SwiftX™ Swabs

(REF: SXS-50-IVD, SXS-200-IVD)

Instructions for Use

Content

Intended use

SwiftX™ Swabs is intended to be used for extraction of RNA and DNA from swab and saliva samples taken from humans. For professional use.

Principles of examination method

SwiftX™ Swabs is designed for rapid extraction of RNA and DNA from swabs with or without transport medium as well as from saliva. SwiftX Swabs is applicable to a variety of swab types such as nasal, skin, oral, oropharyngeal, nasopharyngeal swabs.

The nucleic acid extraction procedure can be performed manually as well as in an automated fashion. Automation can be achieved with a variety of robotic pipetting and liquid handling systems due to the very limited number of working steps. Any adaptation has to be performed and validated by the user.

SwiftX Swabs features a multifunctional formulation. It stabilizes viral particles before lysis and enables an efficient lysis of viral particles during the extraction procedure. Furthermore, it stabilizes extracted viral RNA by inactivation of sample-inherent degrading mechanisms. It is non-inhibiting to a wide range of amplification chemistries, such as PCR as well as isothermal methods.

Viral particles entrapped in eukaryotic cells are efficiently released by application of heat to the sample. Due to the special formulation of SwiftX Swabs, this will not negatively impact the viral RNA itself.

Components

Component E (extraction buffer)
Component C (enzyme blend 1)
Component P (enzyme blend 2)

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™ Swabs reagents shall be stored at 2° to 8°C. Reagents are good to be used until the expiry date indicated on the label.

Activated Component E (see *Reagent preparation*) has a shorter shelf life. The validated stability is 5 days at 2°C to 8°C and 6 weeks at -20°C. If activated Component E is kept frozen, then repeated freezing and thawing must be avoided. Use of activated Component E beyond this shelf life must be validated by the user.

Warnings and precautions

SwiftX™ Swabs contains two enzyme blends in powder form (Component C and P). According to the CLP regulation, these powder formulations shall be considered hazardous substances. The Safety Data Sheets (SDS) are available upon request. The following hazard and precaution statements apply:

Component C (dry powder form):

Danger.

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
P261	Avoid breathing dust
P284	Wear respiratory protection

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.

Primary sample collection, handling and storage

Applicable sample types are swabs from locations known to contain low to medium amount of substances inhibitory to nucleic acid amplification reactions. Examples for such samples are swabs from nose, skin, mouth, oropharynx and nasopharynx. SwiftX™ Swabs has been validated for nasopharyngeal specimens taken with flocked swabs, polyester-woven swabs as well as cotton swabs.

It is recommended to transport swabs dry without any transport medium and then elute and extract them directly using SwiftX Swabs. This provides the highest concentration of nucleic acids in the extract.

If swabs shall be transported in a medium, the latter can also be applied to the extraction procedure. SwiftX Swabs has been validated for use with the following types of transport media: saline and viral transport medium (VTM).

As an alternative to swabs, saliva samples can also be processed with SwiftX Swabs. Saliva should be processed without delay.

Reagent preparation

Before use of SwiftX™ Swabs, Component E must be activated by dissolving Component C and Component P. For correct activation of Component E perform the following steps:

1. **Add 1mL Component E into tube with dry Component C.**
2. **Add 1mL Component E into tube with dry Component P.**
3. **For both tubes: pipet buffer up and down at least 10 times until the powder is dissolved and the solution is homogeneous.**
4. **Pipet dissolved Component C back into bottle with Component E.**
5. **Pipet dissolved Component P back into bottle with Component E.**
6. **Tightly close bottle with Component E and turn it upside down 10 times to prepare a homogeneous solution. Mark the date of activation on the bottle.**

Activated Component E is stable for up to 4 weeks at 2°C to 8°C and up to 3 months at -20°C. Avoid repeated freezing and thawing.

Extraction procedures

Extraction of nucleic acids directly from swabs

This protocol describes the workflow of extraction of RNA and DNA directly from swab specimens.

1. **Swirl swab for 5 seconds in 500µL activated Component E.**
2. **Cut off swab tip to release it into the reaction tube. Close the reaction tube securely to prevent opening during heat incubation.**
3. **Incubate mixture for 15 minutes at 90°C.**
4. **Cool down and immediately proceed with your detection assay. Homogenize the extracted nucleic acids by tapping or vortexing and then transfer an aliquot to your amplification tube.**

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

Extraction of nucleic acids from liquid samples

This protocol describes the workflow of extraction of RNA and DNA from liquid specimens such as transport medium or saliva.

1. **Mix liquid specimen with activated Component E as follows (exact volumes are dependent on the nature of the liquid):**
    a. **100µL transport medium with 400µL activated Component E.**
    b. **100µL saliva with 100µL activated Component E.**
2. **Incubate mixture for 15 minutes at 90°C.**
3. **Cool down and immediately proceed with your detection assay. Homogenize the extracted nucleic acids by tapping or vortexing and then transfer an aliquot to your amplification tube.**

If required, extracted RNA can be stored at 2°C to 8°C for up to 2 days before analysis. Do not forget to homogenize the stored nucleic acids by tapping or vortexing before applying it 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 has to be performed and validated by the user.

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™ Swabs 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™ Swabs was validated using 157 swabbed samples in different laboratories around the world. The swabs were either directly applied to SwiftX Swabs extraction or were eluted in VTM before extraction. Samples were either pre-characterized (based on clinical symptoms of the respective patient or molecular testing) or samples have been simultaneously processed with another reference extraction kit. The nucleic acid extracts were analyzed using SARS-CoV-2 specific RT-qPCR kits. SwiftX Swabs showed concordant results for SARS-CoV-2 detection with the pre-characterization result or the reference extraction in 153 cases (overall accuracy: 96.2%). The sensitivity among the 145 positive samples was 97.2% and specificity among the 12 negative samples was 100%.

The following instruments were validated to perform the heating step of SwiftX Swabs: water bath, dry heat incubator, Rotor-Gene™ Q. All other methods and instruments for conducting the heating step must be validated by the user.

The following RT-PCR mastermixes have been used during the validation studies: Seegene SARS-CoV-2 Allplex, Procomcure Phoenix Dx SARS-CoV-2, Indical Virotype Mastermix, and Genefirst RT-PCR COVID-19 Detection Kit.

Limitations

- Poor sampling can not be cured by any nucleic acid extraction method or nucleic acid amplification method. Thus, it is important to take care on approriate sampling to maximize the amount of specimen subjected to analysis.
- Elution of swabs in transport media leads to a dilution of the diagnostic target, which will in turn lead to lower concentration of the extracted nucleic acids as compared to extraction directly from the swab.
- Samples with high amount of salts, e.g. guanidine hydrochloride, such as the transport and conservation media eNAT®, RNA*later*™ or others are not compatible with SwiftX™ Swabs, because the extracted nucleic acids will show a strong inhibitory effect on the downstream amplification reaction.

- Nucleic acid extracts derived from swab samples known to contain a high amount of inhibitory substances, such as rectal swabs, will lead to inhibition of the downstream amplification reaction.
- It has been observed that some sorts of transport media, i.e. some Viral Transport Media, develop precipitates during the extraction procedure. This does not influence the extraction efficiency. However, it is important to homogenize the extraction sample before applying it to the amplification and detection reaction.
- Transport media such as VTM can contain ingredients, which negatively affect the reverse transcription step of RT-PCR detection kits. This can be detected by a shift of the internal control amplification signal by more than 2 PCR cycles. If this is the case, the amount of extracted RNA applied to the RT-PCR should be reduced to not more than 20 % of the PCR reaction volume.
- If SwiftX Swabs extracts shall be used for isothermal amplification based on either RPA or RAA technology, Component P must not be used for activation of Component E.
- Make sure to work with clean equipment and use pipette tips with aerosol barriers if possible to avoid carryover of specimens or nucleic acid extracts between samples.

Literature references

- Ravi et al. (2020) Biosensors and Bioelectronics Vol. 165: p. 112454
- 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
- Campbell et al. (2013) Journal of Clinical Microbiology Vol. 51: p. 324

Key to symbols

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

Legal manufacturer:

Xpedite Diagnostics GmbH
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