
# LABMASTER Oy 3/2022

Tony Wahlroos, CEO

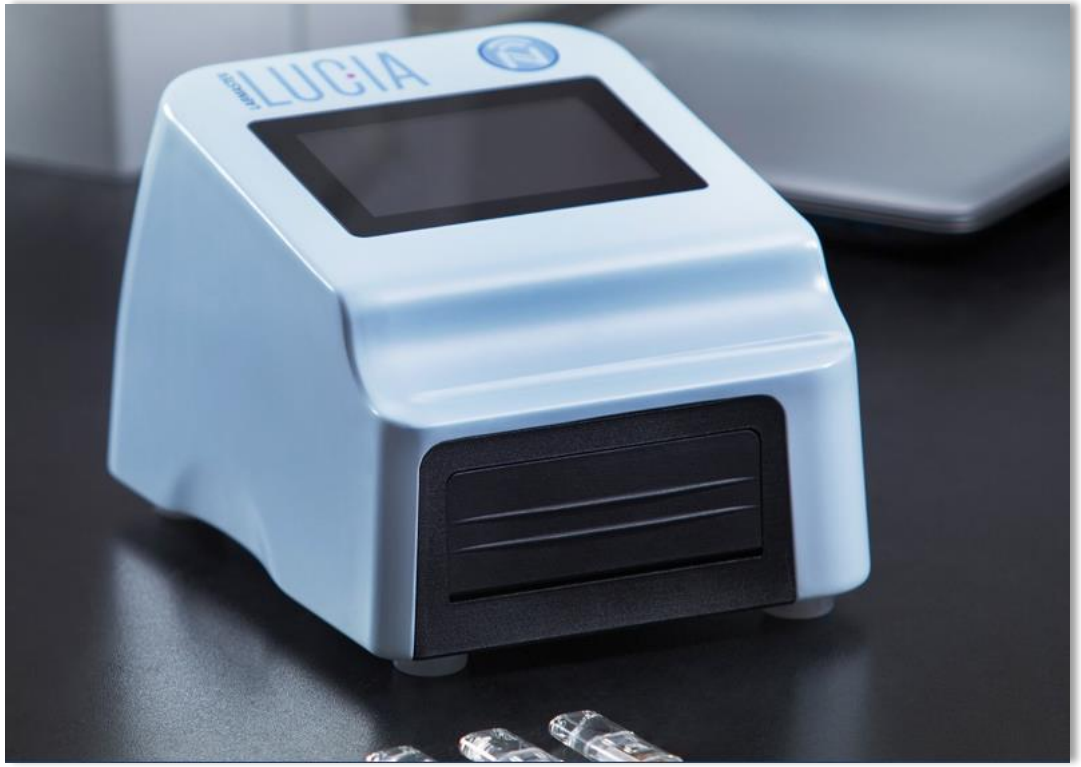
**Testaus & suojaus- ja rajoitustoimet**

LABMASTER
medical devices

# Introduction

**Labmaster Ltd**, based in Kaarina, Finland, is a privately owned company focusing on delivering **innovative tools for clinical diagnostics and research**. We received our ISO 13485:2016-certificate in June 2019.

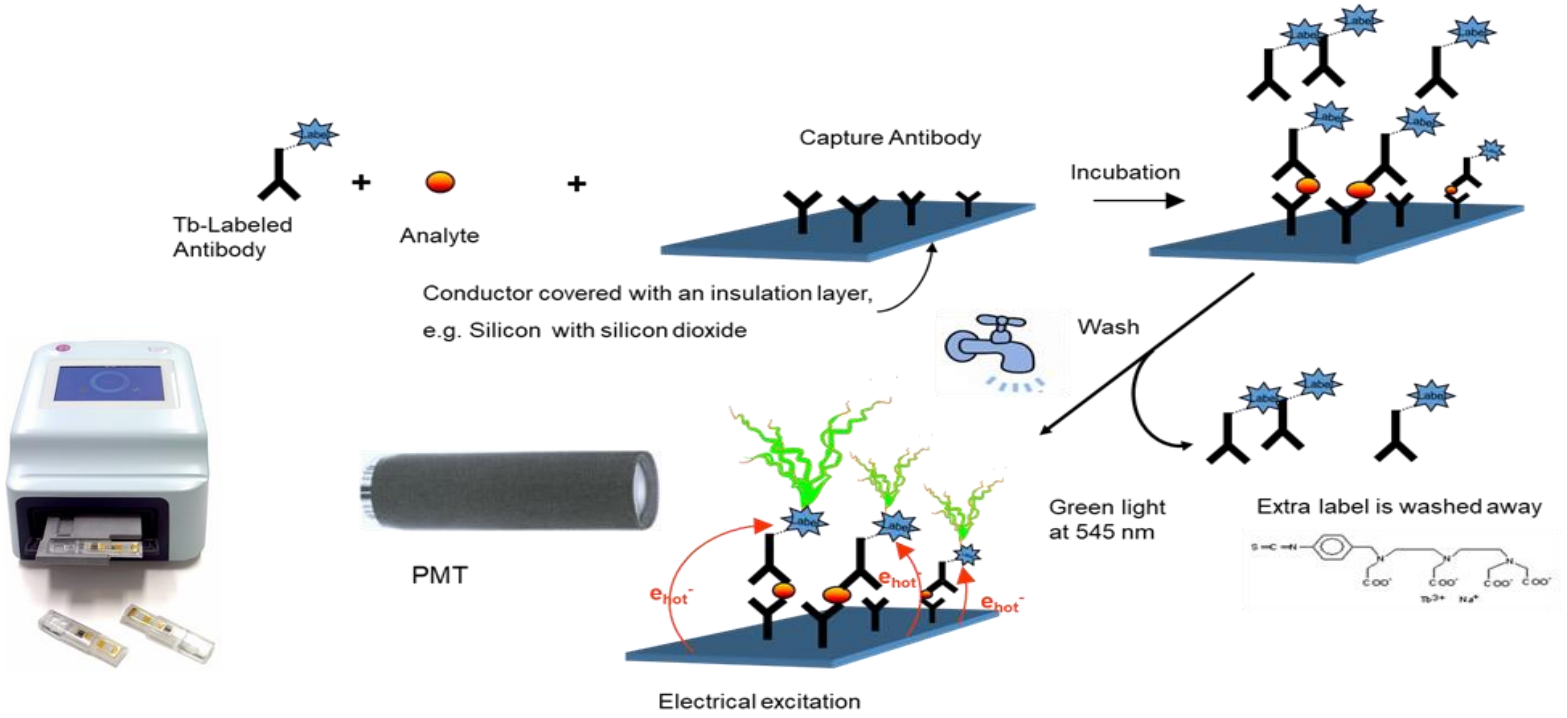
Labmaster develops and commercializes the next generation *in vitro* diagnostic (IVD) medical device detection tools based on its proprietary cathodic electrochemiluminescence-technology (LM-CECL). The superiority of CECL-technology allows it to overcome the performance limitations of previous generations' tests relating to sensitivity, accuracy, versatility, ease of use and cost efficiency.



# TECHNOLOGY, platform & cassette

**Labmaster LUCIA™ platform and Cathodic Electrochemiluminescence technology, C-ECL**

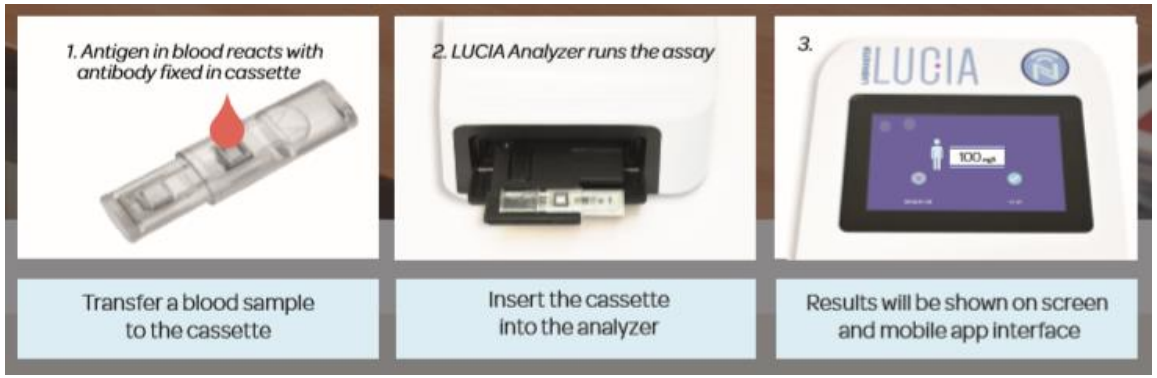
- The main advantage of this unique technology is cost effectiveness achieved by replacing expensive optics with low priced sophisticated electronics.



# PLATFORM, LUCIA® ANALYZER

## IVD medical device for measuring the concentration of designated analytes in the human and animal blood

- SIMPLE and compact mechanics ensuring high reliability, maintenance-free system
- ACCURATE patented technology, cathodic electrochemiluminescence (CECL) with high sensitivity
- FAST AND EASY, whole blood, all-in-one cassette, 5-10 minute assay time, mobile interface
- ECONOMIC, low investment & in-expensive assays
- VERSATILE platform, wide variety of assays for the same instrument
- ALL-IN-ONE CASSETTE, whole blood or serum, washing buffer in the same cartridge

# LUCIA TEST KIT

*LUCIA CRP Kit Contents*

| Component Name | Product number LM42 (40 CRP tests) |
|---|---|
| LUCIA CRP Cassette* | 40 |
| Dilution buffer tube** | 40 x 1.5 mL |
| Heparin-coated capillaries (5µL) and plungers | 2 x 50 |
| LUCIA CRP Quick Guide (see centerfold) | 1 |
| NFC Card | 1 |

**Contains Tris, borate, sodium azide, material of animal origin: bovine serum albumin & bovine gamma globulin*
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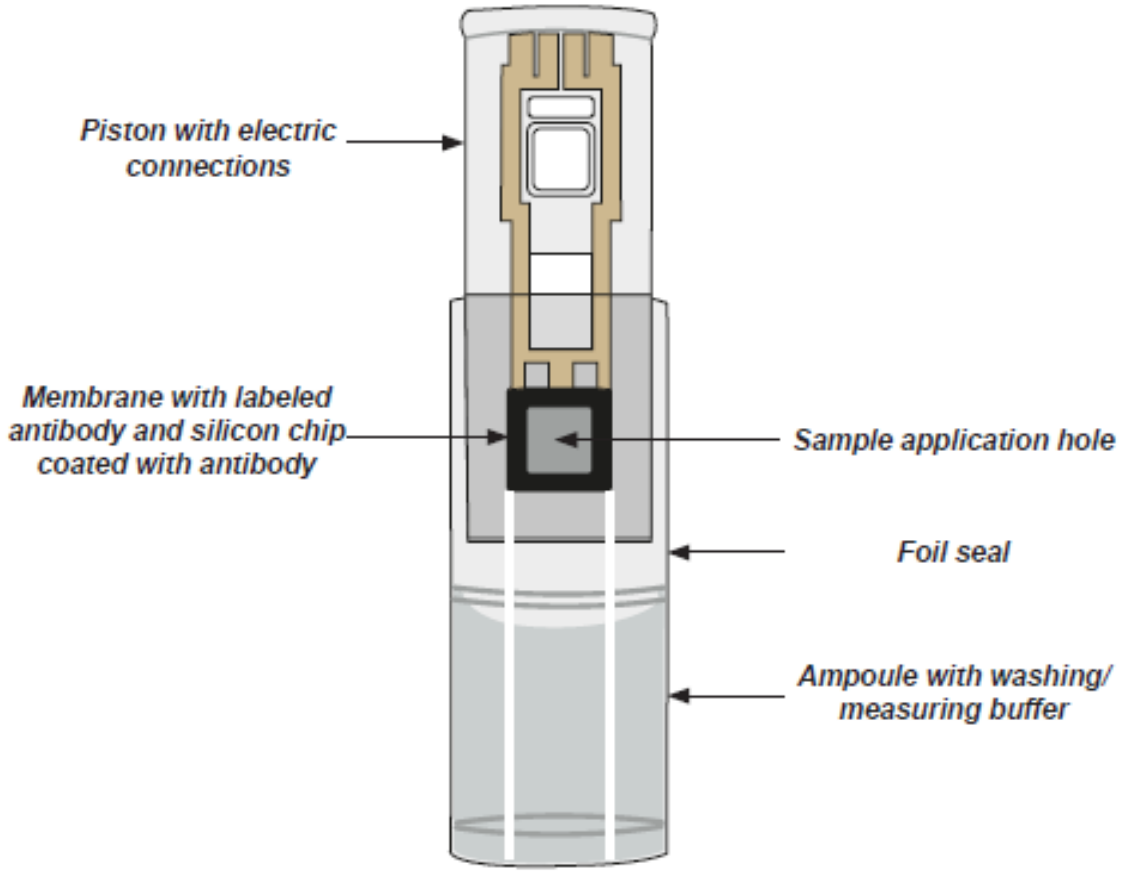
*Description of the LUCIA CRP Cassette*



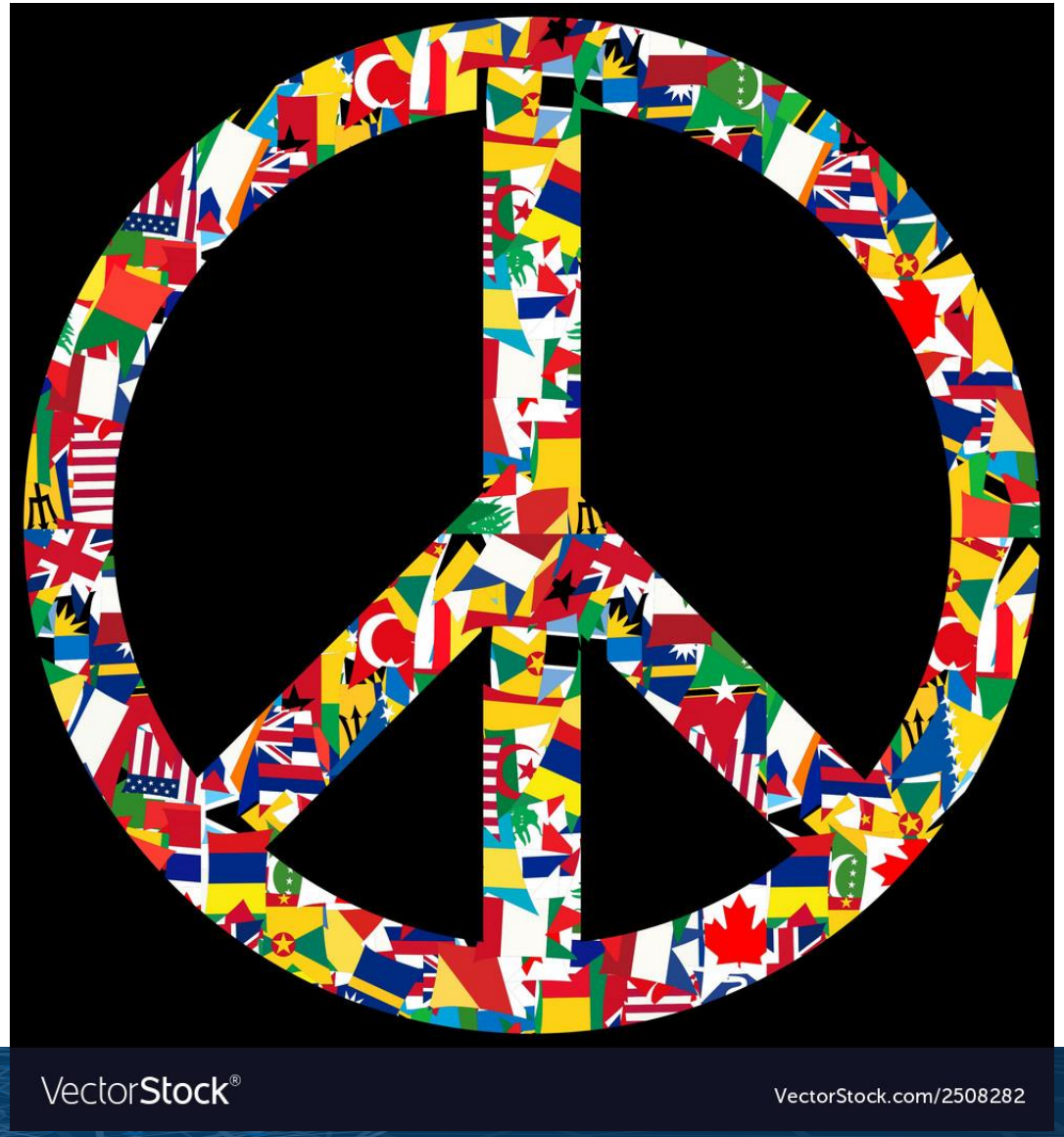
# Testaukseen liittyvät ongelmat

- SARS-CoV-2 muuntuu kausiluonteiseksi hengitystieinfektioksi, jolloin infektion testaus ja jatkotoimet on säädettävä vastaamaan muuntunutta tilannetta
- PCR
  - Hidas menetelmä mutta sensitiivinen
  - Oireettomat SARS-CoV-2 näkyvät PCR:llä
    - → tarpeetonta käyttää kun virus muuttuu kausiluonteisen infektion aiheuttajaksi
- Antigeenitestit
  - Nopea menetelmä mutta puutteellinen sensitiivisyys
  - Toimii parhaiten kun virusten määrä on suuri (> 3vrk infektiosta)
  - kotitestit
- Vasta-ainetestit
  - Nopea menetelmä mutta mittaa potilaan vastetta virukseen/rokotukseen, ei siis mittaa suoraan koronavirusta
  - Hyödyllinen etenkin kun virus on muuntunut vähemmän
  - Auttaa populaatiotason infekiokontrolliin
    - Rokotusstrategiat
    - Populaatiovaste

# Labmasterin portfolio SARS-CoV-2 testaukseen

| Test/Bio-marker | Functional Description | Test Quantitation | Intended use/Purpose (Labmaster) |
|---|---|---|---|
| C-Reactive Protein, CRP. | A generalized biomarker for bacterial inflammatory infections. | Quantitative IVD test. | Labmaster LUCIA™ CRP Test is an in vitro diagnostic test for the quantitative determination (quantitative IVD test) of CRP from whole blood with LUCIA Analyzer by healthcare professionals. |
| Myxovirus resistance protein 1, MxA. | A generalized biomarker for respiratory viral infections, including Coronavirus. | Quantitative IVD test. | Labmaster LUCIA™ MxA Test is a quantitative IVD test for determination of MxA from whole blood. |
| SARS-CoV-2 Sero (NP) | A COVID-19 Panel test to detect antibodies against SARS-CoV-2 Nucleocapsid Protein (NP). | Semi Qualitative IVD test. | Labmaster LUCIA™ SARS-CoV-2 Sero (NP) Test is a threshold-based IVD test (qualitative IVD test) for determination of the presence of antibodies to the SARS-CoV-2 (NP) protein in whole blood. To detect SARS-CoV-2 antibodies max 3 months after onset of the symptoms. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. It should not be used to diagnose or exclude acute SARS-CoV-2 infection. |
| SARS-CoV-2 Sero (RBD) | A COVID-19 Panel test to detect antibodies against the Receptor Binding Domain (RBD) of the SARS-CoV-2 Spike Protein. | Semi Qualitative IVD test. | Labmaster LUCIA™ SARS-CoV-2 Sero (RBD) Test is a qualitative IVD test for determination of the presence of antibodies to the SARS-CoV-2 (RBD) protein in whole blood. It is intended for use as an aid in identifying individuals with adaptive immune response to SARS-CoV-2 vaccines based on the S-protein vectors or indicating recent or prior infection (SARS-CoV-2 antibodies max 3 months after onset of the symptoms). It should not be used to diagnose or exclude acute SARS-CoV-2 infection. |
| SARS-CoV-2 NAb | A COVID-19 Panel test to detect total set of Neutralizing Antibodies (NAb) against SARS-CoV-2. | SemiQualitative IVD test. | Labmaster LUCIA™ SARS-CoV-2 NAb Test is a qualitative IVD test for determination of the presence of NAb in whole blood or serum. Intended use is for measuring neutralising antibodies to Wild Type (Wuhan) & Delta variants following vaccination or natural infection |

# KIITOS!

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