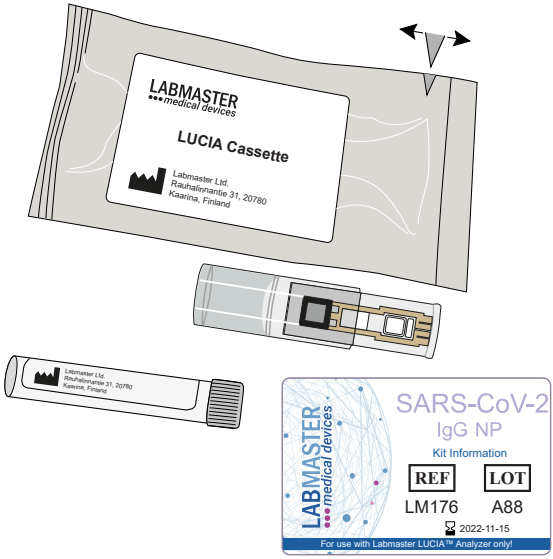
LABMASTER LUCIA

# Instructions for Use

## Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit for Serum/Plasma Samples




LABMASTER
medical devices

# Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit For Serum/Plasma Samples

Product code: LM194

## 1. Intended Use

The Labmaster LUCIA™ SARS-CoV-2 IgG NP test is meant for *in vitro* diagnostic qualitative detection of the presence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nucleocapsid Protein (NP) recognizing immunoglobulin G (IgG) antibodies from serum or plasma samples by measuring the immunochemical interaction between the anti-SARS-CoV-2 NP IgGs and the SARS-CoV-2 NP.

The SARS-CoV-2 IgG NP test kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. Antibody responses to SARS-CoV-2 can be detected in most infected individuals 10–15 d after the onset of COVID-19 symptoms (i). The SARS-CoV-2 IgG NP test should not be used to diagnose or exclude acute SARS-CoV-2 infection, for measuring immune response related to mRNA-based vaccinations or as the sole basis for patient management decisions.

The Labmaster LUCIA SARS-CoV-2 IgG NP 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 immunoglobulin (IgG) Nucleocapsid Protein (NP) serological test” is used to identify the presence of IgG antibodies against the N-protein of SARS-CoV-2 in human serum and plasma samples. The presence of antibodies against SARS-CoV-2 pathogen (N-protein) in blood indicates adaptive immune response to recent or prior infection. Antibody responses to SARS-CoV-2 can be detected in most individuals 10-15 days after the onset of COVID-19 symptoms (i).

The Labmaster LUCIA™ SARS-CoV-2 IgG NP serological test operates with the parameters shown in the table below:

| Unit | Sample Volume | Sample Type | Measuring Time |
|---|---|---|---|
| U | 7 µL | Human serum/plasma | 6 minutes |

## 3. Principle and Procedure

The Labmaster LUCIA™ SARS-CoV-2 IgG NP test is based on the formation of immunochemical complex between SARS-CoV-2 Nucleocapsid protein and anti-SARS-CoV-2 IgGs. The anti-SARS-CoV-2 IgGs from the sample bind to the SARS-CoV-2 NP solid phase on the silicon chip on the LUCIA Cassette. The bound IgGs are stained using Terbium labelled secondary antibodies. After the initial reaction is complete, the unbound excess of the labelled antibodies is separated with automatic washing step. The stained antibody-antigen complex is excited with electricity and the 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. Reagents

***Contents of the Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit for Serum/Plasma Samples***

| Component Name | Product number LM194 (40 SARS-CoV-2 IgG NP tests) |
|---|---|
| Labmaster LUCIA™ SARS-CoV-2 IgG NP Cassette<br>*Contains Tween, sodium borate, sodium azide, bovine serum albumin, bovine gamma globulin* | 40 pcs |
| Labmaster LUCIA™ SARS-CoV-2 IgG NP Dilution Tube for Serum/ Plasma samples<br>*Contains Tween, bovine serum albumin, bovine gamma globulin, sodium azide* | 1.4 mL x 40 pcs |
| NFC Card | 1 pc |

***Materials Required but Not Provided with the Kit***

| Product Name | Product Number |
|---|---|
| Labmaster LUCIA™ Analyzer | LM26 |
| Labmaster LUCIA™ Analyzer Instructions for Use | LM28 |
| Pipette for 7 µL sample transfer and pipette tips | N/A |

***Storage***

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

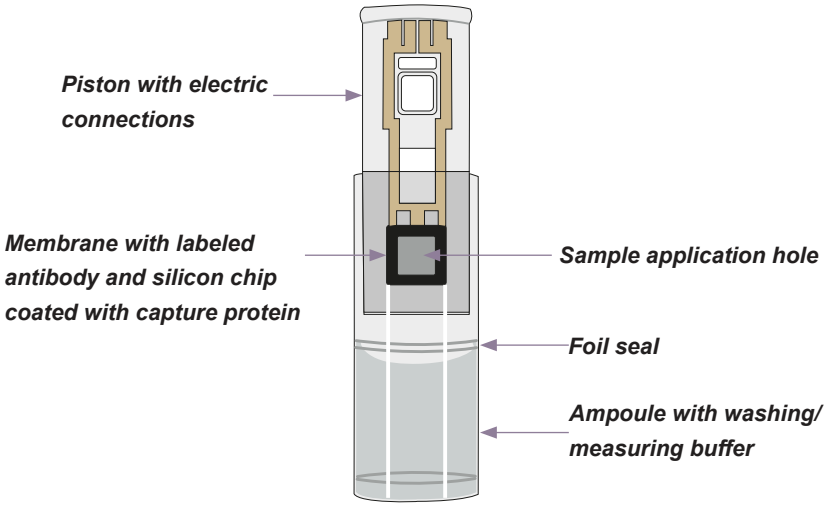



*Figure 1. The Labmaster LUCIA™ SARS-CoV-2 IgG NP Cassette*

## 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 eyes and skin coming into contact with the sample. 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.
- 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 NP Kit must be used only with the master 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 NP tests from the same kit batch. If the NFC Card is lost, a new card can be requested at support@labmaster.fi.
- Cassettes and dilution tubes are for single use. Do not use already used cassettes and dilution tubes.
- The Labmaster LUCIA™ SARS-CoV-2 IgG NP 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 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.
- Use the cassette immediately after cassette pouch has been opened.
- After the measurement, 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, the measurement is unreliable.
- Do not use components of the Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit if they have not been stored as instructed in this kit insert.
- Avoid contaminating the Labmaster LUCIA™ Analyzer.
- 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 Collection |
|---|---|
| Human serum | Venous whole blood is collected into appropriate tube (without anticoagulants) according to user's standardized procedure. Serum samples can be spun after 30-60 minutes of clotting at room temperature. |
| Human plasma | Plasma sample is obtained by separating red blood cells from venous whole blood sample, which is collected into K3EDTA containing tube according to user's standardized procedure. Plasma samples can be spun immediately upon collection. |

** It is not recommended to keep serum/plasma samples at room temperature for longer than 8 hours. Serum/plasma samples can be kept refrigerated (2 to 8 °C) for up to 48 hours. If samples cannot be tested in this timeframe, the samples should be stored frozen (at or below –20°C).(iii)*

## 7. Procedure

**NOTE:** Immediately use the kit compoenents taken to room temperature.

**NOTE:** Each Labmaster LUCIA™ SARS-CoV-2 IgG NP 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 NP Cassette and SARS-CoV-2 IgG NP Dilution Tube batch codes.**

***Sample Dilution***

- Pipette 7 µL of sample into a SARS-CoV-2 IgG NP Serum/Plasma Dilution Tube.
- Close the cap and mix the diluted sample by gently inverting the sample tube at least 5 times upside down. Do not shake the sample tube.
- The sample is now ready to be added to the Labmaster LUCIA™ SARS-CoV-2 IgG NP Cassette.
- The diluted sample must be measured immediately.

***Measurement***

- Open the pouch containing the Labmaster LUCIA™ SARS-CoV-2 IgG NP Cassette and check that there are not 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 Patient sample measurement icon on LUCIA Analyzer's display, enter patient ID and read the NFC Card of the Cassette as instructed in Labmaster LUCIA™ Instructions for Use.

- Read the NFC card as instructed in the Labmaster LUCIA™ Analyzer's Instructions for Use.
- Slide the Cassette on the tray of the Analyzer from the right side of the tray. 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.
- Add the 7 µL of diluted sample to the Cassette by using a fresh pipette tip. Place the tip against the membrane in the sample application hole of the Cassette and dispense the sample. Hold the tip against the membrane until it has spread on the entire membrane.
- Start the measurement by selecting the Accept icon on the display. The total measurement time is 6 minutes.
- When the measurement has been completed, the results will be shown on the analyzer display and the Cassette will come out of the Analyzer.
- Check that the whole silicon chip is not covered by air bubble, membrane or by the foil.
- 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 LUCIA™ SARS-CoV-2 IgG NP Test are factory calibrated. It is recommended to use commercial SARS-CoV-2 IgG controls for quality assurance. This kit is meant for serum and plasma samples.

Commercial controls should be handled according to the instructions in section 7 together with the Instructions for Use provided with the control samples. The user sets the acceptance limit values for the controls.

## 9. Interpretation of Results

When interpreting the Labmaster LUCIA™ SARS-CoV-2 IgG NP 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 NP antibodies |
| ≥ 1. 000 U | Positive for SARS-CoV-2 NP antibodies |

## 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 Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit is intended to be used as an aid in identifying immune response related to SARS-CoV-2. 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 Labmaster LUCIA SARS-CoV-2 IgG NP Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. The test is not intended for determination of the infective disease status: it does not provide information on state, evolution or severity of the COVID-19 disease. The test is not intended for measuring immune response related to mRNA-based vaccinations. The test is not intended for monitoring of levels of medicinal products, substances or biological components. The test is intended for people who have been exposed to SARS-CoV-2.

Antibody responses to SARS-CoV-2 can be detected in most infected individuals 10–15 d after the onset of COVID-19 symptoms (i). IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the post infection duration of antibodies presence is not well characterized.

A negative result should be treated as presumptive. Both positive and negative results should be considered in relation to patient's exposure history and other symptoms consistent with COVID-19.

Heterophilic antibodies in human blood are a well-recognized source of interference in immunoassays. They may react with immunoglobulins included in the assay components. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference potentially causing anomalous results (iv).

## 11. Traceability

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

## 12. Performance Characteristics

***Clinical Performance***

Clinical performance was evaluated with 99 serum and plasma samples measured with Labmaster LUCIA™ SARS-CoV-2 IgG NP Test and comparative method Randox Evidence Investigator SARS-CoV-2 IgG (RBD & NP) Array. Seropositive samples were collected from individuals 15–35 days after confirmed SARS-CoV-2 viral infection as determined by polymerase chain reaction (PCR). The overall agreement with comparative method Randox Evidence Investigator SARS-CoV-2 IgG (RBD & NP) Array was 99% when test is run in intended environment by intended end-users.

| | | | |
|---|---|---|---|
| Seronegative samples (n) | 49 | Negative agreement | 100% |
| Seropositive samples (n) | 50 | Positive agreement | 98% |
| Total (n) | 99 | Overall agreement | 99% |

***Precision***

The precision of the SARS-CoV-2 LUCIA™ NP Test was determined applying the CLSI guidelines EP12-A2 (v) EP05-A3 (vi). The whole blood sample levels (seronegative as low and seropositive as high) 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). The blood donors were tested negative for SARS-CoV-2 IgG (in-house SARS-CoV-2 IgG EIA test of the University of Turku). For low sample level, fingertip blood from pre-screened donors was used as such. For high sample level, fingertip blood was spiked 1:10 with Randox SARS-CoV-2 IgG positive (100x) control.

| **Sample** | **Mean result (U)** | **Repeatability** | | **Between-Run** | | **Between-analyzer/ cassette lot** | | **Within-Laboratory** | |
|---|---|---|---|---|---|---|---|---|---|
| | | **SD** | **CV%** | **SD** | **CV%** | **SD** | **CV%** | **SD** | **CV%** |
| Seronegative (Low) | 0.5 | 0.20 | 40 | 0.05 | 10 | 0.05 | 9 | 0.21 | 42 |
| Seropositive (High) | 5.6 | 1.01 | 18 | 0.21 | 4 | 0.67 | 12 | 1.23 | 22 |

***Cross-reactivity***

Analytical specificity of SARS-CoV-2 IgG (NP) test kit was determined by testing 4 serum/plasma patient samples, each containing multiple potentially cross-reacting IgGs. Each of the 4 samples was measured as 6 replicates. The analytical specificity claim is that there is no cross-reactivity from the 17 substances listed.

| Containing IgG towards | N | Negative | Positive |
|---|---|---|---|
| Human coronavirus HKU1 | 6 | 6 | 0 |
| Human coronavirus OC43 | 6 | 6 | 0 |
| Human coronavirus 229E | 6 | 6 | 0 |
| Human coronavirus NL63 | 6 | 6 | 0 |
| Haemophilus influenzae | 18 | 18 | 0 |
| Respiratory syncytial virus (RSV) | 18 | 18 | 0 |
| Influenza A | 6 | 6 | 0 |
| Influenza B | 18 | 18 | 0 |
| Parainfluenza 1-4 | 18 | 18 | 0 |
| Adenovirus | 6 | 6 | 0 |
| Enterovirus | 12 | 12 | 0 |
| Mycoplasma pneumoniae | 18 | 18 | 0 |
| Legionella | 6 | 6 | 0 |
| Chlamydia pneumoniae | 6 | 6 | 0 |
| Epstein–Barr virus | 6 | 6 | 0 |
| Hepatitis B | 6 | 6 | 0 |
| Bordetella pertussis | 18 | 18 | 0 |
| Total | 180 | 180 | 0 |

***Interfering Substances***

Interference was evaluated in alignment with CLSI guideline EP07-A3 (vii) and Current performance of COVID-19 methods and devices and proposed performance criteria – Working document of Commission services' (viii). Potentially interfering substances (added concentration of tested substance in column Claim) were tested in lithium heparin blood with one analyte level (approx. 6 U). IgG was found to interfere at concentrations above 5.5 g/L. Other tested substances did not interfere at tested concentrations. 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 33 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 5.5 g/L. 40-60% decreased result with concentrations > 5.5 – 20 g/L. |
| Acetylsalicylic acid | No interference found up to 700 mg/L |
| Ibuprofen | No interference found up to 500 mg/L |

## 13. Disposal

All patient samples and materials shall be disposed of according to local laws and regulations. All samples, used cassettes, transfer pipettes and dilution tubes shall be disposed of as biological, potentially infectious materials. Paper, carton and pouches from Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit 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 authorised representative and to your national authority.

## 15. Warranty

The performance data presented here were 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.<br>• 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.<br>• 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.<br>• Cassette has been taken out of the pouch too early. | • Do not use the cassette.<br>• 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.<br>• If the problem reoccurs, contact support@labmaster.fi. |
| • Rejected measurement. | • Air bubble on top of silicon chip during measurement.<br>• Air bubbles or foam in washing/measuring buffer. | • Repeat the measurement using a new cassette.<br>• If the problem reoccurs, contact support@labmaster.fi. |
| • Grinding sound during tray movement. | • Mechanical malfunction.<br>• Cassette is placed on a tray incorrectly. | • Restart the analyzer.<br>• Repeat the measurement using a new cassette.<br>• 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.<br>• Repeat the measurement using a new cassette.<br>• If the problem reoccurs, contact support@labmaster.fi. |

## 17. References


(i) Seow J, Graham C, Merrick B et al. Longitudinal observation and decline of neutralizing antibody responses in the three months following SARS-CoV-2 infection in humans. Nature Microbiology 5(12), 1598-1607 (2020). https://doi.org/10.1038/s41564-020-00813-8.

(ii) 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).

(iii) Clinical and Laboratory Standards Institute (CLSI) guideline GP44-A4.

(iv) Clinical and Laboratory Standards Institute (CLSI) guideline I/LA30-A.

(v) Clinical and Laboratory Standards Institute (CLSI) guideline EP12-A2.

(vi) Clinical and Laboratory Standards Institute (CLSI) guideline EP05-A3.

(vii) Clinical and Laboratory Standards Institute (CLSI) guideline EP07-A3.

(viii) Current performance of COVID-19 test methods and devices and proposed performance criteria – Working document of Commission services.

## 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