Information shared by Safeguard Surveillance, LLC. (3/30/21)
Earlier today the New York Times published an article that maligned and misrepresented Safeguard Surveillance and the work that we do, as well as New Trier High School.
https://www.nytimes.com/2021/03/30/health/coronavirus-trier-schools-testing.html

We were surprised and disappointed that the article did not discuss the effectiveness of our surveillance service. We feel this reflects the one-sided nature of the story, because we know, from your feedback, that our non-diagnostic test has been extremely effective in maintaining a safe learning environment for our clients. Moreover, the article contains numerous inaccurate statements and fails to acknowledge that Safeguard Surveillance has been legitimately operating under previously published CMS guidelines (facts that were relayed to the New York Times reporter but omitted from the article).

There are several misrepresentations we feel strongly we should clarify in case you receive questions from your community. Here are some sample questions stakeholders may have after reading the article:

Are Safeguard Surveillance and New Trier violating any federal regulations on testing?
No federal regulations have been violated. Per CMS: "Generally, SARS-CoV-2 surveillance testing can be performed in a facility that is NOT CLIA certified, and may use a test or technique NOT authorized by the FDA, provided that patient-specific results are not reported. If at any time a patient-specific result is reported, the facility is subject to CLIA and required to obtain an appropriate CLIA certificate in accordance with 42 CFR part 493."
https://www.cms.gov/files/document/clia-university-lab-testing.pdf

Does Safeguard provide patient-specific results, deliver a diagnosis, or provide results?
No, Safeguard Surveillance does not provide patient specific results, provide a diagnosis, or provide results and none of the following terms are utilized by Safeguard Surveillance based on direct guidance from CMS (see both the attached Castillo CMS guidance letter and the CMS guidance email contained below) "negative, positive, inconclusive, presumptive positive, a result of clinical significance, or a result of potential clinical significance".

What language can be used to provide the results of a non-diagnostic?
Per the email below from CMS: **"A CLIA certificate will not be required if you refer a patient to a CLIA certified laboratory."**

Dr. Campbell,

The guidance listed in the CMS letter that you received would be the most current guidance and I would like to summarize the contents of the letter within the framework of your email correspondence.

A CLIA certificate will be required if you report, or provide any of the following diagnostic testing information from your surveillance testing:
Negative, Positive, Inconclusive, Presumptive positive, A result of clinical significance, or a result of potential clinical significance.

A CLIA certificate will not be required if you refer a patient to a CLIA certified laboratory.
CMS does not have any written instructions on the referral of a patient to a CLIA certified laboratory.

Should you have a specific question, kindly forward the question for a written response.
Thank you,
Raymond Castillo
Clinical Laboratory Scientist
Centers for Medicare and Medicaid Services
233 N. Michigan, Suite 600
Chicago, Illinois 60601

Are Dr. Campbell and the Safeguard Surveillance Lab authorized to run a diagnostic test and a diagnostic lab?
Per CMS guidelines, we have been running a non-diagnostic surveillance test and referring participants to diagnostic tests in CLIA certified laboratories, as indicated by those guidelines. However, we have recently submitted a CLIA application and have received a CLIA number, which allows us to perform diagnostic tests. At this time, we prefer to continue to run our lab-developed-non-diagnostic test, as this will not disrupt the workflow we have established with our clients and participants.

Is Safeguard preparing to file for an EUA or FDA approval?
It is a common misconception that CLIA labs need to use FDA approved tests. This is not true. CLIA labs can perform internally validated, Lab Developed Tests (LDTs). We are currently planning to submit an EUA application for our test, and we are aware of other submitted EUAs by our academic colleagues using the same test that would likely cover our test. However, while submitting an EUA application is technically “free”, it requires a tremendous investment of time and resources, and we feel that the article misrepresented this fact in a disappointing way.

Does Safeguard Surveillance provide surveillance or screening?
The issue associated with these terms is that surveillance testing does not normally allow for the reporting of individual results to participants. However, the guidance clearly demonstrates that there is a mechanism to refer individuals to diagnostic tests in the context of surveillance, and we have been extremely careful to adhere to this guidance. This clear CMS guidance was issued in the context of the COVID-19 pandemic, and absent this guidance, the service we are providing to clients could be construed as screening. However, given the very clear CMS guidance, which states that surveillance testing can be used to refer individuals to diagnostic tests, provided below, we are confused as to why the NYT article did not include this information in the story. The author of the

story was provided with this information. We remain firm in our good-faith commitment to this guidance, but should situations develop that force us to leverage our CLIA certification, we are prepared to do this to minimize any interruption of service to our clients to ensure your ability to provide safe in-person learning environments for your students. Doing so would disrupt the workflow we have established with you, our clients, which is why we have not chosen to do this at this time.

Has RT-Lamp been widely used but not been peer reviewed?
This is inaccurate. The test that we use in our surveillance is the same test that is being run in a similar fashion by our colleagues in Colorado, who have been using their test in a similar way to support in person learning in K-12 settings. They have recently published their test in eLife, a highly respected scientific journal. Relevant information regarding this test…. "The Saliva TwoStep test described herein identified infections with 94% sensitivity and >99% specificity in individuals with sub-clinical (asymptomatic or pre-symptomatic) infections."
https://elifesciences.org/articles/65113

Is Safeguard Surveillance under Investigation?
We are unaware of any investigation at this time nor have we been contacted by IDPH concerning any investigation. Our last contact with IDPH was in the context of a December Zoom meeting, called by IDPH, with the stated purpose of "Specimen collection, tests performed, results provided, actions taken based on results, how results are reported and any opportunities for support." At that time, IDPH seemed supportive of our work and the school districts using our services and also offered support related to supply procurement. We have not had any contact with IDPH since that time.

Please do not hesitate to reach out if you have any questions or wish to discuss further. We will be sharing the response that we are preparing to send to the New York Times demanding a retraction and or correction.

Sincerely,
Ed, Elyse, and John
Safeguard Surveillance, LLC