from: Randy True <randy@floodlamp.bio>
to: CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>
date: Oct 4, 2021, 10:53 AM
subject: email for Dr. Tim Stenzel

Dear CDRH staff,
Can you please pass on the following email to Dr. Stenzel?
Thank you,
Randy True

Dear Dr. Stenzel,
I'm the founder of FloodLAMP, a public benefit corporation. We spoke briefly on a Town Hall about RORs and open protocol EUAs in December. I'm writing to see if you would be available in the near future to discuss the path forward for our EUA and pre-EUA submissions. Having been inspired by the SalivaDirect™ open EUA, Anne Wyllie is a close advisor and collaborator and has agreed to join the meeting. We have the shared goal of increasing access to high quality testing here in the U.S. and abroad, and see enormous potential for the open protocol EUA approach, both for the remainder of this pandemic and in the near future for pandemic preparedness.

On the details of our tests and submissions:

- 2 complementary direct tests, duplex PCR and colorimetric LAMP;
- both tests utilize same TCEP+heat inactivation;
- 45min TAT for LAMP, 90min for PCR;
- high throughput of 10K+/day without automation for small team running LAMP test;
- LoD 12,500 cp/mL LAMP, 3,000 cp/mL for PCR - comparable to many of the great EUAs;
- completed our clinical evaluation with the Stanford CLIA lab;
- submitted full EUAs, as open source protocol EUAs in March;
- committed to offering an open Right of Reference to our 3 target LAMP primers to help establish commercially available, ready-to-use products, similar to what the CDC achieved with PCR primers;
- dry swab collection, up to 4 swabs (preliminary validation at 2X LoD swab spikes with Zeptometrix).

Unfortunately, after submitting the EUAs in March, we received a de-prioritization denial of review. We followed up with a pre-EUA (PEUA210313) for pooled home-collection kit and our mobile app in May in an effort to qualify for prioritization, but only received brief comments and closure of the pre-EUA. I recently emailed the FDA staff on our pre-EUA response email, requesting an interactive review. I also recently resubmitted our full EUAs (EUA210581, EUA210582), for the persons suspected of COVID and serial screening indications. We would greatly appreciate your assistance on avoiding the immediate denial of review for these resubmissions. We'd like to request consideration for prioritization as a high impact, rapid molecular test.

While trying to get under FDA review, we've deployed our pooled AN swab colorimetric LAMP test under surveillance, and have been able to demonstrate good real world performance including 2,300+ people tested and counting (see info below). These deployments have primarily been with pop-up labs and non-technical staff.

We've optimized our test system and wrap-around program components for confirming negatives while efficiently and reliably finding the needle-in-a-haystack positives. Our pool size of 4 is optimal for family or exposure units. The protocol of pooled home collection with drop off at the workplace or school has several significant advantages. First it reduces the burden on the organization's administration because the majority of collection does not need to be done on site (though that option should be available). Also, it offers increased protection from community spread by extending the screening to the family and household members, who if infected would trigger a positive pool result one stage earlier in the transmission chain. At a practical level, a family self-collecting pooled AN swabs and registering that collection on our app is far easier than running 4 antigen tests. It takes 15 seconds instead of 15 minutes, and that convenience is a driver for adoption and durability of participation in a frequent screening program. From the organization's perspective, having direct access to samples and results provides compliance assurance that is usually desirable.

If authorized for emergency use by the FDA, our test systems, pooled collection kit and software will have very high public health impact. We've designed these in an integrated manner from the ground up expressly for the use case that is acutely needed in the current phase of the pandemic – distributed assurance screening of interacting populations. With true sample-to-answer turn around times typically 1 to 1.5 hrs and as low as 45min, and high quality molecular performance, our program is ideal for businesses, schools and entire communities seeking to return to normal safely. The test-to-stay model for keeping kids in school with outbreaks, exposure, and high community prevalence requires much higher volumes of testing than currently available. Pooled central lab PCR is not well suited for test-to-stay because of the longer TAT, and antigen programs do not scale well. On-site and near-site rapid molecular is well suited for this important use case.

To date, rapid molecular has only been available at great cost, for example to professional sports teams. Our tests have the potential to greatly expand access to rapid molecular screening. We have proved this out with our current surveillance deployments in communities of first responders. In keeping with our public benefit mission, we're commercializing at very low cost, $1-2 per person. This pricing is transformative and is a driver for high impact. We're interested in exploring options with CMS, the CDC, and public health departments to offer programs, both from our company directly and through partners, that pass on this low price/high volume approach to the end organizations being screened.

Our current surveillance programs are for municipalities that have extensive experience in COVID-19 testing and are currently running both rapid antigen testing programs and lab-based

PCR. The fact that they have chosen to bring up our tests and program, with considerable commitment of human and financial resources, is a testament to the advantages of our offering.

We do understand that the current configuration of our colorimetric LAMP test system does not qualify for CLIA waived status. We are keenly interested in exploring options with the FDA, CMS, and state health departments for CLIA labs to have the capability to extend CLIA licenses to enable on-site and near-site screening under high or moderate complexity. The instrument-free nature of the test system, along with the ability to achieve throughputs of 1-2,000 persons screened per technician shift (without automation), opens up possibilities in the COVID testing space that have not been available to date. We would very much appreciate guidance on the progression of our EUAs toward these objectives.

In terms of commercialization, we are positioned to quickly scale and deploy millions of tests by the end of year. We have 2M tests of production primers on hand, and another 3M at our supplier, LGC Biosearch. We have a close relationship with NEB who can provide the LAMP and PCR master mixes in large quantities. We're leading a 2 phase project in Colombia in partnership with NEB, to validate both EUA submitted tests and deploy the colorimetric LAMP test in a hub and spoke model to remote processing sites. Again due to the fact that we are fully disclosing the constituent components of our test, rather than keeping them trade secret per industry norm, authorization of our test will have high impact globally due to the international recognition of a U.S. FDA EUA. We experienced this firsthand when during India's surge, we sought to donate test kits but were unable to because we did not have an EUA. Also related to global impact, NEB has not only donated a large value of reactions to projects in Africa, and now our project in Latin America, but also seeks to engage in open tech transfer of reagent manufacturing capability to create local resilience. We intend to do the same by sharing our know-how and pilot production processes with low and middle income countries. These systems and processes have been honed over the last year and facilitate decentralized medium scale production at ultra low cost.

In addition to our direct capability to deliver tests, the open source nature of our EUA submissions, like SalivaDirect™, will position us to achieve high leverage and scale quickly. With the full disclosure of the component chemistry and primer sequences, as with what happened with SalivaDirect™, we anticipate that the authorization of our colorimetric LAMP test will result in the proliferation of copy-cat tests offered under LDT. Unlike SalivaDirect™, as a commercial entity, we will offer test kits in addition to designating CLIA labs. It is our goal to bring as many labs as possible under our EUA, thereby improving quality and consistency. We would like to discuss commercialization and designation issues with you in light of the open source protocol EUAs.

Another topic that we would like to discuss is the coordination of our surveillance programs with EUA authorized testing by designated CLIA labs. Prioritized review of our QuickColor™ LAMP test can lead to further impact through facilitating expansion of our surveillance programs. Most interested organizations seeking affordable COVID-19 screening first ask us if we have an EUA. We are very clear in all of our communications and consents that our current test is

non-diagnostic. We have disabled negative result reporting to participants through our mobile app at the request of CMS. In our surveillance testing, we intend to continue to implement best practices with respect to training and quality assurance, while adapting to the differing aspects of public health rather than medical needs. We have engaged a leading learning experience firm to improve our training materials. Your guidance with respect to these efforts to rapidly expand accessible and affordable surveillance testing, in light of entering the clinical space as well, would be greatly appreciated.

Thank you for your attention to these issues related to our EUA submissions, and for your service during the crisis. We look forward to meeting and discussing the next steps.

Best Regards,
Randy True

EUA210581 - FloodLAMP EasyPCR™ COVID-19 Test
EUA210582 - FloodLAMP QuickColor™ COVID-19 Test
PEUA210313 - FloodLAMP Pooled Swab Collection Kit DTC, FloodLAMP Mobile App, Asymptomatic and Pooled Study Designs

Non-diagnostic surveillance deployments of FloodLAMP QuickColor™ test:

- 5 sites in 3 states;
- testing at a EMS leadership conference, youth summer camp, and municipal fire departments;
- 11 staff trained to run the test, 5 non-technical staff;
- approximately 800 pools run (reactions);
- approximately 2,300 people screened;
- use of our FloodLAMP Mobile App by 84 users to register on-site and at-home pooled collections;
- 3 unknown positives detected and confirmed by reflex diagnostic test;
- 26 known positives confirmed;
- no known or suspected false negatives.

We currently have 2 commercial sites operating, performing routine testing of EMS and municipal staff. Both are in the process of scaling up to screen 1,000+ people at least weekly and expand to support broader community testing including schools and workplaces.