



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

May 21, 2020

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, COVID-19 Pandemic Response, Laboratory Data Reporting be processed in accordance with section 1320.13, *Emergency Processing*.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to ensuring a rapid and thorough public health response to the COVID-19 pandemic. Comprehensive laboratory testing data contribute to understanding disease incidence and trends; initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying of supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.

Public Law 116-136 § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).

CDC cannot reasonably comply with the normal clearance given the ongoing public health emergency. Laboratory data serve not only as important information to support decision making related to the public health emergency, but also as a critical piece to better understanding the performance of tests in real-world conditions, the effectiveness of clinical interventions, and patient outcomes and interventions.

Better understanding the characteristics and performance of specific tests can help ensure that healthcare providers are equipped with the maximum information necessary to make clinical decisions, develop recommendations and provide the most appropriate care for their patients. Additionally, with widespread use of electronic health records (EHR), closing the loop by incorporating information related to laboratory testing can add to the robustness of data that will eventually serve as the backbone for clinical research to inform treatments, better understand outcomes, improve the quality and performance of diagnostic tests over time, and shape clinical understanding of COVID-19.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business May 28, 2020.