

# Balancing Quality and Speed in the Market Approval of Diagnostic Tests

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## Viewpoint

# Balancing Quality and Speed in the Market Approval of Diagnostic Tests: Experiences of South Korea, the UK, and the US

Paul Moritz Wiegmann, PhD; Jaime Bonnin Roca, PhD

Mass testing has proven to be a critical pillar in the fight against a pandemic.<sup>1</sup> The COVID-19 crisis has demonstrated, especially in the early months of the pandemic, how a lack of reliable data regarding the number and distribution of infections led to an underestimation of the health risks and late and erratic containment policies.<sup>2</sup> Countries that deployed early mass testing, such as the Republic of Korea (South Korea) did, have been the most successful in dealing with the pandemic. Mass testing eliminates uncertainty around who should quarantine, and it allows health care practitioners to optimize scarce resources (eg, hospital beds, physicians). Mass testing has proven to be a reliable and cost-effective solution that helped manage the COVID-19 pandemic from its outbreak until the large-scale availability of vaccines.<sup>1</sup>

The novelty of the SARS-CoV-2 virus accounted for the early delay of mass testing and necessitated the development of new detection methods. These methods included molecular, antigen, and antibody tests, all of which have specific strengths and weaknesses. These developments and the subsequent commercialization of diagnostic tests required coordination from a wide array of stakeholders in the testing ecosystem—scientists, test manufacturers, clinical laboratories, and others. This coordination is challenging; consequently, COVID-19 tests available on the market vary substantially in their sensitivity and specificity.<sup>3</sup>

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## Approaches Toward Diagnostic Tests

Regulatory agencies around the world are tasked with setting frameworks to ensure that high-quality diagnostic tests become available quickly while low-quality tests are filtered out before hitting the market. These frameworks vary substantially. For example, according to the European Union (EU) New Approach framework,<sup>4</sup> the preferred way for a manufacturer of a new diagnostic test to demonstrate its conformity to regulations is through the use of “harmonized” technical standards. Based on the consensus of subject-matter experts, these standards define minimum performance requirements and methods for demonstrating compliance. Depending on a test’s risk profile, it may be subject to third-party certification by an accredited body, or a manufacturer may issue a “declaration of conformity” themselves. In practice, most diagnostic tests are self-declared. Although the EU system has been lauded for safeguarding product safety while promoting innovation,<sup>5</sup> it has not always succeeded in excluding the bad apples. For example, Spain had to withdraw thousands of faulty COVID-19 test kits in March 2020 despite the manufacturer having self-declared regulatory conformity, and Germany debated whether antibody tests should be used, even though the tests met all regulatory requirements.

Meanwhile, the US follows a different system in which the approval of diagnostic tests is centralized in the Food and Drug Administration (FDA). The manufacturers of diagnostic tests are required to submit evidence of a product’s safety, efficacy, and quality to the FDA. Under normal circumstances, the time and administrative procedures needed to approve a new diagnostic test take considerably longer than would be desired in a pandemic. Accordingly, in emergency situations, the FDA may issue an Emergency Use Authorization to allow the use of an unapproved diagnostic test, whose performance will be monitored after entering the market. While this regulatory pathway allows for a much faster response, it also poses considerable risks. In particular, experts have

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suggested that during the COVID-19 pandemic, the FDA might have lowered its standards too much. As a result, the US market was flooded with a large number of diagnostic tests with less-than-desirable accuracy.<sup>6</sup>

Incorporating elements of both the EU and the US systems, South Korea has been widely praised for its effective approach to mass testing, regulatory review, and implementation. Its regulatory approval system is based on risk classifications of diagnostic tests. For instance, a manufacturer of a test in the lowest risk category only needs to notify the regulatory agencies and to submit information on the test but does not need to wait for a formal approval to begin selling its test. On the opposite end of the spectrum, a manufacturer of a test in a high-risk category needs to obtain certification according to the Korean Good Manufacturing Practices standard before submitting the test for evaluation by approved third parties or the country's Ministry of Food and Drug Safety. These processes were expedited for COVID-19 tests, which is among the reasons for the country's relatively successful response to the pandemic.<sup>7</sup>

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## Preparing for Future Pandemics

In times of a pandemic, such as COVID-19, regulators face a dilemma: while too little oversight may flood the market with inaccurate or faulty test kits, thorough test development may delay availability. Yet, no regulatory system is perfect. The EU's relatively extensive reliance on self-declaration and technical standards allows for faster introduction of tests to the market than in the US. However, multiple potential points of failure in the EU system—related to, eg, the underlying regulatory framework, standardization, or conformity assessment—may impede response time in a pandemic. For example, relying on standards makes the EU system dependent on interactions among experts in standardization.<sup>8</sup> These experts represent stakeholders trying to promote their own interests, which in the worst-case scenario and despite safeguards in the system may lead to regulatory capture. In comparison, the US system depends heavily on the performance of the FDA, and South Korea blends both approaches. Systems that heavily rely on regulatory agencies may face a bottleneck in terms of the financial and human resources required to maintain a minimum level of emergency diagnostic testing oversight. Furthermore, these systems require an effective approach to incorporating stakeholders, such as diagnostic test manufacturers and medical professionals, in rulemaking.<sup>9</sup> In the context of pandemics, existing approaches to involving stakeholders may not always be inclusive enough.

Regardless of the chosen approach, policy makers need to ensure that the diagnostic test community can access the required data infrastructure to evaluate different testing strategies. As it mutates, COVID-19 continues to raise new challenges, and it is unlikely to be the last pandemic that humanity will face. Therefore, national and international bodies should develop comprehensive quick response plans, including appropriate regulatory approval processes, to scale up the production and distribution of diagnostic tests.

In emergency situations, when time plays against us, evidence-based policy making should prevail. Further research is needed to identify each regulatory system's specific strengths and weaknesses in reacting to a pandemic. For example, looking to potential future pandemics, upcoming changes to the EU legislative framework give us cause for concern. Experts from the diagnostic testing ecosystem are worried that the new EU regulations (taking effect in May 2022) may reduce the availability and increase the time to market of medical tests because more of them will require the approval of an accredited body. The exact effects of these new regulations and how they may alter the strengths and weaknesses of the EU system will need to be evaluated.

Another priority for research would be an assessment of each diagnostic test system's performance when it comes under the stress of a pandemic—does it pay off to approve diagnostic tests more quickly, even when it comes at the expense of their accuracy? To our knowledge, there is much conceptual work on this issue of tentative governance in the literature,<sup>10</sup> but the empirical evidence is still sparse, especially in quantitative terms.

**ARTICLE INFORMATION**

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