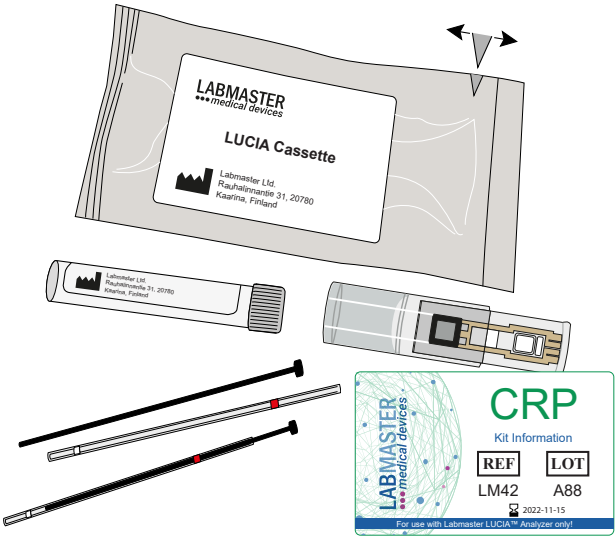
LABMASTER LUCIA

Instructions for Use

Labmaster LUCIA™ CRP Kit
for Whole Blood Samples



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Labmaster LUCIA™ CRP Kit for Whole Blood Samples

Product number: LM42

1. Intended Use

The Labmaster LUCIA™ CRP test is an *in vitro* near-patient diagnostic test for the quantitative determination of C-reactive protein (CRP) from whole blood to assess the inflammatory status of the body. The Labmaster LUCIA™ CRP Kit is to be used with the semi-automated Labmaster LUCIA™ Analyzer by healthcare professionals.

2. Clinical Significance and Summary of the Test

CRP is a well-established acute phase protein which has been used in routine diagnostic testing for decades. In healthy individuals, the concentration of CRP is low, whereas bacterial infections and tissue damage cause an increase in the CRP level. CRP level increases rapidly and elevated values can be detected within 6–12 hours from the beginning of inflammation. The change of CRP concentration has been proven to be a sensitive indicator of the effect of antibiotic treatment (i–iv).

Measuring Range	Unit	Sample Volume	Sample Type	Measuring Time
5–200	mg/L	5 µL	Whole blood	6 minutes

3. Principle and Procedure

The Labmaster LUCIA™ CRP test is based on a formation of immunochemical complex between antibodies and the CRP analyte. There are two different CRP recognizing antibodies in the complex of which the capture antibody binds the analyte on the silicon chip of the LUCIA Cassette. Luminophore-labeled-antibody is dried on the membrane of the LUCIA Cassette. The sample is added to the LUCIA Cassette where the unbound excess of the labeled antibody is separated with automatic washing step. Labeled antibody-analyte complex is excited with electricity. Resulting electrochemiluminescence is measured and the on-board microprocessor calculates the concentration of the analyte in the sample based on a pre-programmed calibration. The calculated and converted result is displayed on the screen of the Labmaster LUCIA™ Analyzer.

4. Kit Components

Contents of the Labmaster LUCIA™ CRP Kit for Whole Blood Samples

Component Name	Product Number LM42 (40 CRP tests)
CRP Cassette*	40 pcs
CRP Dilution tube for Whole Blood Sample**	1.5 mL x 40 pcs
CRP NFC Card	1 pc
Li-heparin coated capillaries (5 µL)	2 x 50 pcs
Plungers for capillaries	2 x 50 pcs
CRP Instructions for Use and Quick Guide (see centrefold)	1 pc

**Contains Tween, disodium tetraborate decahydrate, sodium azide, bovine serum albumin, bovine gamma globulin*

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

Materials Required but Not Provided with the Kit

Product Name	Product Number
Labmaster LUCIA™ Analyzer	LM26
Labmaster LUCIA™ Analyzer Instructions for Use	LM28
Lancets for fingertip blood sample	N/A
CRP Dilution tube for Serum/Plasma Sample	SA20

Storage

Store LUCIA CRP Kit at +2 – +8 °C.

Description of the Labmaster LUCIA™ CRP Cassette

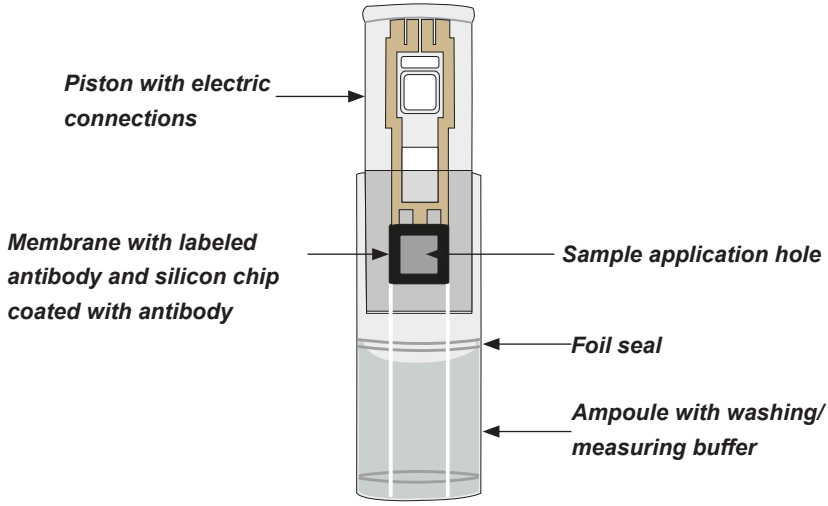

Figure 1. The Labmaster LUCIA™ CRP Cassette

5. Warnings and Precautions

Health and Safety Information

- For *in vitro* diagnostic use only.
- **Danger**: Washing/measuring buffer in cassette ampoule contains 1.7 mL of 1.9% disodium tetraborate decahydrate, which may damage fertility or the unborn child.

- Liquid reagents contain < 0.1% sodium azide, which is not considered a harmful amount.
- 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.
- 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™ CRP 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.
- NFC Card is batch specific and should be used only for CRP tests from the same kit batch. If NFC Card is lost, a new card can be requested from support@labmaster.fi.
- Cassettes, dilution tubes, capillaries and plungers are for single use. Do not use already used cassettes, dilution tubes, capillaries or plungers.
- The CRP Cassette should not be used if the cassette pouch is damaged or broken, if the foil seal in a cassette ampoule has 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 cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette.
- Use 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 result is unreliable.
- Do not use components of LUCIA CRP Kit if they have not been stored as instructed in this kit insert.
- Avoid contaminating the 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 Volume	Sample Collection
Fingertip sample (whole blood)	5 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	5 µL	Use venous blood sample collected in a tube containing EDTA or Li-heparin. Mix whole blood by inverting the tube several times. Collect the sample using a capillary, see section 7, Sample Dilution.

7. Procedure

NOTE: Each LUCIA CRP Kit contains one batch specific NFC Card which is used for all tests in one kit. **Before measurement, ensure that NFC Card batch information corresponds to CRP Cassette and CRP Dilution tube batch codes.**

Sample Dilution

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

- 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. Wipe away any residual sample from outside of the capillary.
- Place the capillary with sample into CRP 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.
- Diluted sample is now ready to be measured.
- The diluted sample must be measured within one hour of dilution preparation.

Measurement

- Place a new plunger inside a new 5 µL capillary tube.
- Open the pouch containing the CRP Cassette and check that there are no small air bubbles or foam in the cassette ampoule before sample application. If there are small air bubbles, try to remove the bubbles by turning cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette. After cassette ampoule has been checked and there are no small air bubbles or foam, use the cassette immediately.
- Select the Patient sample measurement icon on LUCIA Analyzer's display, enter patient ID and read the NFC Card as instructed in the Labmaster LUCIA™ Analyzer's Instructions for Use (see quick guide, step 3).
- Slide the cassette onto 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 window after the NFC Card has been read.
- Fill the capillary (5 µL) with the diluted sample up to the white stopper (see quick guide, step 5). Ensure that there are no air bubbles in the capillary.
- Place the capillary into the sample application hole of the cassette and hold the capillary against the membrane. Dispense the sample by pressing the plunger all the way down. Hold the capillary against the membrane until the sample has spread on the entire membrane (see quick guide, step 6).

- 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 (see quick guide, step 8) and the cassette will come out of the analyzer.
- Check that the silicon chip is not covered by large air bubble or by 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 the LUCIA CRP test are factory calibrated. The use of control material is advised to assure the day-to-day validity of results. It is recommended to use commercial CRP controls for quality assurance. This kit is meant for whole blood samples. If plasma- or serum-based quality control samples are used, serum dilution tubes (product number: SA20) must be used. Sample volume is 5 µL. Commercial controls should be handled according the Instructions for Use provided with the controls. The user sets the limit values for the controls.

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

9. Interpretation of Results

When interpreting the LUCIA CRP test results, take into consideration the patient's medical history, clinical examinations and other laboratory results.

10. Limitations of Procedure

Follow the sample collection, dilution and assay procedures specified in these instructions, otherwise the results might not be reliable. Test results should never be used alone for making a diagnosis. A clinical decision is always required.

Heterophilic antibodies in human serum/plasma are a well-recognized source of interference in immunoassays. They can 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 (viii).

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LABMASTER LUCIA

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

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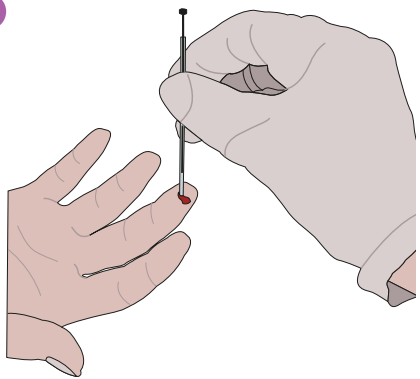
Labmaster LUCIA™ Analyzer

Components needed for one test:
- ***1 cassette***
- ***1 dilution tube***
- ***2 capillaries (5 µL) marked with red***
- ***2 plungers for capillaries***
- ***1 NFC Card (used for all tests in the kit)***

1



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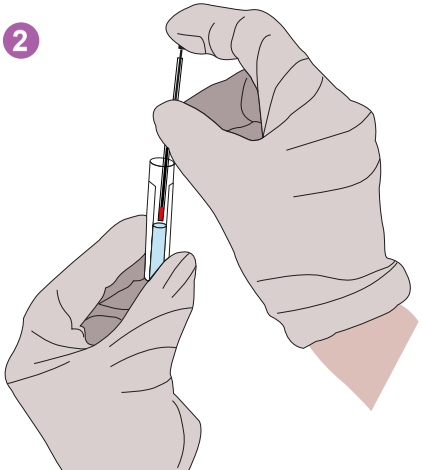

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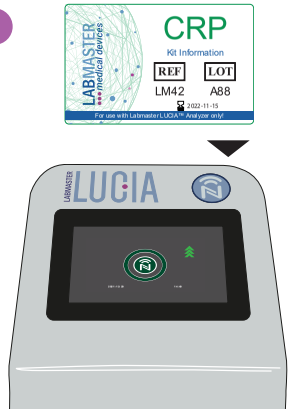

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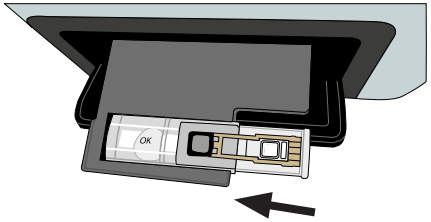

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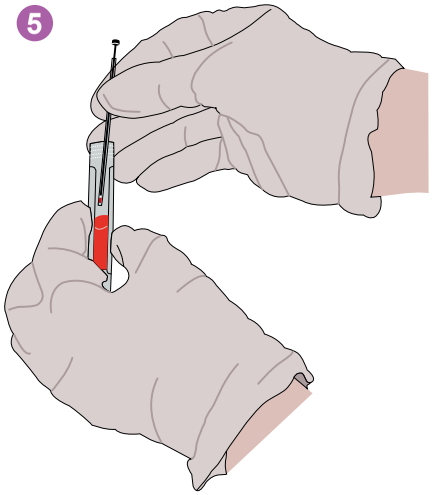

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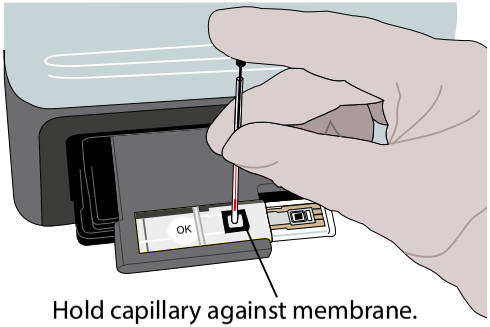

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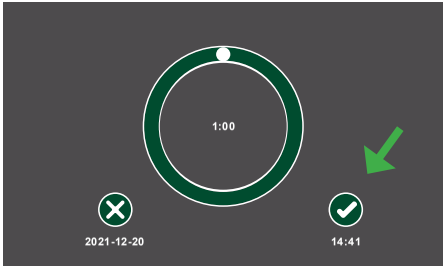

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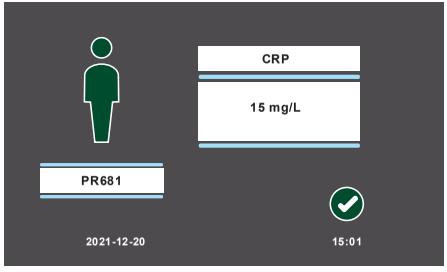

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11. Performance Characteristics

Method Comparison

Method comparison of LUCIA CRP test was performed by measuring the same human whole blood samples with LUCIA Analyzer and a clinical laboratory method. Clinical studies were performed at Turku University Central Hospital and St. Mary's Hospital in South Korea.

LUCIA CRP vs. Clinical laboratory method	**y: LUCIA CRP x: Clinical laboratory method**
Regression line	y = 1.17x – 0.71
Correlation coefficient	r = 0.99
Number of samples (n)	73

Measuring Range

LUCIA CRP test is used for measuring CRP with a range of 5–200 mg/L from whole blood sample. The sample is diluted before measurement. CRP < 5 mg/L is displayed if the CRP concentration is below the measuring range. CRP > 200 mg/L is displayed if the CRP concentration is above the measuring range.

LUCIA CRP measurement from whole blood is based on the assumption that the volume of red blood cells is 40% of the total sample volume.

Precision

Precision study was conducted according to Clinical and Laboratory Standards Institute (CLSI) guideline EP05-A2 (v). Each sample was assayed in duplicate, twice a day. Samples: Liquichek™ Elevated CRP control Level 1 (Low), Level 2 (Medium) and Level 3 (High), Bio-Rad.

Sample	**Mean Value**	**N**	**Repeatability CV%**	**Between-Run CV%**	**Between-Day CV%**	**Within-Laboratory (Total) CV%**
Level 1	9	80	13%	6%	11%	18%
Level 2	74	80	10%	6%	13%	18%
Level 3	140	80	11%	11%	11%	19%

Liquichek™ is trademark of Bio-Rad Laboratories.

Limit of Detection

The Limit of detection study was aligned with the CLSI guideline EP17-A2 (vi). The Limit of detection of LUCIA CRP test can be stated to be under 5 mg/L based on 60 total replicates/ reagent batch (two batches).

Interfering Substances

The CRP Kit was evaluated for interference in alignment with CLSI guideline EP07-A2 (vii).

Substance	No Interference Found up to Concentration
Bilirubin	19 mg/dL
EDTA	1.8 mg/mL
Heparin	15 IU/mL
Triglycerides	650 mg/dL
Vitamin C	200 mg/dL

12. Traceability

The Labmaster LUCIA™ CRP test is calibrated against the WHO 85/506 1st International Standard reference material and controlled with ERM® -DA474 reference material.

ERM® is registered trademark of European Community.

13. Disposal

All patient samples and materials shall be disposed of according to local laws and regulations. All samples, used cassettes, capillary tubes, plungers and dilution tubes shall be disposed of as biological, potentially infectious materials. Paper, carton and pouches from LUCIA CRP Kit can be recycled according local and national instructions. Desiccants and 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 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's (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 inside the cassette 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 membrane.	• Kit has not been stored at the instructed storage temperature 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 a soft paper or cloth. • If the problem reoccurs, contact support@labmaster.fi
• Rejected measurement.	• Air bubble or foil seal on top of silicon chip. • Air bubbles or foam in washing/measuring buffer.	• Repeat the measurement using a new CRP 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 LUCIA Analyzer. • Repeat the measurement using a new CRP 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 CRP Cassette. • If the problem reoccurs, contact support@labmaster.fi

17. References

i. Harrison, M. 2015. Erythrocyte sedimentation rate and C-reactive protein. Aust Prescr 38: 93–94.

ii. U.S. Food and Drug Administration. 2005. Review Criteria for assessment of C-reactive protein (CRP), High sensitivity C-reactive protein (hsCRP) and Cardiac C-reactive protein (cCRP) assays.

iii. Volanakis J. 2001. Human C-reactive protein: expression, structure, and function. Mol Immunol 38: 189–197.

iv. Gewurz H., Mold C., Siegel J., Fiedel, B. 1982. C-reactive protein and the acute phase response. Adv intern Med. 27: 345–372.

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

vi. Clinical and Laboratory Standards Institute (CLSI) guideline EP17-A2.

vii. Clinical and Laboratory Standards Institute (CLSI) guideline EP07-A2.

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

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
	Serious health hazard

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