CE IVD

SwiftX™ Media

(REF: SXM-125-IVD)

Instructions for Use

Content

Intended use

SwiftX™ Media is intended to be used for extraction of DNA and RNA of eukaryotic cells, bacteria, and viruses from human samples in transport media. For professional use.

Principles of the method

SwiftX™ Media is designed for fast extraction of RNA and DNA of viruses, bacteria and eukaryotic cells originating from samples in transport media.

SwiftX™ Media features a multifunctional formulation. It stabilizes viral particles, bacteria, and other cells before lysis. It enables an efficient lysis of these during the enzyme- and heat-driven extraction process. Furthermore, the extracted RNA and DNA are stabilized because of the inactivation of sample-inherent degrading mechanisms. The lysates are non-inhibiting to a wide range of amplification chemistries.

Viral particles and bacteria entrapped in eukaryotic cells are efficiently released by application of heat to the sample. Due to the special formulation of SwiftX™ Media, this will not negatively impact the quality of the extracted RNA and DNA.

Components

Buffer ME (extraction buffer)
Component P (enzyme blend)

Equipment to be provided by the user

For performance of the nucleic acid extraction procedure, the following laboratory equipment is required and needs to be provided by the user:

- Appropriate personal protective equipment
- Pipets and disposable pipet tips (aerosol barrier tips are recommended)
- 1.5ml microcentrifuge tubes (lock-caps or screw-caps are recommended) or, alternatively, a deep-well plate
- Appropriate heating device (water bath, dry heat block, thermo shaker)

Storage and shelf life

Until first use, SwiftX™ Media reagents shall be stored at 2°C to 8°C. Reagents are good to be used until the expiry date indicated on the label.

Activated Buffer ME (see *Reagent preparation*) has a shorter shelf life. The validated stability is 3 weeks at 2°C to 8°C and 3 months at -20°C. If activated Buffer ME is kept frozen, then repeated freezing and thawing must be avoided. Use of activated Buffer ME beyond this shelf life must be validated by the user.

Warnings and precautions

SwiftX™ Media contains an enzyme blend in powder form (Component P). According to the CLP regulation, this powder formulation shall be considered hazardous substance. The Safety Data Sheet (SDS) is available upon request. The following hazard and precaution statements apply:

Component P (dry powder form):

Danger.

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
P264	Wash respective body parts after accidental contact
P280	Wear protective gloves, eye, and face protection
P261	Avoid breathing dust
P284	Wear respiratory protection

Take care when working with biological samples and always treat them as potentially infectious. Users are advised to always wear appropriate personal protective equipment.

Nucleic acid extracts can be disposed off with regular laboratory waste. Please take your national regulations for waste sorting and treatment into consideration.

Make sure to work with clean equipment and use pipette tips with aerosol barriers to avoid carryover of specimens or nucleic acid extracts between samples.

Primary sample types and their collection, handling, and storage

SwiftX™ Media can be used for nucleic acid extraction from swabbed samples eluted in transport media from locations known to contain low to medium concentration of substances inhibitory to nucleic acid amplification reactions. Examples for such samples are swabs from nose, skin, mouth, oropharynx, and nasopharynx. SwiftX™ Media has been validated for nasal and nasopharyngeal specimens.

The following transport media has been validated for extraction using SwiftX™ Media: Universal Transport Medium (UTM), Phosphate-buffered saline (PBS), Viral Transport Medium (VTM), and Liquid Amies medium.

Specific advice on sample collection and storage cannot be given because of the wide applicability of SwiftX™ Media. In general, it is recommended to store specimens at 2°C to 8°C and to process them as soon as possible after collection.

Reagent preparation

Before use of SwiftX™ Media, Buffer ME must be activated by dissolving Component P. For correct activation of Buffer ME perform the following steps:

1. **Add 1mL Buffer ME into the tube with dry Component P.**
2. **Pipet buffer up and down at least 10 times until the powder is dissolved, and the solution is homogeneous.**
3. **Pipet dissolved Component P back into the bottle with Buffer ME.**
4. **Tightly close bottle with Buffer ME and turn it upside down 10 times to prepare a homogeneous solution. Mark the date of activation on the bottle.**

Activated Buffer ME is stable for up to 3 weeks at 2°C to 8°C and up to 3 months at -20°C. Avoid repeated freezing and thawing.

Extraction procedure

This protocol describes the workflow of extraction of RNA and DNA directly from specimens in transport media.

1. **Mix 100µL transport medium sample with 200µL activated Buffer ME.**
2. **Incubate lysis mixture for 10 minutes at 90°C (device must be preheated).**
3. **Cool down and immediately proceed with your detection assay. Mix the extracted nucleic acids by tapping or vortexing the tube and then transfer an aliquot to your amplification tube.**

If required, extracted RNA and DNA can be stored at 2°C to 8°C for up to 2 days before analysis. Do not forget to mix the stored nucleic acids by tapping or vortexing the tube before applying an aliquot to the amplification detection.

Automation of the nucleic acid extraction procedure can be achieved with a variety of robotic pipetting and liquid handling systems due to the very limited number of working steps. Any adaptation must be performed and validated by the user.

Nucleic acid amplification

Always make sure, the nucleic acid extract is well mixed before taking an aliquot for the nucleic acid amplification and detection.

The volume of extracted nucleic acids to be applied to the DNA- or RNA-amplification reaction can vary from 10% to 40% of the total PCR volume and is dependent on the specimen type, the transport medium, and the PCR mastermix.

For DNA detection, a volume of extracted DNA of 40% of the total PCR volume, e.g. 20µL sample added to 30µL PCR mastermix (resulting in 50µL total reaction volume), has been tested to be fully compatible with QIAGEN QuantiNova RT-PCR mastermix.

For RNA detection, a volume of extracted RNA of 20% of the total RT-PCR volume has been tested to be fully compatible with QIAGEN QuantiNova RT-PCR mastermix. Also up to 40% extracted sample have been successfully applied for detection of RNA targets, but the amplification signal of internal control RNA will show a considerable delay of 2 to 5 cycles.

See also the section “Limitations” for further information on extracted nucleic acids from VTM samples.

Control procedure

Current state of the art in molecular diagnostics is to detect a control target next to the diagnostic target. The purpose of the control can be detection of inhibition to the amplification reaction, presence of sufficient amount of sample and so on. Since SwiftX™ Media enables concurrent extraction of RNA and DNA, the user is flexible in the choice of the control target.

In general, the users are responsible for selecting the appropriate control target and for determining appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

Diagnostic performance characteristics

The performance of SwiftX™ Media has been validated with nasal and nasopharyngeal swabs eluted in the following transport media:

- Universal transport medium (UTM)
- Viral transport medium (VTM)
- Phosphate-buffered saline (PBS)
- Liquid Amies medium

The extracted nucleic acids have been tested for presence and amount of the following targets by real-time DNA/RNA amplification using the QIAGEN QuantiNova RT-PCR mix as well as the QIAGEN Investigator Quantiplex kit:

- *Staphylococcus aureus* (nuclease gene)
- SARS-CoV-2 (RdRp gene)
- Human genomic DNA (multi-copy target)

The nucleic acid extraction efficiency of SwiftX™ Media was compared to the QIAGEN QIAamp cador Pathogen Mini Kit as a reference extraction method. All samples showed amplification results equivalent between both methods. Pathogens present in the transport media samples have been detected in all cases.

For the validation of SwiftX™ Media, both water bath and a dry heat block have been used for conducting the heating step. Other methods and instruments must be validated by the user.

Limitations

- Transport media with high content of salts, e.g. guanidine hydrochloride, such as eNAT®, DNA/RNA Shield™ or others are not compatible with SwiftX™ Media extraction methodology, because the extracted nucleic acids will show strong inhibition in downstream amplification reactions.
- Samples known to contain high amounts of inhibitory substances, such as rectal samples or blood samples, are not compatible with SwiftX™ Media, because the extracted nucleic acids will show strong inhibition in downstream amplification reactions.
- Some transport media, especially some VTM formulations, can show precipitation during or after the heat extraction step. This does not influence the extraction efficiency. However, it is important to mix the extracted nucleic acids thoroughly before applying it to the amplification and detection reaction.
- Certain types of Viral transport media contain ingredients, which negatively affect RT-PCR reactions. This can be detected by a shift of the internal control RNA amplification signal by more than 2 PCR cycles. If this is observed, the amount of extracted RNA applied to the amplification reaction should be reduced to less than 20 % of the total reaction volume.
- It has been reported that the use of Component P for activation of Buffer ME may interfere with some isothermal amplification technologies such as RPA and RAA.

Literature references

- Ortiz-Prado et al. (2020) Diagnostic Microbiology and Infect. Disease Vol. 98: p. 115094
- Druce et al. (2012) Journal of Clinical Microbiology Vol. 50: p. 1064
- Ali et al. (2017) BioMed Research International Vol. 2017: Article ID 9306564

Key to symbols

	In-vitro-diagnostic device
	Catalog number
	Number of extractions
	Storage temperature
	Batch number
	Expiry date
	Read Instructions for Use
	Legal manufacturer

General remark

Please be reminded that any serious incident that has occurred in relation to the use of PreLyser shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the affected patient is located.

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