

INTENDED USE

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

PRODUCT NAME

SWABMAX

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SWABMAX is a transport system used for collection and transport of cells 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 dependant on appropriate collection and transport of the samples. SWABMAX is a kit prepared to enable this.

SWABMAX 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: RNA molecules are very susceptible to nuclease digestion that may be coming from degrading cells. If amplification is intended to be done using RNA molecules as template, it is recommended to transport the samples in icebox and isolate nucleic acids within 4 hours.

WHAT'S DIFFERENT BETWEEN FIRST-OLD AND SECOND-NEW GENERATION TEST?

Features of first generation test

In prior COVID-19 tests, it was tried to prevent denaturation of nasopharyngeal or oropharyngeal samples with EDTA or NaCl until the stabilization of the virus and obtaining COVID-19 RNA. This period could sustain 8-10 hours of stabilization. During this time, there was a risk of contamination due to usage errors. In the prior tests, the reaction times for RNA isolation after enzymatic-chemical decontamination and inactivation were 2 times longer than our novel test. Stability was a major problem in prior type of chemical systems for RNA stabilization. RNA instability was very rapid. For this reason, the sample had to be handled in 72 hours.

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Features of second-new generation test

In the novel type (SWABMAX) test, by means of the new enzymatic technology we use, we straightly destroy the protein in biological secretions and mucoid protein barriers showing false negativity and the lipid protein capsid of the virus. By means of our novel chemical technology (SWABMAX), the virus inactivation and RNA isolation are performed simultaneously on the enzymatic inactivation continues during transfer. Thus, the processing time is reduced by ¼. On the other hand, since the virus stabilization is eliminated until RNA is isolated (8-10 hours), the possible contaminations during this period are prevented. On the other hand, it is possible to protect the sample for up to 12 days after sampling due to prolong the inactive RNA stabilization by means of the novel chemical reagent system (SWABMAX).

- Fast results
- Minimize Human Error& Contamination High Specificity & Sensitivity
- High- Accuracy (%99) Worldwide Acceptance Enzyme Include Options

ADVANTAGES

- To check for RNA quality to minimize false-negatives
- To verify the enzyme and other reagents
- Optimized primer/probe sequences to minimize false-positives
- % 100 indusitivity of pullished SARS -Cov-2- sequences in unmutated targeted regions
- To verify the enzyme and other reagents
- Internal Control

PRINCIPLES OF THE PROCEDURE

SWABMAX 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, that is suitable for nucleic acid preservation. Samples may contain nucleases (DNAse and RNAse) which will digest free nucleic acids and

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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 preserve nucleic acids.

INGREDIENTS

- Sterile dacron swab in plastic package.
- Nucleic acid transport medium (20mM Tris (pH 8.0), 2mM EDTA) 3ml in plastic tube.
- Nucleic acid isolation solution.

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.

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STORAGE INSTRUCTIONS

Store at room temperature.

INDICATIONS OF INSTABILITY OR DETERIORATION

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

SPECIMEN COLLECTION

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

TIME RESTRICTIONS

- It is best to isolate nucleic acids from samples obtained in 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. If the samples are needed to be preserved longer, they should be kept at -20°C or better at -85°C, if available. RNA is a nucleic acid which is more fragile than DNA.
- The frozen samples should not be refrozen once thawed for studying when isolating RNA.

QUALITY CONTROL

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

BIBLIOGRAPHY

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GENERAL MARKETING

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