EDDIE BERNICE JOHNSON, Texas
CHAIRWOMAN

FRANK D. LUCAS, Oklahoma
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6301

(202) 225–6375
www.science.house.gov

April 2, 2020

Dr. Robert R. Redfield
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Director Redfield,

When reports of a new virus emerged last December, the international research community sprang into action to develop tests that governments could use to detect and track COVID-19. Researchers in Germany developed an early testing protocol that the World Health Organization (WHO) made available to interested parties in January 2020. Diagnostic testing for COVID-19 is critical to tracking the virus, informing how we treat patients, and suppressing transmission.

According to public reporting, the Centers for Disease Control and Prevention (CDC) determined at some point in January that it would develop its own testing protocols. The Food and Drug Administration posted those protocols on its website on January 28.[1] On February 6 and 7, the CDC sent its first batch of in-house developed test kits for COVID-19 to about 50 laboratories around the country. On February 7, the CDC learned that one of its tests had resulted in a false negative for a patient who had been quarantined in San Diego. Within another day, it became obvious that the CDC test kits were yielding a high percentage of inaccurate results, as 36 of the 50 labs that had received the test kits began reporting issues, including a significant number of false positives. This created a bottleneck of testing in Atlanta, since all COVID-19 testing in the United States had to take place at the CDC, at the time. Public reporting has suggested that a faulty chemical reagent used in the manufacturing of the CDC-produced test may have been to blame.

In addition, around February 22, a senior official from the Department of Health and Human Services (HHS) dispatched to the CDC to help resolve the COVID-19 test issue identified evidence of contamination in the CDC laboratories where the tests were developed – a quality control problem that may also have contributed to the failures of the tests. Finally, on March 1,

[1] https://www.fda.gov/media/134922/download

HHS announced that it would launch an internal investigation into what went wrong in the first round of diagnostic test kits delivered to states by the CDC.

Two critical questions have yet to be addressed by the CDC or any officials within the Trump Administration: Did the CDC consider deploying diagnostic test protocols or kits that had already been made available by the WHO before it worked to develop its own method of testing, given the urgency of the COVID-19 crisis? And what missteps caused the CDC to ship faulty diagnostic kits to outside laboratories during the first week of February?

Because the development of a new diagnostic test takes time, it may have been advantageous for the CDC to start first by seeking to deploy the WHO-published testing protocols as quickly as possible. Unfortunately, delays were compounded by the failures of the CDC test kits, making it impossible for public health authorities to get an accurate picture of how the disease was spreading during a critical period of time. As of April 2, the United States has reported over 213,000 cases of COVID-19 and over 4,500 deaths. Critical questions remain about how science informed consequential CDC decision-making in the first few weeks of 2020.

The health and safety of the American people depend on the CDC's use of the best available science, quality control practices, and complete data sets when making public health conclusions. Until the sequence of events in January and early February around COVID-19 testing are better understood, public confidence in the CDC and its ability to understand and mitigate this crisis - and any future emerging infectious diseases - will remain in doubt. The House Committee on Science, Space & Technology has a responsibility to explore scientific integrity issues at Federal agencies, particularly those instances where the stakes for human health are so staggeringly high.

In order to ensure that all necessary information is available for Congressional oversight purposes going forward, the Committee seeks the following records from the CDC, including all phone calls, teleconferences, meetings, emails and attachments, notes, calendar events, and letters. I appreciate that the CDC continues to respond in real-time to the COVID-19 crisis, which grows more dangerous on a daily basis. To avoid interfering with agency operations during this critical period, we ask at this time that the CDC preserve the records named below. The Committee will work with the CDC and HHS to arrange for an appropriate production schedule for these documents:

1. All agency records on the CDC's process for its initial decision not to request and deploy existing diagnostic testing protocols for COVID-19 that had already been made available by the WHO, including any communications with officials from the Executive Office of the President and HHS officials beyond the CDC.
2. All agency records on the CDC's process for developing its own COVID-19 diagnostic tests;
3. All agency records on the CDC's process for validating its own COVID-19 diagnostic tests before making them available to outside laboratories;
4. All agency records on the CDC's process for communicating with outside laboratories about the failures of its COVID-19 diagnostic tests; and

5. The quality control policies and procedures that the CDC observes before promulgating Testing and Diagnosis guidelines to the public.

Please contact Janie Thompson of the House Science, Space and Technology Committee with any questions at 202-225-6375.

Sincerely,

Eddie Bernice Johnson

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space & Technology