October 20, 2021

In response to the letter on October 13 regarding our EUA submission EUA210582:

1.a. Intended Use Population

We request to ammend our submission to remove the persons suspected of COVID intended use. We propose to retain the screening with serial testing claim, and seek guidance on the appropriate frequency given the test performance data. We also seek guidance on the post authorization clinical study, for which we have submitted a pre-EUA (PEUA210313) and have a IRB approved study protocol (WIRB Tracking Number 20211472). The clinical study in our EUA submissions was performed with de-identified leftover samples selected by the Stanford Clinical Lab.

1.b. Sample Types

We request to ammend our submission to remove NP and OP specimen types. All of our validation and real world testing to date has been with nasal swabs and we intend to exclusively utilize nasal swabs.

1.c Low Performance and 1.d. Low Positive Samples

We understand the PPA threshold for the screening with serial testing claim to be 80%. The analytical and clinical performance of the test exceeds that of many other devices with the same intended use. To the best of our knowledge, the performance of our QuickColor LAMP test exceeds all authorized antigen tests.

During the Stanford clinical evaluation, a PCR test using the SalivaDirect version of the CDC primers, was also run on the same inactivated samples (data shown in columns J,K, and L in Supporting Data, tab "4 Clinical Evaluation" in EUA210582, also attached). Only 4 samples with Ct values higher than 36 were not detected by the QuickColor LAMP test. This viral load threshold is concordant with the LoD of 12,500 copies/mL, measured with contrived positives created by spiking gamma inactivated cell lysate from BEI into negative clinical matrix.

In addition to the Stanford clinical evaluation data, we include real world evidence of good test performance from surveillance our testing programs using the same test protocol and reagents, with pools of up to 4 AN swabs. Through the Sept. 28, this real world data comprises:

- approximately 800 pools run (reactions);
- approximately 2,300 people screened;
- 3 unknown positives detected and confirmed by reflex diagnostic test;
- 26 known positives confirmed;
- no known or suspected false negatives.

We understand that the FDA makes EUA decisions based upon data submitted for specific test systems. In consideration of the potential benefits and known and potential risks of our test, we would like to share that all components of the FloodLAMP QuickColor test, including the exact TCEP/EDTA inactivation solution chemistry, the same primer sequences (all 3 genes or a subset), and the same NEB Colorimetric LAMP Master Mix product (catalog M1804) have been independently validated in several EUA authroized tests and/or submissions (Yu/Rosbash from Brandeis, Kundrod/Richards-Kortum from Rice, Prime Diagnostics, Color Genomic's EUA, Detectachem's EUA). Additionally, a Gates/NEB/IGCEB collaboration has validated a RT-LAMP assay with the same NEB M1804 LAMP Master Mix and 2 of the 3

primers in our test, and published the results of this large multicenter prospective observational study. They are undergoing the Prequalification process with the WHO.

2. Inclusivity Study and Variant Analysis

The inclusivity analysis will be updated and presented in the provided format.

3. Cross Reactivity / Microbial Interference

The provided feedback seems to assume PCR is the amplification technique. With LAMP, near perfect homology across B3, F3, FIP and BIP is necessary to support successful amplification. With the exception of SARS-CoV, which was included in the wet testing, no other organisms showed >80% homology with more than one primer.

4. Endogenous Interfering Substances

The current set of 5 interfering substances were selected based upon those included in authorized EUA tests. In light of the changes to the sample type and intended use, please advise on any updates to the required list.

5. External Controls

The concentration of 100,000 copies/mL was selected to be the same as the SalivaDirect™ test. Please advise on the suitability of mirroring this EUA.

The positive control material was validated with PCR, routinely measuring in the 31-32 Ct range. In our preliminary LoD Study for the EasyPCR™ test, the positive control Ct was 31.1 while the contrived positive with gamma inactivated virus at the same 100,000 copies/mL was 31.7.

6. RUO Reagents

We will qualify specific lots of RUO reagents and post the lot numbers.