



May 21, 2021

By Electronic Mail

Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Policy for Laboratory Developed Tests

Dear Secretary Becerra:

On behalf of the American Clinical Laboratory Association (ACLA), I am reaching out about the critical role that clinical laboratories play in our nation's health care system and to initiate a dialogue with you regarding the policies of the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) regarding laboratory developed tests (LDTs).¹ This dialogue is needed to ensure that all laboratories, including the laboratories that have been, and continue to be, on the front lines of the nation's response to the COVID-19 pandemic, have an appropriate, clear, and predictable regulatory system, so that they may continue to meet our nation's current demands for accurate and reliable COVID-19 testing, and, more broadly, can meet the needs of our health care system going forward.

ACLA believes that a clear and consistent policy for LDTs that reflects alignment among stakeholders is critical to a robust COVID-19 response. We are concerned that regulatory policies for diagnostics, in particular LDTs, have repeatedly shifted over the last year, and this changing landscape has been especially disruptive to the laboratories that have been so instrumental to the pandemic response. More broadly, while the COVID-19 pandemic highlighted the crucial role clinical laboratories play during a public health emergency, laboratory diagnostics are critical to the every-day health of our nation and it should not be lost in the COVID-19 pandemic discussions that the millions of tests administered every day have a profound impact on medical care, from finding cancer in time to treat it to identifying childhood diseases in order to correct them before a lifetime of illness. Shifting regulatory policies inhibit development of the cutting-edge diagnostics that are needed to address the needs of our health care system, including clinical laboratory tests to diagnose and optimize the treatment of a variety of diseases. In the interest of spurring innovation and speeding access to accurate and