



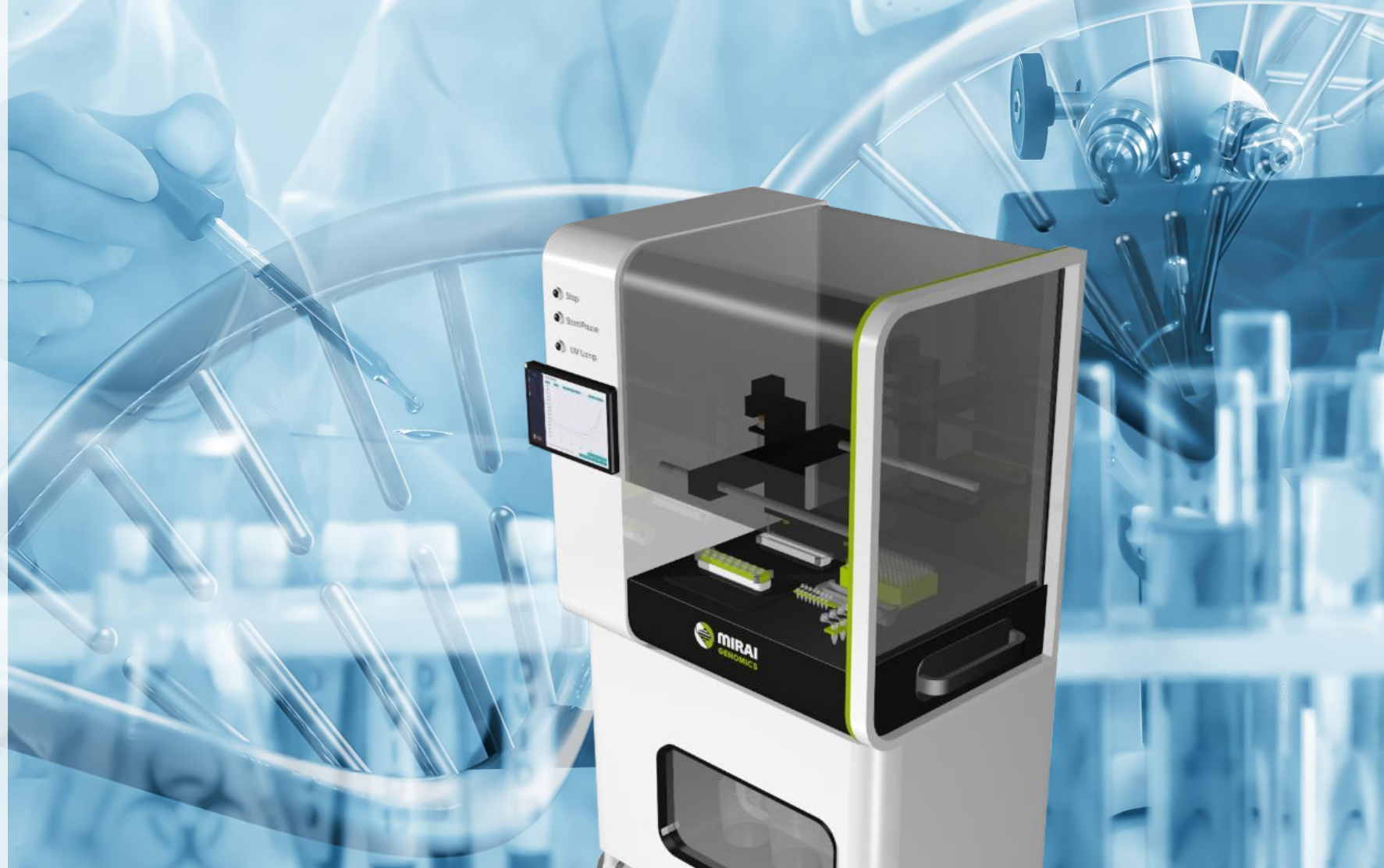
MSE GROUP

Simulation & Diagnostics in Healthcare

A versatile laboratory
test solution

for Sars-CoV-2

- Fast
- Accurate
- Mobile



LifeCase 96

EMG LifeCase 96

for use with EMG's SmartAmp SARS-CoV-2 reagents

The EMG LifeCase 96 is a fully contained mobile laboratory that can be used for the testing of SARS-CoV-2 in field locations or for scaling up increased testing demand in laboratories. It is designed for use with our SmartAmp SARS-Cov-2 RNA Detection kit to detect 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 copies per reaction
- **High Sensitivity and Specificity** Supported by validated research
- **Average laboratory workflow capacity** Starting from 93 samples / hour / per LifeCase

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



EMG SmartAmp SARS-CoV-2 Test Solutions

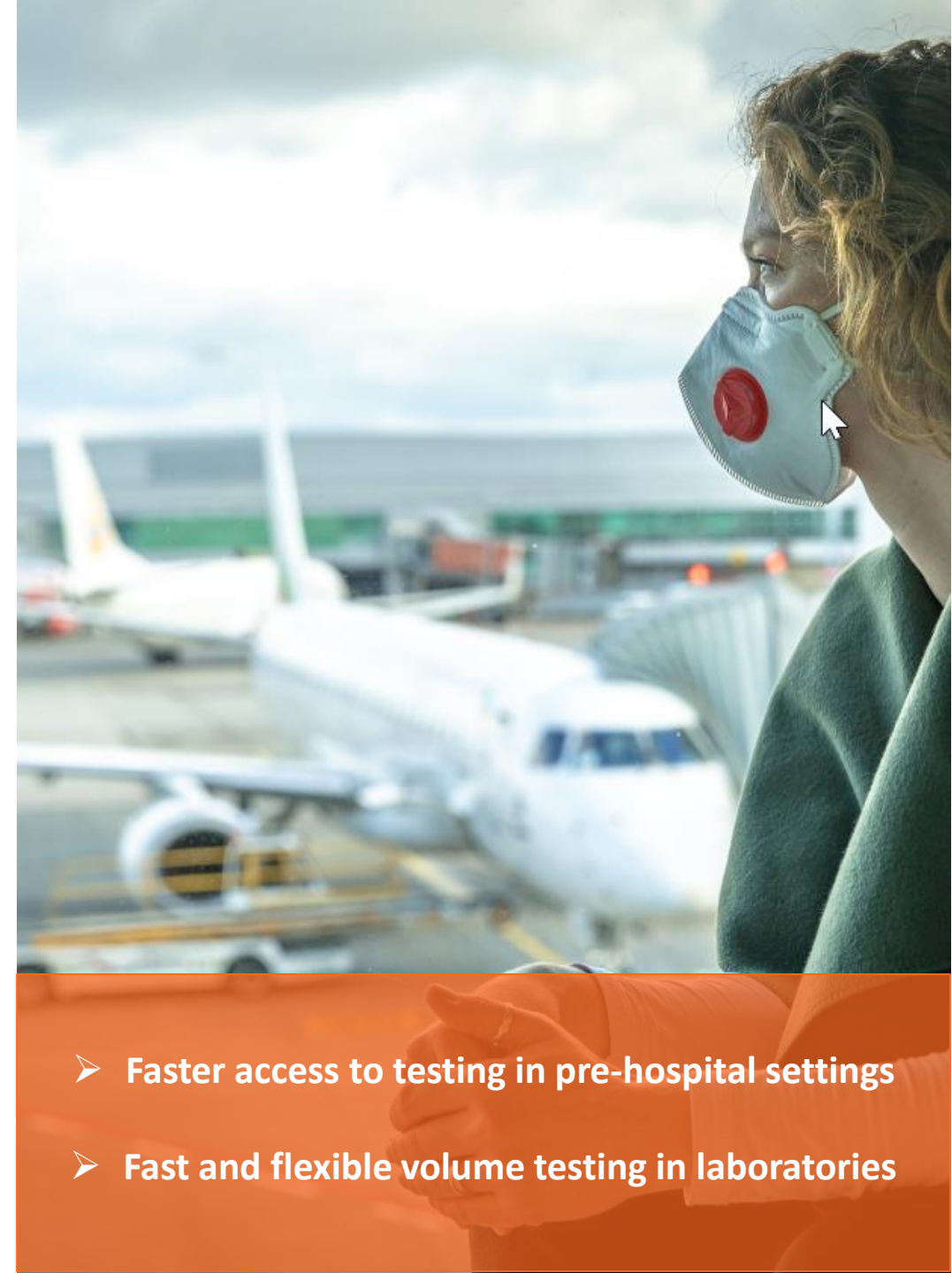
1. LifeCase 96

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
- Transportation Hubs

SmartAmp Reagent Kits for detection of SARS-CoV-2 RNA and RNA Extraction Reagent Kits are required for use with LifeCase 96.

2. The EMG SmartAmp Nucleic Acid Extraction Reagent Kit can be used with standard laboratory equipment, including: Quantstudio 5, CFX 96, LC 480 1 II 96, Rotor Gene Q or any real-time amplifier set to an isothermal reaction.



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

Diagnostic Products from EMG

LifeCase 96

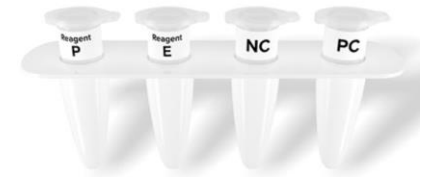
A mobile and comprehensive solution for Covid testing. Includes: Automated 96-slot Extraction Device, 96-slot Isothermal Amplifier and Laptop with touchscreen.

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



EMG SmartAmp Covid Reagent Kit

(Extraction kit + Detection kit)



- Proprietary SmartAmp technology
- Fast
- Accurate
- Reliable
- Can be used with or without LifeCase 96

LifeCase 96 Product Highlights

- Barcode reader included
- Auto opening and auto closing of SSB tube lids
- Clean air ventilation system
- Separate slot is required for internal control
- Competitive pricing
- Warranty - 1 year

Available to order – August 2020

Shipment to customers – September 2020



Extraction and Amplification Kits from EMG

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.

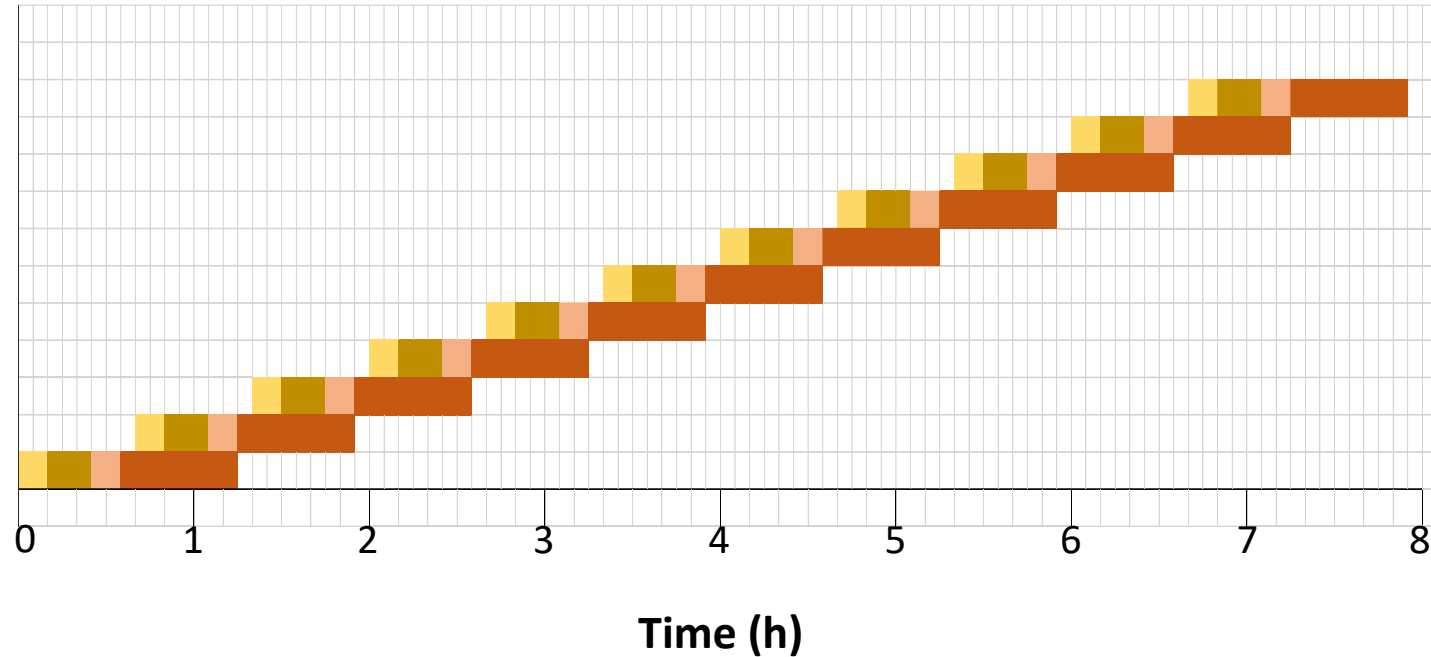
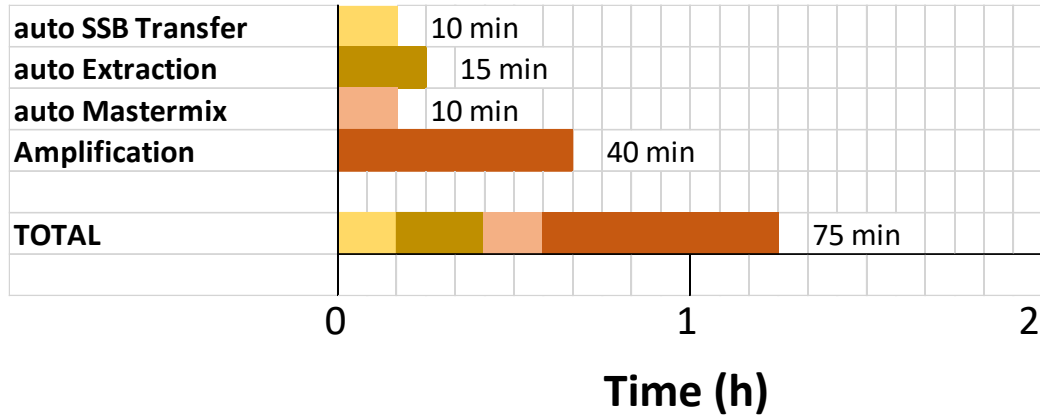
Storage:

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

LifeCase 96 Operational Timeline



- **Included per round of amplification:**
 - 93 samples
 - 1 extraction negative control
 - 1 amplification negative control
 - 1 amplification positive control
- (= For a total of 96 reactions)

	Time to first results	Time to subsequent results	Number of experiments in 8h	Number of tests in 8h
LifeCase 96	1h 15 min	40 min	11	1023 (without IC) 495 (with IC)

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** (LOD 100 copies) and **high sensitivity and specificity rates**.

Clinical tests have been conducted in:

France - Institut Pasteur, Paris have 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 gave 100% sensitivity and specificity results. Cross-reactivity test was successfully completed.

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 and is recommended for use nationwide.

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.

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).

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 with assigned file number PEUA-200099.
- 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 96 utilizes the SmartAmp® SARS-CoV-2 test and is available to order.

Covid-19 Testing – Who are the MSE Group?



To connect with your local Regional Representative
email: hello@mse-group.co

We have offices for
Direct Sales in:

Europe

- Austria
- France
- Germany
- Italy
- Portugal
- Scandinavia
- Spain
- UK

North & South America

Russia

Asia Pacific:

- Japan
- South Korea (Opening soon)

We have Distribution
Partners in:

Europe

- Belgium
- Czech
- Greece
- Hungary
- Luxembourg
- The Netherlands
- Poland
- Romania
- Switzerland

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