

NUCLISWAB®**FOR COLLECTION AND TRANSPORT OF SAMPLES
FOR NUCLEIC ACID AMPLIFICATION TESTS**

Catalogue #: TS060

Instructions for Use

For In Vitro Diagnostic Use

Product name:**NUCLISWAB®****Intended use:**

NUCLISWAB® is a transport system used for collection and transport of cells and viruses from clinical samples or from environment, for isolation of nucleic acids that will be used in nucleic acid amplification tests.

Summary and explanation of the test:

Amplification of nucleic acids isolated of the cells obtained from clinical samples or from environment by methods like polymerase chain reaction (PCR) is widely used for various purposes like detection of infectious agents, identification of their genotypes, identification of DNA sequences that lead to genetic diseases, drug resistance, etc. The sensitivity of these methods is very much dependent on appropriate collection and transport of the samples. **NUCLISWAB®** is a kit prepared to enable this. **NUCLISWAB®** is made up of two parts: Sterile dacron swab in plastic package for collecting the sample and sterile transport medium in crack proof plastic tube. Samples obtained by dacron swab is put in the transport medium. Specimens like biopsy, scrapings, discharge can directly be put into the medium.

Limitations:

The RNA of viruses is pretty stable in intact viruses when protected within the capsid. In enveloped viruses, the lipid envelope will be disrupted by the action of EDTA and the virus will be inactivated. Therefore **NUCLISWAB®** is suitable for the transport of inactivated viruses and not suitable if culture of the viruses is aimed.

Principles of the procedure:

NUCLISWAB® is designed in a way to enable easy collection and appropriate transport of the samples. Polycarbonate tubes will not crack as glass tubes when the samples are frozen to preserve for extended period of time. On the other hand the glass like transparent structure make easy to visualize and manipulate the samples. Dacron swab is kept dry; after collecting the sample the shaft of the swab is broken and the swab is placed into the tube containing the transport medium. The shaft of the swab is made from special plastic to enable easy breaking. The transport medium contains tris which keeps the pH around 8.0, which is suitable for nucleic acid preservation. Samples may contain nucleases (DNase and RNase) which will digest free nucleic acids and prevent their amplification. These enzymes require Mg^{++} as their co-factor to be functional. EDTA that is included in the transport medium strongly binds Mg^{++} and thus inhibits nucleases and preserves nucleic acids.

Ingredients:

One box contains:

- 150 x sterile dacron swabs in plastic package.
- 150 x nucleic acid transport medium (20mM Tris (pH 8.0), 2mM EDTA) 3ml in plastic tube.

Cautions and warnings:

FOR IN VITRO DIAGNOSTIC USE.

Laboratory procedures involving infectious organisms require special equipment and techniques to minimize biohazards. People who apply these techniques are recommended to have special training in this area. Specimen preparation must be done in a biological safety cabinet. To reduce the risks of accidental exposure to infectious agents, additional precautions should be taken. At a minimum, specimen manipulation should be done in a contained environment having controlled access, which has a tuberculosis exposure control plan. The locations should have surfaces that can be easily decontaminated using an appropriate topical disinfectant.

General safety precautions:

- Always wear masks and gloves when working with potentially biohazard material.
- Work in a laminary flow cabin, biosafety level II, when pipetting the samples.
- Never mouth pipette.
- If spills of the contaminated material occur, disinfect with 2.5% hypochloride solution.
- Pathogenic microorganisms including Hepatitis B virus and Human Immunodeficiency Virus (HIV) may be present in specimens. Universal precautions and local laboratory guidelines should be followed in handling

all items contaminated with blood or body fluids. If a tube is leaking or is accidentally broken during collection or transport, use the established procedures in your facility for dealing with infectious spills. At a minimum, universal precautions should be employed.

- Tubes should be discarded in an appropriate manner according to biosafety principles.

Storage instructions:

Store at room temperature, in a dry place.

Indications of instability or deterioration:

Do not use the media if you observe any turbidity or leakage of the liquid.

Specimen collection:

- 1- Remove the swab from its package paying attention to sterility.
- 2- Touch the swab to the surface where it is aimed to obtain the sample.
- 3- Break the shaft of the swab so that it will fit in the tube.
- 4- Remove the tube cap and put the swab into the transport medium.
- 5- Close the cap securely.
- 6- Write on the tube the necessary information about the patient and sample. Send the tube as soon as possible to the laboratory.
- 7- At the laboratory, vortex the sample. Take a sample from the fluid and proceed to nucleic acid extraction.

Time restrictions:

- Viral nucleic acids are expected to be stable for one week at room temperature and up to one month at 2-8°C in **NUCLISWAB®**. This may change according to the type of virus. If the samples are needed to be preserved longer, they should be kept at -20°C or better at -85°C, if available.
- The frozen samples should not be refrozen once thawed for studying when isolating RNA.
- The cell membrane of eucaryotic cells can easily be disrupted and nucleic acid can be released from the cells. Therefore it is best to isolate nucleic acids from samples obtained in **NUCLISWAB®** which contains a nucleic acid transport medium. If it is planned to isolate DNA the samples can be preserved at 2-8°C up to 4 days.
- RNA is a nucleic acid which is more fragile than DNA. Therefore, it is advised to isolate RNA within 4 hours after obtaining the cell sample or the sample should be frozen at -85°C for best results.

Quality control:

Quality control of this kit is done by nucleic acid amplification of viral DNA extracted from samples carried in **NUCLISWAB®**.

Bibliography:

- 1- Laboratory Methods in Basic Virology. Bailey & Scott's Diagnostic Microbiology, Ninth Edition. Mosby-Year Book Inc. St. Louis, MO. USA. 1994, chapter 42, p:641-680.
- 2- Grant PR, Kitchen A, Barbara JA, Hewitt P, Sims CM, Garson JA, Tedder RS. Effects of handling and storage of blood on the stability of hepatitis C virus RNA: implications for NAT testing in transfusion practice. Vox Sang. 2000;78(3):137-42.
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- 4- Maintenance of viability and comparison of identification methods for influenza and other respiratory viruses of humans. Baxter BD, Couch RB, Greenberg SB, Kasel JA. J Clin Microbiol. 1977 Jul;6(1):19-22.

Manufacturer:

SALUBRIS, Inc.
One Boston Place, Suite 2600
Boston, MA 02108, U.S.A.
Tel: (800) 326-1484
Fax: (617) 249-0803
Website: www.salubrisinc.com

Authorised**representative :**

SALUBRIS
2, Clos de Toussue
27300 Menneval - FRANCE
Tel: +33 683 00 84 77

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