Home Specimen Collection Molecular Diagnostic Template

A. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the **FloodLAMP Pooled Swab Collection Kit DTC** for the **unsupervised collection** of **1 to 4 pooled nasal swabs** in a **dry tube** to transport viral SARS-CoV-2 RNA, from **any individual, including individuals without symptoms or other reasons to suspect COVID-19**. The collection kit is for use in conjunction with molecular diagnostic testing performed at a clinical laboratory using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that is authorized for use with the **FloodLAMP Pooled Swab Collection Kit DTC**.

Testing is limited to laboratories designated by **FloodLAMP Biotechnologies, PBC** that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Test results may be delivered to the user via the **FloodLAMP Mobile App or Web Portal**. Individuals with positive or inconclusive will be referred to a healthcare provider. The direct to consumer home collection system is intended to enable individuals and organizations to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The **FloodLAMP Pooled Swab Collection Kit DTC** is for use by unsupervised adults 18 years and older, to self-collect dry anterior nasal swab specimens, including for use by such individuals without symptoms or other reasons to suspect COVID-19. Collection for minors under the age of 18 may be assisted by pre-authorized individuals, including by a parent, guardian or other responsible person who is contributing a nasal swabs specimen to the same pool as the minor.

The **FloodLAMP Pooled Swab Collection Kit DTC** is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

B. APPLICANT

FloodLAMP Biotechnologies, a DE Public Benefit Corporation

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C. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - **FloodLAMP Pooled Swab Collection Kit DTC**

Established Name - **FloodLAMP Pooled Swab Collection Kit DTC**

D. REGULATORY INFORMATION

Approval/Clearance Status:

The **FloodLAMP Pooled Swab Collection Kit DTC and FloodLAMP Mobile App** are not cleared, approved, or subject to an approved investigational device exemption.

Product Code:

QJR

E. PROPOSED INTENDED USE

1) Intended Use:

The proposed IU will be finalized based on, among other things, the data and recommendations from Public Health authorities at the time of authorization – example text is provided below.

Example text for a home collection kit where the manufacturer does not hold the COVID-19 NAAT test EUA:

The **FloodLAMP Pooled Swab Collection Kit DTC** is a direct to consumer (DTC) product for **self-collecting pooled anterior nasal swabs in a dry tube** at home (which includes a community based setting), **including individuals without symptoms or other reasons to suspect COVID-19**. Specimens collected using the **FloodLAMP Pooled Swab Collection Kit DTC** are transported at ambient temperature for testing at a laboratory. SARS-CoV-2 RNA from the **nasal swabs** is maintained in the specimen packaging and is suitable for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that has been issued an EUA for use with Home Collection Kits, that includes the **FloodLAMP Pooled Swab Collection Kit DTC**.

Testing is limited to laboratories designated by **FloodLAMP Biotechnologies** and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Testing is also limited to molecular diagnostic tests that are authorized for use with Home Collection Kits for collection of nasal swab specimens, including the **FloodLAMP Pooled Swab Collection Kit DTC**.

The **FloodLAMP Pooled Swab Collection Kit DTC** is only for use under the Food and Drug Administration's Emergency Use Authorization.

Example text for a home collection kit where the manufacturer also holds the COVID-19 NAAT test EUA (e.g., an already issued EUA is being revised to authorize home specimen collection as an option):

The **FloodLAMP QuickColor™ COVID-19 Test** is a reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) assay that indicates the presence of the SARS-CoV-2 viral RNA with a simple visual color change. The **FloodLAMP EasyPCR™ COVID-19 Test** is a real-time reverse transcriptase polymerase chain reaction (RT-qPCR) assay that utilizes a

RT-PCR instrument. These tests are RNA extraction-free tests intended for the qualitative detection of RNA from SARS-CoV-2 in upper respiratory specimens including nasopharyngeal swabs, anterior nasal and mid-turbinate 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 a weekly interval with no more than 9 days between tests.**

These tests are also for use with the **FloodLAMP Pooled Swab Collection Kit DTC** for **self-collecting pooled anterior nasal swabs in a dry tube** at home (which includes a community based setting), **including individuals without symptoms or other reasons to suspect COVID-19**. Specimens collected using the **FloodLAMP Pooled Swab Collection Kit DTC** are transported at ambient temperature for testing at a laboratory.

Testing is limited to [***specify laboratory/laboratories***] certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in **upper respiratory specimens** during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The **FloodLAMP QuickColor™ and EasyPCR™ COVID-19 Tests** are intended for use by **qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures**. The **FloodLAMP QuickColor™ and EasyPCR™ COVID-19 Tests** are only for use under the Food and Drug Administration's Emergency Use Authorization.

2) Special Conditions for Use Statements:

For Emergency Use Authorization (EUA) only.
For prescription use and over-the-counter use.
For in vitro diagnostic use only.
For use **unsupervised** by people 18 years of age or older.
For use by **minors under the age of 18 with assistance by individuals pre-authorized by a parent or guardian.**
The **FloodLAMP Pooled Swab Collection Kit DTC** is only authorized for use in conjunction with an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that has been issued an EUA and is authorized for use with this collection device.

F. DEVICE DESCRIPTION

1) Device Description:

The **FloodLAMP Pooled Swab Collection Kit DTC** consists of **nasal swabs, barcoded transport tube, zip-seal biohazard safety bag, and instructions**. Some kit configurations include multiple transport tubes and biohazard safety bags for multiple collections. Additionally, the kit may include other tubes for simultaneous collection of individual (non-pooled) swabs, along with a barcode label and additional zip-seal bag.

2) Home Collection Kit Ordering and Processing:

The **FloodLAMP Pooled Swab Collection Kit DTC** is available direct to consumer (DTC) without a prescription for any individual 18 years and older. Individuals may receive kits by purchasing through an authorized distributor or as a part of a screening program. Instructions included with the kit guide users on how to properly collect the anterior nasal swab specimens. After collection of all swabs in the pool, the transport tube is capped and placed inside the biohazard bag, which is then sealed. The biohazard bag with specimens is returned to a designated location and placed inside a secure receptacle or given to responsible program staff. The biohazard bag may also be couriered or placed inside an appropriate labeled mailer for shipping to a designated location for processing. The time from collection to receipt for processing is not to exceed 48 hours.

If using the **FloodLAMP Mobile App**, the following steps are performed to complete a pooled collection event:

- all participants sign up for an account on a computer or mobile device, confirm their identity via email or text message, set a password, login to the app, and digitally sign a consent;
- a single individual (the "pool sponsor"), who may be a participant in the pool, initiates a collection event and oversees the proper collection of specimens by all participants in the pool;
- participants are instructed to swab both nostrils per the printed instructions which are reproduced in the app;
- next, the pool sponsor scans the barcode of the transport tube used for collection of the swab specimens for the collection event;
- next, the pool sponsor enters the names, emails, or phone numbers of the other participants contributing specimens to the pool;
- if this collection event is the first time the pool sponsor is including a participant in the pool, the participant is required to provide authorization via the app;
- after all participants are added, the pool sponsor completes a collection confirmation consisting of questions that are required to be checked.

If not using the **FloodLAMP Mobile App**, the registration of which individuals contribute specimens to the pools may be accomplished through secure lookup tables containing barcodes and PII in a process managed by administrators of the serial screening program.

Barcoded specimen tubes are received at the clinical laboratory for testing and undergo the following accessioning prior to acceptance for testing:

- biohazard bags are opened and barcoded transport tubes removed;

- transport tubes are inspected and if cap is missing, tube is improperly capped, or tube is cracked or otherwise damaged, then the tube is intake scanned for intake and rejected for testing;
- participants with specimens in rejected tubes are notified, and if appropriate, requested to provide another specimen;
- tubes that are not rejected are placed into a queue for processing.

Clinical laboratories may use an existing LIS or use the lightweight LIS provided in the **FloodLAMP Mobile App**. The app LIS is accessed by switching to "staff mode" which is only available to permitted users. Staff users can place intake scanned tubes into batches both physically and digitally, for example in batches of 94 to run in an amplification plate. The status and results for individual tubes or batches of tubes is set by staff users. After completion of the test (amplification reaction), results (positive, negative, inconclusive/invalid) can be entered by scanning tube barcodes or imported from a file (for example the output file from a RT-PCR instrument). All data is protected by secure login to the **FloodLAMP Mobile App**.

Test results are communicated back to individuals that used the **FloodLAMP Pooled Swab Collection Kit DTC** via the **FloodLAMP Mobile App.** Users set their notification preference as email or text message. When a new result is available, they receive a short message to check the app for that new result. From the home screen in the app, users select "Results" to see their test results. Additionally, administrators receive an email with information on a positive pool including the participants names and contact information.

3) Specimen Collection Control:

Though it may also be used for individual specimen collection, the primary use case for the **FloodLAMP Pooled Swab Collection Kit DTC** is for pooled collection as part of a serial screening program. The pool sponsor who registers the collection event in the **FloodLAMP Mobile App** is instructed to observe all participants contributing specimens to the pool to control for proper nasal swabbing technique. This oversight provides a baseline level of specimen collection control.

The **FloodLAMP EasyPCR™ COVID-19 Test** which is intended for use with the **FloodLAMP Pooled Swab Collection Kit DTC** has an internal process control to assure sufficient specimen quantity and quality. It consists of a primer/probe set targeting the human RNaseP gene that is included in a single PCR amplification reaction. The RNAseP Internal Process Control uses a fluorescent reporter in a separate channel from the SARS-CoV-2 channel (i.e. in duplex).

4) Partnering Laboratories:

Laboratory	**EUA Assay**	**Lab Testing Capacity (per day or week)**
Lab Name Address Phone: CLIA #:	Assay Name **Identify if Commercial Assay or LDT**	

5) Test Result Reporting:

All test results will be reported to healthcare providers and relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Public health reporting will be supported by the **FloodLAMP Mobile App**, through an API or a results export file. Alternatively, reporting may be done through the CDC's SimpleReport application (https://simplereport.gov/). For pooled results, the reporting occurs during deconvolution testing of individual samples, according to local public health requirements.

6) Mobile Applications and Software:

The **FloodLAMP Mobile App** requires 4 MB of device memory and an internet connection. The **FloodLAMP Mobile App** is supported in IOS, Android and mobile web browsers.

IOS is supported from versions 12 through 14. Android is supported from version 5.1 through version 1. Mobile browser testing occurs on safari and chrome using the most recent stable release.

End-to-end testing and validation occurs on the oldest and most recent supported devices for all platform changes. FloodLAMP tests each user stage (onboarding and account creation, sample collection, pooling and deposit, and results) during server and platform updates. All permutations of required and non-required fields are tested for corresponding error codes and successful database entries.

Records are not stored on user devices and are stored on a secure cloud based database.

G. PRODUCT MANUFACTURING

The**FloodLAMP Pooled Swab Collection Kit DTC** **[**has been] validated using only the components referenced in this submission.

1) Overview of Manufacturing and Distribution:

The product will be manufactured at **Eralab Scientific Instrument (HK) Co., Limited by Ningbo Dasky Life Science** personnel consistent with practices for the production of **diagnostic collection kits** based on **CE standards**. Material manufactured by **Ningbo Dasky Life Science** may be bottled and kitted by **FloodLAMP Biotechnologies** at their manufacturing facility.

The current manufacturing capabilities include the ability to manufacture approximately **50,000 products per week**. In the event of a surge in demand, this could be increased to **4.9 million products per week within a two week timeframe**.

The product will be distributed by **FloodLAMP Biotechnologies and its distribution partners**.

2) Components Included with the Home Collection Kit

Components manufactured by **Eralab Scientific Instrument (HK) Co., Limited** and supplied with the home collection kit include:

Kit components

Name	Description	Quantity	Material Supplier
Biohazard safety bag	Zip-seal biohazard safety bag	1	Various
Sterile Collection Tube	Sterile collection tube with QR code	1	Various
Nasal Swab	Foam or spun polyester swab	4	Various
Instructions for self collection	Printed card with graphical instructions for self collection	1	Printed
Fact sheet for individuals	Contains information on risks and benefits	1	Printed
Return shipping mailer (optional)	Postage paid return mailer	1	Various

3) Collection Device Stability:

No collection reagents are used in the **FloodLAMP Pooled Swab Collection Kit DTC**.

H. PERFORMANCE EVALUATION

1) Home Collection Sample Stability Study:

Shipping stability of foam and dry spun polyester swabs has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and UnitedHealth Group. The Quantigen study demonstrated 56-hour stability for dry anterior nasal foam and spun polyester swabs when subjected to both summer and winter thermal excursions. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as FloodLAMP Biotechnologies, PBC pursuing an EUA for which a claimed specimen type is foam or dry spun polyester swabs. Therefore, the stability of anterior nasal samples collected using foam or dry spun polyester swabs were not evaluated in the sample stability study.

Dry Swab Rehydration Validation:

The rehydration protocol for dry swabs collected with the **FloodLAMP Pooled Swab Collection Kit DTC** varies depending upon the downstream test chemistry of the COVID-19 NAAT test EUA. Principally, it comprises addition of between 1 mL and 3 mL of solution/media to the tube of pooled dry swabs, with less than 1 mL potentially for individual swabs. The solution/media may contain an inactivation/lysis chemical or it may be VTM or saline solution. After addition of

the solution/media, the tube is agitated to facilitate extraction of the specimen from the swab. Typically, 30 seconds of vortexing is recommended. The specific volume, composition of solution/media, and agitation protocol must be validated for all COVID-19 NAAT test EUAs using the **FloodLAMP Pooled Swab Collection Kit DTC**.
For the **FloodLAMP QuickColor™ and EasyPCR™ COVID-19 Tests**, the rehydration protocol for pools of up to 4 dry swabs collected with the **FloodLAMP Pooled Swab Collection Kit DTC** comprises:

1) addition of [1] mL of 1X Inactivation Saline Solution;
2) vortex for 30s at 3-5,000 rpm.

Following are the steps of heat inactivation, cooling of samples, and amplification. Please see the test IFUs for the complete SOP.

For validation of the dry swab rehydration protocol for the **FloodLAMP QuickColor™ and EasyPCR™ COVID-19 Tests** for pools of up to 4 dry swabs collected with the **FloodLAMP Pooled Swab Collection Kit DTC**, contrived positives specimens at 20,000 copies/swab were prepared by

2) General Acceptance Criteria:

* Please see acceptance criteria in section F-2 above and reference to the dry swab stability study in H-1.

3) Human Usability Study: Pooled Self-Collection Validation

PROPOSED USABILITY STUDY

- Testing will include a minimum of 30 participants in each arm and will take place in an actual or simulated home environment.
- Study Arm 1 will provide only printed IFU instructions with the collection kit and include barcoded collection tubes that have been pre-registered to the participant. This arm assesses usability of a workflow for a serial screening program that uses pre-registration of collection kits.
- Study Arm 2 will provide printed IFU instructions with the collection kit and require the participant to register the kit using the **FloodLAMP Mobile App**.
- The entire workflow will be performed by each individual participant using the collection kit, including kit registration, sample collection, packaging of the sample, and return of the sample (by mail or dropoff depending upon the study arm).
- The participants will be observed either in person or by recorded video conference during sample collection and all difficulties will be noted.
- Participants will collect pooled samples of between 1 and 4 swab specimens.
- After the entire process is completed, the user will be given the attached 12 question survey assessing the ease of use of the kit and sample collection as well as understanding of the consequences if steps are not performed correctly. The participant will be able to provide comments if needed.
- The laboratory personnel will inspect the packaging and specimens upon delivery and note all packaging errors and acceptability of the sample for testing.

- The samples collected during the study will be tested for specimen adequacy using the **FloodLAMP EasyPCR™ COVID-19 Test** which includes an internal human sample control (RNaseP). The RNaseP Ct value will be used to determine if sufficient sample was collected by the user. [To CDRH Reviewers: Is it acceptable to utilize the FloodLAMP EasyPCR™ COVID-19 Test for determining the pass/fail of specimen adequacy? It is not yet an EUA authorized test but a full EUA submission is included along with this pre-EUA for review. The test uses the CDC primers from the EUA authorized SalivaDirect™ Test. In the clinical evaluation performed by the Stanford University Clinical Lab, the test showed a 98% sensitivity. The LoD was determined at 3,100 copies/mL.]
- Participants will include individuals representing varying education levels and ages. Participants with prior medical or laboratory training will be excluded. ~~Participants who have prior experience with self-collection should be excluded.~~ [To CDRH Reviewers: Is it acceptable to strike this exclusion since self-collection has become much more widespread?]
- The study will have pre-defined acceptance criteria and errors identified in the study will be mitigated by modifying the instructions.

Inclusion and Exclusion Criteria for Usability Study (both arms)

Inclusion Criteria	Exclusion Criteria
Participant is 18 years or older.	Participant has participated in a prior COVID-19 collection kit usability study.
Participant resides in the United States.	Participant is suspected of COVID-19.
Participant speaks English.	Participant is experiencing symptoms of COVID-19.
Participant is willing to read the study information and informed consent.	Participant has received a positive COVID-19 test result.
Participant is willing to sign the informed consent.	Participant has prior medical or laboratory training.
Participant is willing to complete the survey.	Participant regularly uses home use diagnostic tests, such as glucose meters.
Participant is willing to have the interview recorded.	Participant does not speak English.

Inclusion and Exclusion Criteria for Usability Study (additional for arm 2)

Inclusion Criteria	Exclusion Criteria
Participant has a valid email address.	Participant is a professional software developer or UX/UI designer.
Participant has access to an iOS or Android mobile device.	
Participant has access to a stable internet connection.	

4) User Labeling:

You should submit for review your packaging and directions for your specimen collection kit. FDA will review these documents for their ease of use and clarity of instructions. We recommend all directions be written at a 7th grade reading level or below.

The print version of the Instructions for Use for the **FloodLAMP Pooled Swab Collection Kit DTC** are included as a pdf document with this submission.

I. UNMET NEED ADDRESSED BY THE PRODUCT

This section will be completed by FDA.

J. APPROVED/CLEARED ALTERNATIVE PRODUCTS

Currently no methods for specimen self-collection in conjunction with a laboratory-based molecular in vitro diagnostic EUA test for the detection of the SARS-CoV-2 have been approved/cleared by FDA.

K. BENEFITS AND RISKS:

This section will be completed by FDA.

L. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS:

As set forth in the EUAs, Fact Sheets for Patients and Healthcare Providers generally are to be provided with the assays that will be used with the home collection kit - ***see examples for authorized EUA tests on our website and templates will be made available.***

M. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

Include Instructions for Use, Box Labels, Vial Labels and any other proposed labeling for the test and/or home collection kit. You should also include copies of any questionnaires used to determine eligibility of the patient to receive the home collection kit.

N. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

If authorized, conditions would likely be included in the EUA to require the following -

FloodLAMP Biotechnologies will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report adverse events, and this website is referenced through the **FloodLAMP Biotechnologies** Product Support website: **floodlamp.bio/support**. Each report of an adverse event will be processed according to **FloodLAMP Biotechnologies**'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the

FDA as required. Through a process of inventory control, **FloodLAMP Biotechnologies** will also maintain records of device usage/purchase. **FloodLAMP Biotechnologies** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which **FloodLAMP Biotechnologies** becomes aware. **FloodLAMP Biotechnologies** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.