## 2021-10-13_Email from FDA lead reviewer - Request for Additional Information pdf

from: Li, Liang <Liang.Li1@fda.hhs.gov>
to: "randy@floodlamp.bio" <randy@floodlamp.bio>
cc: "Li, Li (CDRH)" <Li.Li2@fda.hhs.gov>,
"Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
"EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>,
"Post, Justin" <Justin.Post@fda.hhs.gov>
date: Oct 13, 2021, 8:25 AM
subject: EUA210582-Additional Information needed
signed-by: fda.hhs.gov

Dear Mr. True,

I'm Liang Li, the lead reviewer for your submission EUA210582 Flood LAMP QuickColor COVID-19 Test.

Attached, please find FDA's letter with the request for additional information for your EUA submission.

Best Regards,

Liang

**Liang Li, Ph.D.**
*Scientific Reviewer*
General Bacteriology and Antimicrobial Susceptibility Branch
Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Phone: (240)-402-8107
Liang.Li1@fda.hhs.gov

Attachment - EUA210582-Additional Information-Final.pdf

## 2021-10-13_Email Followup from FDA lead reviewer offering zoom meeting next day

from:**Li, Liang** <Liang.Li1@fda.hhs.gov>to:"randy@floodlamp.bio" <randy@floodlamp.bio>
cc:"Li, Li (CDRH)" <Li.Li2@fda.hhs.gov>,
"Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
"Post, Justin" <Justin.Post@fda.hhs.gov>,
"EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>
date:Oct 13, 2021, 10:15 AMsubject:EUA210582-Setting up a meetingsigned-by:fda.hhs.gov

Dear Mr. True,

Just would like to follow up by email and offer that we could have a quick zoom meeting (30 minutes) tomorrow to discuss about your EUA210582 submission. Please let us know if you are available:

10:30 - 11:00 am EST or
12:30 -1:00 pm EST
Please let us know your availability and we will send out a zoom invite.

Thanks,
Liang

## 2021-10-14_Zoom Meeting Notes for FloodLAMP and FDA

FloodLAMP: Randy True (CEO), Anne Wyllie (Advisor)
FDA: Liang Li, Silke Schlottmann, Kris Roth

- Discussed open protocol EUA approach
- Silke asked about designation, said they would not want us to make IFU publicly available
- Randy relayed initially we'll deploy like Saliva direct but subsequently FloodLAMP will produce full reagent kit
- Randy communicated request to amend intended use to only serial screening (not persons suspected of COVID)
- Silke asked about showing data for intended population, Randy replied the clinical samples were remnant with no clinical info
- Kris mentioned there are 6 criteria for serial screening amendment, risk-benefit different for POC/at-home vs lab based tests
- Kris said we could consider the use bulb pipet to qualify for POC, calibrated pipet is "on edge" for POC
- Anne asked if we could validate with blinded ref panel
- Silke said ref panel is no longer available
- Agreed FloodLAMP would provide written response by Oct 20

## 2021-10-20_Email from FloodLAMP - Reply to FDA Additional Information Request

from: Randy True <randy@floodlamp.bio>
to: "Li, Liang" <Liang.Li1@fda.hhs.gov>
cc: "Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
"EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>
date: Oct 20, 2021, 8:06 AM
subject: Re: EUA210582-Additional Information needed
mailed-by: floodlamp.bio

Dear Liang, Silke, Kris,

Thank you for your patience in this response. Attached is a letter addressing your letter last week. We think this resolves some of the points, and we have follow up questions on others.

It seems that the central issue is that the current risk-benefit analysis does not allow us to utilize the streamlined screening with serial testing because our submission is for a lab rather than POC test. Did I understand that correctly from our call?

I would like to better understand the risk-benefit analysis and see if there is more information or data that we can share to support authorization. I would expect that a high complexity CLIA lab rather than POC setting would be a risk mitigating factor. I understood from our call that a lab rather than POC test reduces the benefit, however I would ask for consideration of the fact that our test being instrument-free with a visual readout does not have the usual scalability problems and high capital investment costs typically associated with molecular lab tests. Is that able to be factored into the risk-benefit analysis/calculation?

Kris, you mentioned there are 6 criteria for the serial screening claim. I cannot find those in the FDA statement from March or in the supplemental template. Can you please point me to those or share them?

Also attached is the letter to Tim Stenzel that I mentioned on our call. This letter provides more details on the potential for impact of the test and our company's work. SalivaDirect was developed and initially supported by a small but dedicated team of just 4 people. It has been very successful, in the U.S. and globally, due to the fact that it was FDA authorized as an open source protocol EUA test. In the assessment of a leading CEO, it has caused cost compression in the entire industry. As with SalivaDirect, we at FloodLAMP expect an outsized impact due to the open source protocol approach combined with the highly scalable configuration of our colorimetric LAMP test.

We have not received any communication back from Dr. Stenzel. If you have any feedback on engaging with CDRH leadership regarding prioritization and the potential for impact of our tests, please let me know.

On the submission, it would greatly expedite our ability to add significant screening in the coming winter months if we are granted authorization in the near term. If it's helpful, we are willing to consider conditions of authorization to minimize potential risks. It is much more difficult to make rapid progress on the dissemination and commercialization of this high impact, rapid molecular test and the screening programs it enables, prior to any FDA authorization.

Thank you for your constructive feedback and engagement. Please let me know the next step. I am generally available to meet and expect to be able to respond in writing quickly, typically within 24 hours, 2 days max.

Best Regards,

Randy

**Attachment 1:**

2021-10-20_Response to FDA re QuickColor - EUA210582 10-13

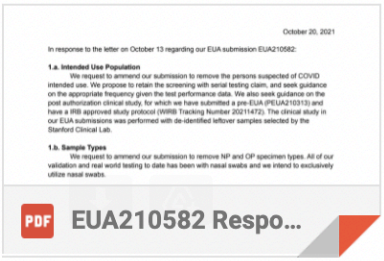
**Attachment 2:**

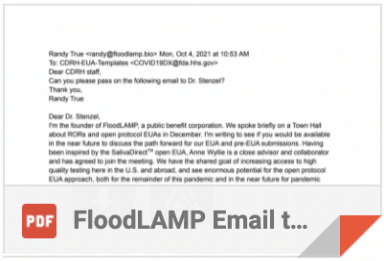
2021-10-04_FloodLAMP Email to Tim Stenzel - 4 pages

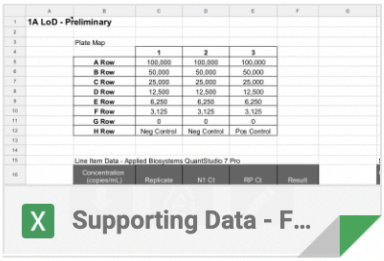
**Attachment 3**

2021-03-22_EUA Sub Supporting Data - FloodLAMP EasyPCR COVID-19 Test

**3 Attachments**



# 2021-10-21_Email from FDA lead reviewer - Final Decision

from: Li, Liang <Liang.Li1@fda.hhs.gov>
to: "randy@floodlamp.bio" <randy@floodlamp.bio>
cc: "EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>,
"Post, Justin" <Justin.Post@fda.hhs.gov>,
"Li, Li (CDRH)" <Li.Li2@fda.hhs.gov>,
"St. Pierre, Don J." <don.st.pierre@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
oir-policy <CDRH-OIR-POPS@fda.hhs.gov>,
"Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>
date: Oct 21, 2021, 5:57 AM
subject: Final Decision for EUA210582 Request – letter attached

Dear Mr. True,

The additional information you provided does not demonstrate that your device is adequately validated for its intended use. Please see attached letter regarding your EUA request, EUA210582. This is the final decision on your EUA request, and your EUA is now closed. For additional information on FDA's priorities with respect to review of EUA requests for COVID-19 tests, see our website's FAQs on Testing for SARS-CoV-2.

Please confirm receipt of this email and attached letter.

Thanks,

Liang

**Liang Li, Ph.D.**
*Scientific Reviewer*

Dear Mr. True:
This letter is in response to your request for an Emergency Use Authorization (EUA) for the Flood LAMP QuickColor COVID-19 Test, intended for the following use(s): the qualitative detection of SARS-CoV-2 in anterior nasal swabs from individuals suspected of COVID-19 by their healthcare provider and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested at least once per week. Given the volume of EUA requests the Agency has received, FDA is prioritizing review of EUA requests for tests, taking into account a variety of factors such as the public health need for the product, availability of the product, extent to which the product would serve a significant unmet medical need, and availability and adequacy of the information concerning the likelihood that the product may be safe and effective in diagnosing the disease/condition. Based on these factors, our review of yoursubmission thus far, and the anticipated resources needed to continue review of your EUA request, FDA has determined that further review of your EUA request is not a priority. FDA therefore declines to issue an EUA for the product at this time.

This test has not been authorized to be distributed or used as proposed. FDA is committed to doing everything possible to help combat the COVID-19 outbreak and appreciates your efforts in this matter.

Sincerely,

_____

Donald J. St.Pierre
Deputy Director, New Product Evaluation

# 2021-10-28_Email from FloodLAMP - Reply to Final Decision

Randy True <randy@floodlamp.bio>
to: "Li, Liang" <Liang.Li1@fda.hhs.gov>
cc: "EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>,
"Post, Justin" <Justin.Post@fda.hhs.gov>,
"Li, Li (CDRH)" <Li.Li2@fda.hhs.gov>,
"St. Pierre, Don J." <don.st.pierre@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
oir-policy <CDRH-OIR-POPS@fda.hhs.gov>,
"Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>
date: Oct 28, 2021, 8:56 AM
subject: Re: Final Decision for EUA210582 Request – letter attached

Hi Liang,
Yes I did receive the letter and have been consulting with our advisors and regulatory experts on the next step.

The letter specifies that our intended use includes persons suspected of COVID-19 by their healthcare provider. We requested to amend our submission to be limited to screening with serial testing. The intention was for that to be a formal amendment, rather than a question.

Can you please confirm that the intended use amendment was understood by all prior to the decision to deprioritize and close our submission?

If it was not understood, I'd kindly ask the team to reconsider the closure and work with us in an efficient, focused manner to resolve whether our current clinical study is adequate for the screening with serial testing intended use. We believe that our clinical data along with our analytical LoD data shows superior performance to all antigen tests that have been authorized for this intended use.

If our current clinical study data is acceptable (completing items 1a,c and d), we will pull out all the stops to quickly complete the other items to demonstrate adequate performance. Updating the inclusivity study, variant analysis, cross reactivity, and interfering substances (items 2, 3, 4) are straightforward and low risk. This streamlined path to authorization, for which it seems the serial testing indication was created, would enable us to rapidly deploy the millions of tests we have ready in the coming months.

If our current clinical study is not acceptable, then we would request feedback on the new clinical study design for the general screening intended use. We've included that in a pre-EUA (PEUA210313) but did not receive feedback on the study design. That pre-EUA included several other complex components, so we would be happy to resubmit a focus pre-EUA or send a Qsub to the email box. We have an IRB in place already with an enrichment study design, so we think the feedback here could be very efficient as well. It's my understanding this study

design is required as a condition of authorization for the screening with serial testing intended use as well. We will proceed with completing the other items in parallel as performing a new clinical study will take more time.

Best Regards,
Randy

## 2021-10-29_Email from FDA lead reviewer - Reply regarding Deprioritization

from: Li, Liang <Liang.Li1@fda.hhs.gov>
to: Randy True <randy@floodlamp.bio>
cc: "EUA210582@docs.fda.gov" <EUA210582@docs.fda.gov>,
"Post, Justin" <Justin.Post@fda.hhs.gov>,
"Li, Li (CDRH)" <Li.Li2@fda.hhs.gov>,
"St. Pierre, Don J." <don.st.pierre@fda.hhs.gov>,
"Roth, Kristian" <Kristian.Roth@fda.hhs.gov>,
oir-policy <CDRH-OIR-POPS@fda.hhs.gov>,
"Schlottmann, Silke" <Silke.Schlottmann@fda.hhs.gov>
date: Oct 29, 2021, 11:03 AM
subject: RE: [EXTERNAL] Re: Final Decision for EUA210582 Request – letter attached

Hi Mr. True,

Thanks for acknowledging the receipt of my email and the DTI letter.

We understood the intended use amendment when we sent the Deprioritization Letter. Your current clinical study is not acceptable to support testing a screening population with serial testing. Regarding PEUA210313, it appears it was reviewed and closed on 6/17/21. If you have additional questions regarding an appropriate study design, you can refer to the new molecular EUA template and/or send in an PEUA amendment/supplement for FDA feedback.

Thanks,

Liang