Sacace BIOTECHNOLOGIES

IVD For *in Vitro* Diagnostic Use

REF K502/100/A Σ 96

CE

M-Sorb-S

For use with **SaMag-96** automatic nucleic acids purification system

VIRAL RNA/DNA ISOLATION KIT **NEW VERSION**
(03.07.23)

NAME
M-Sorb-S

INTENDED USE
The **M-Sorb-S** kit is designed for the rapid, efficient magnetic preparation of highly pure viral nucleic acids from human nasopharyngeal swab specimens, sputum, bronchoalveolar lavage and urogenital swabs using automated magnetic separator Sacace SaMag-96 or equivalent instruments. It is recommended to carefully read the automatic extraction instrument operation manual before using this extraction kit.

PRINCIPLE OF ASSAY
Purification begins with the addition of Lysis reagents to clinical sample. DNA/RNA are immobilized on magnetic particles surface and contaminants (potential PCR inhibitors) like salts, metabolites and soluble macromolecular cellular components are removed in simple washing steps using Washing Reagent. The nucleic acids can be eluted in the Elution Reagent and are ready to use in subsequent reactions like RT-PCR (for nucleic acids detection of viruses like SARS-Cov-2, HPV or sexually transmitted bacteria like *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, etc) DNA sequencing, or any kind of enzymatic manipulation. We highly recommend the use of controls provided with the PCR amplification kit such as internal control, positive and negative controls to monitor the purification, amplification and detection processes.

MATERIALS PROVIDED
- **Lysis Reagent, LR** – 50 ml each;
- **Sorbent Reagent, SR (suspension of magnetic particles)** – 4 ml;
- **Wash reagent, WR** - 65 ml;
- **Elution Reagent, ER** - 18 ml;

Contains reagents for 96 tests.

MATERIALS REQUIRED BUT NOT PROVIDED
- **Tip Comb Sleeve (SaMag-96) plastic** – or equivalent consumable
- **96 Deep Well plate (SaMag-96) plastic** –or equivalent consumable
- Biological cabinet
- SaMag-96 Nucleic Acids Purification system or equivalent instrument
- Desktop microcentrifuge for “eppendorf” type tubes
- Vortex
- Tube racks for 1.5 ml tubes;
- RNAse free disposable reagent reservoirs
- Dry thermal block
- Multi-channel Micropipettes
- Sterile, RNase-free pipette tips with filters
- Biohazard waste container
- Disposable gloves, powderless

SPECIMEN COLLECTION AND CONSERVATION
M-Sorb-S nucleic acid extraction kit is optimized for **RNA/DNA** extraction and purification from:
- Nasopharyngeal swabs: Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Place swab immediately into sterile tubes containing 0,5-2 ml of viral transport media.
- Oropharyngeal swab (e.g., throat swab, OP): Swab the posterior pharynx, avoiding the tongue. Place swab immediately into sterile tubes containing 0,5-2 ml of viral transport media.
- Urogenital swab:insert the swab into a nuclease-free 1,5 ml tube,add 0,2 mL of Transport medium.Vigorously agitate for 15-20 sec.
- Non-viscous, clear and homogenous sputum and bronchoalveolar lavage samples can be used directly for nucleic acid extraction. Transfer the appropriate sample volume (e. g. 200 µL) to a suitable reaction tube and proceed with the standard protocol starting with the sample lysis step.
- Viscous sputum and bronchoalveolar lavage samples should be liquefied before subjecting them to the nucleic extraction procedure. Transfer the appropriate sample volume (e. g. 200 µL) to a suitable reaction tube, add 500 µl of of Lysis reagents to the sample and incubate at 70 °C for 10 min with moderate shaking. Proceed with the standard protocol starting with the sample lysis step.

Note: Handle all specimens as if they are potentially infectious agents.
Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

STORAGE CONDITIONS AND
- **M-Sorb-S** kit should be stored dry at **+2-8°C**. The kit can be shipped at **25°C** for up to 10 days but should be stored at **+2-8°C** immediately on receipt. **M-Sorb-S** reagents can be stored for up to 1 year under the above conditions without showing any reduction in performance.

PREPARATION OF WORKING SOLUTIONS
- Before use **Lysis Reagent** must be prewarmed at **60°C** for **5 min** in order to dissolve salts.
- Vortex gently vials with **Sorbent Reagent and Wash reagent** until obtaining a homogeneous suspension.

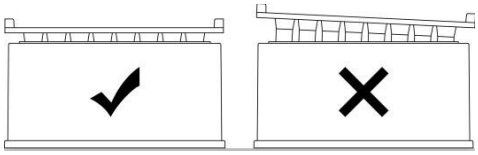
PROTOCOL FOR AUTOMATIC EXTRACTION WITH SAMAG-96 INSTRUMENT

1. Turn the instrument ON, open the lateral transparent door. Navigate through positions using the physical buttons.

NOTE: for all 96 Deep Well plates, make sure the orientation is correct. Well A1 corner of each plate must always be in the bottom left position as indicated on the plate socket.

2. Put first one 96 Deep Well plate in **position "1"** of the SaMag-96. Then place one Tip Comb Sleeve consumable inside such 96 Deep Well plate as in the pictures below (always careful not to touch the magnetic rods):

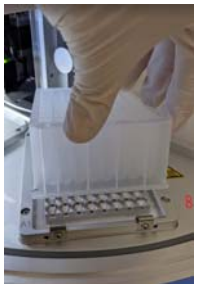


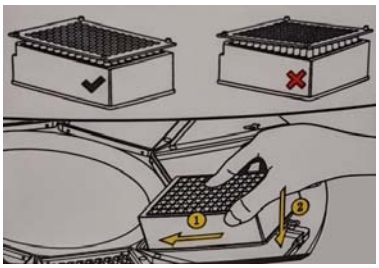


Correct setting *Wrong setting*

Disposable reagent reservoir example, smooth bottom is recommended

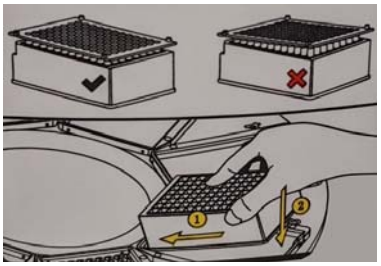
3. Prepare three 96 Deep Well plates, mark one for "Elution", one for "Wash", one for "Lysis".
4. Transfer the content of Elution reagent to a clean, RNAse free disposable reagent reservoir (not provided, see example picture above). Using a multi-channel micropipette add **120 µl** of **Elution reagent** to each well of the 96 Deep Well **plate marked as "Elution"**.
5. Transfer the content of Wash reagent to a clean, RNAse free disposable reagent reservoir. Using a multi-channel micropipette add **600 µl** of **Wash reagent** to each well of the 96 Deep Well **plate marked as "Wash".**
6. Mix the entire content of **Lysis Reagent, Sorbent reagent**, and **960 µl** of Internal Control (if provided with the amplification kit) into a clean, RNAse free disposable reagent reservoir.
7. Using a multi-channel micropipette, add **550 µl** of the solution prepared in step 6 to each well of the 96 Deep Well **plate marked as "Lysis".**
8. Add **100 µl** ***(see Note 2)*** of each **Sample** and **Negative Control of Extraction** to the appropriate wells (according to previously prepared sample position scheme of the plate) of the 96 Deep Well **plate marked as "Lysis".**
9. Insert carefully the prepared **"Elution"** 96 Deep Well plate inside the SaMag-96 instrument in **position "8"**





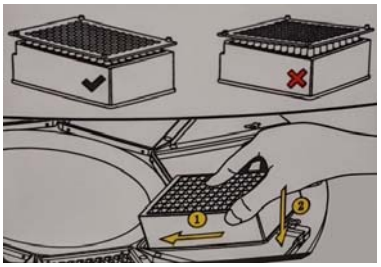
10. Insert carefully the prepared **"Lysis"** 96 Deep Well plate inside the SaMag-96 instrument in **position "2"**





11. Insert carefully the prepared **"Wash"** 96 Deep Well plate inside the SaMag-96 instrument in **position "3"**





12. Close the SaMag-96 door and using touch-screen select the program **"M-Sorb-Sac"** (if not present inside the instrument, download from https://www.sacace.com/support.htm) and press **"Run"** to start the extraction process.
13. After ~30 minutes the extraction is completed, collect the extracted Viral RNA/DNA contained in the **"Elution"** 96 Deep Well Plate in position "8", cover it with tape film if necessary. Discard the other used deep well plates.

Viral RNA/DNA is stable for up to one year when stored at –20°C or –70°C.

PROTOCOL OPTION FOR LESS THAN 96 SAMPLES

If testing of less than 96 samples is necessary, steps 1-3 of standard protocol are the same, then you can adjust the quantity for plates in this way: for N samples, add to each RNAse free disposable reservoir (not provided):

- ✓ For **plate marked as "Elution":** add N x **120 µl** of **Elution reagent** to the RNAse free disposable reservoir and then using multi-channel micropipette transfer **120 µl** to each well to be tested in the "Elution" deep well plate.
- ✓ For **plate marked as "Wash":** add N x **600 µl** of **Wash reagent** to the RNAse free disposable reservoir and then using multi-channel micropipette transfer **600 µl** to each well to be tested in the "Wash" deep well plate.
- ✓ For **plate marked as "Lysis"** prepare*:
  N x **500 µl** of **Lysis reagent**
  N x **41 µl** of **Sorbent reagent**
  N x **10 µl** of **Internal Control** (if provided with the amplification kit)
  and then add **550 µl** of such prepared mix to each well of "Lysis" deep well plate.
- ✓ Add **100 µl** of each **Sample** and **Negative Control of Extraction** to the appropriate wells (according to previously prepared sample position scheme of the plate) of the 96 Deep Well **plate marked as "Lysis".**
- ✓ **Then proceed from step 9 of the standard protocol.**

** it is recommended to add 1 to N number in order to account for possible pipetting error.*

Note1: in case of using protocol option for less than 96 samples, additional consumables will be needed and they can be ordered from Sacace Biotechnologies using the following product codes:

SM-17061-01 (Tip Comb Sleeve)
SM-17061-02 (96 Deep Well Plate)

Note2: if starting from 200 µl sample, we recommend adding 10 µl of RNA carrier (not supplied) to each sample, and to change the elution volume to 100 µl.

WARNINGS AND PRECAUTIONS

- THIS KIT IS NOT COMPATIBLE WITH SACACE SAMAG-12 AND SAMAG-24 INSTRUMENTS.
- SACACE products are intended for GENERAL LABORATORY USE ONLY! SACACE products are suited for QUALIFIED PERSONNEL ONLY!
-  Component Lysis Reagents contain guanidine thiocyanate. Guanidine thiocyanate is harmful if inhaled or comes into contact with skin or if swallowed. Contact with acid releases toxic gas. (Xn; R: 20/21/22-36/38; S: 36/37/39).
- Wear disposable gloves, laboratory coats and eye protection when handling specimens and reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
- Do not use a kit after its expiration date.
- Dispose of all specimens and unused reagents in accordance with local regulations.
- Specimens should be considered potentially infectious and handled in biological cabinet in accordance with Biosafety Level 2 or other appropriate biosafety practices.
- Clean and disinfect all spills of specimens or reagents using a disinfectant such as 0,5% sodium hypochlorite, or other suitable disinfectant.
- Avoid contact of specimens and reagents with the skin, eyes and mucous membranes. If these solutions come into contact, rinse immediately with water and seek medical advice immediately.
- Material Safety Data Sheets (MSDS) are available on request.
- Use of this product should be limited to personnel trained in the techniques of RNA/DNA amplification.
- Workflow in the laboratory must proceed in a uni-directional manner, beginning in the Extraction Area and moving to the Amplification and Detection Area. Do not return samples, equipment and reagents in the area where you performed previous step.

KEY TO SYMBOLS USED

REF	Reference Number		Caution!
LOT	Lot Number		Contains sufficient for <n> tests
IVD	For *in Vitro* Diagnostic Use	VER	Version
	Store at		Expiration Date
	Manufacturer		Warning
	Consult instructions for use		

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