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Simulation & Diagnostics in Healthcare

Fast and Accurate SmartAmp Testing

for the Coronavirus in Laboratories and at Point of Care

LifeCase and Rapid SARS-CoV-2 Test

Results < 35 minutes

Presented by the MSE Group
Partners of EMG

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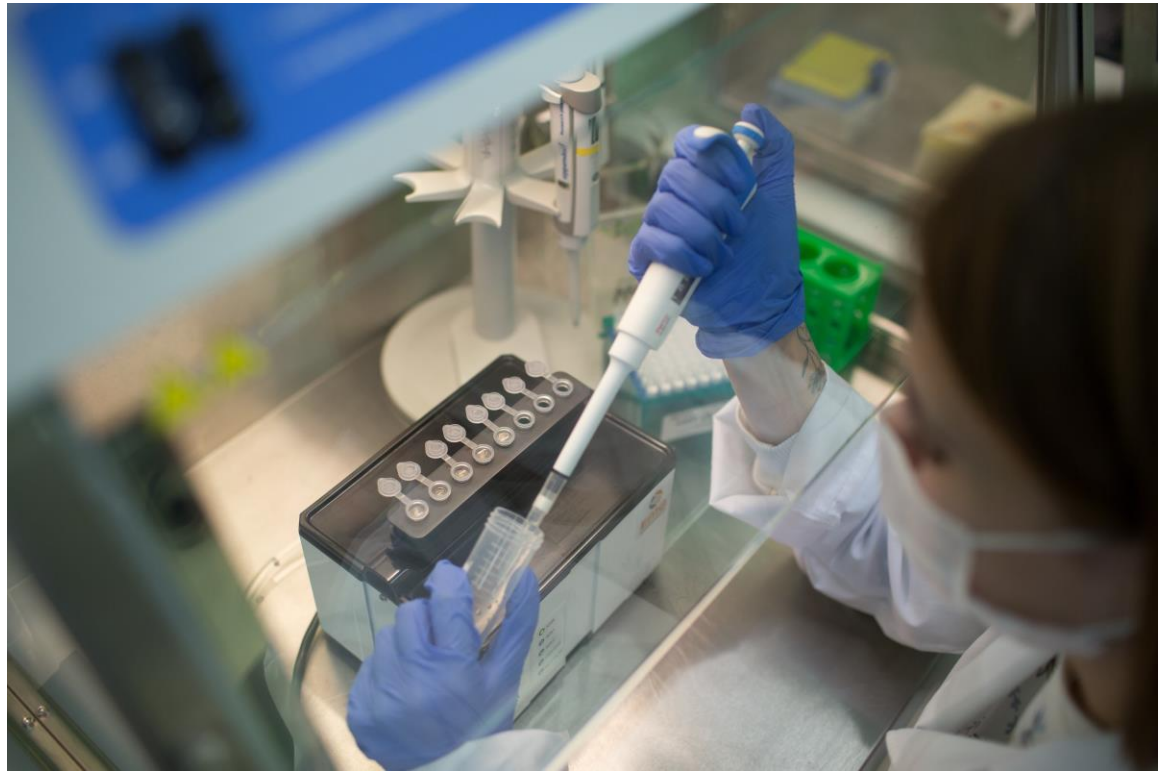
GENOMICS FOR LIFE

LifeCase – Watch the mobile mini laboratory in action….



Watch LifeCase on youtube - Click Here...

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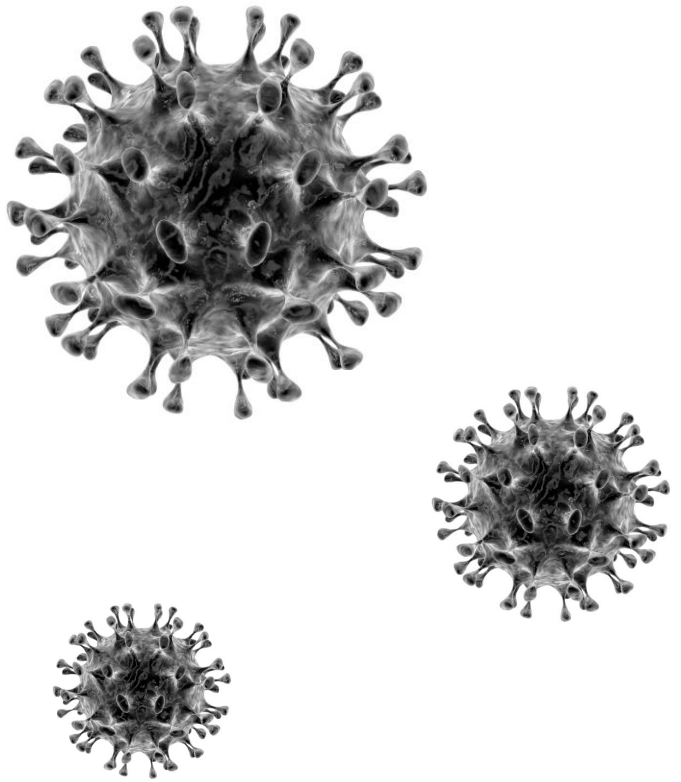
EMG SmartAmp SARS-CoV-2 Test Snapshot - Performance and Accuracy

The EMG SmartAmp SARS-Cov-2 RNA Detection kit is designed to detect the viral material presence in biological samples by implementing reverse transcription and real-time isothermal amplification reactions.

➢ Fast Reaction Rate	Typically **10 minutes - 35 minutes**
➢ High detection limit	Starting from 100 CFU per swab
➢ High Sensitivity	From 100 copies
➢ High Specificity	
➢ Average laboratory workflow capacity	Starting from 20 samples / hour / per single PCR machine



EMG's SmartAmp SARS-CoV-2 RNA test aligns with the *Laboratory Testing WHO Interim Guidance* published 19th March 2020

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EMG's SmartAmp Reagent Kit for Detection of SARS-CoV-2

- Tested, implemented and more healthcare systems to follow…

Austria

The Austrian Agency for Health and Food Safety (AGES) has recently completed trials of the SARS-CoV-2 test created by Evotech-Mirai Genomics (EMG).

Overseeing the trials, Univ.Prof.Dr. Franz Allerberger confirmed that the EMG SmartAmp SARS-CoV-2 RNA test is currently the **most time saving and accurate** Covid-19 detection test currently available and has recommended this test be distributed to laboratories throughout Austria with immediate effect.

Japan

The National Institute of Infectious Diseases, part of the Japanese Government Ministry of Health, Labour and Welfare has just announced the approval of the EMG SmartAmp SARS-CoV-2 Test. The use of these kits will be covered under the Japanese insurance system with related costs covered by Social Insurance. Read report…

Trials of the EMG SmartAmp SARS-CoV-2 RNA test are currently taking place by the University of Southampton, **UK.** Trials are underway by **Charité (Germany), France, Italy and Switzerland.**

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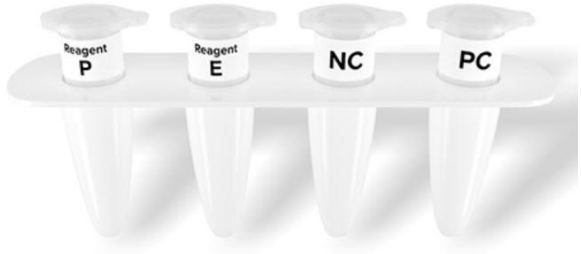
Diagnostic Products from EMG

LifeCase

A portable and comprehensive solution for Covid testing. Includes: EMG SmartAmp Detection Kit, Extraction Kit (both required for use with LifeCase.

- Quick to deploy
- Complete functionality
- Mobile
- Rapid tests

EMG SmartAmp Covid Reagent Kit



(Extraction kit + Detection kit)

- Proprietary SmartAmp technology
- Fast
- Accurate
- Reliable
- Inexpensive
- Can be used with or without LifeCase

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Extraction and Amplification Kits

Extraction

- **Tube 1: SSB** - Swab Suspension Buffer
- **Tube 2: WS1** - Washing Solution 1
- **Tube 3: WS2** - Washing Solution 2
- **Tube 4: ES** - Elution Solution

Expiry Date:
12 months from production date. Do not use the expired Extraction Kit.
Storage:
Store at t = +2° C … +30° C for 12 months
Avoid direct sunlight

Amplification

- **Tube 1: Reagent E** - Target NA amplification enzymatic catalysis
- **Tube 2: Reagent P** - Primers required to initiate the real-time isothermal amplification process and detect the fluorescence signal
- **Tube 3: Positive Control** – Sample of positive control
- **Tube 4: Negative Control** - Sample of negative control

Expiry Date:
12 months from the production date. Do not use after the designated expiry date.
Storage:
Store all components at - 20°C.
After unfreezing to be stored for no longer than one week at +4°C
Keep reagents separate from sample material to avoid contamination

SmartAmp SARS-CoV-2 Test Solutions

1. LifeCase

This solution has been designed specifically for use with the following clinical settings in mind:

- Moderate and High Complexity Laboratories
- EMS and Emergency Departments (Triage)
- Military Field Hospitals
- Departments of Public Health
- Quarantine
- Transportation Hubs

SmartAmp Reagent Kits for detection of SARS-CoV-2 RNA and RNA Extraction Reagent Kits are required for use with LifeCase.

2. The EMG SmartAmp Nucleic Acid Extraction Reagent Kit for use **in large laboratories with RT-PCR based detection systems** using the isothermal amplification method is available for the detection of SARS-CoV-2. (96 tests in a kit)

LifeCase

The LifeCase is designed to quickly detect SARS-CoV-2 RNA presence in biological material by using real-time isothermal amplification from nasopharyngeal and oropharyngeal swabs and sputum. The LifeCase includes:

- Test time - 30 minutes on average including pre-treatment procedure (3 minutes/sample) and the isothermal amplification reaction (not more than 25 minutes)
- Average laboratory workflow capacity is 20 samples/hour
- Sensitivity from 100 copies

- Pre-treatment device
- 24 samples simultaneous detection amplifier – 1pc
- Pipettes – 2pcs
- Single-use tips for pipettes
- Microtube rack
- Laptop

- **Faster access to testing in pre-hospital settings**
- **Fast and flexible volume testing in laboratories**

Storage:
Portable Lab has no expiry date when
t = +2…+35° C (non-condensing)

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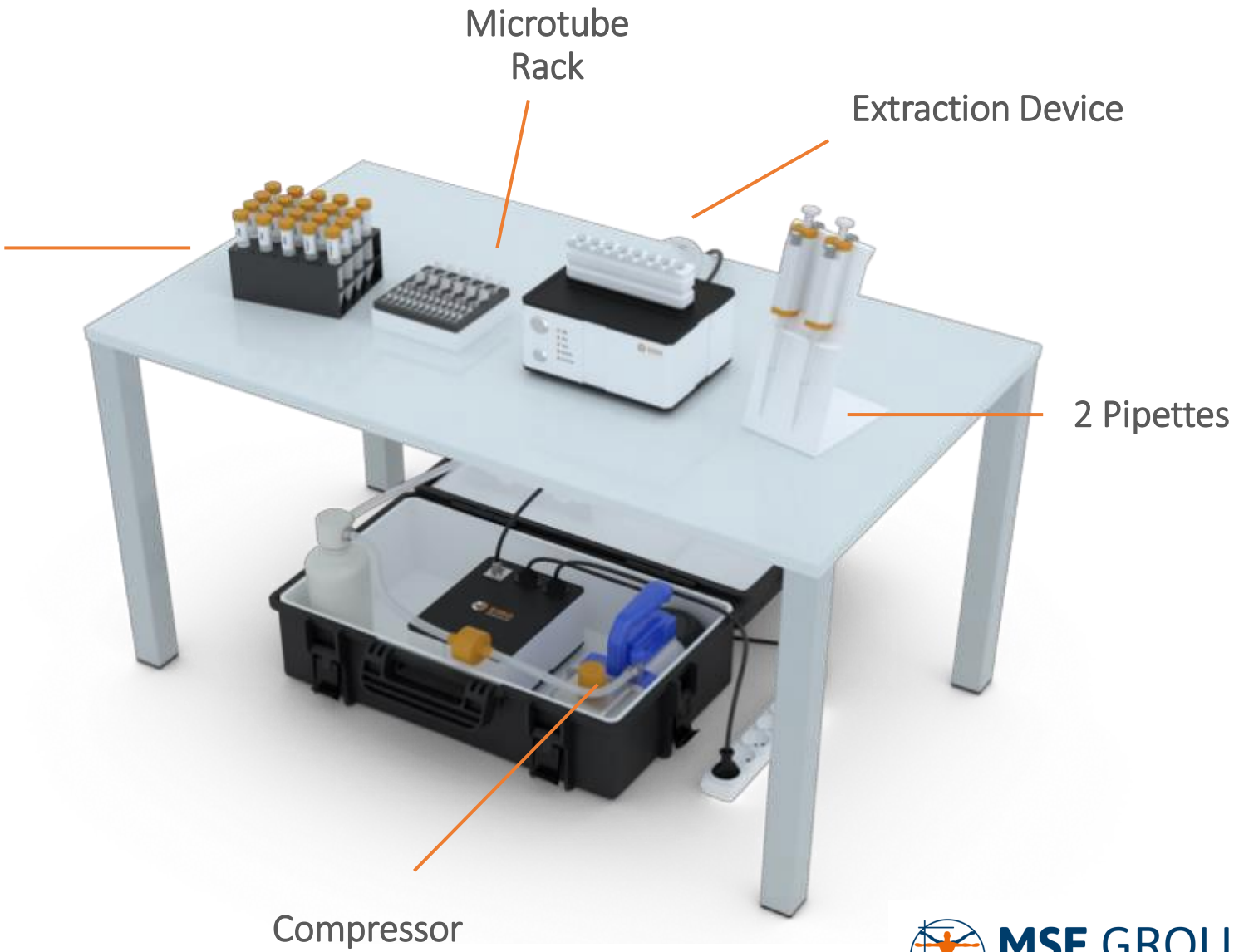
LifeCase contents…



Case 1: The Extraction Kit

Operating conditions:
Temperature +15 to +35 °C Relative humidity 30 to 85% (avoid condensation)

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LifeCase contents…

Case 2: The Amplification Kit

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The technology behind the EMG SmartAmp SARS-CoV-2 RNA Test

- Isothermal PCR (single temperature reaction)
- Specific to a highly conserved sequence: NSP-15
- High reaction rate (10 – 35 minutes)
- High sensitivity and specificity (LOD – 100 CFU / swab)
- Minimum number of steps (amplification = result)
- Own patents and reagent components production, including agents, polymerase and pre-treatment reagents
- Japanese technology

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Clinical Test Results

- for SARS-CoV-2 genetic detection test using EMG's SmartAmp technology for Isothermal PCR

This method delivers a **fast reaction rate** (10 – 35 minutes), **high detection limit** (starting from 100 CFU per swab) and **high sensitivity and specificity rates**.

Clinical tests have been conducted in:

France - Institut Pasteur, Paris have just published data from trials evaluating the analytical sensitivity of the EMG SmartAmp SARS-CoV-2 test and the LifeCase portable laboratory, and stated, "The National Reference Centre for Respiratory Infections Viruses considers that the SmartAmp Covid-19 Kit (including LifeCase) has an acceptable detection sensitivity of SARS-CoV-2". View Test Results…

Russia – The State Research Center of Virology and Biotechnology VECTOR (WHO reference laboratory) and test validation showed that 800 samples tested 100% sensitivity and specificity results were achieved as well as cross-reactivity test was successfully done.

Austria – The Austrian Agency for Health and Food Safety (AGES) confirmed that the EMG SmartAmp SARS-CoV-2 RNA test is the most time saving and accurate Covid-19 detection solution currently available.

Japan – The National Institute of Infectious Diseases, part of the Japanese Government, Ministry of Health, Labour and Welfare has announced the approval of the EMG SmartAmp SARS-CoV-2 test. The use of these kits will be covered under the Japanese insurance system with related costs covered by Social Insurance.

Validation Status in Europe

- for SARS-CoV-2 genetic detection test using EMG's SmartAmp technology for Isothermal PCR

- The producer applied for the IVD Certificate at the State Research Center of Virology and Biotechnology VECTOR in Russia and successfully finished the reference test on 18th March 2020.

- According to the EU IVD Directive 98/79 EC (In Vitro Diagnostic Medical Devices) the respective certification process based on the preparation of the EC declaration of conformity, whereby the producer ensures and declares that the products concerned meet the provisions of this Directive was started - w/c 30th March 2020 and as of the **27th April 2020**, the **Declaration of Conformity** from EMG is now complete.

- The tests are already (a) used in Russia under the federal program of COVID-19 detection, (b) implemented in Japan under National Social Insurance (c) started for laboratory use in UAE and (d) recommended by the Austrian Agency for Health and Food Safety (AGES).

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Validation Status in the US

- for SARS-CoV-2 genetic detection test using SmartAmp technology for Isothermal PCR

- Given the current healthcare crisis caused by the Covid-19 pandemic and the acute global shortage of diagnostic tests, we have sought the emergency authorisation from the FDA for the SmartAmp®SARS-CoV-2 Test.
- Our application for the SARS-CoV-2 Test was submitted on the March 16, 2020 and was immediately acknowledged by the FDA on the March 17, 2020.
- Due to the ongoing global demand for test kits of the SARS-CoV-2, the FDA has issued new guidelines on March 16, 2020 which lawfully allows the 'marketing and selling' of Coronavirus tests while applications for FDA approval are in progress.
- LifeCase utilizes the SmartAmp® SARS-CoV-2 test and is available to order.

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Future products coming from Evotech Mirai Genomics (EMG)

Available: Influenza A &B. Coming soon: STDs

The LifeCase currently processes wet tests

LifeRing COVID-19

Dry 1.0

LifePad COVID-19

Dry 2.0

EMG are developing LifeCase to process dry tests for Covid-19 detection as a simple, automated and cartridge-based system.

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