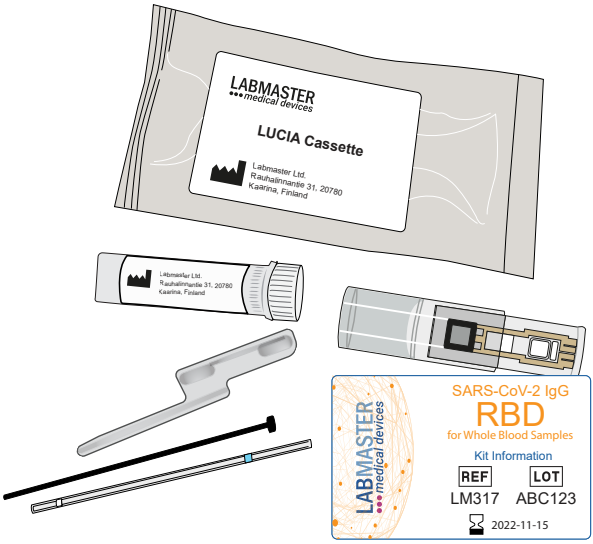
LABMASTER LUCIA

Instructions for Use

Labmaster LUCIA™ SARS-CoV-2 RBD Kit for Whole Blood Samples



LABMASTER
medical devices

Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit for Whole Blood Samples

Product Number: LM317

1. Intended Use

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD test is meant for in vitro diagnostic qualitative detection of the presence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Receptor Binding Domain IgG antibodies from whole blood samples in near-patient testing by measuring the immunochemical interaction between the Anti-SARS-CoV-2 immunoglobulin G (IgG) and the SARS-CoV-2 Receptor Binding Domain (RBD).

Current SARS-CoV-2 mRNA vaccines, such as Comirnaty (Pfizer-BioNTech) (i) and Moderna (ii) are based on SARS-CoV-2 spike protein vector, which contains RBD subunit. Thus, vaccines trigger the immune system to produce antibodies against SARS-CoV-2 RBD. Antibodies against SARS-CoV-2 RBD are also formed as a result of native SARS-CoV-2 infection.

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD test is designed for measuring immune response related to mRNA-based vaccinations or recovery from COVID-19 disease. The SARS-CoV-2 IgG RBD test should not be used to diagnose or exclude acute SARS-CoV-2 infection or as the sole basis for patient management decisions.

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD test Kit is to be used with semi-automated Labmaster LUCIA™ Analyzer by healthcare professionals.

2. Clinical Significance and Summary of the Test

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD is a serological test used to detect the presence of IgG antibodies against RBD of the Spike protein of SARS-CoV-2 in whole blood samples. The presence of antibodies against a SARS-CoV-2 pathogen (RBD-protein) in blood indicates an adaptive immune response to SARS-CoV-2 due to recent or prior infection, or vaccination. After exposure to pathogen, the anti-RBD IgG levels start gradually rising to reach their maximum levels within the period of 3-4 weeks (iii). As a result of vaccination, the antibodies can be detected from one week after first dose of vaccination and start to decrease after 25 days (iv).

Unit	Sample Volume	Sample Type	Measuring Time
U	7 µL	Whole blood	6 minutes

3. Principle and Procedure

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD test is based on the formation of immunochemical complex between SARS-CoV-2 RBD and anti-SARS-CoV-2 IgGs. The anti-SARS-CoV-2 IgGs from the sample bind to the SARS-CoV-2 RBD solid phase on the silicon chip on the LUCIA Cassette. The bound IgGs are stained using lanthanide-labeled secondary antibodies.

After the reaction, the unbound excess of the labeled antibodies is separated with automated washing step. The formed antibody-antigen complex is excited with electricity. Resulting electrochemiluminescence is measured. The on-board microprocessor calculates the presence of the analyte in the sample based on a pre-programmed calibration. The calculated result is displayed on the screen of the Labmaster LUCIA™ Analyzer.

4. Kit Components

Contents of the Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit for Whole Blood Samples

Component Name	Product number LM317 (40 SARS-CoV-2 IgG RBD tests)
SARS-CoV-2 IgG RBD Cassette*	40 pcs
SARS-CoV-2 IgG RBD Dilution Tube for Whole Blood sample**	0.84 mL x 40 pcs
Li-Heparin coated capillaries (7 µL)	50 pcs
Plungers for capillaries	50 pcs
Transfer Pipette	40 pcs
RBD Instructions for Use and Quick Guide (see centrefold)	1 pc
SARS-CoV-2 IgG RBD NFC Card	1 pc

** Contains Tween, sodium borate, sodium azide, bovine serum albumin, bovine gamma globulin*

*** Contains sodium azide*

Materials Required but Not Provided with the Kit

Component Name	Product Number
Labmaster LUCIA™ Analyzer	LM26
Labmaster LUCIA™ Analyzer Instructions for Use	LM28
Lancets for fingertip blood sample	N/A

Storage

Store the Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit at +2 – +8°C.

Description of the Labmaster LUCIA™ SARS-CoV-2 IgG RBD Cassette

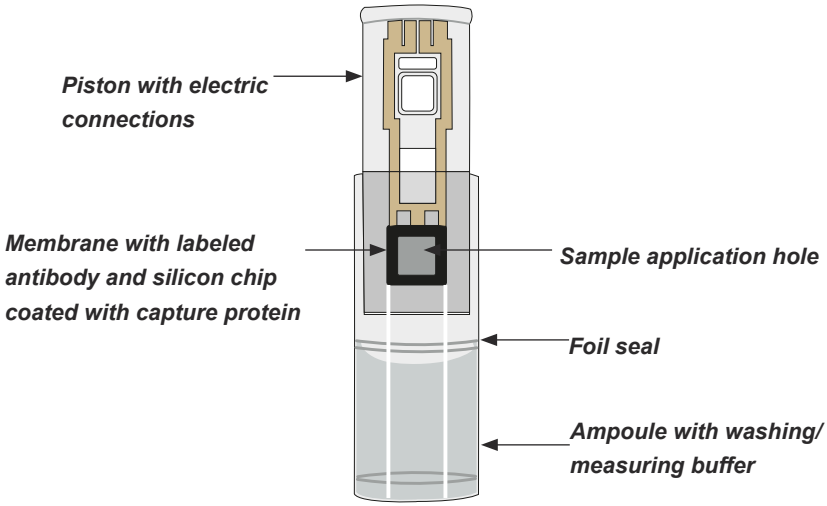


Figure 1. The Labmaster LUCIA™ SARS-CoV-2 IgG RBD Cassette

5. Warnings and Precautions

Health and Safety Information

- For *in vitro* diagnostic use only.
- The kit should only be used by adequately trained personnel, e.g., healthcare professional with formal education in a relevant healthcare or medical field.
- Wear protective clothing and single use laboratory gloves when handling the samples or performing the test. Wash hands properly after performing the test.
- Avoid contact of liquids with eyes and skin. If exposed, rinse immediately with plenty of water.
- All patient samples and controls should be handled as potentially infectious material.
- Liquid reagents contain < 0.1 % sodium azide, which is not considered a harmful amount.
- Washing/measuring buffer contains < 2 % borate, which is not considered a harmful amount.
- Cassette packaging contains a desiccant. This material shall not be used in the assay. Discard the desiccant.
- Disposal: See section 13.

Analytical Precautions

- The Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit must be used only with the Labmaster LUCIA™ Analyzer.
- Do not use kit components after the expiry date printed on the kit label.
- Do not mix components with other kit batches.
- The NFC Card is batch specific and should be used only for the Labmaster LUCIA™ SARS-CoV-2 IgG RBD tests from the same kit batch. If the NFC Card is lost, a new card can be requested at support@labmaster.fi.
- Cassettes, dilution tubes, capillaries, plungers and transfer pipettes are for single use. Do not use already used cassettes, dilution tubes, capillaries, plungers or transfer pipettes.
- The Labmaster LUCIA™ SARS-CoV-2 IgG RBD Cassette should not be used if the cassette pouch is damaged or broken, if the foil seal in a cassette ampoule is broken and washing/measuring buffer has leaked from ampoule, or if there is crystal formation on the cassette. Please see section 16.
- Check that there are no air bubbles or foam in the cassette ampoule before use. If there are air bubbles, try to remove the bubbles by turning the cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette.
- Use the cassette immediately after cassette pouch has been opened.
- The measurement result is unreliable, if there is a large air bubble which covers the whole surface of the silicon chip of the cassette or if the chip is covered by the foil seal after the measurement.
- Do not use components of the Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit if they have not been stored as instructed in this kit insert.
- Avoid contaminating the Labmaster LUCIA™ Analyzer.
- Heterophilic interference may cause erroneous result. Do not use the Labmaster LUCIA™ SARS-CoV-2 IgG RBD test if presence of heterophilic antibodies in the sample is suspected.
- There is a possibility that other substances and/or factors may interfere with the test and cause erroneous results (e.g. technical or procedural errors).

6. Sample Material and Collection

Sample Material	Sample Volume	Sample Collection
Fingertip sample (whole blood)	7 µL	Prick a clean and dry fingertip with a lancet and wipe away the first drop of blood. Aspirate the sample using a capillary, see section 7, Sample Dilution. The collected fingertip whole blood sample must be used immediately.
Anticoagulated whole blood	7 µL	Use venous blood sample collected in a tube containing Li-heparin. Mix whole blood by inverting the tube several times. Collect the sample using a capillary, see section 7, Sample Dilution. The collected whole blood sample must be used immediately.

7. Procedure

NOTE: Immediately use the kit components taken to room temperature.

NOTE: Each Labmaster LUCIA™ SARS-CoV-2 IgG RBD Kit contains one batch specific NFC Card, which is used for all the tests in one kit. **Before measurement, ensure that NFC Card batch information corresponds to Labmaster LUCIA™ SARS-CoV-2 IgG RBD Cassette and SARS-CoV-2 IgG RBD Dilution Tube batch codes.**

Sample Dilution

- Place the plunger inside the capillary tube from the end marked with the colour blue.

- Fill the capillary with the sample up to the white stopper (see quick guide, step 1). Ensure that there are no air bubbles in the capillary.
- Place the capillary with sample into the SARS-CoV-2 IgG RBD Dilution Tube (see quick guide, step 2).
- Dispense the sample into the buffer by pressing the plunger all the way down. Make sure that the capillary is completely empty.
- Close the cap and mix the diluted sample by inverting the sample tube at least 5 times upside down. Do not shake the sample tube.
- The sample is now ready to be measured.
- The diluted sample must be measured immediately after preparation.

Measurement

- Open the pouch containing the Labmaster LUCIA™ SARS-CoV-2 IgG RBD Cassette and check that there are no air bubbles or foam in the cassette ampoule before sample application. If there are air bubbles, try to remove the bubbles by turning the cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette. After the cassette ampoule has been checked and there are not small air bubbles or foam, use it immediately.
- Select the Patient sample measurement icon on LUCIA Analyzer's display, enter patient ID and read the NFC Card as instructed in Labmaster LUCIA™ Instructions for Use (see quick guide, step 3).
- Slide the cassette on the tray of the analyzer from the right side of the tray (see quick guide, step 4). Note that the diluted sample has to be dispensed into the cassette during the 1-minute sample application time after the NFC Card has been read.
- Fill the Transfer Pipette with the diluted sample as follows: squeeze the top bulb and dip the tip of the Transfer Pipette into the diluted sample. Release the bulb so that the pipette can draw the sample in (see quick guide, step 5).
- Squeeze the top bulb to dispense one drop of the sample to the cassette without touching the membrane. Release the pressure entirely from the top bulb, do not draw the dispensed sample into the Transfer Pipette. Touch the membrane with the tip of

the pipette (see quick guide, step 6). Hold the Transfer Pipette against the membrane until the sample has spread on the entire membrane.

Scan the QR code to access the Thermo Scientific Volume Transfer Pipettes - instructional Youtube video[1]

- Start the measurement by selecting the Accept icon on the display (see quick guide, step 7). The measurement time is 6 minutes.
- When the measurement has been completed, the result will be shown on the analyzer's display and the cassette will come out of the analyzer (see quick guide, step 8).
- If silicon chip of the cassette is covered by large air bubble, membrane or by foil, do not use the result.
- Dispose of the cassette immediately after use.
- Place the NFC Card back into the kit box.

See the Labmaster LUCIA™ Analyzer's Instructions for Use for more detailed measurement instructions.

8. Quality Control

Both the Labmaster LUCIA™ Analyzer and Labmaster LUCIA™ SARS-CoV-2 IgG RBD test are factory calibrated. It is recommended to use commercial SARS-CoV-2 IgG controls for quality assurance. This kit is meant for whole blood samples. Dilution tubes and instructions for handling serum and plasma-based controls are available at Labmaster separately. The user sets the acceptance limit values for the controls.

9. Interpretation of Results

When interpreting the Labmaster LUCIA™ SARS-CoV-2 IgG RBD test results, take into consideration the patient's medical history, clinical examinations and other laboratory results.

Result	Interpretation
< 1.000 U	Negative for SARS-CoV-2 IgG RBD antibodies
≥ 1.000 U	Positive for SARS-CoV-2 IgG RBD antibodies

1 For more detailed instructions, see www.thermofisher.com/samco or the instructional video on Youtube (Thermo Scientific Samco Exact Volume Transfer Pipettes on Youtube). Labmaster Ltd accepts no liability or responsibility to any person as a consequence of any reliance upon the information contained on this website. Labmaster Ltd gives no assurance or warranty that information on this website is current, and takes no responsibility for matters arising from changed circumstances or other information or material which may affect the accuracy or currency of information on this website.

LABMASTER LUCIA

A Point-of-care platform based on patented CECL technology

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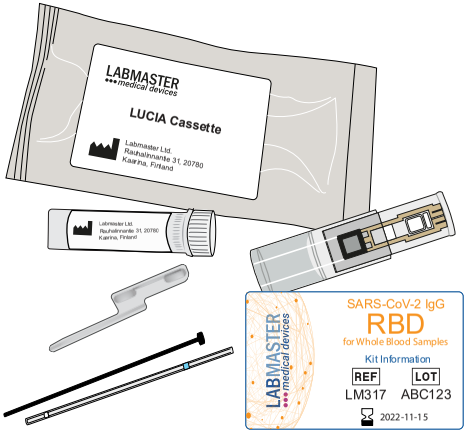
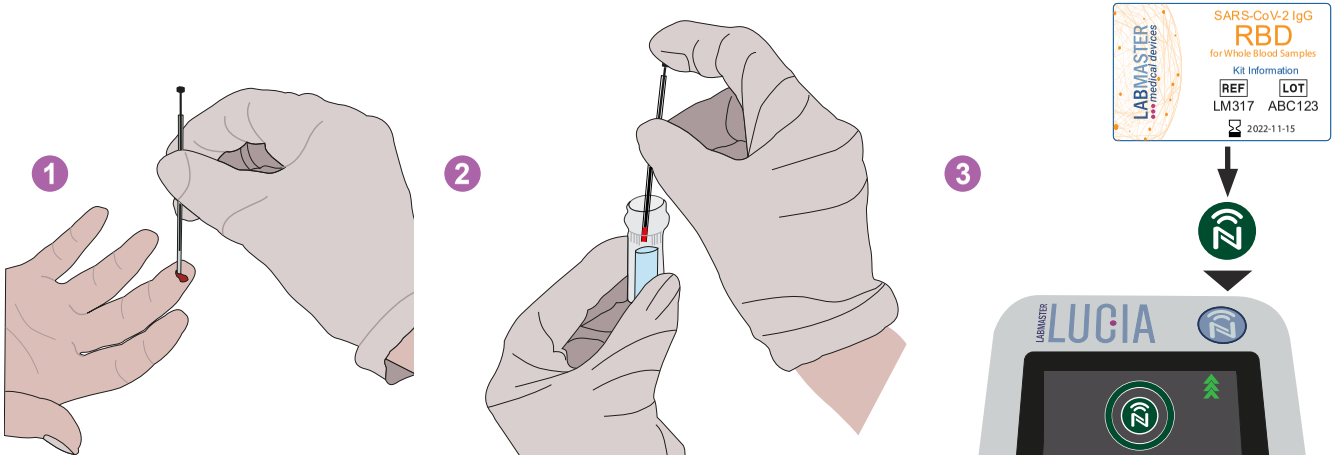
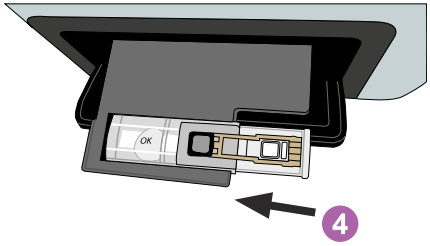
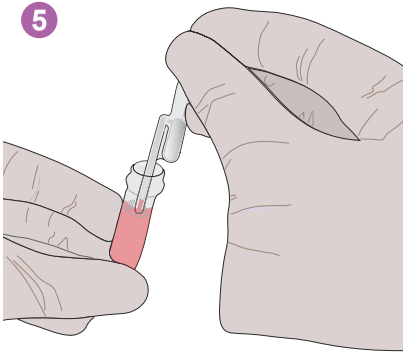
Labmaster LUCIA™ Analyzer

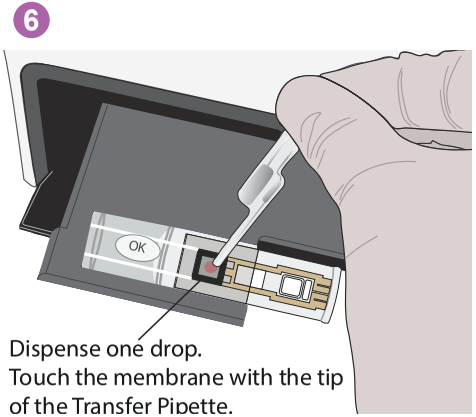


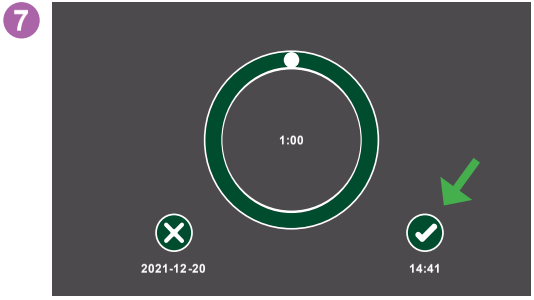
Labmaster LUCIA™ RBD Kit for Whole Blood Samples. Contents: 40 cassettes, 40 tubes, 50 capillaries, 50 Plungers, 40 Transfer Pipettes, 1 NFC Card

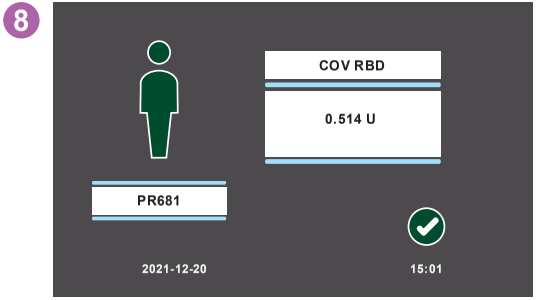












10. Limitations of the Procedure

Follow the sample collection, dilution and assay procedures specified in these instructions, otherwise the results might not be reliable. The result is only for clinical reference and should never be the sole basis for making a diagnosis. A clinical decision is always required.

The SARS-CoV-2 IgG RBD test kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection or vaccination.

The test is intended for people who have been vaccinated with SARS-CoV-2 spike vector-based vaccines. The secondary testing population of the test is for people who have recovered from suspected or confirmed SARS-CoV-2 infection or may have previously developed an asymptomatic infection. The antibodies can be detected from one week after first dose of vaccination and start to decrease after 25 days (iv).

The test is intended for the detection of antibodies against the infectious agent. The test is not intended for determination of the infective disease status: it does not provide information on the state, condition or evolution of COVID-19 disease. The test is not intended for diagnose acute infection nor the determination of distinct phases or periods in the course of a disease, or the level of severity of a disease.

The test is not intended for monitoring of levels of medicinal products, substances or biological components. The test does not provide an important, critical, or sole determinant for the correct patient management decision as treatments/interventions.

Heterophilic interference may cause erroneous result. Do not use the Labmaster LUCIA™ SARS-CoV-2 IgG RBD test if presence of heterophilic antibodies in the sample is suspected. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference potentially causing anomalous results (v).

11. Performance Characteristics

Clinical Performance

Clinical performance was evaluated with 61 lithium-heparin whole blood samples measured with the Labmaster LUCIA™ SARS-CoV-2 IgG RBD test and comparative method in-house SARS-CoV-2 N and S1 based EIA at the University of Turku (xi).

Seronegative samples (n)	22	Negative agreement	100%
Seropositive samples (n)	39	Positive agreement	93%
Total (n)	61	Overall agreement	95%

Precision

The precision of the SARS-CoV-2 IgG RBD test was determined applying the CLSI guidelines EP12-A2 (vi) EP05-A3 (vii). Two whole blood sample levels (Low <1.000 U and High ≥1.000 U) were measured as 5 replicates, 3 times (runs) a day, during 1 day, using 3 different Labmaster LUCIA™ Analyzers and 3 cassette lots (total n=45/sample).

Sample	Mean result (U)	Repeatability		Between-Run		Between-Analyzer/ Cassette Lot		Within-Laboratory	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%
Low	0.8	0.13	16	0.03	4	0.02	3	0.13	17
High	5.0	0.57	11	0.26	5	1.31	26	1.45	29

Cross-reactivity

Analytical specificity of SARS-CoV-2 IgG RBD test was determined by testing 5 serum/plasma patient samples, each containing multiple potentially cross-reacting IgGs. Each of the 5 samples was measured as 6 replicates. The analytical specificity claim is that there is no significant cross-reactivity from the 16 substances listed.

Containing IgG towards	N	Negative	Positive
Human coronavirus HKU1	6	5	1
Human coronavirus OC43	6	5	1
Human coronavirus 229E	6	5	1
Human coronavirus NL63	6	5	1
Haemophilus influenzae	18	16	2
Respiratory syncytial virus (RSV)	24	22	2
Influenza A	6	6	0
Influenza B	6	5	1
Parainfluenza 1-4	24	22	2
Adenovirus	6	5	1
Enterovirus	6	5	1
Mycoplasma pneumoniae	18	16	2
Legionella	6	6	0
Chlamydia pneumoniae	6	6	0
Epstein–Barr virus	6	5	1
Bordetella pertussis	6	5	1
Total	156	139	17

Interfering Substances

Interference was evaluated in alignment with CLSI guideline EP07-A3 (viii), CLSI EP37 (ix) and the 'Current performance of COVID-19 methods and devices and proposed performance criteria – Working document of Commission services' (x). Potentially interfering substances (added concentration of tested substance in column Claim) were tested in lithium heparin blood with one analyte level (approx. 4 U). All test concentrations are in addition to endogenous level in blood.

Substance	Claim
Haemoglobin	No interference found up to 10 g/L
Triglycerides	No interference found up to 15 g/L
Bilirubin, conjugated	No interference found up to 400 mg/L
Bilirubin, unconjugated	No interference found up to 400 mg/L
IgG	No interference up to 19 g/L.
Acetylsalicylic acid	No interference found up to 30 mg/L
Ibuprofen	No interference found up to 219 mg/L

12. Traceability

The Labmaster LUCIA™ SARS-CoV-2 IgG RBD test is traceable to WHO 20/136 1st International Standard Anti-SARS-CoV-2 Immunoglobulin (human).

13. Disposal

All patient samples and materials shall be disposed of according to local laws and regulations. All samples, used cassettes, capillaries, plungers, transfer pipettes and dilution tubes shall be disposed of as biological, potentially infectious materials. Paper, carton and pouches can be recycled according local and national instructions. Desiccants and the NFC card can be disposed of in general waste. This product will not cause any health risk if used in accordance with the Instructions for Use.

14. Notice on Reporting Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

15. Warranty

The performance data presented here was obtained using the assay procedure indicated. Any change or modification of the procedure not recommended by Labmaster Ltd. may affect the results. In which event it disclaims all warranties expressed, implied or statutory including the implied warranty of merchantability and fitness for use and shall not be liable for damages indirect or consequential.

16. Troubleshooting

For Analyzer-related questions see Labmaster LUCIA™ Analyzer (LM26) Instructions for Use (LM28).

Indication	Probable Causes	Corrective Action
• Washing/measuring buffer has leaked from ampoule or there is crystal formation on the cassette.	• Foil seal in the cassette ampoule has broken.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Washing/measuring buffer has foamed.	• Cassette has been handled heavy-handedly or cassette has been dropped.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Sample does not go through the membrane.	• Kit has not been stored at the instructed storage conditions or the cassette pouch has broken. • Cassette has been taken out of the pouch too early.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Liquid residue on the tray.	• Washing/measuring buffer has leaked from ampoule.	• Blot the liquid into soft paper or cloth. • If the problem reoccurs, contact support@labmaster.fi.
• Rejected measurement.	• Air bubble or foil seal on top of silicon chip during measurement. • Air bubbles or foam in washing/measuring buffer.	• Repeat the measurement using a new cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Grinding sound during tray movement.	• Mechanical malfunction. • Cassette is placed on the tray incorrectly.	• Restart the analyzer. • Repeat the measurement using a new cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Foil seal covers the silicon chip after measurement.	• Defective cassette.	• Measurement result is unreliable, do not use the result. • Repeat the measurement using a new cassette. • If the problem reoccurs, contact support@labmaster.fi.

17. References

i. WHO, World Health Organization, 2020. Transmission of SARS-CoV-2. https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions.
ii. WHO, World Health Organization, 2021. COVID-19 vaccines. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines.
iii. Peng Z, Xing-Lou Y, Xian-Guang W et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature 579:270-273 (2020).
iv. Pang, N.YL., Pang, A.SR., Chow, V.T. et al., 2021. Understanding neutralising antibodies against SARS-CoV-2 and their implications in clinical practice. Military Medical Research 8:47 (2021). https://mmrjournal.biomedcentral.com/articles/10.1186/s40779-021-00342-3.
v. Clinical and Laboratory Standards Institute (CLSI) guideline I/LA30-A.
vi. Clinical and Laboratory Standards Institute (CLSI) guideline EP12-A2.
vii. Clinical and Laboratory Standards Institute (CLSI) guideline EP05-A3.
viii. Clinical and Laboratory Standards Institute (CLSI) guideline EP07-A3.
ix. Clinical and Laboratory Standards Institute (CLSI) guideline EP37.
x. Current performance of COVID-19 test methods and devices and proposed performance criteria – Working document of Commission services.
xi. Jalkanen, P., Kolehmainen, P., Häkkinen, H.K. et al. COVID-19 mRNA vaccine induced antibody responses against three SARS-CoV-2 variants. Nat Commun 12, 3991 (2021).

18. Explanation of Symbols

Symbol	Description
	The CE marking Conformity to the European directive 98/79/EC on in vitro diagnostic medical devices
	Manufacturer
	Use by date (YYYY-MM-DD)
	Temperature limit
	Do not reuse
	Consult Instructions for Use
	Catalog number
	Batch code
	In vitro Diagnostic medical device
	Contents sufficient for <n> tests
	Caution

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CE
IVD