June 8, 2020

SENT VIA EMAIL

Cheryl Dobbe
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Division of CLIA Laboratory Improvement & Quality
Centers for Medicare & Medicaid Services
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Re: CLIA Survey 46D0936317

Dear Ms. Dobbe:

We are providing this letter in response to the survey, virtually conducted at Timpanogos Regional Hospital (hereafter, the “Hospital”) on May 18, 2020. This letter constitutes the Hospital’s credible allegation of compliance and is accompanied by acceptable evidence of correction. Such is provided using CAP Deficiency Response forms with accompanying exhibits, numbered A-SS. Pursuant to your instruction in an email sent today, to [REDACTED] the Lab Administrative Director, we are sending this letter via electronic mail to the addresses listed above.

To ensure the necessary background understanding and to define terms that are used throughout the Hospital’s responses, we provide the following situational overview:

The Hospital has a clinical laboratory which is certified under the Clinical Laboratory Improvement Amendments of 1988 (hereafter, “CLIA”) to perform high-complexity testing (the “Lab”). The Lab opened in 1998, over 20 years ago, and conducts testing for Hospital inpatients as well as several healthcare facilities and medical practices throughout the community. The Lab is accredited by the College of American Pathologists (“CAP”) and has always performed molecular micro testing, even prior to COVID-19.

The Lab is currently processing COVID-19 tests on behalf of the State of Utah through a program called ‘TestUtah’ (hereafter, “Public Testing” or “Public COVID-19 Testing”). The State of Utah developed TestUtah in conjunction with a Utah technology industry group, Silicon Slopes. The stated goal is “to dramatically increase the rate of COVID-19 testing so Utahns can have better access to testing and help stem the spread of COVID-19, to get us back to normal as quickly as possible.” See https://www.testutah.com/en. The Lab is not a party to any contract with the State of Utah but became involved in the Public Testing efforts at the request of Silicon Slopes and out of a desire to help Utah in its fight against Coronavirus.

1 While the CMS May 18, 2020 letter requested that our response be provided in the CMS Form 2567, we understand that this requirement was removed in 2017. (See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-22-FL)
It is our understanding that the State of Utah, via the Utah Department of Health (hereafter, “UDOH”), developed nearly all of the Public Testing processes and protocols. We also understand that the State of Utah contracted with Qualtrics, a software and analytics company, to develop the necessary software and data flow to effectuate the Public Testing (hereafter, the “Utah Software”). This Utah Software generally controls and dictates the entire Public COVID-19 Testing process, including but not limited to (i) the test request from a member of the public, (ii) patient information, (iii) specimen collection, (iv) procedures to be followed by all those involved in the Public COVID-19 Test process (including the Lab), and (v) test reporting. The UDOH has been heavily involved in directing Qualtrics in all development aspects of the Utah Software and controls the administrative and access settings to the Utah Software.

To provide an overview of the Public Testing program, members of the Utah public that are concerned they may have COVID-19, fill out an online questionnaire. Based on their responses, if the individual qualifies for COVID-19 testing, they are issued a unique QR code (digitally connected to all personally-provided information) and directed to one of several collection sites around the State. Once the patient arrives at a collection site, our understanding is that the patient’s unique QR code is scanned and then digitally connected to a pre-labeled specimen collection kit which has its own QR code. The specimen collection kit, with its own QR code (as well as a second alpha-numeric identification number) (collectively, the “Unique Specimen ID”) consists of: (i) a bag, which is pre-labeled with the instructions to be used for specimen collection and the Unique Specimen ID; and (ii) a pre-labeled vial with the same Specimen ID in which the collection site personnel place the patient specimen (hereafter, the “Specimen” or “Sample”). The Specimen vial is then placed back in the Specimen bag (again, containing the same Unique Specimen ID), and securely sealed. (Hereafter, the Specimen bag and Specimen vial will sometimes be referred to as the “Specimen Kit”). The Specimen Kit is then sent to the Lab for processing.

The Public Testing uses a commercially-manufactured COVID-19 test, The LogixSmart Coronavirus Disease 2019 (COVID-19) (hereafter, “Logix Smart™” or the “COVID-19 Test”), developed by Co-Diagnostics. Logix Smart™ is authorized to be distributed pursuant to an emergency use authorization (“EUA”) issued by the U.S. Food and Drug Administration (“FDA”). (See https://www.fda.gov/media/136684/download.) The FDA instituted the EUA process due to the urgency of the COVID-19 pandemic and the need for COVID-19 tests to be quickly developed and implemented in the United States. Pursuant to its EUA, the Logix Smart™ test can be processed by any laboratory that is CLIA-certified to perform high complexity tests.

Every commercially-developed COVID-19 test distributed in the United States is required to have an EUA. Additionally, according to each test’s EUA, the manufacturer can distribute their test if it is labeled consistently with the labeling authorized by FDA, including the particular test’s instructions for use (hereafter, “IFU”). These IFUs can be revised. (See the Logix Smart™ EUA at page 3.)

Logix Smart™ has an internal quality control measure which is proprietary to this particular test and, we assume, is one of the reasons it was chosen to be used in the Public Testing. Specifically, built into the Logix Smart™ test is an internal “positive” control, meaning that the reagent is capable of amplification if human material is present in the Specimen. If present, there is an orange fluorescence and the test results can be released. If not present, the Specimen was either not properly collected, degraded or the extraction failed; thus, showing a Specimen problem that precludes the test results from being released. The foregoing is detailed in the Lab’s internal COVID-19 Test procedures, and is referred to herein as “Internal Positive Control” or “IPC”).

Additionally, for each Sample test batch run by the Lab (referred to herein as a “Sample Batch Run”), there is another quality control method where an external control, a known COVID-19 ‘negative’ Sample
and known ‘positive’ COVID-19 Sample, is included.² If the known positive COVID-19 Specimen or
known negative COVID-19 Specimen does not report as expected, the entire Sample Batch Run is
considered ‘invalid.’ (The foregoing control measure is referred to herein as the “External Controls.”) If
the Sample Batch Run is invalid, the test results cannot be reported. These External Controls are part of
every Specimen Batch Run conducted by the Lab.

The FDA has issued non-binding guidance for clinical laboratories, commercial manufacturers, and its own
FDA staff related to COVID-19 testing and the EUA process. (May 11, 2020 version found here
https://www.fda.gov/media/135659/download, hereafter, the “FDA Guidance.”) The FDA Guidance has
been updated several times since the beginning of the COVID-19 pandemic. The stated purpose of the FDA
Guidance is to:

...provide a policy to help accelerate the availability of novel coronavirus (COVID-19)
tests developed by laboratories and commercial manufacturers for the duration of the
public health emergency. Rapid detection of COVID-19 cases in the United States requires
wide availability of testing to control the emergence of this rapidly spreading, severe
illness. This guidance describes a policy for laboratories and commercial manufacturers
to help accelerate the use of tests they develop in order to achieve more rapid and
widespread testing capacity in the United States.

We also feel it important to point out that the COVID-19 is an unprecedented pandemic, with federal and
state agencies waiving or otherwise providing flexibility for hundreds of normal laws, rules, regulations
and procedures. This was done quickly, with agency officials doing their best to identify the relevant laws
and regulations, and, where possible, providing swift accommodation. As a result, the federal and state
waivers, flexibilities and/or current agency guidance initially issued have since been clarified or revised
multiple times. Moreover, various agencies’ flexibilities and guidance often conflict, making it difficult to
determine the proper procedures to be followed during the pandemic.

Notably, CMS recently acknowledged this dilemma in a FAQ related to its enforcement of CLIA. Therein,
CMS acknowledged that while it lacks the statutory authority to waive certain CLIA requirements, it “is
willing to explore flexibilities...” to accommodate the practical realities facing laboratories processing
emergency-frequently-asked-questions.pdf)

Additionally, it has been approximately four months since the COVID-19 pandemic hit the United States
and only three months since noticeably impacting Utah. Thereafter, commercial manufacturers and
laboratories, under unprecedented waivers of federal and state regulations, raced to develop, make available
and/or commence processing COVID-19 tests.

Given the circumstances, our Lab, like thousands of others, had to quickly write and implement relevant
policies and procedures for a new test, only authorized by the FDA under an EUA, which provided little
guidance. Understandably, initial drafts of relevant policies and procedures were not as detailed and explicit
as they would otherwise be. However, as labs gain experience and knowledge from running COVID-19
tests, ongoing refinement are being made to written policies and procedures.

The Lab’s CLIA inspection occurred between May 6 and May 18, 2020, in response to an undisclosed
complaint. This occurred following a local newspaper article, wherein an individual affiliated with a

² Each Sample Batch Run includes up to 46 Public Testing Specimens plus the one known negative and one known
positive Specimen, for a total of up to 48 Specimens.
prominent competitor criticized the Public Testing program, including the Lab, to UDOH officials. The CLIA investigation seemed to focus solely on the Lab’s processing of the COVID-19 Test. Due to the COVID-19 pandemic, the CLIA surveyor conducted the inspection virtually, through phone calls, emails and live video communications. Lab personnel did their best to communicate and explain necessary information \textit{via} this remote inspection. However, understandably, the remote nature of this inspection may have led to miscommunication and misunderstandings.

Significantly, it is our understanding that the Utah Public Health Laboratory ("UPHL"), a division of the UDOH, is the contracted state agency that is responsible for overseeing and conducting CLIA investigations of laboratories in the State of Utah on behalf of the Centers for Medicare & Medicaid ("CMS"). (See https://uphl.utah.gov/certifications/clinical-laboratory-certification/.) Thus, procedures established and governed by the Utah Department of Health (here, an agent of CMS) for the Public COVID-19 Testing, have driven the processes for which the Lab is now being cited.

Finally, in responding to this CLIA survey, the Lab has invested hundreds of hours of critical lab staff that would otherwise have been focused on COVID-19 testing. In the current situation, COVID-19 testing is a priority for our patients and our communities. This unprecedented demand for quickly-evolving and innovative COVID-19 testing requires collaboration and flexibility among practitioners, governmental entities, agencies, and surveyors alike. Current CLIA standards are ill-suited for pandemic situations wherein unprecedented laboratory testing is the critical step toward public health and economic recovery.

In conclusion, on behalf of the Timpanogos Regional Hospital Laboratory, I submit for your consideration credible allegations of compliance for each of the asserted deficiencies detailed in CMS Form 2567 and provided on May 29, 2020. We look forward to the prompt resolution of this matter.

Sincerely,

Dr. Blair F. McGirk, M.D.
Laboratory Director
Timpanogos Regional Hospital

cc: Kimball Anderson, CEO, Timpanogos Regional Hospital