FDA expands policy on COVID-19 testing

March 19, 2020—The FDA updated on March 16 a policy originally issued on Feb. 29 on diagnostic testing for COVID-19 in order to achieve more rapid testing capacity in the U.S. The updated guidance, which addresses laboratories and commercial manufacturers, will help to expand the number and variety of diagnostic tests, as well as available testing capabilities, in health care settings and reference and commercial laboratories.

In a statement from the FDA, commissioner of food and drugs, Stephen M. Hahn, MD, outlined three key elements of the update. In brief, the updates include putting a policy in place in which states can set up a system in which they take responsibility for authorizing tests developed and used by laboratories within their state, and the laboratories will not engage with the FDA; expanding who the policy applies to—the agency does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an EUA, under certain circumstances; and providing recommendations for test developers that wish to develop serological tests.

“We urge state authorities and commercial developers to take all necessary steps to ensure the availability of accurate tests,” Dr. Hahn said in the release.