RapiPREP Nucleic Acid Extraction Kit for SARS-CoV-2 (RPNA.2-1000 and RPNA.2-100)

Instructions for Use (Version 01)

CE

IVD

for in vitro diagnostic use only

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INTENDED USE

The RapiPREP Nucleic Acid Extraction Kit for SARS-CoV-2 (RPNA.SARS-CoV-2) enables the extraction of nucleic acids in a rapid, simple and solvent-free protocol for the clinical specimens (throat, nasal, nasopharyngeal, saliva swabs).

The RapiPREP Nucleic Acid Extraction Kit for SARS-CoV-2 (RPNA.SARS-CoV-2) Kit is intended to be used either manually or together with the Thermo Scientific Kingfisher liquid handling robot instrument.

The kit is an in vitro diagnostic product for use in medical laboratories and for professional use only.

PRINCIPLES OF THE PROCEDURE

The RapiPREP Nucleic Acid Extraction Kit (RPNA.SARS-CoV-2) is based on magnetic bead technology which enables the extraction of nucleic acids in a rapid, simple and solvent-free protocol. Nucleic acids eluted from swabs into Viral Lysis Buffer (VLB2.1000, MicrosensDx Ltd) or Viral Transport Medium are captured by the magnetic beads (RPNAB.2-1000). The beads are then washed in a wash buffer (RPNAW.2-1000) and eluted from the beads into elution buffer (RPNAEB8.8-1000) by heating. Eluted nucleic acids can be detected by LAMP or PCR.

REAGENTS AND MATERIALS

(for 1000 extractions):

RPNACB.2-1000	1000 ml	RapiPREP-NA Capture Buffer
RPNAB.2-1000	40 ml	RapiPREP-NA Bead Solution

The two solutions above are mixed to make the Bead Solution as is needed.

RPNAW.2-1000	3000 ml	RapiPREP-NA Wash Buffer
RPNAEB8.8-1000	40 ml	RapiPREP-NA Elution Buffer

(for 100 extractions):

RPNACB.2-100	100 ml	RapiPREP-NA Capture Buffer
RPNAB.2-1000	4 ml	RapiPREP-NA Bead Solution

The two solutions above are mixed to make the Bead Solution as is needed.

RPNAW.2-1000	300 ml	RapiPREP-NA Wash Buffer
RPNAEB8.8-1000	4 ml	RapiPREP-NA Elution Buffer

MATERIAL REQUIRED BUT NOT INCLUDED IN THE KIT

For manual extraction:

A magnetic rack that holds 1.5-2.0 ml microfuge tubes.

A heating block at 65ºC that can hold 1.5-2.0 ml microfuge tubes.

Also desirable: a repeat pipette (stepper) that can deliver multiple volumes of 1 ml to make washing easier; vacuum source to easily remove liquid from tubes.

A vortexer at low power may also be used at the elution stage.

For automated extraction.

The Thermo Scientific KingFisher Flex system.

PRECAUTIONS FOR HANDLING KIT CONSTITUENTS

1. All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
2. To be used by trained personnel only
3. Wear gloves, lab coats and safety glasses when handling the reagents.
4. Handle all samples as if they contain infectious agents.
5. Never use reagents from another kit or another batch.
6. Discard waste in accordance with national and local guidelines for infectious materials.
7. RapiPREP-NA Capture Buffer is an irritant and is corrosive, containing guanidine thiocyanate and Triton-X100. Please read the associated SDS before use and dispose of used and unused RapiPREP-NA Capture Buffer accordingly. In case of skin contact; take off contaminated clothing and shoes immediately. Wash off with soap and water. In case of eye contact; flush eyes with water for at least 15 minutes Consult a doctor.

H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.
Precautionary statement(s)

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
Supplemental Hazard information (EU) EUH032 Contact with acids liberates very toxic gas.

STORAGE

Store all kit components at room temperature (15-25°C) and used until the expiry date on the packaging. Store the Capture Buffer, RPNACB.2-1000 in the dark. Before use, check that the Capture Buffer is free of crystallisation. If crystals are present, warm at 37°C with mixing until crystals are dissolved.

QUALITY CONTROL

Observe the usual precautions for nucleic acid extraction. It is essential that all materials (such as pipette tips) coming in contact with the reagents are free from RNases and DNases.

It is advised that laboratories evaluate this kit with in-house control samples appropriate for the molecular detection method that is being used. For detection of possible contamination events a negative control sample should be included in the sample set during DNA extraction. A positive control sample should be extracted, as required, in order to evaluate the performance of the extraction. The preparation of negative and positive controls is described in the chapter Preparation of Samples.

PRECAUTIONS FOR HANDLING SPECIMENS

Patient specimens must always be considered as potentially infectious and must be handled accordingly. Always wear suitable protective clothing and gloves. Follow local safety guidelines for handling specimens.

PREPARATION OF SAMPLES

Preparation of patient specimens

The working area must be free from contaminating RNA and DNA. Using a disposable transfer pipette, mix decontaminated specimen carefully but

thoroughly by pipetting up and down. Swabs that have been placed in Viral Transport Material can be used. To inactivate the virus before extraction, heat at 80°C for 30min.

If dry swabs are used, place the dry swab in 1 ml of Virus Lysis Buffer which contains guanidine thiocyanate and 0.5% (v/v) TritonX-100 (VLB.2-1000, available from MicrosensDx Ltd) and leave for 30 min to inactivate the virus.

Nucleic acid capture, wash and elution

(Capture > Wash x3 > Elute)

Preparing the Bead Solution

Before beginning, the Bead Solution has to be prepared. For the number of samples to be extracted, work out how much Bead Solution is needed in total. For each ml of Bead Solution required, mix 1 ml of RapiPREP-NA Capture Buffer and 40µl of RapiPREP-NA Bead Solution (resuspend the beads well before using).

PROCEDURE

1. Take 1 ml of prepared Bead Solution into a 1.5 or 2 ml tube. NOTE: before using the Bead Solution ensure that the beads are resuspended in the solution by shaking vigorously for 5 seconds. Do not allow to settle if in constant use.

2. Agitate the swab in its solution (Viral Transport Medium or Viral Lysis Buffer) and then take 0.2 ml of this solution into the 1 ml of Bead Solution. Mix the beads with the sample by pipetting gently up and down and leave for 3 min. After 2 min pipette gently up and down once more to resuspend any settled beads. NOTE: a longer total time will not affect the result. It is best not to close tube lids to avoid guanidine solution contaminating the underside of the lid.

3. Place the tubes in a magnetic rack and once the beads are captured, remove the liquid (vacuum aspiration makes this easier for multiple samples. The same tip can be used as suction prevents cross contamination). If there is any liquid on the underside of the lid, remove this too as residual guanidine will inhibit subsequent amplification.

4. Remove the tubes from the magnet and add 1 ml of RapiPREP-NA Wash Buffer (RPNAW.2-1000) to each tube. The beads should resuspend. NOTE: A repeat pipettor or multipipette to add 1 ml to multiple samples will speed up this process.

5. Place the tubes back in the magnetic rack and once the beads are captured, remove the liquid as before.

6. Repeat steps 4 and 5 twice more.

7. Place the tube back in the magnetic rack and once the beads are captured, remove as much liquid as possible. NOTE: briefly removing the tubes from the magnet before placing back on the magnet will drain more liquid from the beads.

8. Add 40 µl RapiPREP-NA Elution Buffer (RPNAEB8.8-1000) to each tube and away from the magnet resuspend the beads with a gentle mix or vortex.

9. Heat the tubes at 65ºC for 5 min. At the end of this time gently resuspend the beads in the Elution Buffer and place in the magnetic rack. Avoiding the beads, take the volume of eluate required for amplification (the volume required must be determined by the end-user for their analysis but is usually 2-8 µl in a 20 µl LAMP or PCR).

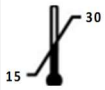
LIMITATIONS OF THE KIT

Strictly adhere to the established protocols and procedures in order to obtain correct test results and to avoid contaminations.
Use of this kit is limited to qualified personnel well trained in the procedure and familiar with molecular biological methods.

The performance evaluation of the RapiPREP Nucleic Acid Extraction Kit for SARS-CoV-2 (RPNA.2-1000, RPNA.2-100) was carried out with manual extraction in combination with compatible LAMP test kits from MicrosensDX and with automated extraction in combination with compatible CE-marked RTPCR kits applying the conditions indicated in the respective instructions for use. The starting materials included in the respective instructions for use (throat, nasal, nasopharyngeal, saliva swabs) were tested. Until the present edition of the instructions on hand, the performance of the extraction method has not been validated with other test kits or other sample materials. Performance data can be requested through email at info@microsensdx.com.

The results generated with nucleic acid extracted with this kit may only be interpreted in conjunction with additional laboratory and clinical data available to the responsible physician.

INDEX OF CE SYMBOLS

	catalogue Number		Invitro Medical Device
	Lot Number		contains sufficient for 1000 and 100 tests
	use by		consult instructions for use
	Store between 15 – 30˚C		Manufacturer