia of unknown etiology in Wuhan City, China, was initially reported to the World Health Organization (WHO) on December 31, 2020.<sup>17,18</sup> From there, the virus initially spread to surrounding countries in Asia.<sup>19</sup> The first cases of COVID-19 in the U.S. and South Korea were

<sup>11</sup> “List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS,” MFDS (November 27, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=37&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=37&data_tp=A&file_seq=1).

<sup>12</sup> “In Vitro Diagnostics EUAs,” FDA, updated regularly, available at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

<sup>13</sup> See e.g. K.H. Hong, et al., “Guidelines for Laboratory Diagnosis of Coronavirus Disease 2019 (COVID-19) in Korea,” *Annals of Laboratory Medicine* Volume 40, Issue 5 (September 1, 2020), available at:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7169629/>; A.J. Dy, J. Latimer, A. Dekkers, K. Mechem, and D. Hochberg, “US SARS-CoV-2 Testing Response: What can be learned from South Korea and Germany?,” *Health Advances Blog* (April 16, 2020), available at: <https://healthadvancesblog.com/2020/04/16/us-sars-cov-2-testing-response-what-can-be-learned-from-south-korea-and-germany/>.

<sup>14</sup> “Flattening the curve on COVID-19: How Korea responded to a pandemic using ICT,” Government of the Republic of Korea (May 2020), available at:

[http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH\\_000000000013739&fileSn=2](http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH_000000000013739&fileSn=2).

<sup>15</sup> IDCPA, Act No. 9847, amended arts. 13, para. 2 & 80, subpara. 2-2, Korean Law Translation Center (amended December 2015), available at:

[https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); see also “South Korea: Parliament Responded Quickly to COVID-19 by Amending Three Acts,” United States Library of Congress (June 4, 2020), available at: <https://www.loc.gov/law/foreign-news/article/south-korea-parliament-responded-quickly-to-covid-19-by-amending-three-acts/>.

<sup>16</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>17</sup> “Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV) in Wuhan, China,” CDC (January 17, 2020), available at: <https://emergency.cdc.gov/han/han00426.asp>.

<sup>18</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>19</sup> Id.

confirmed on January 20, 2020.<sup>20,21</sup> In early April 2020, numerous sources around the world declared South Korea’s response strategy had successfully “flattened the curve”<sup>22</sup> of COVID-19 (i.e., slowed down the spread of a virus to prevent a spike in people getting sick, which would have the potential to overwhelm healthcare systems and workers).<sup>23</sup> According to the South Korean government, they achieved success in “fighting COVID-19 without resorting to massive lockdowns by pursuing a systematic response strategy that consists, in part, of robust laboratory diagnostic testing to confirm positive cases, rigorous contact tracing to prevent further spread, and treating those infected at the earliest possible stage.”<sup>24</sup>

As South Korea’s experience may be informative for future considerations, the FDA reviewed information, including reports in the press and information made publicly available by the South Korean government about their COVID-19 response strategy. This report describes the approach used by the South Korean government to address COVID-19, particularly regarding development, authorization, and use of diagnostic tests. The FDA recognizes different approaches may work for different countries, and this report does not make recommendations for what approaches could or should be adopted in the U.S. for emerging infectious diseases.

### III. South Korea’s Lessons Learned from Prior Public Health Emergencies

Much of South Korea’s success in responding to the current pandemic has been attributed to lessons learned from its response to an influenza outbreak in 2009 and a deadly outbreak of MERS in 2015.<sup>25</sup> MERS hit South Korea harder than the U.S.; South Korea had almost 200 cases while the U.S. only reported two. Following this experience, South Korea implemented changes in five noteworthy areas: (1) elevating the roles and responsibilities of certain public health agencies; (2) investing in research and development (R&D) by domestic manufacturers; (3) designing rapid response processes for emerging infectious diseases; (4) creating a national stockpile to manage and distribute medical countermeasures; and (5) amending legislation to increase access to data and engender public trust.

First, the Korea Centers for Disease Control and Prevention (KCDC), which is the counterpart to the U.S. CDC, created two departments within KCDC to improve responses to infectious disease outbreaks.<sup>26</sup> The

<sup>20</sup> M. Holshue, et al., “First Case of 2019 Novel Coronavirus in the United States,” *The New England Journal of Medicine* 382:929-936 (March 5, 2020), available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>.

<sup>21</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>22</sup> “COVID-19: What Does “Flattening the Curve” Mean?,” Geisinger (March 18, 2020), available at: [https://www.geisinger.org/health-and-wellness/wellness-articles/2020/03/18/16/20/covid-19-what-does-flattening-the-curve-mean?utm\\_source=organicsocial-facebook&utm\\_medium=socialmedia&utm\\_campaign=covid](https://www.geisinger.org/health-and-wellness/wellness-articles/2020/03/18/16/20/covid-19-what-does-flattening-the-curve-mean?utm_source=organicsocial-facebook&utm_medium=socialmedia&utm_campaign=covid).

<sup>23</sup> J. Park and E. Chung, “Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea,” *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

<sup>24</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>25</sup> J. Park and E. Chung, “Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea,” *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

<sup>26</sup> J.Y. Hur and K.W. Kim, “Crisis Learning and Flattening the Curve: South Korea’s Rapid and Massive Diagnosis of the COVID-19 Infection,” *American Review of Public Administration* Volume 50, Issue 6-7 (2020), available at: <https://journals.sagepub.com/doi/pdf/10.1177/0275074020941733>.

Center for Public Health Emergency Preparedness coordinates epidemic response efforts, such as information collection, epidemic investigation, preparation of emergency plans, collaboration with hospitals, and coordination with national and subnational agencies.<sup>27</sup> The Center for Laboratory Control of Infectious Disease<sup>28</sup> is a laboratory-based department which develops testing methods to diagnose pathogens of infectious disease and coordinates plans for laboratory diagnoses.<sup>29</sup> In August 2020, the legislature amended the Government Organization Act to make KCDC a standalone agency, known as KDCA, as of September 12, 2020, in order to promote “[g]reater authority and autonomy as the control tower for infectious disease control.”<sup>30</sup>

Second, the South Korean central government began investing in domestic R&D of diagnostic reagents necessary for infectious disease testing.<sup>31</sup> From 2017 to the present, MSIT invested 28.6 billion South Korean won (approximately 25 million U.S. dollars) in infectious disease diagnosis technology.<sup>32</sup> The MSIT<sup>33</sup> also formed the Research Council for Infectious Disease and Medical Devices,<sup>34</sup> which is responsible for assisting technology companies by providing technology, equipment, and research networks when companies face challenges.<sup>35</sup> The testing technologies developed by commercial manufacturers through government investments in R&D, including for artificial intelligence (AI), proved critical for the government’s rapid launch of an effective COVID-19 response strategy.<sup>36</sup>

Third, the KCDC,<sup>37</sup> the Korea Society for Laboratory Medicine (KSLM),<sup>38</sup> and the Korean Association of External Quality Assessment Service (KEQAS) designed rapid response processes for emerging

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<sup>27</sup> Id.

<sup>28</sup> Id.

<sup>29</sup> Id.

<sup>30</sup> Once promoted to a standalone agency, KCDC was renamed the KDCA. This report refers to the agency as KDCA for all events in 2020 and 2021. See “About KDCA: Center for Public Health Emergency Preparedness and Response,” KDCA (updated August 19, 2019; originally as KCDC), available at: <http://www.cdc.go.kr/contents.es?mid=a30109030000>; see also “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>31</sup> “How We Fought COVID-19: A Perspective from Science & ICT,” MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>32</sup> Id.

<sup>33</sup> See Ministry of Science and ICT Webpage (updated regularly), available at: <http://english.msip.go.kr/english/main/main.do>.

<sup>34</sup> The Research Council is comprised of 7 government-funded research institutes that specialize in infectious disease and medical devices, including: the Korea Research Institute of Bioscience and Biotechnology (KRIBB), Korea Institute of Radiological & Medical Sciences (KIRAMS), Korea Institute of Machinery and Materials (KIMM), Korea Electrotechnology Research Institute (KERI), Korea Research Institute of Chemical Technology (KRICT), Electronics and Telecommunications Research Institute (ETRI), and BioNano Health Guard Research Center (H-Guard). See “How We Fought COVID-19: A Perspective from Science & ICT,” MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>35</sup> “How We Fought COVID-19: A Perspective from Science & ICT,” MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>36</sup> Id.

<sup>37</sup> See “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>38</sup> The KSLM is a professional society comprised of clinical pathologists and doctors in training. See generally “About Us,” KSLM, undated, available at: <http://www.kslm.org/eng/sub01/sub01.html>.

infectious diseases.<sup>39</sup> These processes included an EUA program formally established through amendment of the Medical Device Act in 2016.<sup>40</sup> The EUA program in South Korea, designed to model the system used in the United States,<sup>41</sup> allows the temporary production, sale, and use of test kits during a pandemic when there is no authorized product available on the domestic market.<sup>42</sup> South Korea’s EUA pathway is available once the KDCA and the MFDS determine the need for the pathway exists in response to a public health crisis,<sup>43</sup> whereas the U.S. EUA pathway becomes available upon declaration of a public health emergency under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C) Act by the Secretary of the U.S. Department of Health and Human Services (HHS).<sup>44,45</sup> In the U.S., developers conduct their own performance evaluations and submit them directly to the FDA for review and authorization. In South Korea, test developers submit their EUA requests first to the KDCA.<sup>46</sup> The KDCA reviews the developer’s performance data and manufacturing capabilities and can utilize its laboratories in the Infectious Disease Analysis Bureau to conduct their own clinical evaluation of a test. If the KDCA concludes that a test’s performance data (including those generated by the test developer and by the KDCA’s own analysis) meet the established EUA requirements, the agency forwards the documents to the MFDS with a request to issue an EUA.<sup>47</sup> The MFDS reviews the documents and if all requirements for an EUA are met, the MFDS authorizes the test for emergency use.<sup>48,49</sup>

Fourth, South Korea created a National Stockpile Plan for management and distribution of medical countermeasures after an H1N1 influenza outbreak in 2009.<sup>50</sup> The KCDC identified 11 priority infectious diseases, based on their high mortality rates and rates of transmission, and established the Strategic National Stockpile to maintain stock of appropriate medical countermeasures, equipment, and other

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<sup>39</sup> H. Sung, et al., “Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor,” *Clinical Chemistry* Volume 66, Issue 7 (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>40</sup> Id.

<sup>41</sup> Id.

<sup>42</sup> Article 46 (2) of the Medical Device Act and Article 13 (3) of its Enforcement Decree (December 2, 2016), available at: <http://www.law.go.kr/LSW/eng/engMain.do?eventGubun=060124>.

<sup>43</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>44</sup> “Emergency Use Authorization,” FDA (updated December 16, 2020), available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

<sup>45</sup> “EUA (Emergency Use Authorization) Process for COVID-19 in Korea,” MFDS (July 2, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_75/view.do?seq=16](https://www.mfds.go.kr/eng/brd/m_75/view.do?seq=16).

<sup>46</sup> Id.

<sup>47</sup> Id.

<sup>48</sup> Id.

<sup>49</sup> Importantly, South Korea commonly refers to a product under an EUA as “approved,” which is the same term used for products approved under their traditional review pathway. *See e.g.* “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do) (stating, in relevant part: “MFDS notified KCDC that one product was approved for an EUA”).

<sup>50</sup> “OECD Reviews of Public Health: Korea: A Healthier Tomorrow,” Organization for Economic Cooperation and Development (OECD) (March 21, 2020), available at: <https://www.oecd-ilibrary.org/sites/7ba9cad3-en/index.html?itemId=/content/component/7ba9cad3-en>.

supplies for outbreaks of these diseases, including testing supplies.<sup>51</sup> After the MERS outbreak in 2015, changes were introduced for real-time stockpiling management and plans were introduced to develop a five-year Strategic National Stockpile Plan.<sup>52</sup> In January 2016, the KCDC established an Emergency Operations Center within their Center for Public Health Emergency Preparedness and Response (“the Center”), which collects and analyzes infectious disease information in real time and responds through an emergency reaction team.<sup>53</sup> The Center’s Division of Resource Management is responsible for accumulating, stockpiling, and distributing medicine and medical supplies in response to infectious diseases, and coordinates with the Emergency Operations Center.<sup>54</sup> Guidelines were developed for stockpiling, management, storage, and distribution of medication and other medical supplies.<sup>55</sup> As local stockpiles are also maintained at all levels of government, a joint utilization system for sharing and mobilizing stockpiles was developed with regional partners.<sup>56</sup> Fifth, the South Korean legislature amended the IDCPA in 2015 to allow relevant authorities to collect personal data on confirmed and suspected cases of an infection, during an infectious disease emergency,<sup>57</sup> and to engender public trust by mandating disclosure of information to the public by central and local governments during a public health emergency.<sup>58</sup>

#### IV. South Korea’s Development of Tests for COVID-19

In early January 2020, the South Korean government “placed a priority on early detection of the virus through preemptive laboratory diagnostic testing and strict epidemiological investigation.”<sup>59</sup> The KDCA obtained the deoxyribonucleic acid (DNA) sequence of a novel virus from China sometime in late December 2019 to early January 2020, and immediately began developing a pan-coronavirus diagnostic test, which is designed to detect all types of coronavirus.<sup>60</sup> In choosing to develop a pan-coronavirus test, the KDCA had applied the same test development strategy it used for the MERS outbreak in 2015.<sup>61</sup> The

<sup>51</sup> “Joint External Evaluation of IHR Core Capacities of the Republic of Korea. Mission Report: 28 August – 1 September 2017,” WHO (August 28 to September 1, 2017), available at:

<https://apps.who.int/iris/bitstream/handle/10665/259943/WHO-WHE-CPI-2017.65-eng.pdf?sequence=1>.

<sup>52</sup> “OECD Reviews of Public Health: Korea: A Healthier Tomorrow,” Organization for Economic Cooperation and Development (OECD) (March 21, 2020), available at: <https://www.oecd-ilibrary.org/sites/7ba9cad3-en/index.html?itemId=/content/component/7ba9cad3-en>.

<sup>53</sup> “About KDCA: Center for Public Health Emergency Preparedness and Response,” KDCA (updated August 19, 2019; originally as KCDC), available at: <http://www.cdc.go.kr/contents.es?mid=a30109030000>.

<sup>54</sup> Id.

<sup>55</sup> “Joint External Evaluation of IHR Core Capacities of the Republic of Korea. Mission Report: 28 August – 1 September 2017,” WHO (August 28 to September 1, 2017), available at:

<https://apps.who.int/iris/bitstream/handle/10665/259943/WHO-WHE-CPI-2017.65-eng.pdf?sequence=1>.

<sup>56</sup> Id.

<sup>57</sup> IDCPA, Act No. 9847, Article 6(2), Korean Law Translation Center, amended December 2015, available at: [https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at:

[http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>58</sup> Id.

<sup>59</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>60</sup> Id.

<sup>61</sup> J. Park and E. Chung, “Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea,” *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

test that the KDCA developed in January 2020, however, was difficult to use and took one to two days to obtain laboratory results, which the government determined was an unreasonable delay for confirmation of positive cases.<sup>62</sup> As such, on January 10, 2020, the KDCA began developing a specific SARS-CoV-2 diagnostic test.<sup>63</sup> On January 30, 2020, the KDCA finished developing their SARS-CoV-2 molecular diagnostic test by reverse transcription polymerase chain reaction (RT-PCR), which used a two-target protocol.<sup>64</sup> The agency reported that results from the test could be obtained in six hours.<sup>65</sup> The KDCA's test was deployed to public testing agencies nationwide until commercial tests became available. In contrast to the FDA's authorization of the CDC's test for emergency use (as discussed in section V.A. of this report), it appears that the KDCA's test was not authorized for emergency use by the MFDS.<sup>66</sup> As described more fully below, the KDCA required labs to undergo a certification process and receive training in order to become a COVID-19 molecular diagnostic testing facility.<sup>67</sup>

Concurrent with the KDCA's development of a specific diagnostic test, commercial South Korean in vitro diagnostic (IVD) test developers on their own recognized the need to begin developing their own specific SARS-CoV-2 diagnostic tests.<sup>68</sup> Several commercial test manufacturers had received investments from South Korea's government for R&D of diagnostic test technology; the technologies developed through these investments gave domestic manufacturers the tools necessary to expeditiously develop a SARS-CoV-2 molecular diagnostic test with the expectation that they would do so to support government testing efforts.<sup>69</sup>

On January 10, 2020, the full genome sequence of SARS-CoV-2 was published by the Global Initiative on Sharing All Influenza Data (GISAID), a global science initiative that provides open-access to genomic data of viruses.<sup>70</sup> On January 13, 2020, the WHO published a protocol and preliminary evaluation for diagnostic detection of SARS-CoV-2 virus by real-time RT-PCR developed by Charité Virology in Berlin.<sup>71</sup> South Korean test developer Kogene Biotech, one of the companies which received R&D

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<sup>62</sup> "All About Korea's Response to COVID-19," Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>63</sup> Id.

<sup>64</sup> Id.

<sup>65</sup> Id.

<sup>66</sup> "List of COVID-19 Diagnostic Kits Authorized for Use under Emergency Use Authorizations," MFDS, March 26, 2020, available at: [https://www.mfds.go.kr/eng/brd/m\\_60/view.do?seq=74424](https://www.mfds.go.kr/eng/brd/m_60/view.do?seq=74424); "List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS," MFDS (November 27, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=37&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=37&data_tp=A&file_seq=1).

<sup>67</sup> H. Sung, et al., "Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor," *Clinical Chemistry Volume 66, Issue 7* (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>68</sup> See e.g. "Kogene Biotech, Korea's Leading Diagnostic Kit Developers," *KBS World* (March 23, 2020), available at: [https://world.kbs.co.kr/service/contents\\_view.htm?lang=e&menu\\_cate=business&id=&board\\_seq=381751](https://world.kbs.co.kr/service/contents_view.htm?lang=e&menu_cate=business&id=&board_seq=381751).

<sup>69</sup> "How We Fought COVID-19: A Perspective from Science & ICT," *MSIT* (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>70</sup> See generally GISAID Initiative, available at: <https://www.gisaid.org/> (log-in required to view posted genome sequence).

<sup>71</sup> "Diagnostic detection of Wuhan coronavirus 2019 by real-time RTPCR," *WHO* (January 13, 2020), available at: <https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf>. WHO has posted several test protocols for COVID-19 tests on its website. WHO posts these protocols for informational purposes. Such postings do not represent a formal endorsement by WHO and have not been assessed through WHO's emergency use listing procedure.



investment from the MSIT for diagnostic tests,<sup>72</sup> used the information published by the GISAID and the WHO to begin developing their own SARS-CoV-2 diagnostic test using a PCR method.<sup>73</sup> On January 16, 2020, Seegene, another South Korean biotech firm, also began independently developing a SARS-CoV-2 diagnostic test by RT-PCR using the published genetic sequence.<sup>74</sup> Seegene, like Kogene, did not have access to the actual virus, but the company was able to design its test by entering the published genetic sequence into its proprietary AI-based big data system.<sup>75</sup>

While South Korean biotech companies independently began developing SARS-CoV-2 diagnostic RT-PCR tests, on January 16, 2020, the KSLM launched the COVID-19 Laboratory Response Task Force (LR-TF) to assist governmental clinical laboratories in analyzing COVID-19 diagnostic test results.<sup>76,77</sup> The LR-TF met with the KDCA the following day to discuss ways to also begin using nongovernmental clinical laboratories to analyze diagnostic test results.<sup>78</sup> The evaluation of commercial products is not part of the KDCA’s mandate, but it is conducted when necessary for response to infectious disease, as was the case for MERS and Zika. At the meeting, the KDCA and diagnostic testing specialists also reviewed the WHO’s recommended protocol, which was partially modified according to the domestic situation, and discussed how to expand the number of testing institutions in response to the increase in testing volume. The test method was disclosed to reagent manufacturers through a separate meeting. The two bodies agreed to cooperate on training laboratory personnel, implementing an external quality assessment program, and evaluating test kits submitted to the KDCA for EUA.

While the U.S. encouraged the development of tests by laboratories and commercial manufacturers for the diagnosis of SARS-CoV-2, the South Korean government chose not to rely on diagnostic tests developed by laboratories as part of their national strategy.<sup>79</sup> Under normal circumstances, it is possible to use diagnostic tests developed by laboratories in South Korea in medical institutions, but in the case of COVID-19, such tests were not used. Instead, the South Korean government developed diagnostic testing

<sup>72</sup> “How We Fought COVID-19: A Perspective from Science & ICT,” MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

<sup>73</sup> “Kogene Biotech, Korea’s Leading Diagnostic Kit Developer,” KBS World (March 23, 2020), available at: [https://world.kbs.co.kr/service/contents\\_view.htm?lang=e&menu\\_cate=business&id=&board\\_seq=381751](https://world.kbs.co.kr/service/contents_view.htm?lang=e&menu_cate=business&id=&board_seq=381751).

<sup>74</sup> “How this South Korean company created coronavirus test kits in three weeks,” CNN (March 12, 2020), available at: <https://www.cnn.com/2020/03/12/asia/coronavirus-south-korea-testing-intl-hnk/index.html> (summarizing interview with Chun Jong-yoon, chief executive and founder of molecular biotech company Seegene).

<sup>75</sup> Id.

<sup>76</sup> H. Sung, et al., “Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor,” *Clinical Chemistry* Volume 66, Issue 7 (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>77</sup> As described above, the TTFED was established in the U.S. in 2019 and serves a similar function to the LR-TF by providing recommendations to laboratories for rapid implementation of tests after they have been authorized for use under FDA’s EUA authority. See Charter: Tri-Agency Task Force for Emergency Diagnostics, FDA, available at: <https://www.fda.gov/media/120328/download#:~:text=The%20Tri%2DAgency%20Task%20Force,future%20emergency%20diagnostic%20response%20needs>.

<sup>78</sup> H. Sung, et al., “Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor,” *Clinical Chemistry* Volume 66, Issue 7 (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>79</sup> See e.g. K.H. Hong, et al., “Guidelines for Laboratory Diagnosis of Coronavirus Disease 2019 (COVID-19) in Korea,” *Annals of Laboratory Medicine* Volume 40, Issue 5 (September 1, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7169629/>; A.J. Dy, J. Latimer, A. Dekkers, K. Mechem, and D. Hochberg, “US SARS-CoV-2 Testing Response: What can be learned from South Korea and Germany?,” *Health Advances Blog* (April 16, 2020), available at: <https://healthadvancesblog.com/2020/04/16/us-sars-cov-2-testing-response-what-can-be-learned-from-south-korea-and-germany/>.

through public-private partnerships with commercial manufacturers.<sup>80</sup> On January 27, 2020, the KDCA and the LR-TF held a conference with about 20 IVD commercial test manufacturers to request that they begin developing SARS-CoV-2 diagnostic testing kits in order to meet the government objective of providing testing nationwide.<sup>81</sup> The KDCA stressed that the agency preferred use of the real time PCR test method, given the convenience of administering PCR tests and the relative speed with which results could be obtained (possibly in several hours instead of days).<sup>82</sup> Further, to incentivize these manufacturers to begin developing diagnostic tests, they were informed that the government would set and purchase the necessary quantities of test kits in order for manufacturers to meet overhead during test review and production for any test authorized by the MFDS,<sup>83</sup> South Korea’s FDA counterpart.<sup>84</sup> In doing so, the South Korean government absorbed the financial risk of developing SARS-CoV-2 diagnostic tests.<sup>85</sup> These steps to de-risk and incentivize product development, although later taken for vaccine development, were not taken early on for test development by the U.S. government.

## V. Emergency Use Authorization of Tests

### A. Emergency Use Authorization of Molecular Diagnostic Tests

On January 28, 2020, the KDCA issued a public notification requesting commercial test developers submit EUA requests for SARS-CoV-2 diagnostic tests using RT-PCR, and in that notification, published EUA submission requirements.<sup>86</sup> The KDCA’s EUA requirements are based on performance equivalence with the KDCA’s diagnostic test method, with the performance criteria determined through an advisory meeting and then approved. The general expectations are similar to those in the U.S., but with some differences. For example, unlike South Korea’s MFDS, the FDA does not generally expect endogenous interference studies when an established nucleic acid extraction method is used, and generally waives most quality systems requirements for the duration of the EUA. In the case of COVID-19, consistent with its previously established approach, the KDCA leveraged patient specimens they had access to and used select civilian laboratories to conduct independent studies of test clinical performance, whereas the FDA generally expected test developers to conduct their own small clinical evaluations using synthetic viral material, inactivated viral material, live virus, or patient specimens (as no independent testing capability

<sup>80</sup> J. You, “Lessons From South Korea’s Covid-19 Policy Response,” *The American Review of Public Administration* Volume 50, Issue 6-7 (July 2020), available at: <https://journals.sagepub.com/doi/full/10.1177/0275074020943708>.

<sup>81</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>82</sup> *Id.*

<sup>83</sup> As described previously, when KDCA concludes that a test’s performance data meet the established EUA requirements, the agency forwards the documents to MFDS with a request for EUA. MFDS reviews the documents and if all requirements for an EUA are met, MFDS authorizes the test for emergency use. *See* “EUA (Emergency Use Authorization) Process for COVID-19 in Korea,” MFDS (July 2, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_75/view.do?seq=16](https://www.mfds.go.kr/eng/brd/m_75/view.do?seq=16).

<sup>84</sup> “COVID-19 and Korea’s Response (Video),” Ministry of Foreign Affairs (October 27, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/view.do?seq=37&srchFr=&srchTo=&srchWord=&srchTp=&multi\\_itm\\_seq=0&itm\\_seq\\_1=0&itm\\_seq\\_2=0&company\\_cd=&company\\_nm=&page=1&titleNm=](http://www.mofa.go.kr/eng/brd/m_22591/view.do?seq=37&srchFr=&srchTo=&srchWord=&srchTp=&multi_itm_seq=0&itm_seq_1=0&itm_seq_2=0&company_cd=&company_nm=&page=1&titleNm=)

<sup>85</sup> *Id.*

<sup>86</sup> “Approval of emergency use of new coronavirus gene test reagents: Notification of application for evaluation,” Infectious Disease Diagnosis Management Division (January 28, 2020).

existed in the U.S. at that time). The FDA and the MFDS have similar analytical study and labeling expectations.

The following table compares the information generally reviewed for EUAs in South Korea<sup>87</sup> and the U.S.:<sup>88</sup>

<b>Data</b>	<b>U.S.</b>	<b>South Korea</b>
Quality system	No	Yes (Korea Good Manufacturing Practice [KGMP] equivalent to International Organization for Standardization [ISO] 13485)
Development history	No	Yes (requires references)
Measurement principles and methods	Yes	Yes (requires references and requires two genes)
Raw materials and manufacturing methods	No	Yes
Control materials	Yes	No
Intended use	Yes	Yes
Reagent stability	Yes (may be completed post-authorization)	Yes
Analytical sensitivity (Limit of Detection [LoD])	Yes (n=20; allowed use of synthetic RNA until viral RNA became available)	Yes (allowed use of synthetic RNA)
Analytical specificity (cross-reactivity)	Yes	Yes
Analytical specificity (interference)	Depending on the results of cross-reactivity	Yes
Analytical specificity (inclusivity)	Yes	Yes
Precision	No	Yes
Clinical performance data	Yes (n=30 conducted by manufacturer)	Yes (conducted by KDCA collaboration; data not shared with manufacturers)
Safety for personnel handling reagent	No	Yes

<sup>87</sup> Id.

<sup>88</sup> “Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders,” FDA (January 2017), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities> (explaining FDA’s general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the FD&C Act as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)).

Comparison with the pre-approved reagent	No	Yes
Labeling	Fact sheets, instructions for use, box labels, vial labels	Pictures of finished product (package and accessories), user manual

The KDCA’s notification set the submission period to request EUA from January 28 to February 28, 2020.<sup>89</sup> Given that commercial test developers in South Korea had already begun developing SARS-CoV-2 molecular diagnostic tests in mid-January 2020 before meeting with the KDCA, the first requests for an EUA were submitted to the KDCA the day after the notice published, on January 29, 2020.<sup>90</sup> The individual developers submitted their products to the KDCA for clinical evaluation alongside their EUA applications with their own analytical data and manufacturing information. The KDCA, along with experts from the KSLM, conducted their own performance evaluation with clinical specimens. The KDCA reviewed the performance data from the test developers and the results of their own performance evaluations. For those tests that the KDCA recommended for emergency use authorization, the KDCA submitted the first EUA documents to the MFDS on February 3, 2020.<sup>91</sup>

The MFDS reviewed the documents and issued the first EUA to Kogene Biotech on February 4, 2020,<sup>92</sup> and the second EUA to Seegene on February 12, 2020.<sup>93</sup> The MFDS authorized two additional RT-PCR molecular diagnostic tests for emergency use on February 27, 2020 from SD Biosensor and Solgent Co.<sup>94</sup> On March 13, 2020, the MFDS issued an EUA to BioSewoom, the fifth test authorized for emergency use in South Korea.<sup>95</sup> Three of these five companies (Kogene, Solgent, and SD Biosensor) had previously received R&D investment and support from the government in order to develop infectious disease test technology, which enabled these companies to rapidly develop the SARS-CoV-2 tests early in the pandemic.<sup>96</sup> Also, none of these five tests used proprietary instruments or platforms, making them accessible to a variety of laboratories.

During South Korea’s initial EUA application submission period from January 28 to February 28, 2020, the KDCA received 64 applications and completed its review of 22 EUA applications by March 17, 2020. As described previously, at the KDCA’s recommendation, the MFDS issued EUAs to five test developers by mid-March 2020. Scholars have noted that by fast-tracking the authorization of test kits for COVID-19, “the government made a strategic decision to take swift action, even though doing so meant foregoing

<sup>89</sup> “Approval of emergency use of new coronavirus gene test reagents: Notification of application for evaluation,” Infectious Disease Diagnosis Management Division (January 28, 2020).

<sup>90</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>91</sup> Id.

<sup>92</sup> “Latest COVID-19 News: Emergency Use of COVID-19 test kit authorized, COVID-19 tests also conducted at medical institutions,” MFDS (February 4, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_64/view.do?seq=14&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_64/view.do?seq=14&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1).

<sup>93</sup> “List of COVID-19 Diagnostic Kits Authorized for Use under Emergency Use Authorizations,” MFDS (March 26, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_60/view.do?seq=74424](https://www.mfds.go.kr/eng/brd/m_60/view.do?seq=74424).

<sup>94</sup> Id.

<sup>95</sup> Id.

<sup>96</sup> “How We Fought COVID-19: A Perspective from Science & ICT,” MSIT (July 6, 2020), available at: [https://www.mofa.go.kr/eng/brd/m\\_22591/down.do?brd\\_id=20543&seq=28&data\\_tp=A&file\\_seq=1](https://www.mofa.go.kr/eng/brd/m_22591/down.do?brd_id=20543&seq=28&data_tp=A&file_seq=1).

standard clinical trials aimed at quality assurance.”<sup>97</sup> A member of the KSLM acknowledged the challenging balance of efficiently authorizing tests while assuring test quality, stating “[o]f course, a kit that’s approved in one week isn’t as good as one that goes through a year of clinical trials.”<sup>98</sup>

In the U.S., the FDA issued the first EUA for a SARS-CoV-2 molecular diagnostic test to the CDC on February 4, 2020, one day after the FDA received the complete EUA submission from the CDC.<sup>99</sup> Unlike in South Korea, at that time, the FDA accepted EUA requests from “all comers,” including laboratories, yet the FDA did not receive any additional complete EUA requests until the end of February 2020. On February 29, 2020, FDA issued an EUA to the New York State Department of Health (NYSDOH) Wadsworth Center<sup>100</sup> and Integrated DNA Technologies (IDT), a contract manufacturer, began distributing test kits to public and non-public health laboratories under the CDC’s EUA. A second manufacturer, LGC Bioscience, also began distributing test kits to these labs under the CDC’s EUA in early March 2020. On March 12 and 13, 2020, the FDA authorized commercial tests from Roche<sup>101</sup> and Thermo Fisher (TF),<sup>102</sup> respectively, both on the same day each EUA request submission was received by the FDA. Many of the traditional infectious disease test developers in the U.S. use proprietary instruments or platforms, which limits their use to laboratories that have those specific systems.

The FDA did not receive EUA requests from the developers of any of the first five tests authorized for emergency use by the MFDS until several weeks after the MFDS issued their EUAs, because they were serving the needs of the South Korean market. In addition, in South Korea, the KDCA oversaw one phase of evaluating test performance in support of an EUA application – the clinical evaluation – whereas in the U.S., test developers perform all evaluations themselves. The South Korean companies would have to perform the clinical evaluation of their tests themselves to support a U.S. EUA because they and the FDA did not have access to the clinical evaluation performed by the South Korean government. The FDA issued an EUA to Seegene on April 21, 2020; to SD Biosensor on April 23, 2020; to Solgent on May 21, 2020; to BioSewoom on July 9, 2020;<sup>103</sup> and to Kogene on July 13, 2020.<sup>104</sup>

In South Korea and the U.S., the EUA pathway is intended to, among other things, expedite access to accurate diagnostic tests during emergencies. It typically takes eight to 12 months to review and approve

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<sup>97</sup> D. Ladner, K. Hamaguchi, and H. Kim, “The Republic of Korea’s First 70 Days of Responding to the COVID-19 Outbreak,” Global Delivery Initiative (April 13, 2020), available at: <http://www.globaldeliveryinitiative.org/library/case-studies/republic-korea%E2%80%99s-first-70-days-responding-covid-19-outbreak#:~:text=Global%20Delivery%20Initiative-.The%20Republic%20of%20Korea%27s%20First%2070%20Days,to%20the%20COVID%2D19%20Outbreak&text=The%20Republic%20of%20Korea%20was,at%20813%20on%20February%2029.>

<sup>98</sup> C. Terhune, D. Levine, H. Jin, and J.L. Lee, “Special Report: How Korea trounced U.S. in race to test people for coronavirus,” Reuters (March 18, 2020), available at: <https://www.reuters.com/article/us-health-coronavirus-testing-specialrep/special-report-how-korea-trounced-u-s-in-race-to-test-people-for-coronavirus-idUSKBN2153BW.>

<sup>99</sup> Letter from RADM Hinton (FDA) to Robert Redfield (CDC), dated February 4, 2020.

<sup>100</sup> Letter from FDA to NYSDOH dated March 10, 2020 (detailing authorization issued on February 29, 2020), available at: <https://www.fda.gov/media/135661/download>.

<sup>101</sup> Letter of Authorization from FDA to Roche Molecular Systems, Inc., dated March 12, 2020 available at: <https://www.fda.gov/media/136046/download>.

<sup>102</sup> Letter of Authorization from FDA to Thermo Fisher Scientific, Inc., dated March 13, 2020 available at: <https://www.fda.gov/media/136113/download>.

<sup>103</sup> Letter from FDA to BioSewoom dated July 9, 2020, available at: <https://www.fda.gov/media/139938/download>.

<sup>104</sup> Letter from FDA to KogeneBiotech dated July 13, 2020, available at: <https://www.fda.gov/media/140066/download>.

a medical device under the traditional pathway in South Korea. The first two EUA requests were reviewed and authorized by South Korea within days of receiving each application. In the U.S. during fiscal year 2019, review and approval or clearance of IVDs averaged eight months for the de novo pathway, 10-11 months for the premarket approval (PMA) pathway, and four months for the 510(k) premarket notification pathway. As of mid-March 2020, the FDA had reviewed and issued four EUAs for IVD molecular diagnostic tests in the U.S., each within one day of receiving the EUA submission and added two contract manufacturers to one of the EUAs.

In addition, in order to increase access to testing, on February 29, 2020, the FDA implemented a flexible policy for laboratories offering their own tests prior to EUA issuance but after notifying the FDA. As of March 15, 2020 almost 50 additional tests were being used for clinical testing under the FDA’s February 29, 2020 notification policy.

### *B. Emergency Use Authorization of Rapid Molecular Diagnostic Tests*

In the U.S., the first rapid molecular diagnostic test authorized for emergency use at the point-of-care (such as doctors’ offices, pharmacies, nursing homes), Abbott’s ID Now, was authorized on March 27, 2020, and was capable of delivering test results in under 15 minutes.<sup>105</sup> As the pandemic evolved, concerns grew in South Korea about the lack of rapid diagnostic tests available for patients in emergency settings. On June 11, 2020, the KDCA published a notice seeking EUA requests for the emergency use of rapid molecular diagnostics for COVID-19, specifically for the screening of patients in emergency settings.<sup>106</sup> Thirteen EUA requests were received by the KDCA<sup>107</sup> and on June 24, 2020, the MFDS issued EUAs to SML Genetree, BioSewoom, and LabGenomics for molecular diagnostic tests that take less than one hour from pre-treatment of samples to test results in order to quickly screen emergency patients.<sup>108</sup> LabGenomic’s test was added to the export list by the MFDS on March 3, 2020 and the FDA issued an EUA for the test on April 29, 2020.<sup>109,110,111</sup>

### *C. Emergency Use Authorization of Antigen Tests*

Antigen tests usually provide results of an active infection faster than molecular tests (in as little as 15 minutes), but have a higher rate of false negatives.<sup>112</sup> The FDA authorized the first SARS-CoV-2 antigen test for emergency use on May 8, 2020 and had authorized 11 antigen tests for emergency use as of late

<sup>105</sup> “Abbott Launches Molecular Point-of-Care Test to Detect Novel Coronavirus in as Little as Five Minutes,” Abbott (March 27, 2020), available at: <https://abbott.mediaroom.com/2020-03-27-Abbott-Launches-Molecular-Point-of-Care-Test-to-Detect-Novel-Coronavirus-in-as-Little-as-Five-Minutes>.

<sup>106</sup> “Press Release: Ministry of Food and Drug Safety approves emergency use of COVID-19 diagnostic reagents,” MFDS (June 24, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_64/view.do?seq=34&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_64/view.do?seq=34&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1).

<sup>107</sup> Id.

<sup>108</sup> Id.

<sup>109</sup> P. Wood and L. Broadwater, “Maryland secures 500,000 coronavirus tests from South Korea; Hogan’s initiative sparks criticism from Trump,” Baltimore Sun (April 2020), available at: <http://www.baltimoresun.com/coronavirus/bs-md-hogan-testing-20200420-atxs3grvbjdgpzzt4tfhuhnbm-story.html>.

<sup>110</sup> “List of COVID-19 in-vitro diagnostic devices approved by MFDS,” MFDS (August 13, 2020), available at: [https://www.mfds.go.kr/eng/brd/m\\_65/download.do?brd\\_id=engcovid1902&seq=21&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/download.do?brd_id=engcovid1902&seq=21&data_tp=A&file_seq=1).

<sup>111</sup> Letter from FDA to LabGenomics Co., Ltd., dated April 29, 2020, available at: <https://www.fda.gov/media/137484/download>.

<sup>112</sup> “Coronavirus Disease 2019 Testing Basics,” FDA (updated November 6, 2020), available at: <https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics>.

December 2020.<sup>113,114</sup> South Korean healthcare experts warned that rapid diagnostic tests were too inaccurate, with the KSLM stating that historically “the sensitivity of antigen testing for influenza infection is 50-70 percent of that of PCR tests.”<sup>115</sup> Six South Korean professional societies issued a joint statement warning “[i]t is very dangerous to introduce rapid diagnostic tests to detect COVID-19 during this global pandemic” because of low sensitivity in comparison to PCR tests.<sup>116</sup> As of September 2020, South Korea had not approved or authorized for emergency use any antigen or antibody tests domestically.<sup>117</sup> Ultimately, on November 11, 2020, the MFDS authorized for emergency use in South Korea the first rapid antigen test from SD Biosensor.<sup>118</sup> This test is capable of producing results in 15 to 30 minutes.<sup>119</sup>

#### *D. Emergency Use Authorization of Antibody Tests*

In the spring of 2020, the MFDS officials publicly stated antibody tests were too low in accuracy to meaningfully support South Korea’s pandemic response strategy.<sup>120</sup> At this same time, the U.S. had announced a policy of enforcement discretion for developers to market or use their antibody tests without prior FDA review when those tests were validated and clearly labeled that they could not be used as the sole basis to diagnose or exclude active infection. The FDA adopted this policy to facilitate epidemiologic research; better understand whether the development of antibodies conveys immunity to reinfection and, if so, for how long; and determine whether these tests have clinical utility. The FDA, however, later revised this policy in response to concerns raised with the quality of such tests.<sup>121</sup> The U.S. government established an independent testing capacity for serology tests, similar to that established in South Korea in January 2020 for diagnostic tests.<sup>122</sup> Data from these evaluations informed FDA’s regulatory decisions – in addressing problematic tests on the market, as well as supporting authorizations of tests that performed well. The FDA issued the first EUA for a serology test on April 15, 2020 and had issued EUAs for 71

<sup>113</sup> Letter from FDA to Quidel Corporation dated May 8, 2020, available at: <https://www.fda.gov/media/137886/download>.

<sup>114</sup> “In Vitro Diagnostics EUAs,” FDA (updated regularly), available at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

<sup>115</sup> S. Soo-youn, “10-minute diagnostic tests not recommended due to inaccuracy,” Korea Biomedical Review (March 19, 2020), available at: <https://www.koreabiomed.com/news/articleView.html?idxno=7762>.

<sup>116</sup> Id.

<sup>117</sup> Since March, South Korea has approved numerous antigen and antibody tests to be exported only. See “List of COVID-19 In Vitro Diagnostic Devices for Export Only Approved by MFDS,” MFDS (December 17, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=43&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=43&data_tp=A&file_seq=1).

<sup>118</sup> “List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS,” MFDS (November 27, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=37&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=37&data_tp=A&file_seq=1).

<sup>119</sup> “Korea MFDS approved for the FIRST STANDARD Q COVID-19 Ag test,” SD Biosensors (November 13, 2020), available at: <http://sdbiosensor.com/x/promotionNews/21736>.

<sup>120</sup> “Introduction of autoantibody testing in Korea is yet to be decided (translated),” Medical Observer (May 30, 2020).

<sup>121</sup> For a more detailed discussion, see “Insight into FDA’s Revised Policy on Antibody Tests: Prioritizing Access and Accuracy,” FDA (May 4, 2021), available at: <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy>.

<sup>122</sup> “FDA News Release: Coronavirus (COVID-19) Update: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study,” FDA (June 4, 2020), available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-publicly-shares-antibody-test-performance-data-kits-part-validation>.

serology tests as of January 5, 2021.<sup>123</sup> On November 3, 2020, the MFDS authorized for emergency use in South Korea the first antibody test from SD Biosensor.<sup>124</sup>

### *E. Continuous Monitoring of Test Performance*

When South Korea activated its EUA program in January 2020, the KDCA proactively took steps to ensure the laboratories running the tests were producing accurate results.<sup>125</sup> Specifically, the KDCA worked with the KEQAS to certify and designate laboratories, which already had certified laboratory excellence programs under the Korean Laboratory Accreditation Program, as COVID-19 molecular diagnostic testing facilities.<sup>126</sup> In order to receive designation, interested laboratories were first required to evaluate a proficiency test panel comprised of six plasmid DNAs with varying concentrations and one negative control.<sup>127</sup> On February 5, 2020, the panels were shipped to interested laboratories which already had accreditation under the Korean Laboratory Accreditation Program.<sup>128</sup> The KEQAS designated laboratories as COVID-19 molecular testing facilities when they correctly reported test results from the proficiency test panel.<sup>129</sup> The KDCA also coordinated with the KSLM to conduct mandatory technical training on standardized laboratory guidelines, and with several universities in South Korea to perform external quality assessments (EQA) of all designated laboratories.<sup>130</sup> By February 6, 2020, the KEQAS had certified 46 out of the 47 interested non-governmental laboratories to begin COVID-19 molecular diagnostic testing; this number grew to 95 as of March 31, 2020.<sup>131</sup> After certification, the EQAs were performed to ensure the accuracy of tests and to compare different processes.<sup>132</sup> South Korea also purchases marketed tests and conducts additional performance evaluations.

In the U.S., the Centers for Medicare and Medicaid Services (CMS) certifies laboratories and monitors laboratory operations, whereas the FDA monitors performance of the tests. As part of its monitoring efforts, the FDA created and distributed a reference panel to developers of authorized molecular diagnostics. The FDA analyzes results and posts them online; these results provide insight into the

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<sup>123</sup> In Vitro Diagnostics EUAs, FDA (updated regularly), available at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

<sup>124</sup> “List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS,” MFDS (November 27, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=37&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=37&data_tp=A&file_seq=1).

<sup>125</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>126</sup> H. Sung, et al., “Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor,” *Clinical Chemistry* Volume 66, Issue 7 (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>127</sup> Id.

<sup>128</sup> Id.

<sup>129</sup> Id.

<sup>130</sup> The requirement to undergo mandatory technical training and EQAs was established in 2016 when the EUA program was designed. See H. Sung, et al., “Nationwide External Quality Assessment of SARS-CoV-2 Molecular Testing, South Korea,” *Emerging Infectious Diseases Journal* Volume 26, Number 10 (October 2020), available at: [https://wwwnc.cdc.gov/eid/article/26/10/20-2551\\_article#r7](https://wwwnc.cdc.gov/eid/article/26/10/20-2551_article#r7).

<sup>131</sup> H. Sung, et al., “Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea: Letters to the Editor,” *Clinical Chemistry* Volume 66, Issue 7 (July 2020), available at: <https://academic.oup.com/clinchem/article/66/7/979/5823883>.

<sup>132</sup> “Nationwide External Quality Assessment of SARS-CoV-2 Molecular Testing, South Korea,” *Emerging Infectious Diseases Journal* Volume 26, Number 10 (October 2020), available at: [https://wwwnc.cdc.gov/eid/article/26/10/20-2551\\_article#r7](https://wwwnc.cdc.gov/eid/article/26/10/20-2551_article#r7).



relative performance of different molecular diagnostic tests under an EUA. For serology tests, FDA partnered with the CDC and the National Institutes of Health (NIH) to establish a capacity within the U.S. government to independently evaluate the tests themselves. As described previously, the FDA analyzes results and posts them online.

## VI. South Korea’s National Strategy

South Korea quickly designed and implemented a comprehensive, government-led core strategy comprised of three elements: testing, tracing, and treatment (3Ts).<sup>133</sup> Their COVID-19 response strategy sought to “prevent the spread of the disease, protect public health, keep the society and economy open, and thereby allow daily life to continue.”<sup>134</sup> South Korea has asserted that the “core of Korea’s COVID-19 response lies in its robust laboratory diagnostic testing capability.”<sup>135</sup> To implement this strategy, as soon as the first molecular diagnostic tests were authorized for emergency use on February 4, 2020, South Korea leveraged the available diagnostic tests and public-private partnerships into a federally-coordinated, nationwide testing effort.<sup>136</sup> Specifically, the central government collaborated closely with state governments and the private sector to establish testing locations and to implement standardized testing procedures.<sup>137</sup>

### A. Testing by the Numbers

The first test kits under EUA were distributed February 7, 2020 to private medical institutions.<sup>138</sup> Manufacturers which were granted an EUA began selling their diagnostic test kits directly to public and private hospitals and treatment centers where large-scale testing was to be completed.<sup>139</sup> Also on February 7, 2020, the Ministry of Health and Welfare, the South Korea counterpart to the U.S. HHS, announced a reimbursement scheme for diagnostic tests.<sup>140</sup> As of December 20, 2020, the South Korean government had performed 3,683,094 tests within its borders, with a population of 51 million.<sup>141</sup> With slightly over 51,000 confirmed positive cases, South Korea had a 1.4 percent positivity rate.<sup>142</sup> The U.S., by comparison, has a population of 328.8 million and had performed over 234 million tests as of late December 2020.<sup>143</sup> With over 18 million confirmed positive cases, the U.S. had a positivity rate of around

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<sup>133</sup> Id.

<sup>134</sup> Id.

<sup>135</sup> Id.

<sup>136</sup> Id.

<sup>137</sup> Id.

<sup>138</sup> Id.

<sup>139</sup> J. Park and E. Chung, “Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea,” *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

<sup>140</sup> See Document detailing temporary reimbursement code and criteria, Government of the Republic of Korea (February 7, 2020).

<sup>141</sup> South Korea has been testing all people who enter its borders, regardless of whether they are Korean citizens. “Coronavirus Disease-19,” Republic of Korea (updated regularly), available at: <http://ncov.mohw.go.kr/en>.

<sup>142</sup> “Coronavirus Disease-19,” Republic of Korea (updated regularly), available at: <http://ncov.mohw.go.kr/en>.

<sup>143</sup> The number of SARS-CoV-2 diagnostic tests conducted in the U.S. reflects repeat testing, including for employees working in laboratories and healthcare whose employers have required regular testing as part of job fitness. “The COVID Tracking Project,” *The Atlantic*, updated regularly, available at: <https://covidtracking.com/>.

7 percent (the positivity rate for daily new cases reached a high of 20 percent in April 2020).<sup>144,145</sup> The number of different tests the two countries relied upon is remarkably different. At the end of November 2020, South Korea had authorized approximately two dozen diagnostic tests,<sup>146</sup> whereas the U.S. had authorized over 200,<sup>147</sup> in addition to receiving over 400 notifications from laboratories offering their diagnostic tests prior to EUA issuance.

### *B. Guidelines for Laboratories*

On September 1, 2020, the COVID-19 Diagnosis Test Management Committee<sup>148</sup> published “Guidelines for the Laboratory Diagnosis of COVID-19 in Korea and Q&A for COVID-19 Laboratory Diagnosis,” aimed at establishing and managing COVID-19 diagnoses in hospital laboratories and commercial laboratory centers.<sup>149</sup> The guidelines explain that all diagnostic test kits marketable in South Korea as of September 2020 are capable of detecting two or more genes.<sup>150</sup> Some manufacturers, however, have interpreted detection of only one gene to be a COVID-19 positive result.<sup>151</sup> The guidelines recommend declaring a positive result only when all genes are detected; when only one gene is detected, retesting or consulting the reference laboratory is recommended.<sup>152</sup> All clinical laboratories are advised to transfer their test results and all positive specimens to the KDCA.<sup>153</sup> Further, clinical laboratories are recommended to not use the following: (1) methods other than real-time RT-PCR, (2) laboratory-developed tests, and (3) reagents not authorized for emergency use as a diagnostic.<sup>154</sup>

### *C. Testing Locations*

The network of testing locations in South Korea was initially comprised of private medical institutions and the KDCA, but quickly expanded to include research institutes and quarantine stations.<sup>155</sup> The number of institutions with on-site COVID-19 diagnostic testing grew from 118 by April 24, 2020, to 146 by August 10, 2020, to 599 by September 22, 2020 (including the KDCA, National Quarantine Stations, the Research Institutes for Public Health and Environment, the Armed Forces Medical Science Research Institute, civil hospitals, and referral laboratories).<sup>156</sup> Private facilities with historically high traffic, such

<sup>144</sup> “The COVID Tracking Project,” The Atlantic (updated regularly), available at: <https://covidtracking.com/>.

<sup>145</sup> “Coronavirus Resource Center,” Johns Hopkins University (updated regularly), available at: <https://coronavirus.jhu.edu/testing/individual-states>.

<sup>146</sup> “List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS,” MFDS (November 27, 2020), available at:

[https://www.mfds.go.kr/eng/brd/m\\_65/down.do?brd\\_id=engcovid1902&seq=37&data\\_tp=A&file\\_seq=1](https://www.mfds.go.kr/eng/brd/m_65/down.do?brd_id=engcovid1902&seq=37&data_tp=A&file_seq=1).

<sup>147</sup> “In Vitro Diagnostics EUAs,” FDA (updated regularly), available at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

<sup>148</sup> H. Sung, “COVID-19 Molecular Testing in Korea: Practical Essentials and Answers From Experts Based on Experiences of Emergency Use Authorization Assays,” *Annals of Laboratory Medicine* Volume 40, Issue 6 (November 1, 2020), available at: <https://www.annlabmed.org/journal/view.html?doi=10.3343/alm.2020.40.6.439>.

<sup>149</sup> K.H. Hong, et al., “Guidelines for Laboratory Diagnosis of Coronavirus Disease 2019 (COVID-19) in Korea,” *Annals of Laboratory Medicine* Volume 40, Issue 5 (September 1, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7169629/>.

<sup>150</sup> Id.

<sup>151</sup> Id.

<sup>152</sup> Id.

<sup>153</sup> Id.

<sup>154</sup> Id.

<sup>155</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>156</sup> Id.

as coffee shops and fast food restaurants, also set up testing facilities in coordination with the central government.<sup>157</sup> Three types of testing facilities were designed: screening stations (in hospital emergency rooms and outside venues to screen visitors and patients before entering hospitals); drive-through screening stations (screening of travel history and symptoms, fever check, and specimen collection performed through the window without the subject leaving the car); and walk-through screening stations (for those without a car or living in regions prone to bad weather, utilizing a portable booth to separate medical staff from suspected cases).<sup>158</sup> On average, screening stations are capable of conducting two tests per hour<sup>159</sup> and drive-through stations are capable of conducting six per hour;<sup>160</sup> both types of stations are open 10 hours per day.<sup>161,162</sup>

Throughout the pandemic, South Korea has also mandated nationwide diagnostic testing as necessary based on evolving factors.<sup>163</sup> On March 22, 2020, they began requiring mandatory testing within three days for all arrivals from COVID-19 hot spots (mainly from Europe), to be conducted at airports and government-identified facilities.<sup>164</sup> On April 15, 2020, this mandatory testing requirement was expanded to travelers from the U.S., and on May 11, 2020, expanded again to include all inbound travelers worldwide.<sup>165</sup> Through amendment of South Korea’s IDCPA in early 2020, civil money penalties may be imposed against a suspected person with COVID-19 who refuses to take a diagnostic test ordered by health authorities.<sup>166</sup>

The South Korean government covers all costs associated with receiving a COVID-19 diagnostic test.<sup>167</sup>

#### *D. Tracing through use of Information Technology Systems*

The tracing component of South Korea’s 3Ts strategy was built on information technology systems and a self-quarantine program.<sup>168</sup> For example, the Epidemiological Investigation Support System collects and

<sup>157</sup> Id.

<sup>158</sup> Id.

<sup>159</sup> Id.

<sup>160</sup> “Standardized Operating Model for Drive-Through Screening Clinics,” KDCA (March 2020), available at: <https://covidtranslate.org/KCDC-drive-thru-manual.pdf>.

<sup>161</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>162</sup> “Standardized Operating Model for Drive-Through Screening Clinics,” KDCA (March 2020), available at: <https://covidtranslate.org/KCDC-drive-thru-manual.pdf>.

<sup>163</sup> As of early September, given that every suspected case of COVID-19 is required to undergo testing at a government-designated testing location, no home collection kits had been authorized in South Korea for emergency use.

<sup>164</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>165</sup> Id.

<sup>166</sup> IDCPA, Act No. 9847, amended arts. 13, para. 2 & 80, subpara. 2-2, Korean Law Translation Center (amended December 2015), available at: [https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); see also “South Korea: Parliament Responded Quickly to COVID-19 by Amending Three Acts,” United States Library of Congress (June 4, 2020), available at: <https://www.loc.gov/law/foreign-news/article/south-korea-parliament-responded-quickly-to-covid-19-by-amending-three-acts/>.

<sup>167</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>168</sup> Id.

analyzes personal data, including credit card transactions, CCTV footage, and mobile phone GPS data for up to 14 days on confirmed cases to quickly identify paths and modes of transmission.<sup>169</sup> As described previously, the authority to collect personal data on confirmed and suspected cases comes from an amendment to the IDCPA in 2015, following lessons learned from MERS in 2015.<sup>170</sup> After citizens expressed concern about data privacy invasions, the government asserted that the data are accessible only to essential personnel and are deleted after 14 days.<sup>171</sup> The government reported that automating the systems necessary for tracing has reduced the time required to analyze data from 24 hours per case to 10 minutes.<sup>172</sup>

### *E. Self-quarantine Program*

Testing has been an effective tool for South Korea to contain the COVID-19 outbreak because it has been combined with other important measures. South Korea’s expansive diagnostic testing and tracing supported a self-quarantine program, which, along with mask wearing, social distancing, selective, temporary business closures, and an effective communications strategy helped contain the spread of COVID-19 in South Korea.<sup>173</sup> Under the self-quarantine program, all suspected and probable cases of COVID-19 are subject to 14-day self-quarantine.<sup>174</sup> Each person under self-quarantine receives an official “Notice of Isolation/Quarantine,” an assigned case officer to monitor twice per day for symptoms, access to the Self-Quarantine Safety Protection App, and random onsite inspections.<sup>175</sup> Under the IDCPA amended in 2020, violators of self-quarantine are subject to imprisonment.<sup>176</sup> The violation rate has been less than 0.2 percent. As of September 22, 2020, 686,198 cases had been placed under self-quarantine, and only 1,139 of those were identified to have violated the requirements of self-quarantine.<sup>177</sup>

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<sup>169</sup> “Flattening the curve on COVID-19: How Korea responded to a pandemic using ICT,” Government of the Republic of Korea (May 2020), available at:

[http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH\\_000000000013739&fileSn=2](http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH_000000000013739&fileSn=2).

<sup>170</sup> IDCPA, Act No. 9847, Article 6(2), amended 2015, Korean Law Translation Center (amended December 2015), available at:

[https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); “All About Korea’s Response to COVID-19,”

Government of the Republic of Korea (October 13, 2020), available at:

[http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>171</sup> “Flattening the curve on COVID-19: How Korea responded to a pandemic using ICT,” Government of the Republic of Korea (May 2020), available at:

[http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH\\_000000000013739&fileSn=2](http://www.moef.go.kr/com/cmm/fms/FileDown.do?atchFileId=ATCH_000000000013739&fileSn=2).

<sup>172</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>173</sup> Id.

<sup>174</sup> Id.

<sup>175</sup> Id.

<sup>176</sup> IDCPA, Act No. 9847, amended arts. 13, para. 2 & 80, subpara. 2-2, Korean Law Translation Center (amended December 2015), available at:

[https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); see also “South Korea: Parliament Responded Quickly to COVID-19 by Amending Three Acts,” United States Library of Congress (June 4, 2020), available at:

<https://www.loc.gov/law/foreign-news/article/south-korea-parliament-responded-quickly-to-covid-19-by-amending-three-acts/>.

<sup>177</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

#### F. Four Societal Principles

South Korea also attributes its successful pandemic response to the active participation of its citizens. In order to encourage voluntary participation with the 3Ts response strategy, South Korea established four societal principles: (1) openness – keep borders and society open without blanket entry ban and mandatory lockdown measures; (2) transparency – full and prompt disclosure of data on global and domestic COVID-19 trends, along with information about government decisions and strategies; (3) civic engagement – implementing policies based on clear communication and citizen participation; and (4) innovativeness – embracing creative problem-solving and resilient and flexible responses.<sup>178</sup> Each amendment to the IDCPA,<sup>179</sup> described previously, reflected these four societal principles and provided tools for South Korea to design an adequate COVID-19 response.<sup>180</sup> An amendment to the Government Organization Act in August 2020 also engendered public trust by transferring pandemic response decision-making from the President of South Korea to the public health experts, which was demanded by the public in March 2020.<sup>181</sup>

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<sup>178</sup> Id.

<sup>179</sup> IDCPA, Act No. 9847, Article 6(2), amended 2015, Korean Law Translation Center (amended December 2015), available at:

[https://elaw.klri.re.kr/eng\\_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I](https://elaw.klri.re.kr/eng_mobile/ganadaDetail.do?hseq=37239&type=abc&key=INFECTIOUS%20DISEASE%20CONTROL%20AND%20PREVENTION%20ACT&param=I); “All About Korea’s Response to COVID-19,”

Government of the Republic of Korea (October 13, 2020), available at:

[http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>180</sup> “All About Korea’s Response to COVID-19,” Government of the Republic of Korea (October 13, 2020), available at: [http://www.mofa.go.kr/eng/brd/m\\_22591/list.do](http://www.mofa.go.kr/eng/brd/m_22591/list.do).

<sup>181</sup> J. Park and E. Chung, “Learning from past pandemic governance: Early response and Public-Private Partnerships in testing of COVID-19 in South Korea,” *World Dev.* 2021 Jan; 137: 105198 (September 18, 2020), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500944/#!po=0.245098>.

## Appendix A: Timeline for South Korean Response to COVID-19

- December 31, 2019: An outbreak of pneumonia of unknown etiology in Wuhan City, China, is initially reported to the World Health Organization (WHO).<sup>182</sup>
- Late December 2019 to early January 2020: The KDCA obtains the DNA sequence of SARS-CoV-2 from China and began developing a pan-coronavirus diagnostic test, which is designed to detect all types of coronavirus.
- January 3, 2020: The Minister of Health and Welfare adjusts the National Infectious Disease Risk Alert to “Level 1.” The KDCA forms the Countermeasures Team for Unidentified Pneumonia Outbreak in Wuhan, China.
- January 9, 2020: With the DNA sequence obtained from China, the KDCA completes COVID-19 pan-coronavirus testing method. The test is difficult to use and takes one to two days to obtain results.
- January 10, 2020: Given the difficulty and delay in results with using the pan-coronavirus test, the KDCA begins developing a specific SARS-CoV-2 test.
- January 10, 2020: The GISAID publishes the full genome sequence of SARS-CoV-2. Without assistance from the KDCA, private test developers in South Korea use the genome sequence to begin developing SARS-CoV-2 molecular diagnostic tests.
- January 13, 2020: The WHO publishes the protocol and preliminary evaluation for diagnostic detection of SARS-CoV-2 virus by real-time RT-PCR, developed by Charité Virology in Berlin, Germany.
- January 16, 2020: The KSLM launches the LR-TF to assist clinical laboratories in establishing diagnostic testing.
- January 17, 2020: The KDCA and the KSLM meet to discuss ways to expand diagnostic testing by non-governmental clinical laboratories. They agree to cooperate on training laboratory personnel, implementing an external quality assessment program, and evaluating test kits submitted to the KDCA for EUA. The KSLM and the KEQAS agree to provide “civilian experts” to evaluate the clinical performance of each diagnostic test submitted through an EUA request.
- January 20, 2020: South Korea reports first its confirmed case. The National Infectious Disease Risk Alert level is raised to “Level 2.” The Central Disease Control Headquarters begins operation.
- January 27, 2020: The South Korea National Infectious Disease Risk Alert level is raised to “Level 3.” The Central Disaster Management Headquarters begins operation. The KDCA holds a briefing session with 20 private IVD test manufacturers on development of diagnostic reagents and testing kits. The KDCA provides these developers with EUA timelines, stresses that the PCR method is preferred, and assures them that the government will purchase minimum quantities of tests necessary to meet their overhead.
- January 28, 2020: The KDCA issues a public notification requesting that test developers submit EUA applications for the emergency use of genetic testing reagents by RT-PCR to diagnose COVID-19. The notification includes EUA submission requirements and sets the initial submission period to request an EUA for diagnostic tests from January 28 to February 28, 2020.
- January 29, 2020: Private test developers submit to the KDCA the first EUA requests for SARS-CoV-2 molecular diagnostic tests.

<sup>182</sup> “Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV) in Wuhan, China,” CDC (January 17, 2020), available at: <https://emergency.cdc.gov/han/han00426.asp>.

- January 30, 2020: South Korea expands nationwide COVID-19 testing method to public testing agencies.
- January 31, 2020: The KDCA finishes developing their SARS-CoV-2 molecular diagnostic test by RT-PCR, which can obtain results in six hours. The test is designed with a two-target protocol.
- February 3, 2020: The KDCA completes its review of the first EUA requests of SARS-CoV-2 molecular diagnostic tests and submits its recommendations for EUA issuance to the MFDS.
- February 4, 2020: The MFDS authorizes the first SARS-CoV-2 molecular diagnostic test for emergency use from Kogene Biotech.
- February 5, 2020: The KDCA and the KEQAS ships proficiency test panels to South Korea laboratories which are interested in receiving certification and designation as COVID-19 molecular testing facilities, and which already have accreditation under the Korean Laboratory Accreditation Program.
- February 6, 2020: The KEQAS has certified 46 out of the 47 interested South Korea non-governmental laboratories to begin COVID-19 molecular diagnostic testing.
- February 7, 2020: Test kits under EUA are shipped nationwide to private medical institutions to begin government-coordinated COVID-19 testing.
- February 12, 2020: The MFDS authorizes the second SARS-CoV-2 molecular diagnostic test for emergency use from Seegene. The test uses a three-gene protocol and a different dye from the test developed by the KDCA.
- February 23, 2020: The South Korea National Infectious Disease Risk Alert level is raised to “Level 4 (Highest).” The Central Disaster and Safety Countermeasure Headquarters begins operation. Drive-through screening starts.
- February 27, 2020: The MFDS authorizes the third and fourth SARS-CoV-2 molecular diagnostic tests for emergency use from SD Biosensor and Solgent Co.
- February 28, 2020: The initial period to submit EUA requests to KDCA closes. During this period from January 28 to February 28, the KDCA receives 64 EUA requests.
- March 7, 2020: The Self-Quarantine Safety Protection App is launched to connect confirmed and suspected cases under quarantine with case managers and to track symptoms.
- March 13, 2020: The MFDS authorizes the fifth SARS-CoV-2 molecular diagnostic test for emergency use from BioSewoom.
- March 22, 2020: South Korea mandates diagnostic testing for all arrivals from COVID-19 hot spots.
- March 31, 2020: The KEQAS has certified 95 interested non-governmental laboratories to begin COVID-19 molecular diagnostic testing.
- From mid-March to mid-April 2020: South Korea confirms an additional 2,000 cases of COVID-19. The U.S. confirms an additional 200,000 cases.
- Early April 2020: Numerous sources internationally report that South Korea has successfully “flattened the curve” of COVID-19 (i.e., slowed down the spread of a virus to prevent a spike in people getting sick, which would have the potential to overwhelm healthcare systems and workers).
- April 21, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer Seegene.
- April 23, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer SD Biosensor.

- April 24, 2020: 118 private and public medical institutions in South Korea have on-site COVID-19 diagnostic testing.
- April 29, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer LabGenomics.
- May 11, 2020: South Korea mandates all arrivals undergo testing for COVID-19.
- May 21, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer Solgent.
- June 11, 2020: The KDCA publishes a notice seeking EUA requests for the emergency use of rapid diagnostic reagents for COVID-19, specifically for the screening of patients in emergency settings.
- June 24, 2020: The MFDS issues EUA to SML Genetree, BioSewoom, and LabGenomics for three COVID-19 molecular diagnostic reagents which take less than one hour from pre-treatment of samples to test results in order to quickly screen emergency patients.
- July 9, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer BioSewoom.
- July 13, 2020: The FDA authorizes for emergency use the SARS-CoV-2 molecular diagnostic test from South Korea test developer Kogene.
- August 10, 2020: 146 private and public medical institutions in South Korea have on-site COVID-19 diagnostic testing.
- September 1, 2020: The Committee for Laboratory Diagnosis Management, established by KDCA and KSLM, publishes “Guidelines for the Laboratory Diagnosis of COVID-19 in Korea and Q&A for COVID-19 Laboratory Diagnosis,” aimed at establishing and managing COVID-19 diagnoses in hospital laboratories and commercial laboratory centers.
- September 12, 2020: By amendment of South Korea’s Government Organization Act, the KDCA becomes a standalone agency in order to promote greater authority and autonomy as the control tower for infectious disease control.
- September 22, 2020: 599 private and public medical institutions in South Korea have on-site COVID-19 diagnostic testing.
- As of September 22, 2020: 686,198 confirmed and suspected cases of COVID-19 in South Korea have been placed under self-quarantine. The majority of persons placed under self-quarantine have been suspected cases, defined by South Korea as persons suspected of having the pathogen enter his/her body, but in the stage before being identified as a confirmed case. 1,139 have been identified to have violated the requirements of self-quarantine.
- As of September 2020: South Korea test manufacturers are producing test kits capable of performing 90,000 diagnostic tests per day.
- As of September 24, 2020: The MFDS has authorized for emergency use 16 real-time RT-PCR IVD tests, seven for traditional screening and nine for rapid detection in one hour in emergency rooms only.
- November 3, 2020: The MFDS authorizes for emergency use the first antibody test from SD Biosensor.
- November 11, 2020: The MFDS authorizes for emergency use the first rapid antigen test from SD Biosensor. This test is capable of producing results in 15 to 30 minutes.
- As of late November: The MFDS has authorized for emergency use in South Korea approximately two dozen COVID-19 diagnostic tests.





- As of November 27, 2020: The MFDS has authorized an additional six SARS-CoV-2 molecular diagnostic tests for emergency use.
- As of late December 2020: South Korea has performed over 3.68 million tests within its borders and has confirmed approximately 51,000 cases of COVID-19 (population of 51 million).