savyonDIAGNOSTICS
member of the Gamida Diagnostics Division

savvy·gen

NA Extraction Kit

REF A689-01, 96 reactions;

B689-01, 192 reactions

Store at 2°- 8°C

For use with the following instruments:

HAMILTON STARlet
HAMILTON STAR
TECAN

For Professional Use Only CE IVD

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Intended Use

The Savvygen™ NA Extraction kit is a system that enables isolation of high-quality SARS-CoV-2 RNA from human nasopharyngeal swabs, oropharyngeal swabs, anterior nasal swabs, and mid-turbinate nasal swabs. The system is intended for either automated or manual extraction of the viral RNA.

For *in-vitro* professional diagnostic use.

Principle and Procedure

The Savvygen™ NA Extraction kit technology is based on magnetic beads isolation of nucleic acids (NA) from biological samples. The basis of this method is the use of Carboxylate-Modified Magnetic beads, capable of binding the NA in the presence of a chaotropic agent. This is a simple, rapid, and reliable method for the purification of NA from biological samples. The method could be used both for manual or in an automated, large-scale extraction-purification system.

The Savvygen™ NA Extraction kit was validated on TECAN, HAMILTOM STARlet and STAR instruments, but it can be used with any other open, automated extraction system. It offers fully automated extraction of up to 96 or 192 specimens within 90 minutes.

The extraction process for isolating nucleic acids from samples by magnetic beads consists of the following 3 steps (Figure 1):

1. **Lysis/Binding**: The specimen is added in the presence of lysis buffer for cell destruction. Addition of binding buffer, which contains a large amount of chaotropic substance, in the presence of the magnetic beads, enables binding of released nucleic acids.

2. **Washing**: The magnetic beads are washed several times with washing solutions to remove contaminants that may inhibit downstream procedures (e.g. PCR).

3. **Elution**: Purified nucleic acids are eluted from the magnetic beads using elution buffer.

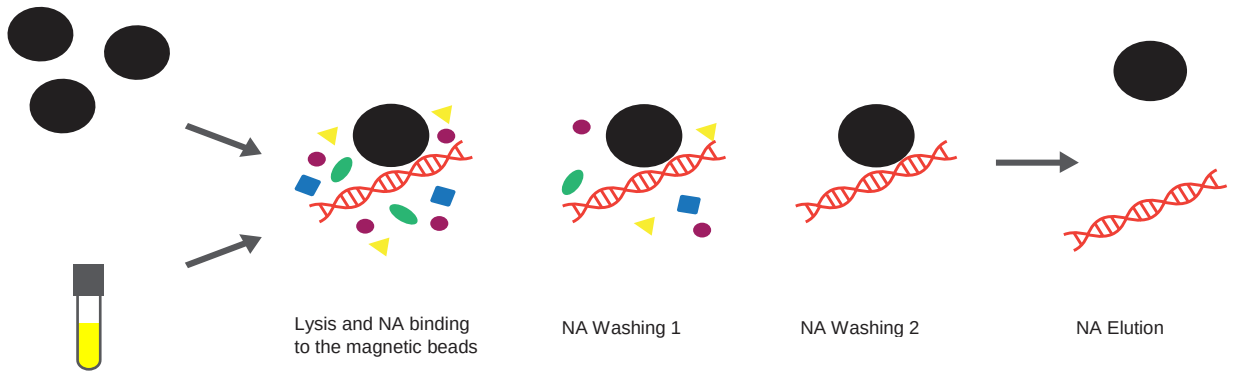

Figure 1: Nucleic acid extraction process using magnetic beads

Kit Contents

<table>
<tr><th>Product Description</th><th>Contents</th><th>Specimen type</th></tr>
<tr><td>Savvygen™ NA Extraction kit

REF: A689-01 96 extractions

REF: B689-01 192 extractions</td><td>
<table>
<tr><th>Reagent</th><th>Volume 96 extractions</th><th>Volume 192 extractions</th></tr>
<tr><td>Savvy Beads</td><td>1 ml</td><td>2 x 1 ml</td></tr>
<tr><td>Savvy Bind buffer</td><td>25 ml</td><td>50 ml</td></tr>
<tr><td>NA Lysis Buffer</td><td>18 ml</td><td>35 ml</td></tr>
<tr><td>Wash Buffer 1</td><td>50 ml</td><td>2 x 50 ml</td></tr>
<tr><td>Wash Buffer 2</td><td>50 ml</td><td>2 x 50 ml</td></tr>
<tr><td>Savvy Elute</td><td>15 ml</td><td>30 ml</td></tr>
</table>
</td><td>Chemically/physically inactivated nasal swabs, VTM/UTM</td></tr>
</table>

Equipment to be supplied by the User

1) Disposable powder-free gloves
2) Appropriate pipettes
3) Sterilized, filtered pipette tips
4) Vortex mixer
5) Tabletop centrifuge

For the automated procedure – by an open automated extraction system, please refer to the instrument manual for more details. The script for purification protocol will be supplied by Savyon Diagnostics.

For the manual procedure:

6) Thermo block
7) Magnetic stand

Storage

Savvygen NA extraction kit can be stored at 2-8°C up to 6 months, without showing any reduction in performance.

WARNINGS & PRECAUTIONS

- All samples must be treated as potentially biohazardous. Wear appropriate protective eye-wear, clothing and gloves.
- Avoid direct skin contact with kit reagents. In case of contact, immediately wash thoroughly with water.
- Minimize the inhalation of chemicals. Do not leave chemical containers open.
- All work should be conducted in properly equipped facilities for safety reasons (i.e. physical containment devices).
- Individuals should be trained according to the relevant regulations and requirements of the company/institution, prior to working with potentially infectious materials.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

The reagents contain ethanol and a chaotropic salt. These substances should be considered flammable, harmful and irritants. The Savvygen™ NA Extraction Kit is designed to be used with potentially infectious substances.

The Savvygen™ NA Extraction Kit contains guanidine hydrochloride and guanidine thiocyanate. Do not allow direct contact between guanidine hydrochloride and sodium hypochlorite (bleach) or other highly reactive reagents, such as acids and bases. These mixtures can release a noxious gas.

Quality control

In accordance with Savyon Diagnostics ISO-Certified Quality Management system, each lot of the Savvygen NA Extraction Kit is tested against predetermined specifications to ensure consistent product quality.

Sample Collection and Storage

Sample Collection:

The Savvygen™ NA Extraction Kit is optimized for SARS-CoV-2 RNA extraction from heat inactivated nasal swabs in VTM/UTM. RNA should be isolated from clinical samples within 3 days after collection.

Sample Storage:

The clinical samples are suggested to be stored for 3 days at 2-8°C. For longer storage, see recommendation of VTM/UTM manufacturer.

Protocols

Automated NA extraction

1) Vigorously vortex Savvy Beads vial.
2) For Hamilton STARlet Place Savvy Beads vial in slot according to software prompt.

For Hamilton START:

- when using NA Extraction kit for 96 samples, add 975ul of the Savvy beads solution to the 25ml "Savvy Bind" bottle and mix gently to a full resuspension of the beads.
- when using NA Extraction kit for 192 samples, add 2X 975ul of the Savvy beads solution to the 50ml Savvy Bind bottle and mix gently to full resuspension of the beads.

3) Pour the entire contents of Savvy Bind bottle into the correct position, as prompted by the software.

***NOTE*: For physically inactivated samples go immediately to step 5**

4) Pour the entire contents of NA Lysis buffer bottle into the correct position, as prompted by the software.
5) Pour the entire contents of Wash 1 bottle into the correct position, as prompted by the software.
6) Pour the entire contents of Wash 2 bottle into the correct position, as prompted by the software.
7) Pour the entire contents of Savvy Elute bottle into the correct position, as prompted by the software.
8) Place the samples on the sample rack.
9) Place the deep well plate in place, as prompted by the software.
10) Place the PCR plate in place, as prompted by the software.
11) Start protocol.
12) Script for extraction in HAMILTON STARlet, HAMILTON START and TECAN will be supplied by Savyon Diagnostics.

Manual NA extraction

***NOTE*: For physically Heat- Inactivated sample go to section A.**

For chemically Inactivated sample by Guanidine lysis medium go to section B.

A. Lysis and Binding for Heat- Inactivated samples

1) Vigorously vortex Savvy Beads vial.
2) Add 100ul of NA Lysis buffer to 100ul sample medium into Eppendorf tube.
3) Leave to stand at RT for 5 minutes.
4) Add 7 µl of Savvy Beads
5) Add 180 µl Savvy Bind Buffer.
6) Leave to stand at RT for 3 minutes.
7) Mix well.
8) Incubate at RT for 6 minutes; (mix every 2 minutes by pipetting or taping).
9) Place the tubes onto magnetic stand – wait 2 minutes, until the solution is clear.
10) Gently remove the solution with a tip.

B. Lysis and Binding steps for Guanidine lysis medium samples

1) Vigorously vortex Savvy Beads vial.
2) Add 200ul sample medium into Eppendorf tube.
3) Add 7 µl of Savvy Beads
4) Add 180 µl Savvy Bind Buffer.
5) Leave to stand at RT for 3 minutes.
6) Mix well.
7) Incubate at RT for 6 minutes; (mix every 2 minutes by pipetting or taping).
8) Place the tubes onto magnetic stand – wait 2 minutes, until the solution is clear.
9) Gently remove the solution with a tip.

Remove the tubes/plate from the magnet

C. Wash 1

1) Add 500 µl Wash Buffer 1 to the sample tube.
2) Mix the sample by pipetting.
3) Place the tubes onto the magnetic stand. Wait 2 minutes, until the solution is clear.
4) Gently remove wash solution using pipettor.

Remove the tubes/plate from the magnet

D. Wash 2

1) Add 500 µl Wash Buffer 2 to the sample tube.
2) Mix the sample by pipetting.
3) Place the tubes onto the magnetic stand. Wait 2 minutes, until the solution is clear.
4) Gently remove wash solution using pipettor.
5) Gently remove residual solution using pipettor.

Place the open tube in a Thermoblock (30°C) for 3 minutes.

E. Elution

1) Remove tubes from Thermoblock.
2) Add 50 µl of Savvy Elute, incubate for 2 minutes.
3) Transfer the tube to the magnet. Wait 2 minutes.

Remove the extracted nucleic acids to a new tube.

The Eluted NA can be used immediately or stored frozen.