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EMG
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LifeCase COVID-19

MANUAL

RUO Research Use Only ***(IVD** application pending)*

EVOTECH-MIRAI GENOMICS

SN 006201_xxxx

Contents

Information about this Manual

All new users should carefully read this **Manual** for the portable mini laboratory for SARS-CoV-2 RNA detection – LifeCase COVID-19.

Intended Use

The "LifeCase COVID-19" portable mini laboratory using the SmartAmp® real-time PCR technology (the „Device") is designed to detect SARS-CoV-2 RNA in nasopharyngeal and oropharyngeal swab and sputum specimens collected from people with clinical symptoms of a respiratory disease or free of symptoms but suspected of being infected with SARS-CoV-2, people arriving from areas heavily affected by the epidemic and people who came in contact with them.

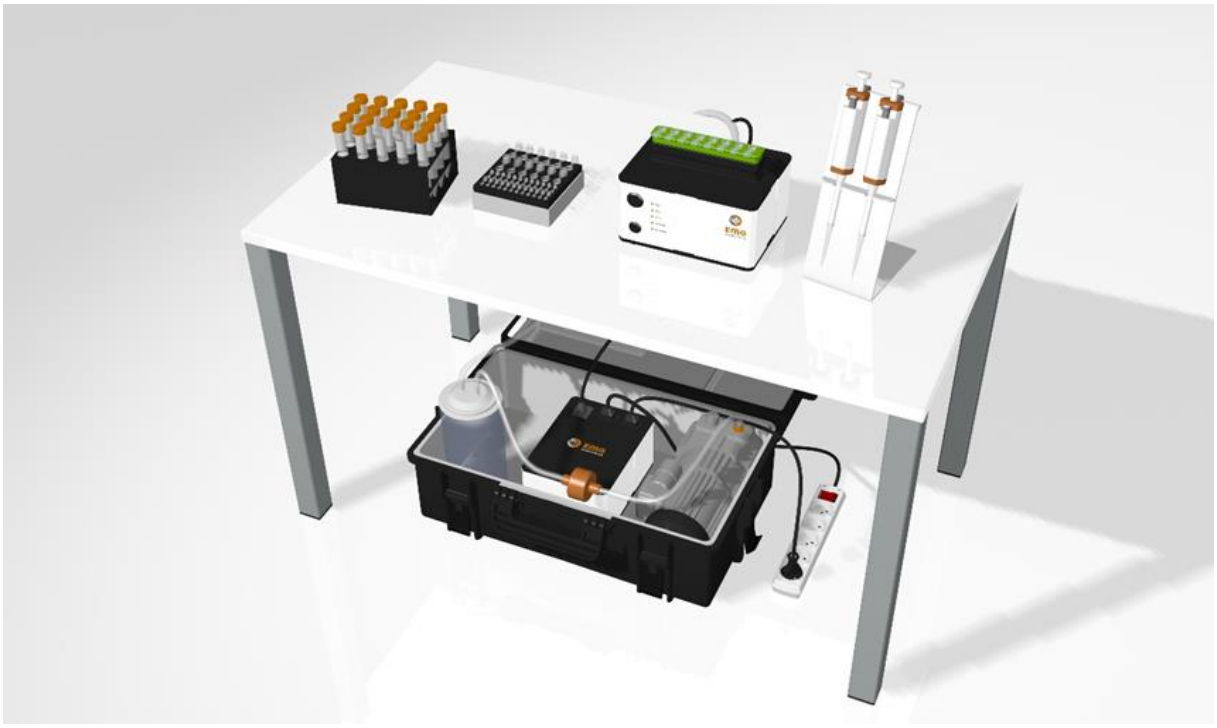
SmartAmp® provides a unique isothermal amplification test solution to detect the presence of highly specific gene sequences of SARS-CoV-2. SmartAmp® has a higher standard of sensitivity and specificity and is more cost-effective compared to usual RT-PCR technologies.

This mobile solution has been designed specifically for use at **Point of Care** with the following clinical settings in mind:

- quarantine
- transportation hubs
- moderate and high complexity laboratories
- EMS and emergency departments
- military field hospitals
- mobile lab solutions
- departments of public health.

Components of LifeCase COVID-19

CASE 1 Pre-PCR



CASE 2 Post-PCR

Caution - the pre-PCR (RNA Extraction) and PCR (Amplification) handling zones should be in different rooms!

The “LifeCase COVID-19” portable mini laboratory includes:

Case 1 Pre-PCR	
Pretreatment device for the nucleic acids extraction from the biological samples for SARS-CoV-2 isothermal amplification performance (the “Pretreatment Device”)	1
Interface unit	1
Tray	1
Rack 1 (plugged unit)	1
Rack 2 (filtration unit)	1
Rack 3 (eluate collection unit)	1
Waste collection container with a lid	1
Antibacterial air filter	1
Connection tube 1.8 m	1
Connection tube 0.6 m	2
Connecting cable	1
Compressor	1
Compressor connecting cable	
Power cord	1
Operational documents:	Enclosed inside Case 2
Handbook	1
Datasheet	1
Additional equipment (optional):	
Automatic pipette 0.5 - 10 μl	1
Automatic pipette 100 - 1,000 μl	1
Microtube rack	3

Case 2 Post-PCR	
Isothermal amplifier for SARS-Cov-2 nucleic acid detection according to TU 26.51.53-003-06931260-2020 (the “Isothermal Amplifier”)	1
Power supply unit	1
USB A-B 2.0 high-speed cable	1
USB drive with software	1
Operational documents:	
Handbook	1
Datasheet	1
Accessories:	
Laptop PC (optional)	1

Please note, that the following procedures must be performed in different rooms:

- Isolating the nucleic acids of viruses from biological material using the Pretreatment Device
- Preparing the reaction mixture and performing the isothermal amplification using the Isothermal Amplifier

Pretreatment Device

Pretreatment procedure with specimens must be executed with a set from Case 1, containing the Pretreatment Device, i.e. a device to extract nucleic acids of viruses from biological material and then run isothermal amplification of SARS-CoV-2 RNA.

Operating conditions

- Temperature +15°C to +35°C
- Relative humidity 30% to 85% (avoid condensation)
- Do not use the Pretreatment Device, if packaging is damaged or the Pretreatment Device has signs of damage.
- Do not use the Pretreatment Device, if transportation and storage conditions were not met.

1. Additional materials and equipment required

I. Equipment and materials included

(a) Pretreatment device for the nucleic acids extraction from the biological samples.

1. SSB - Swab Suspension Buffer
2. WS1- Washing Solution 1
3. WS2- Washing Solution 2
4. ES - Elution Buffer

The aim of the pretreatment procedure is to extract the virus RNA genome from the specimens containing virus particles as well as epithelial cells, mucosa and other human cells. The method stages are as follows:

SSB Virus particles lysis
Chaotropic salts release viral RNA and inactivate nucleic acids degrading enzymes, RNase and DNase from specimens.
WS1 Binding of nucleic acid to the glass filter
WS2 Washing out substances that interfere with amplification reaction
EB Nucleic acid elution
Elution Buffer removes nucleic acid from the filter, and then nucleic acid is being collected for further analysis by SmartAmp.

(b) Filter column

(c) 2.0 ml tubes.

II. Additional equipment and materials used

- Laminar Flow Cabinet as RNA extraction must be performed in a desktop biological safety cabinet
- Microtube racks
- Disposal containers for pipette tips and microtubes
- Disposable tips for variable volume microliter pipettes with an aerosol barrier of up to 200 µl, 1,000 µl
- Container with liquid disinfectant
- Swabs

- *Measuring equipment and materials used must have appropriate certification and registration for your country.*
- *Only use (a) sterile, (b) disposable, (c) plastic and (d) "RNase-free" marked materials when working with RN.*

2. Personal protective equipment

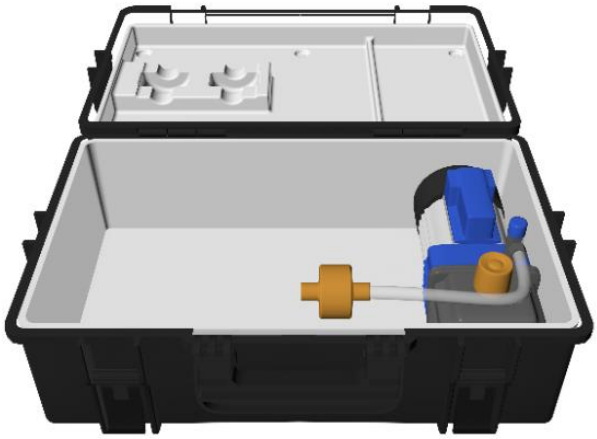
Disposable personal protective equipment is required when using the Pretreatment Device:

- Medical masks/respirators
- Lab safety goggles
- Lab coats
- Gloves

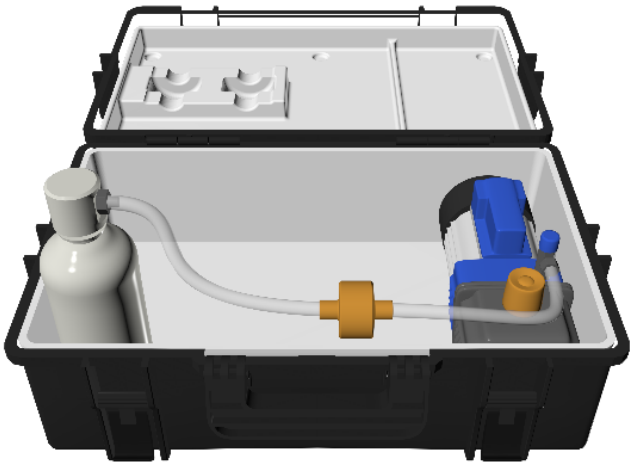
3. Installation and start-up

3.1 Installation

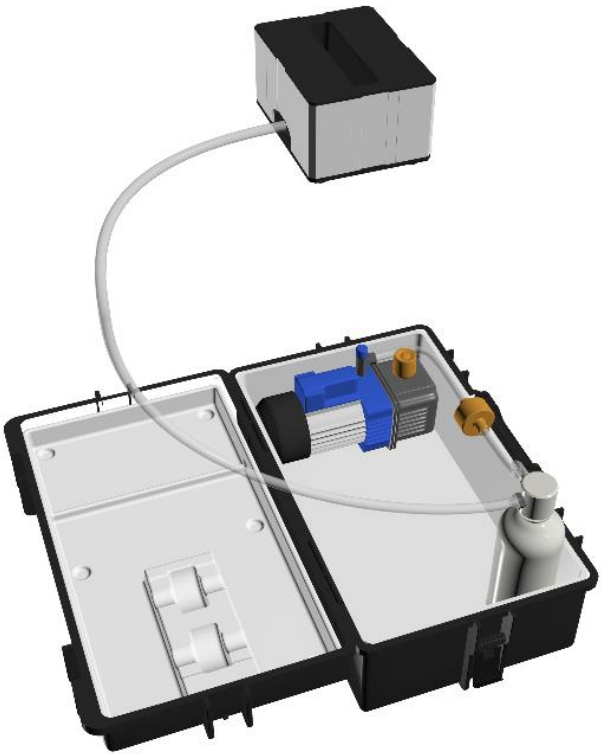
I. Use transparent connection tube №1 (0.6m) to connect the filter output to the compressor inlet (take special care to connect to the proper inlet)



II. Use transparent connection tube №2 (0.6m) to connect the filter inlet to the waste collection bottle output: "OUT"

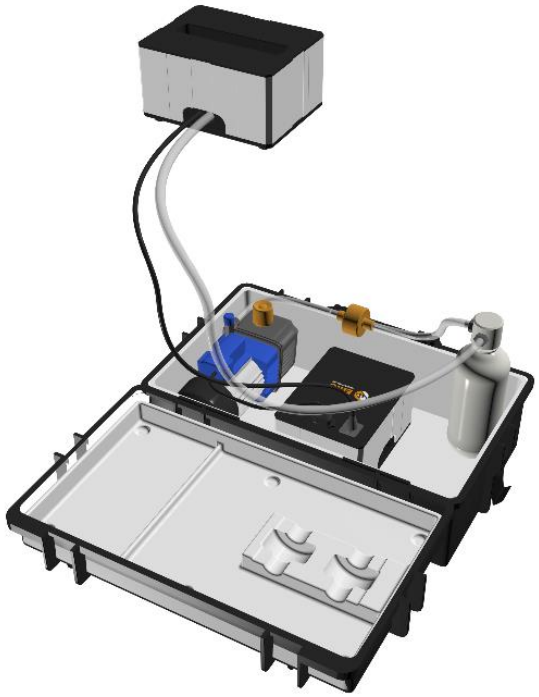


III. Use transparent connection tube №3 (1.8m) to connect the output of the interface unit to the input “IN” of the waste collection bottle.

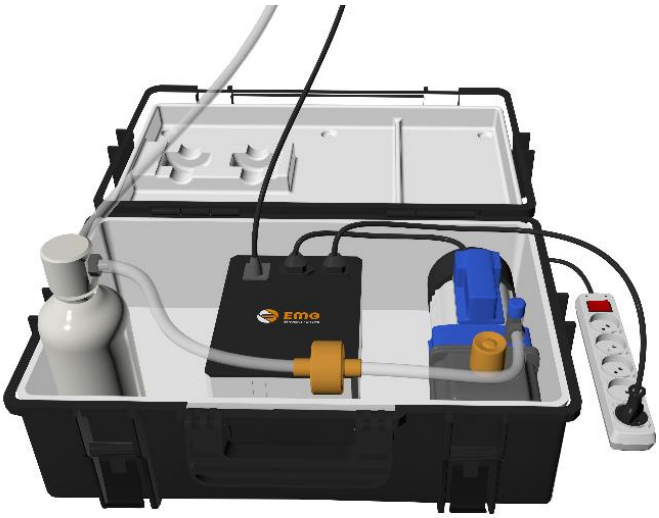


IV. Connect the compressor power cable to the appropriate connector on the interface unit

V. Connect the Pretreatment Device interface cable to the appropriate connector of the interface unit



VI. Connect the Interface Unit to a 220v outlet with the included power cable.



3.2 Turning the Pretreatment Device On

- Place the Pretreatment Device on a flat, solid and stable surface.
- Ensure adequate ventilation by installing the Extraction Device in a manner when the distance between the compressor and the wall is minimum 20cm.
- Power ports of Pretretment Device and Compressor are marked with DEVICE and COMPRESSOR indications, respectively. You must not connect any devices other than those provided for in this Manual.

- The SSB indicator LED shows if the device is on and ready for operation. When the device is ON, the SSB indicator LED shows a steady yellow light.

3.3 Turning Off

3.3.1 Do the following steps before turning the Pretreatment Device off:

- Make sure all used components of the Reagent Kit (tubes and filter column) have been removed from the Pretreatment Device.

To turn off the Pretreatment Device, unplug the power cord.

3.3.2. After the Pretreatment Device has been unplugged:

- Remove the waste collection container with a lid, deactivate and dispose of the collected waste.

- Clean and disinfect the container, pneumatic tubes, tray and Rack 1 by immersing into a disinfectant solution. Clean and dry the components.

- If necessary, replace antibacterial air filters. Filters should be replaced every 24 hours.

- If necessary, remove all contaminants from the surface of the Pretreatment Device and disinfect the surface in an appropriate manner.

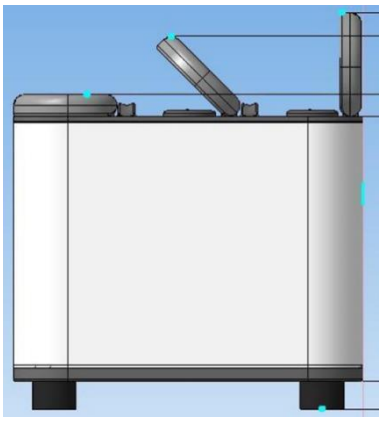
4. Operation

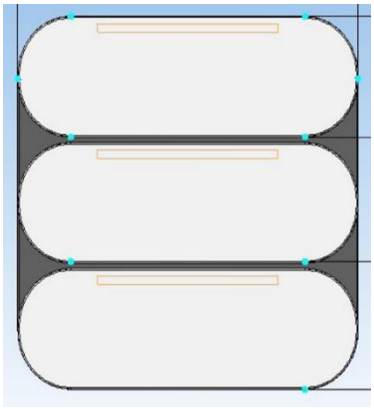
See TESTING PROTOCOL

5. Troubleshooting

- During the Pretreatment Device operation, errors may occur.
- If there is an error, the light indicator of the next stage will be off.
- If a malfunction occurs, turn the power to the Pretreatment Device off and contact the Manufacturer.

Isothermal Amplifier





- The Isothermal Amplifier is intended for conducting isothermal amplification of a specific SARS-CoV-2 RNA sequence isolated from a sample of biological material and for detection of real-time Isothermal Amplification results.
- The Isothermal Amplifier is intended for use together with Detection kit for the SARS-CoV-2 RNA presence in biological material using real-time isothermal amplification method in different versions ("Detection Kit") produced by EMG.
- The Isothermal Amplifier allows conducting SmartAmp analysis based on the principles of fluorescence detection of the reaction product. Estimation of the amount of accumulated SmartAmp amplification product occurs directly during the temperature cycles of the reaction (real-time Isothermal Amplification).
- The Isothermal Amplifier is a device that combines the functions of precision heating and temperature maintenance and an optical system that allows to record the fluorescence of the reaction mixture in test tubes directly during the polymerase chain reaction.
- The Isothermal Amplifier consists of three independent heating units (channels) of up to 8 test tubes containing the reaction mixture, which can be installed in each channel. The heating temperature of the Isothermal Amplifier is pre-set by the Manufacturer and must not be changed by the user.
- The Amplifier Client software is used to control the Isothermal Amplifier and display fluorescence detection in real time. The Amplifier Client software is pre-installed on the included laptop PC.

Operating conditions

- Temperature +15°C to +35°C
- Relative humidity 30% to 85% (avoid condensation)
- Do not use the Isothermal Amplifier, if packaging is damaged or the Isothermal Amplifier has signs of damage.
- Do not use the Isothermal Amplifier, if transportation and storage conditions were not met.

1. Additional materials and equipment required

Detection kit for the SARS-CoV-2 RNA presence in biological material using real-time isothermal amplification method in different versions (the "Detection Kit") produced by EMG.

The Detection Kit includes:
1. Reagent E, transparent colorless liquid, 0.6 ml, 1 tube
2. Reagent P, transparent colorless liquid, 0.4 ml, 1 tube
3. Positive control sample, transparent colorless liquid, 150 µl, 1 tube
4. Negative control sample, transparent colorless liquid, 150 µl, 1 tube

Additional materials and equipment required:

- A set of electronic or mechanical variable volume microliter pipettes, with a variable volume of 20-200µl, 100-1,000 µl
- Laminar flow cabinet
- Microtube racks
- Disposal containers for pipette tips and microtubes
- Single-use disposable tips for variable volume pipettes with aerosol barriers of up to 200, 1000µl
- Disinfectant solution container
- Nasopharyngeal swab
- Tests should be conducted in a desktop biological safety cabinet under a bactericidal lamp

  - *Measuring equipment and materials used must have appropriate certification and registration for your country.*
  - *Only use (a) sterile, (b) disposable, (c) plastic and (d) "RNase-free" marked materials when working with RNA.*

2. Personal protective equipment

Disposable means of personal protective equipment is required when using the Isothermal Amplifier:

- Medical masks/respirators
- Lab safety goggles
- Lab coats
- Gloves

3. Installation and start-up

3.1 The Isothermal Amplifier must be installed in a place convenient for continuous operation, with adequate ventilation to prevent condensation and free access to the Isothermal Amplifier.

3.2 Before starting up the Isothermal Amplifier, make sure the power outlet you are plugging the Isothermal Amplifier into has protective grounding and the Isothermal Amplifier and its power adapter have no signs of external or internal damage.

3.3 First, connect the power adapter that is included to the Isothermal Amplifier. Plug the cable into the power outlet.

3.4 Connect the Isothermal Amplifier to the laptop PC with the included USB A-B 2.0 high speed cable.

3.5 Before turning the Isothermal Amplifier off, please make sure all the tubes were removed from the Isothermal Amplifier.

3.6 To cut power off completely from the Isothermal Amplifier, access the back side of it and the power outlet to unplug the power cable and the USB 2.0 connection cable.

4. Operation

4.1 Turning On and Launching the Software

- Make sure the Isothermal Amplifier is connected to the laptop PC with a USB A-B 2.0 cable. Turn on the Isothermal Amplifier and laptop PC.
- When the Isothermal Amplifier is connected to the laptop PC, AmplificatorClient program will launch automatically.

4.2 Preparing the Device to perform PCR

- The Device self-checks its status every time it is turned on. The thermal system is checked as well, i.e. thermal block temperature, thermostat temperature, lid temperature, are all checked for conforming parameter values.
- The Device does not require setting thermal parameters, choosing detection channels and is optimized to work with the Detection Kit for SARS-CoV-2 Coronavirus RNA detection in biological material using real time isothermal amplification.
- The amplification reaction is carried out at a set temperature, product registration occurs at excitation/detection wavelengths of 464 nm and 520 nm, respectively.

4.3 Operating the Device

- Open the required channel lid
- Install prepared reaction tubes into slots
- Tightly close the channel lid
- Choose the tab corresponding to selected channel in the software
- Press “START” in the software
- Press “YES” in the pop-up window to confirm
- The reaction in selected channel has started

- Do not open the channel lid of the Isothermal Amplifier until analysis is complete.
- During the test, you can see how much time has passed since starting the amplification for each of the channels in corresponding tabs, you can also monitor progress and the current heater temperature. In the main part of the tab you can also see reaction curves for each slot, where X-axis represents the fluorescent signal, and Y-axis represents the reaction time. Displayed borders can be adjusted with “min X” and “min Y” settings. Set desired borders and press “Apply”, to roll back to automatic scale, press “Reset”.
- Make sure the “Raw data” box is ticked when conducting the procedure and reading results.
- If needed, you can abort the reaction by pressing “STOP” in the software.
- Each of the three channels can be loaded up, launched and aborted individually. To control them, go to their corresponding tabs in the software.
- To restore the analysis data in case of accidental interruption of connection between the Isothermal Amplifier and PC, press “Reload data from device” button in the software.
- To export the analysis results, press “Export” in the software.

4.4 Troubleshooting and possible fixes.

Error description	Possible reason	Possible fix
After turning the Isothermal Amplifier on, slots didn't light up.	No power in the power outlet.	Check if current is present in the power outlet, check if the power outlet is serviceable.
	Poor electrical contact or damaged power cable.	Check the power cable and its connection to the Isothermal Amplifier.
Isothermal Amplifier is not recognized in the status bar in the software, Isothermal Amplifier is turned on.	Poor electrical contact or damaged PC power cable	Check the power cable its connection to the PC
	Isothermal Amplifier driver is not installed	Install Isothermal Amplifier driver
	Windows error/malfunction	Restart PC
Error message popped up during amplification procedure	Isothermal Amplifier to PC connection was lost.	Restore the connection between the Isothermal Amplifier and the PC, the program will detect the Isothermal Amplifier.

Please contact the Manufacturer if you are experiencing a problem that is not mentioned here.

Swabbing procedure

Preparation for swabbing procedure

- A patient or contact person should not drink or eat, gargle or wetten the throat at least 1 hour before swabbing.
- Nasal inhalers and use of oil-based sprays on the day of swabbing are not allowed
- Spray use is allowed at least 1 hour before swabbing
- The nose should be cleaned from excess secretions 1 hour before swabbing

Two samples should be taken: nasopharyngeal and oropharyngeal.

To take a nasopharyngeal swab, insert the swab into the nasal passage to such a depth where you feel a slight resistance to the further advancement of the swab; rotate the swab for 5 seconds and remove it.

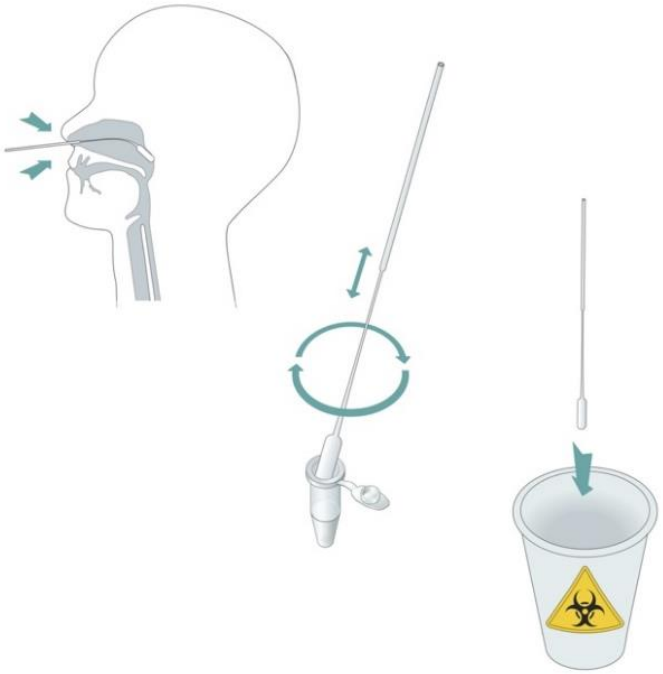
Option 1:

Place the swab into a tube containing 1 ml of the SSB solution. Follow the **TESTING PROTOCOL**. Place the used swab into a tube and dispose of it in accordance with relevant standards.

Option 2: Place the swab into a tube containing 1 ml of the SSB solution. Transport. Use no later than 12 hours after swabbing.

Option 3:

Place the swab into a tube with a transport medium, rotate the swab for 15-20 seconds, squeeze it against the tube walls, continue to rotate. Place the used swab into a tube and dispose of it in accordance with relevant standards. Transfer 200 µl of the transport medium to a tube containing 1 ml of the SSB solution, resuspend with the pipette nozzle for at least 5 times. Follow the **TESTING PROTOCOL**.



Tubes with the transport medium for SARS-CoV-2 detection are Eppendorf-type microtubes of 2 ml of volume with a cap containing 0.8 ml of special transport medium. Tubes with the transport medium should be stored at 2 ℃ to 8℃.

Shelf life of tubes with transport medium is up to 6 months.

Testing Protocol

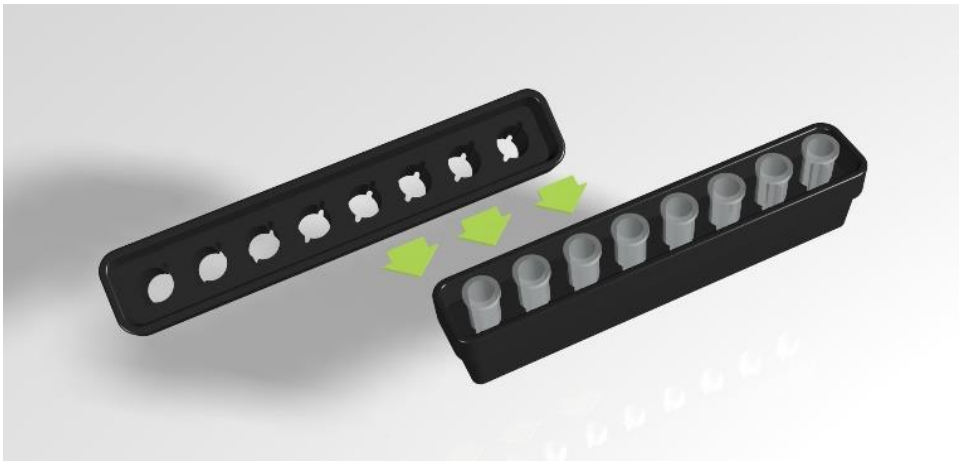
Please perform Steps 1-4 in a separated pre-PCR area using the Pretreatment Device

Stage 1. Preparation.

I. Firmly install the Tray (included into the Pretreatment Device set) into the respective slot of the Pretreatment Device.

II. Firmly fit Rack 1 onto the Tray

III. Firmly install 8 empty DNA LoBind, PCR-clean tubes included in the Reagent Kit in the holes of Rack 3 for collecting the eluate.



IV. Firmly fit Rack 2 onto Rack 1.

V. Firmly install 8 filter columns included in the Reagent Kit in the holes of Rack 2.

Stage 2. Sample Preparation *(see also for the Swabbing procedure)*

It is recommended to carefully label all the tubes to keep record of the samples.

2.1 **Pipette 1 ml of the *SSB*** reagent into a DNA LoBind, PCR-clean Eppendorf disposable tube of 2 ml volume to suspend the patient sample.

2.2 **Perform sampling** with a swab. Products used to collect material must be certified as medical products.

2.3 **Place the swab into a tube** containing 1 ml of the SSB solution. Rotate the swab in the tube for ~20 seconds, squeezing the swab against walls of the tube.

Dispose of the swab according to the local clinical waste disposal regulations.

The resulting lysate does not contain any viable viruses (it is achieved by the composition of the ***SSB*** solution) and can be used in further pretreatment procedure.

Stage 3. Sample Extraction

3.1 **Step 1: SSB**

Carefully pipette **500 µl of the SSB** solution containing your sample into a filter column and press the Control button. Closely monitor filtration and once all the solution has passed through the silica membrane filter, press the Control button again to turn the device's vacuum system off.

Repeat this step with the remaining 500 µl of the sample.

3.2 **Step 2: WS1**

Carefully pipette **500 µl of the WS1** reagent into the filter column and press the Control button. Closely monitor the WS1 reagent to ensure it has completely passed through the silica membrane filter in the column. Once complete, press the Control button again to turn the device's vacuum system off.

Repeat this step 1 more time to the total of 1ml of WS1 solution used.

3.3 **Step 3: WS2**

Pipette **700 µl of the WS2** reagent into the filter column and press the Control button. Closely monitor the WS2 reagent filtration to ensure solution has completely passed through the silica membrane filter in the column. Once complete press the Control button to turn the device's vacuum system off.

Repeat this step 3 more times to the total of 2.8ml of WS2 solution used.

3.4 **Step 4: DRYING**

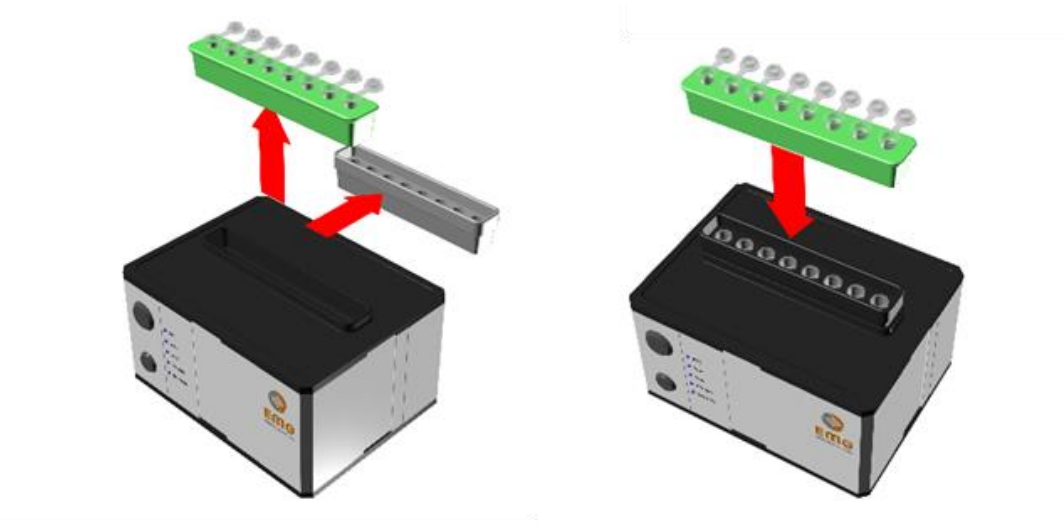
Press the Control button to initiate the **DRYING** step. Perform **DRYING for at least 5 minutes.** Visually monitor the process to ensure complete silica membrane drying.

While performing the DRYING step, insert 2 ml collection tubes in Rack 3, if haven't done so yet

Note: If ***WS2*** reagent stays at the tips of the columns, this can lead to inhibition of the amplification reaction and, as a result, to a false negative result.

3.5 **Step 5: ELUTION**

Replace Rack 1 with Rack 3 containing the eluate collection tubes. Fix in place tightly.



3.6 Step 6:

Carefully pipette **120 µl of the EB** reagent directly onto the silica membrane and press the Control button. After the EB reagent has completely passed through the membrane filter, press the Control button again to turn the device's vacuum system off.

3.7 Step 7:

Visually check the liquid has accumulated in the eluate collection tube located in Rack 3. Collected solution is an eluate containing extracted RNA from the sample. The eluate solution can now be used in the amplification reaction.

3.8 Step 8:

After completing all stages of pre-treatment, disconnect Rack 2 from Rack 3. Transfer the eluate from Rack 3 to the corresponding signed tube and use it in accordance with the amplification instructions.

3.9 Step 9:

Disinfect Racks with a 3% hydrogen peroxide solution adding 0.5% detergent or with 1% chloramine solution.

Immediately proceed to Step 4 of the Testing Protocol!

If sample components or used reagents are on the surface of the Pretreatment Device, disinfect the surfaces by wiping in compliance with effective in-house rules.

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Stage 4. SARS-CoV-2 RNA Detection

Sample preparation:

4.1 Pipette **4 µl** of ***Reagent P*** into each 0.2 ml test tube;

4.2 Add **10 µl** of the extracted RNA sample into each test tube, mix by pipetting;

4.3 Add **6 µl** of ***Reagent E*** into each test tube, mix 5 times by pipetting.

Positive Control Sample Preparation:

4.4 Pipette **4 µl** of ***Reagent P*** into the positive control tube;

4.5 Add **10 µl** from the **Positive Control Sample** tube, mix by pipetting;

4.6 Add **6 µl** of ***Reagent E***, mix 5 times by pipetting.

Negative Control Sample Preparation:

4.7 Pipette **4 µl** of **Reagent P** into the negative control tube;

4.8 Add **10 µl** from the **Negative Control Sample** tube, mix by pipetting;

4.9 Add **6 µl** of **Reagent E**, mix 5 times by pipetting.

Recommendations: When performing the pretreatment procedure, use the Negative Control Sample for data interpretation reliability. For these purposes, all the sample extraction stages (SSB, WS1, WS2, Drying, Elution) must be performed on one of the columns, without placing the Sample into SSB.

Sample preparation (including if necessary, Positive Control Sample and Negative Control Sample preparation) must be performed only with the use of the Pretreatment Device and corresponding tubes signed and afterwards forwarded to a separate post-PCR-area and installed into the Isothermal Amplifier!

If sample components or used reagents are on the surface of the Pretreatment Device, disinfect the surfaces by wiping in compliance with effective in-house rules..

Please perform Stages 5-6 in a separated area using the Isothermal Amplifier

Stage 5. Amplification.

5.1 Install the prepared test tubes into the slots of the Amplifier channels.

5.2 Perform incubation reaction with preinstalled settings (67°C, cycle time is 60 seconds, registration of the fluorescent signal performed at the end of each minute), expected reaction time shall not exceed 40 minutes, however **only 30 cycles are to be considered for interpretation.**

If the fluorescence curve starts developing after 30th cycle, this might be a false positive. In case of doubt, repeat the test of this particular sample.

Avoid moving, shaking or causing any vibration to the Isothermal Amplifier during amplification, this might affect your results.

Stage 6. Results Evaluation.

- Amplification and results recording are performed in accordance with the operational documentation of the device.
- Interpretation of the results and the reliability of the reaction is carried out by positive and negative control.
- The results are interpreted based on the presence (or absence) of the fluorescence accumulation curve.

Experimental results are valid if:

a) Fluorescence curve has developed for the positive control sample. This indicates that primers have attached to DNA strand.

b) No fluorescence curve has developed for the negative control sample. This indicates that no contamination with foreign DNA has occurred.

Please keep record of all samples tested positive:

c) Positive sample is indicated by a fluorescence curve developed.

The result is considered positive if a fluorescence accumulation curve develops and reaction time does not exceed 40 minutes. **The Ct value must be lower than 30**. The amplitude of the signal does not matter.

The result is considered negative if there is no rise in the fluorescent curve.

Stage 7. Safe Disposal

7.1 Used components, which have contacted biological samples, are subject to disinfection and then must be stored in waste collection containers or plastic bags and disposed of as Class C extremely hazardous waste. Kits that have become unusable, inclusive of expired Kits and Kits that were opened but not used, are disposed of as Class D waste. The packaging is disposed of as Class A waste. Waste classification might differ in your country, please contact the manufacturer if additional info is required.

Maintenance

1. General provisions

- Device technical maintenance is aimed at prolonging its lifespan and keeping it in a proper working condition.
- Device technical maintenance must be carried out by a qualified specialist, after carefully reading the Manual.
- Device is designed in a way that requires minimal technical maintenance during regular laboratory use.
- Device must be protected from mechanical damage and fluids getting on it or inside of it.
- Always keep the Isothermal Amplifier channel lids closed when not in use to keep contamination, dirt, fluids or other particles from getting inside. This will help keep the optics and the slots clean (except for when you must open the lids to install or remove the tubes).

2. Maintenance instructions

2.1. The following procedures can be performed by the maintenance staff:

- Visual examination to make sure there is no physical damage (every time before starting the Device).
- Checking the power adapter and all the cables and ports for connection reliability and stability.
- Keeping the Device surfaces clean from dust and dirt with a clean dry disposable wipes.

2.2 The Device is designed in a way that eliminates the possibility of it spraying or spattering fluids.

2.3 In case of potentially contagious reagents or samples getting on the Device, disinfect it following relevant guidlines.

2.4 Cleaning the Isothermal Amplifier channel slots with a cotton swab dampened in 96% ethanol or 100% isopropyl alcohol (can use regular cotton swabs sold in pharmacies).

2.5 Do not use metal objects to clean the Isothermal Amplifier channel slots.

2.6 When cleaning the Isothermal Amplifier channel slots, avoid alcohol getting into the device gaps or edge clearances.

2.7 Isothermal Amplifier channel slot cleaning frequency: every 20 cycles of tests, cleanliness of the slots must be examined. If there are foreign bodies, dirt or contamination present in the slots, please remove them.

3. Current Repairs and Maintenance

The current repair and maintenance of the Device is carried out by an authorized service department.

Users must not carry out any repairs or maintenance by themselves.

4. Storage

The Device in the manufacturer's packaging must be stored in well-ventilated rooms at -20°C to + 40°C and relative humidity of 30% to 85% (non-condensing). Atmospheric pressure must be from 53.0 kPa to 106.0 kPa.

5. Transportation

5.1 The Device is transported by all types of covered transport in accordance with the rules of cargo transportation applicable to this type of transport. Vehicles must be covered, dry and clean.

5.2 The device is transported in the manufacturer's packaging at -40°C to +65°C and relative humidity of 10% to 90% (non-condensing).

5.3 During loading, unloading, transportation of and storage, measures must be taken to protect the Device from mechanical damage and contamination.

Warnings and Precautions

PLEASE READ THIS SAFETY INFORMATION CAREFULLY BEFORE YOU GET STARTED!

General Safety Rules

- Any reagents and materials used in testing must be handled and disposed of in compliance with the guidelines for handling potentially infectious materials. Avoid direct contact with these reagents. Avoid their leakage or spraying. Waste management and disposal must be carried out in compliance with safety regulations. Disposable combustible materials should be incinerated. Liquid waste containing acids or bases must be neutralized before disposal.
- Use protective clothing and gloves, protect your eyes and face. Do not ever use your mouth to pull the liquid into a pipette.
- Do not eat or drink, smoke or apply makeup at the workplace. Wash hands thoroughly after handling samples and reagents.
- Waste disposal or unused reagent handling is carried out in compliance with applicable safety standards and guidelines.
- Before running a test, read the Instruction for Use supplied with the kit.
- When running a test, follow the guidelines specified in the Instruction for Use.
- Do not use an expired kit.
- Use only the reagents contained in the kit or recommended by the manufacturer.
- Do not mix reagents from different kits or series.
- Before you start using the device, read these guidelines carefully paying special attention to safety rules. To avoid personal injury and damage to the device and supplementary equipment, please follow these safety rules.
- A violation of the operating guidelines or intended use can impair the protection provided by the equipment and pose a health risk.
- You must not use the device if the humidity indicators in the room exceed 85%. Condensation may damage the electronics of the Device.
- Protect the Device from strong vibrations, impacts and falls.
- The Device should only be stored and transported in an upright position.
- After high-humidity and low-temperature transportation or storage, it is necessary to dry the Device out (for 2 to 3 hours) before connecting it to a power supply. During drying, the internal protection may be impaired.
- Avoid getting any liquids or objects inside the Device. This may cause damage to the Device.
- EMG LLC is not responsible for any injuries or damage to health caused by improper use of the Device or its repair and modifying performed by the user.

Biosafety guidelines

- Biological hazard! Samples may contain infectious agents. You must be aware of the health risks caused by such agents and must use, store and dispose of such samples in compliance with required safety regulations.
- Any samples of biological material must be used and disposed of in compliance with the guidelines for handling potentially infectious materials. Avoid direct contact with samples of biological material. Avoid leakage or spraying of samples of biological material.

Electrical Safety Rules

Before connecting the Device to a power supply, make sure the Device can be properly grounded. To do this, check the outlet, to which the device will be connected, for grounding and the connector cable for any damage. You must not connect the device to a non-grounded electrical outlet. To connect the Device to a power supply, use the connector cable included with the device.

If any liquid gets inside the device, disconnect the power supply and contact Customer Service.

During operation

Do not expose the device to heat or sunlight or other strong light sources.

Service

Do not attempt to open the device yourself! There are no components inside the device the user is required to service.

The device is an IVD medical device and does not cause any direct biological hazard. Maintenance should only be carried out by specially trained and qualified staff.

Environmental Impact

Decommissioning for repair or disposal: The device does not cause any biological hazard when in normal use.

The device must be disposed of in compliance with effective regulations. The device contains no substances causing a direct threat to the environment.

Limitations

1. Test results will depend heavily on biological sample swabbing quality, preparation, transportation, storage conditions and storage time.
2. Carefully follow the protocol to ensure true results.
3. Negative test results may not eliminate CoViD-19 infection possibility, since test results may be affected by a number of factors: biological sample quality, protocol errors, sample mixup, technical errors, local power grid instability, lack of disinfection or PPE, contaminated tubes or pipette tips, operator being infected, improper premises, lack of biological safety cabinet, improper ventilation, unskilled labor, etc.
4. SmartAmp Detection and Reaction reagents must be stored and transported in accordance with their storage conditions.
5. SmartAmp technology has high specificity and sensitivity rates, however false-negative or less sensitive results might be obtained due to sequence heterogeneity within the target region of clinical subtypes that are not yet described
6. When interpreting results, consider clinical findings as well as laboratory findings.
7. Please note, that since there is no proven immunity to CoViD-19 at the time of writing of this Manual, people who recovered from CoViD-19 might be infected again.

Thank you for reading this Manual!

Please contact the Manufacturer or local Distributors of EMG products should you need any assistance or additional info.