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CAUTION! Professional use only.
Follow instruction manual before use.
Reading and carefully following these warnings will minimize usage errors, other possible risks and hazards.
Wear safety glasses, clothes, and gloves.

NAT BUFFER (WITH NASAL SWABS)

User Guide

Catalog Number	Pack Size
ZT-NAT-100	100 TUBE - 100 SWAB

Content and Storage Condition

Content	Quantity	Storage Condition
Softec NAT Buffer Tubes (2ml)	100	Room temperature
Nasal Swabs [individually wrapped]	100	Room temperature

Intended Use

Softec NAT Buffer is a viral nucleic acid extractive and preservative liquid. It is designed to quickly make viral nucleic acids from respiratory tract samples such as nasopharyngeal swab, oropharyngeal swab, nasal swab and oral/saliva swab ready for RT-PCR study. The prepared nucleic acids are suitable for RT-PCR applications. Softec NAT Buffer inactivates the viral pathogens in the sample within 5 minutes after contact with the clinical specimen.

Safety and Hazards

General Safety

Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

Chemical Safety

To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below.

Biohazard

Follow all applicable local, state/provincial, and/or national regulations and standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.

General Requirements for Good Practices on PCR and RT-PCR

Laboratory Setup

To prevent contamination of the reaction mixture by previously amplified target sequences, it shall be ensured that separate work areas with their own apparatus are available. If possible, maintain separate work areas, dedicated equipment, and supplies for: Sample preparation, PCR setup, PCR amplification, Analysis of PCR products.

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Personnel

Softec NAT Buffer is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the molecular techniques and in vitro diagnostic procedures. Different sets of laboratory coats should be worn pre- and post-PCR. Disposable gloves should be worn at sample preparation and when setting up PCR.

Protection of Product Performance and Analysis Efficiency

The components in the kit should not be mixed with components with different lot numbers or chemicals of the same name but from different manufacturers. Master stock reagents should be kept on the cold block during the PCR setup; if possible, the PCR setup should be performed on the cold block. Kit components should be mixed by gently shaking before use.

Preventing Contamination

The kit should be stored away from nucleic acid sources and qPCR amplicons. The micropipettes used for pipetting qPCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.

Plate Layout Suggestions

In multi-targeted PCR runs, separate different targets by a row or by a column if enough space is available. If possible, put at least one well between unknown samples and controls.

Features, Applications and Benefits

- Softec NAT buffer is colorless, transparent and clear if only stored properly according to the user guide.
- Each tube should be used individually for the nasal swab of each patient.
- Softec NAT buffer tubes contain viral nucleic acid extractor and protector solution.
- Softec NAT buffer is used for transporting the nasopharyngeal swab, oropharyngeal swab, nasal swab and oral/saliva swab samples for viral nucleic acid extraction, preservation, and pathogen inactivation.
- The nucleic acid extractive and preservative buffer inactivates the viral pathogens in the sample within only 5 min after contact with the clinical specimen. The extract can be directly used as a template for RT-PCR.
- It is highly recommended using positive and negative controls to monitor the extraction, amplification, and detection processes.
- Collected swab samples must be tested by RT-PCR or any other enzymatic reaction within 24 hours.
- Samples tested within 24 hours can be stored at 4°C for 48h or -20°C 3 months.
- Samples that would not be tested within 24 hours should be stored for up to 1 year at -70°C or below [if there is no storage condition at -70°C, the samples should be stored temporarily in the refrigerator at -20°C].
- During transfer of the collected specimens, SOFTEC NAT buffer breaks down the virus and reveals the nucleic acids. Thus, the sample can be used directly to the RT-PCR reaction without any pre-processing. As pathogen inactivation takes place during transfer, it ensures biosecurity.
- It prevents the nucleic acids from deteriorating during transfer, allowing the detection of the true viral load of the taken sample. This preservative feature eliminates the resampling problem caused by weak internal control signals.
- RT-PCR compatibility has been verified with several diagnostic one-step RT-PCR kits.
- Softec NAT buffer is also compatible with colorimetric LAMP assays.
- Methods of Use

- Nasopharyngeal swab, oropharyngeal swab, nasal swab, and oral/saliva swab shall be collected by a healthcare provider in accordance with the updated version of CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens.
- Sampling procedure must be followed to avoid affecting the accuracy of the results.
- Take out the collection swab and collect the specimen from the nasopharyngeal, oropharyngeal, nasal, or oral/saliva samples.
- Place the swab into the tube.
- Cut the stick off the swab and leave the tip in the tube.
- Tighten the tube cap and shake by hand or by vortex for 10 seconds.
- Samples used for virus isolation and nucleic acid testing should be tested in 24 hour.

Warning

Do not preserve the product when the package is damaged, or the buffer is contaminated by any environmental material.

Softec NAT Buffer is intended for general laboratory use only. It should exclusively be used in an adequate test environment. ZET MEDICAL does not assume any responsibility for damages due to improper application of our products in other fields of application. Application on the human body is strictly forbidden. The respective user is liable for all damages resulting from such application.

Assay Limitations

- Softec NAT buffer is intended for use in a laboratory environment by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
- The clinical specimens shall be collected by a healthcare provider in accordance with the updated version of CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens.
- A false negative result may occur if a specimen is improperly collected, transported, or handled.
- Performance of Softec NAT buffer has only been established in nasopharyngeal swab, oropharyngeal swab, nasal swab, and oral/saliva swab specimens suspected of respiratory tract viruses' samples.
- The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false negative results since they may contain substances that inactivate some viruses and inhibit PCR. Flocked (polyester) or Dacron swabs are recommended for collection of nasopharyngeal/ oropharyngeal swab samples.
- Detection of viral RNA may be affected by patient factors and/or stage of infection

Troubleshooting

1. Observation: In the Positive Control wells, no target-specific and no internal control signals are detected.

Possible Cause: PCR amplification failure

Recommended Action: Check that the thermal cycler settings and amplification program are correct. If there is no error in these, there may be a reagent problem; contact the manufacturer, renew the reagents, and repeat the reaction

Observation: In the Negative Control wells, target-specific and/or internal control signals are detected

Possible Cause: Contamination of the PCR.

Recommended Action: Contamination may be due to errors in sample handling, reagent contamination, or environmental contamination. Decontaminate benchtop surfaces and other equipment where PCR is performed with 10% bleach solution. Use fresh reagents and repeat the PCR. Set up the Positive Control reactions last to avoid cross-contamination. Pay attention to the issues in the "General Requirements and Warnings for Good Practices on PCR and RT-PCR" section.

3. Observation: In unknown wells (sample wells), no internal control signal is detected, but target-specific signal is detected.
Possible Cause: A high copy number of target nucleic acid exists in samples, resulting in preferential amplification of the target-specific NA.
Recommended Action: No action is required. The result is considered positive.
4. Observation: In sample wells, no internal control and no target-specific signal is detected.
Possible Cause: Inhibition Problem:
Recommended Action: Dilute the nucleic acid isolate 1/10 and repeat the PCR. If the diluted sample does not give a positive result in the IC channel, request for a new sample and repeat the NA extraction. If the problem persists, contact ZET MEDICAL's Technical Support.
Possible Cause: Extraction Problem
Recommended Action: Repeat the nucleic acid extraction and the PCR. If the problem persists, contact ZET MEDICAL's Technical Support.
Possible Cause: Sampling Problem
Recommended Action: Request for a new sample, repeat the nucleic acid extraction and the PCR. If the problem persists, contact ZET MEDICAL's Technical Support.