

# Report on social implementation research of automated nucleic acid testing device

## 1. Background of the project

Early testing at facilities and business enterprises and preventing the occurrence of clusters is being currently at issue in continuing spread of the omicron variant of COVID-19. LifePad as nucleic acid testing device with high sensitivity and high accuracy can provide test results quickly (POCT (Point of Care Test)) .

We have tried to make mechanism that could connect to preventing infection by implementing research focused on quick tests and making use of the strength of its lightweight and portability.

※In Japan our product is intended for research purposes.

The product has not been approved or certified as an in vitro diagnostic drug based on the Pharmaceuticals and Medical Devices Act.

## 2. Purposes

Device was implemented in four fields: medical field, social welfare facilities field, sports field and office field in cooperation with some medical facilities, nursing homes, sports organizations and business enterprises to check the way of use and usability.

## 3. About the project

### 3.1 Period

January 28, 2022 – March 15, 2022

### 3.2 About participants

Medical field: clinics, small clinics

Social welfare facilities field: nursing homes

Sports field: sports organizations

Office workers field: business enterprises

### 3.3 About targets

(1) Device: LifePad

(2) Detection target: COVID-19 (novel coronavirus)

(3) Persons who operated the device: doctors, nurses, laboratory technicians, staff working at the nursing home, athletes, trainers, and staff working at business enterprises.

(4) Test targets: the symptomatic persons, the persons who have been contacted with an infected person, the asymptomatic persons at the occurred cluster, screening tests.

(5) Sample collecting targets: the symptomatic persons, the persons who have been contacted with an infected person, asymptomatic persons.

## 4. About results

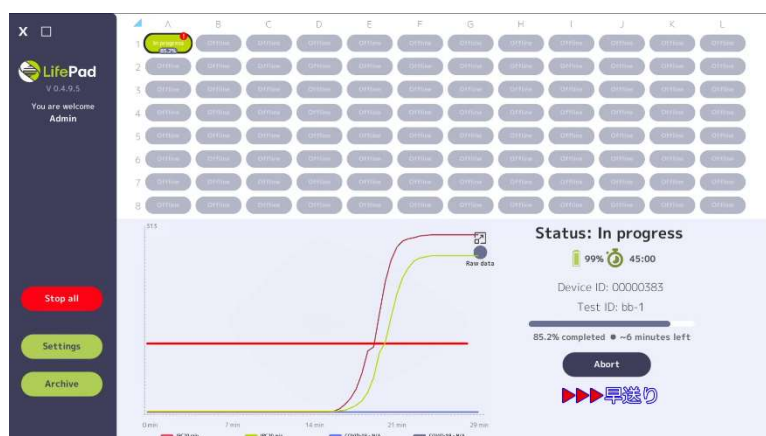
During this project feedback from 913 persons was obtained, feedback from the medical field – from 30 persons, feedback from social welfare facilities field – from 37 persons, feedback from sports field – from 83 persons, feedback from office workers field – from 763 persons, totally – from 913 persons. 769 samples were measured, 762 were negatives and 7 were positives.

«It looks simple, but it has solid internal control and after using some time we can say that negative results can be clearly diagnosed, this system is very excellent” LifePad was appreciated by doctor. However, some tasks were noted and it became clear that we need improvement.



Also, according to questionnaire and measurement results, the device is simple-to-use and any staff at medical facilities or nursing homes, even staff at a business enterprise may simply perform testing with the same results even with no experience and skills.

#### 4.1 About cases in each field and feedback survey



##### (1) Medical field

###### Case 1 Medical facilities

The child of a doctor who was working out of the clinic had tested positive for coronavirus (COVID-19) and the doctor has been contacted with his child. Clinic staff every morning make a rapid antigen covid test or PCR test, and after having tested negative may work this day, so usually after coming to work clinic staff make antigen test and after having tested negative start their work.

To be sure he made the test using LifePad and coronavirus (COVID-19) was detected, he got out of his consultation work. On this day he was going to make round in a nursing home, that prevented the spread of infection.

###### Feedback 1 Doctor

Want to use when staff in a medical facility has mild symptoms of upper respiratory tract infections after the device will be registered as in vitro diagnostic medical device.

###### Feedback 2 Doctor

In case someone in the family of medical facilities staff has been contacted with an infected person, generally, medical staff is not relevant to the person who has been contacted with an infected person and does not get out of work (staying home). After LifePad will be registered as in vitro diagnostic medical device it will be possible to confirm negative results and the staff, and his family can spend safe.

##### (2) Social welfare facilities field

###### Case 1 Nursing home

An elderly person who was using several day-service centers underwent an antigen test after a bus driver in one of the centers had tested positive for coronavirus (COVID-19). He had negative antigen test results and LifePad test results were also negative (not detected).

###### Case 2 Nursing home

The family of a user of a nursing home had tested positive for coronavirus (COVID-19) and had negative antigen test results, after it he had confirmed measuring on LifePad and had tested positive for coronavirus (COVID-19).

### Case 3 Nursing home

cluster in the nursing home

- ① User had tested positive for coronavirus (COVID-19) but other users who were in the same room had tested negative for coronavirus (COVID-19). LifePad test returned positive results.
- ② User had fever with suspect COVID-19 had negative antigen test results, LifePad test returned positive results.

### Case 4 Nursing home

The user staying at the nursing home had fever of 38°, fatigue, and sore throat symptoms but had negative antigen test results. LifePad test also returned negative results, after consultation and treatment he was diagnosed infection of his tooth. After confirmation of negative results, it becomes available to perform a detailed examination and appropriate treatment.

### Feedback 1 Doctor

It looks simple, but it has solid internal control and after using some time we can say that negative results can be clearly diagnosed, this system is very excellent. Omicron variant of COVID-19 is spreading, and the most pressing problem is patient beds capacity in secondary hospitals due to clusters occurring in nursing homes. To prevent clusters the countermeasures are an urgent task for nursing homes, we are going to take clusters countermeasures using such keywords as “early diagnosis, early contain”. Performing symptomatic person and “close contact” person who contacted an infected person’s testing on the spot helps the doctor make an early diagnosis and after confirmation can prevent clusters by isolating. If a cluster had occurred, using LifePad we can follow up with the persons who had positive test results and make screening tests. If test results are negative (not detected) it will be possible to determine the content of cluster.

After using my impression was as staff of nursing homes can operate without problem and doctors may appropriately control it so can say that this device may be used in nursing homes.

### Feedback 2 Doctor

Using LifePad staff at the nursing homes can work safely and users can spend safely too. We would like to use this device, if possible, at our office. Our anxiety may be changed to relief – every time we feel that we need to buy this device.



## (3) Sports field

### Case 1 Sports organization

LifePad was prepared for the case of fever or bad health condition on a training day or match day. LifePad has high accuracy than antigen tests and can prevent the spread of infection. Fortunately, nobody had a fever on match day so there was no need to use LifePad.

### Case 2 Sports organization

Athletes going to participate in the match undergo LifePad test for coronavirus (COVID-19). All had tested negative, and the match was opened.

#### (4) Office workers' field

##### Case 1 Business enterprise

The dealer who usually visits the office had tested positive for coronavirus (COVID-19) and the staff who contacted this dealer became relevant to "close contact" with him. Staff who has been in close contact with the infected dealer stayed at home for 5 days and performed follow-up. During 5 days had tested negative and was allowed to work.

##### Case 2 Business enterprise

LifePad was delivered to the staff's family which had tested positive for coronavirus (COVID-19) for follow-up everyday member who contacted an infected member. During a week the staff had tested negative and was allowed to work.

##### Feedback 1 Office staff

If a family member had tested positive for coronavirus (COVID-19), staff could take home LifePad and perform a follow-up at home. This can prevent cluster occurrence at the office by confirming negative results after staying at home.

##### Feedback 2 Office staff

LifePad was delivered to the staff who had a fever and was staying at home for follow-up. If test results were negative, he could stay at home for follow-up and if results were positive could visit a medical facility for testing.

##### Feedback 3 Office staff

Testing at the office helps prevent clusters of the asymptomatic case by isolating immediately the asymptomatic person.



## 5. About future development

### 5.1 Using LifePad in each field

#### (1) Medical field

- For medical staff:  
Regular screening tests, tests before starting to work, tests when a person has symptoms including fever, cough
- Home-visit tests
- For in-patients: screening tests, tests before discharge, preoperative tests
- For out-patients: screening tests, symptomatic persons who visited the clinic for the test
- Tests at medical facilities where clusters occurred

#### (2) Social welfare facilities field

- For staff: screening tests, tests before starting to work, tests when a person has symptoms including fever, cough
- For users staying at nursing homes: screening tests, tests for symptomatic persons, before the visit to the family at the hospital
- For day service users: screening tests
- For visitors: tests before the visit

- Tests at nursing homes where cluster occurred

### (3) Sports field

- For athletes, staff, crew, visitors: negative confirmation at opening matches
- For athletes, staff: tests before and after the tour in Japan and out of Japan, pretraining negative confirmation, tests at athlete camps, screening tests

### (4) Office workers' field

- For staff: tests for symptomatic persons, tests before and after the business trip in Japan and out of Japan, negative confirmation tests before and after meetings and dinner, tests before starting to work, tests in case of close contact, tests before coming back home after posted away from the family, screening tests
- For visitors: tests before the visit

## 5.2 About customer support

To support our customers we performed as below. We are going to make content full and frequent.

- ① Open a customer support center in the office
- ② Open Web site only for LifePad customers
- ③ Open master class educational programs of LifePad
- ④ ZOOM Meeting: teaching how to use



### **【Attention】**

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