

*Sent to CDRH email address on Nov 10, received response saying it was forwarded to Tim Stenzel a few days later*

Dr. Stenzel,

I run FloodLAMP Biotechnologies, a Public Benefit Corporation. On Friday we submitted a pre-EUA for an ultra-low-cost, scalable, LAMP-based test based on the Rabe Cepko assay out of Harvard. We are intending to provide this as an "open source" protocol, inspired by Dr. Anne Wyllie and the SalivaDirect team. FloodLAMP is collaborating with Dr. Wyllie and Prof. Connie Cepko, who are on our Scientific Advisory Board.

Dr. Wyllie and I would greatly appreciate the chance to meet with you to discuss expanding the open source EUA approach, as well as several overlapping EUA issues for the SalivaDirect and FloodLAMP tests (asymptomatic screening, pooling, and on-site/at-home collection).

We are currently helping a third group who has submitted an EUA and is also seeking to provide their test as an open source protocol, and we continue to receive interest from yet more groups that are interested in taking this approach. Our goal is to build a consortium of like-minded, mission-driven test developers committed to bringing online a suite of properly validated and well supported open-access SARS-CoV-2 molecular tests. As SalivaDirect has shown, these molecular tests can be deployed in a scalable, non-proprietary way that is truly game-changing. We see the potential for these tests to become high-impact public goods, with far-reaching benefits both in pandemic preparedness and broader human health.

There's a lot of hard work to be done to achieve this ambitious goal, and we would like to discuss with you how to most efficiently proceed. Please let us know if you are available soon to discuss.

Best Regards