

lakameda+	Product Specification Document	Document No:	PSD-01
	C19 PASSPORT	Version:	01
		Effective Date:	2020-05-20
		Page No.	1/4

1. Purpose and scope

- 1.1 This document describes the C19 PASSPORT system generally and should be used together with other user instructions and descriptions.

2. Description

- 2.1 C19 PASSPORT system is designed for safe registration of test results related to COVID-19 for the use of the individual. The system creates a possibility for the customers to allow authorized institutions to register their test results or vaccination as well as a tool to track any national recommendations according to the individual test results.
- 2.2 The C19 PASSPORT broadens the perspective for persons tested and registered since it's a trustworthy tool to prove the result. If the National authorities recognize the system and consider, the test result may allow free travel, socialize, and work, without meaningfully increasing the risk for the population that hasn't contracted the virus. Also, since a lot of clinical trials based information, as well as government restrictions, are changing rapidly, the test results, which are considered not reliable now, could be valuable in the future- this can be followed by the individual online.

3. Summary

- 3.1 Every customer who is tested for the COVID-19 virus, antibody test, or had a vaccination, by the authorized institution can request that their results be registered on the C19 PASSPORT. The authorized institution registers the test results of the client at a secured website and issues the C19 safecard containing unique code and a safety institutional label. The client can check the test results and any recommendations on C19Safecard.com by entering the security codes and the personal ID number.

4. Registration of institutions

- 4.1 The permission and access to register test results can be provided to the authorized institutions that meet mentioned above requirements:
 - 4.1.1 Public or private health institutions, which is accredited at the national level as a medical laboratory.
 - 4.1.2 Public or private health institutions licensed as personal health care institutions.
- 4.2 The authorized institution which wants to provide a C19 PASSPORT service should apply for access to the system by registering the institution at the C19Safecard.com website.
- 4.3 During registration, the institution shall provide contact details. Then Lakameda will send a special application form, which needs to be filled and submitted.
- 4.4 Lakameda has internal procedures for control provided information against public records and other control steps. If the institution meets all the requirements, then the agreement will be sent out to the institution and the institution will be included in the C19 Passport authorized institution list.

5. Authorization of distribution

- 5.1 The permission to sell and/or distribute C19 safecard can be provided to the pharmacies.
- 5.2 Pharmacy chains that want to sell and/or distribute the C19 safecard should apply as a distributor of the system by registering the pharmacy at the C19Safecard.com website.
- 5.3 During registration, the pharmacy shall provide contact details. Then Lakameda will send a special application form, which needs to be filled and submitted.
- 5.4 Lakameda has internal procedures for control provided information against public records and other control steps. If the pharmacy meets all the requirements, then the agreement will be sent out to the pharmacy and the institution will be included in the C19 safecard distributor list.

lakameda+	Product Specification Document	Document No:	PSD-01
	C19 PASSPORT	Version:	01
		Effective Date:	2020-05-20
		Page No.	2/4

6. C19 Safecard, institutional label, and code

5.1 To be able to provide a C19 PASSPORT service, the institution should receive a special institutional label including a traced unique code and access to the C19 Safecard website. The pharmacy may send pre-order and sell the C19 Safecard directly to the customer. Lakameda is responsible to issue the C19 safecard, special institutional label as well as access to the C19 Safecard website.

5.2 C19 safecard

The C19 safecard is produced from approved, stable and safe material: Invercote G 300gsm carton paper, and specially designed by Lakameda. Every card contains an integrated unique security code. The Card code is traced in the database and not valid without the special institutional label attached by the authorized institution.

5.3 Institutional label

The Institutional label material meets the same specification as a pharma anti-tamper label. Every institutional label contains a unique code issued by a special, safe, and approved program. The institutional label is one of the keys to label validation. The authorized institution placed that label on the card after registration of test results on the C19Safecard.com.

Note: Due to safety issues, the Institutional label is sent to the authorized institution only to approved address a with attention to the named contact person.

5.4 C19Safecard.com

5.4.1 Access control

5.4.1.1 The C19Safecard.com website is created by Lakameda UAB. The Lakameda has the right to change the design of the website. Lakameda has access to control the list of test types and brands in the system. All test types, brands listed in the system are analyzed and grouped according to manufacturer specification and internal procedure.

5.4.1.2 Lakameda has the access control for issuing the rights for authorized institutions to register the COVID-19 test results.

5.4.1.3 If the institution meets all the requirements the Lakameda issue the access by registering the authorized institution in the system (see section 4).

5.4.1.4 Lakameda has access to connect national recommendations to test types.

5.4.2 Personal data access

5.4.2.1 Access to personal data is secured directly at the submission of data. Neither Lakameda, neither authorized institution can access the personal details or manage/change the test result or other personal information. The person who is registered at the system can access only by itself to the personal information about test results, check the information, or delete the results. To sign in to personal account, the security code from safecard and personal ID details shall be entered.

5.4.2.2 The system is designed in the way, that no personal information data is archived in the system. The personal ID number at the time of submission will be hashed to human not readable code, e.g. \$2b\$12\$94JnpRlueBNtMy/vu5AOIObg5VnlAp7RAg1YStK1nU9UYycOHMpSm.
All other data like test results are encrypted to human not readable code, e.g. \$2b\$12\$94JnpRlueBNtMy/vu5AOIObg5VnlAp7RAg1YStK1nU9UYycOHMpSm.

lakameda+	Product Specification Document	Document No:	PSD-01
	C19 PASSPORT	Version:	01
		Effective Date:	2020-05-20
		Page No.	3/4

5.4.3 Sign in

5.4.3.1 Personal sign in

To sign in to personal account, the security code from safecard and personal ID number shall be entered. During the first login to the C19Safecard.com website, the system asks for the customer to confirm the consent of the data storage.

5.4.3.2 The authorized institution

To sign in to the institution account, the institution ID No. and Master code number shall be entered.

5.4.4 Test types and Brands

The test types are listed into three groups in the system according to the the specificity:

- a) Quantified antibody test
- b) Antibody test
- c) COVID-19 test (Sensitivity included)

Vaccination assign in to separate category

All the tests and vaccination brands will be categorized according to the sensitivity and specificity by manufacturer specifications, to be able to provide the test reliability according to changing clinical trials results and government recommendations.

With any knowledge of significant difference between manufacturer specification and verified objective testresult the test specification may be: changed to verified specification or excluded as a test. Lakameda have a procedure to handle and hold public these changes and exlutions for all stakeholders.

Status in different countries

The customer will be able to check their national status, based on the test results, in different countries if recommendations are available. According to the type of the test, test or vaccination brand, and the test result, the system provides government recommendation status for the individual client. The government regulations and recommendations will be updated, keep the customer in date with the newest information when going online for a result.

7. Data registration

- 6.1 The authorized institution shall enter the card security code, institutional label security code, and personal ID number to be able to register person test results. Then authorized institutions shall pick from the test lists, which type of test was made, and shall mark the test result in the special field. If vaccination is done, the vaccine brand shall be selected from the list. The test/vaccination date shall also be stated by the authorized institution. When details are filled in, the registration is submitted.

8. Activation of the card

- 7.1 The authorized institution which provides a C19 PASSPORT service shall inform the customers about the possibility to register the test results. After registration of COVID-19 test results the authorized institution issuing the COVID-19 safecard to the customer. The card is not valid until the authorized institution marks the card with a special institutional label containing a unique ID code.

9. Availability

- 9.1 **Users. C19 safecard** is available to buy at the pharmacy or authorized institution providing C19 PASSPORT service.

lakameda+	Product Specification Document	Document No:	PSD-01
	C19 PASSPORT	Version:	01
		Effective Date:	2020-05-20
		Page No.	4/4

Note: The card is not valid until the authorized institution marks the card with a special institutional label containing a unique ID code.

The test registration at C19Safecard.com is available at the authorized institution providing C19 PASSPORT service.

- 9.2 **The authorized institution.** To register the authorized institution for C19 PASSPORT service available at the C19Safecard.com website.

10. **Contact address**

Lakameda JSC

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