



June 19, 2020

**Summary of the Findings of the Immediate Office of the General Counsel's Investigation
Regarding CDC's Production of COVID-19 Test Kits**

This summarizes the findings of the Office of the General Counsel (OGC) regarding the Centers for Disease Control and Prevention (CDC) manufacturing of the initial COVID-19 test kits that could not be validated by public health laboratories in early February. These findings are based on interviews conducted by two OGC attorneys with science backgrounds with nine CDC employees and contractors¹ who were involved in the production of the test kits. OGC also spoke with Dr. Timothy Stenzel of the Food and Drug Administration (FDA), who visited the CDC labs in question in late February, and one other FDA scientist in a consulting capacity. OGC has received and reviewed documents from interviewees and other identified custodians.²

I. Executive Summary

In late January 2020, CDC produced two types of test kits. The first was used by CDC to test specimens sent to it by public health authorities, hospitals and other providers. There is and was no problem with the laboratory developed test kit, and there is no evidence to suggest otherwise. There was a problem, though, with the second type of test kit, one that was developed to be manufactured by CDC as a first wave of testing to be shipped to public health laboratories across the country until commercial laboratories and diagnostic companies were able to come on line with mass produced test kits. One of the three reagents in this initial batch of manufactured test kits was likely contaminated.³ These tests are so sensitive that this contamination could have been caused by a single person walking through an area with positive control material and then later entering an area where tests reagents were being manipulated. After receiving these tests from CDC in early February, public health laboratories attempted to validate the test kits before using them on real specimens. They could not validate the test—a negative control gave a positive result—and thus, the test kits were not used and no patient received an inaccurate test result. Upon learning of this problem around February 8, 2020, CDC scientists immediately alerted CDC leadership. Shortly thereafter when the Secretary learned of the problem, he ordered CDC to figure out the cause of the problem and remedy it. Within two weeks, CDC recognized that the test could be run without the contaminated reagent which was not designed to be specific to the COVID-19 virus and worked with FDA to allow the tests to be run without it. New, uncontaminated reagents manufactured by private laboratories for CDC were distributed to public health laboratories beginning in late February.

Thereafter, the Secretary instructed this Office to conduct a review to determine the cause of the problem, if possible. This review began on March 1, 2020.

¹ These interviews were conducted with the heads of the Core Lab and the Respiratory Virus Diagnostic Lab (RVD), key employees of Core Lab and RDSB who worked on and were responsible for test production, the RVD individual responsible for test design, and individuals responsible for handling the bulk materials and conducting the QC/QA at RVD.

² Documents were collected from all interviewees as well as other relevant custodians.

³ We state our conclusions in likelihoods, rather than with absolute certainty, due to the inherent complexities of this presumptive contamination and of the underlying science.



II. Findings

In early January 2020, the Respiratory Virus Diagnostic Lab (“RVD”) became aware of the virus emerging in China and began developing a genetic test. RVD designed the genetic sequences for the test kit reagents, and ordered them from another CDC lab responsible for their manufacture: the Biotechnology Core Facility Branch (“Core Lab”). Around January 10-13, the Core Lab made the first developmental test reagents for RVD. RVD also requested that the Core Lab produce shortened sequences of positive control materials used for test development, called templates, after learning that an outside private company would take up to 10 days to produce them. The Core Lab initially declined, but ultimately agreed, to make templates given the time pressure, but only under a stringent protocol designed to eliminate any chance of contamination. These templates were produced on January 14-15, along with two other templates later in January following the same stringent protocol.

The CDC test is a genetic test that uses reagents to detect three different segments of the SARS CoV-2 RNA gene sequence. The CDC’s three test kit reagents, N1, N2, and N3, were provided in separate vials.

An essential set of components of the tests are the positive and negative controls used to validate that the test reagents work properly. The “positive control” is designed to match the genetic material of the virus. When any of the test reagents are added, there should be a positive result 100% of the time. It was included as a separate vial in a separate part of the CDC’s test kit. The “negative control” is often purified water and should always yield a negative result when test reagents are added. If the negative control generates a positive result, it indicates a flaw in the test, including possible contamination of the reagents with positive control material.

On January 22 after completing test development, RVD ordered the reagents for the final test kits from the Core Lab. Core Lab manufactured the bulk reagent materials around January 23-27 and then provided them to RVD on January 28 for quality assurance and quality control, and for additional processing.

It was at this stage of the manufacture, when the bulk reagent materials for the test kits were processed and tested at RVD, that they were most likely exposed to positive control material. First, RVD had already made multiple uses of positive control material at the time bulk test kit reagents were being handled, increasing the opportunities for contamination. Second, a number of CDC interviewees and Dr. Stenzel of FDA described lab practices that may have been insufficient to prevent the risk of contamination, though it is likely that time pressure also contributed.⁴ Third, the QC and QA of the reagents — conducted both around the time of production and later during “heightened QC” retests — began showing issues with negative controls showing positive results only at stages after the bulk materials had been processed at RVD, indicating this lab was the likely source of the contamination.

While it is possible that Core Lab’s production of templates during test development could have contaminated the final test kit reagents that were later manufactured by that lab

⁴ This investigation did not include a comprehensive analysis of the RVD lab’s layout, processes, protocols, training, staffing, etc., as that lab was not performing kit manufacturing by the time we visited. Our conclusion here is based upon the concurring impressions of multiple experienced percipient witnesses, both within CDC and Dr. Stenzel of FDA.



around January 23-27, that event is highly, if not extremely, unlikely. First, the Core Lab took extreme precautionary measures in the processing of the positive control material to minimize any risk of contamination: they segregated the workspaces entirely and did not conduct other customary processing or testing on the templates that could allow the positive control material to spread. Both the Core Lab and RVD agreed that these measures should be sufficient to prevent contamination. Second, subsequent heightened QA/QC retests done in February (after the test kits failed validation) showed no contamination in the bulk material that came from the Core Lab.

After QC/QA testing and processing at RVD, RVD sent the bulk material to the third lab in the production chain, the DSR (Division of Scientific Resources)/RDSB (Reagent Diagnostic Services Branch) Lab (“RDSB”). Contamination of the test kit reagents at the RDSB Lab is even more unlikely because this lab vialled and dried-down the test kit reagents on January 29, a full day before it received any positive control materials from RVD. The positive controls were vialled and dried on January 30 in a different lab space. And although RDSB later assembled the test kit reagents and positive controls into separate kits in a third room after being vialled and dried down, all interviewees agreed that the risk of contamination at that stage in processing was exceedingly low.

On February 1, RDSB assembled the final test kits and was informed that they would be shipped out to the International Reagent Resource (IRR) the next day. This was prior to final kit QC and QA being performed, though RVD ultimately gave QC/QA approval after shipment to IRR. IRR shipped the kits to the public health laboratories in the following days. It appears that time pressure to ship test kits out quickly — and before QC had been conducted on them — might have compromised sufficient QC/QA to identify certain anomalies in data and realize the possibility of contamination before shipment.

By February 6, CDC had sent test kits to 33 states and 70 labs in 66 countries. On or about February 8, CDC laboratory personnel first learned of a problem with their test kits. Public health laboratories began reporting that the test kits were failing to validate because negative controls were producing positive results for the N3 reagent. This suggested a possible contamination of the test kits.

CDC confirmed that this problem was real shortly thereafter and informed CDC leadership. The next day, the Association of Public Health Laboratories notified their member labs that the test kits had an issue, and CDC pulled the tests from labs that encountered problems. Shortly thereafter the Secretary told CDC it needed to resolve the problem. CDC ultimately solved the testing problem by creating new tests without their third reagent, N3, and outsourcing the vialing of the N1 and N2 reagents (and ultimately their manufacture) to private third-party manufacturers. No issues were discovered with the reagents in those newly produced test kits. CDC worked with FDA to issue a new Emergency Use Authorization for the test kit without the N3 reagent on March 15, 2020.

The review did not uncover any evidence of false positive or false negative test results for patient specimens caused by the potential contamination.