



Billing Code: 4150-28

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Testing for Coronavirus Disease 2019 (COVID-19) - Surge Capacity

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Request for Information.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) in the Department of Health and Human Services (HHS) seeks to obtain information regarding the ability of Clinical Laboratory Improvement Amendments (CLIA)-certified/accredited commercial, academic, medical center, and public health laboratories to feasibly provide additional COVID-19 testing capability if supplementary testing instruments were made available. A set of questions is available in the Supplementary Information section below.

DATES: To be considered, comments must be received electronically at the email address provided below, no later than 5:00 p.m. Eastern Time (ET) on [INSERT 10 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Individuals are encouraged to submit responses electronically to LCDR Natalie Gibson, 200 Independence Avenue SW, Washington, DC 20201, (240) 743-1757, COVID19TestSupplies@hhs.gov.

Please indicate “RFI RESPONSE” in the subject line of your email. Submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Respond concisely and in plain language. You may use any structure or layout that presents your information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information, and place it in its own section or file. Your response will become government property, and we may publish some of its non-proprietary content.

SUPPLEMENTARY INFORMATION: HHS is working together with state, local, tribal and territorial governments, public health officials, health care providers, researchers, private sector organizations, and the public to execute a whole-of-America response to the COVID-19 pandemic to protect the health and safety of the American people. Timely and accurate diagnostic testing is paramount to the response. Diagnostic testing must be maximized across all platforms and venues to enable early detection, containment of potential outbreaks, and protect all Americans—especially the vulnerable and otherwise high-risk populations.

In order to expand diagnostic testing capacity and fully leverage the national testing ecosystem, the purpose of this request for information (RFI) is to obtain information regarding the ability of CLIA-certified or accredited commercial, academic, medical center and public health laboratories to feasibly provide additional testing capability if supplementary testing instruments and reagents from Thermo Fisher Scientific were made available. Because HHS is seeking to significantly expand testing capability, responses that propose substantial increases in capability, and provide

adequate justification (e.g., can demonstrate the necessary personnel, infrastructure and other ancillary support needs to accommodate such expansions) are preferred.

We encourage eligible performers to answer the follow questions:

- Do you represent a CLIA-certified or accredited laboratory?
- What is your current laboratory testing capacity (e.g., installed base of platforms, throughput, level of personnel, etc.)?
- What is your current ability to accession specimens and report out laboratory results in no less than 24-48 hours?
- What level of additional capacity could your laboratory provide if additional testing instruments were made available?
 - Please provide a proposed request for instruments and any other requirements.

Please provide a timeline for implementation of increased capacity, assuming the laboratory receives the requested instruments.

This information will inform the ongoing response to the COVID-19 pandemic.

Dated: September 3, 2020.

Tammy R. Beckham,

Director, COVID-19 Laboratory Testing and Diagnostics Working Group.

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