

SwiftX™ Swabs

Instructions for Use

Content

Storage	2
Product Use	2
Safety information	2
Quality control	3
Principles	4
Equipment provided by the user	4
Before start: Activation of Component E	5
Extraction Procedure (Swab Protocol)	6
Extraction Procedure (Media Protocol)	7
Contacts and disclaimer	8

Storage

SwiftX™ Swabs comprises of several components with different recommended storage temperatures.

Component **E** must be stored **at 2-30°C** until the expiry date indicated on the label.

Component **C** and Component **P** must be stored **at 2-8°C** until the expiry date indicated on the label.

Product Use

For Research Use Only.

SwiftX™ Swabs is designed for rapid extraction of RNA and DNA from swabs, transport media and saliva. The procedure can be performed manually as well as in an automated fashion.

Automation of the nucleic acid extraction protocol is possible with a variety of robotic pipetting and handling systems due to the very limited number of working steps. Any adaptation has to be performed and validated by the user.

Safety information

SwiftX™ Swabs comprises of a buffer (Component E) and two enzyme blends in powder form (Component C and P). The buffer is free of hazardous substances. However, be careful when handling Component C and P. According to the CLP regulation, these powder formulations shall be considered hazardous substances. The material safety data sheet (MSDS) for SwiftX™ Swabs is available upon request.

The following hazard and precaution statements apply:

For Component C (in dry powder form only):

Danger.



H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

P261 Avoid breathing dust

P284 Wear respiratory protection

For Component P (in dry powder form only):

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.

Quality control

Each batch of SwiftX™ Swabs is tested against defined specifications to ensure consistent product quality. A Certificate of Analysis can be sent upon request.

Principles

SwiftX™ *Swabs* is designed for fast extraction of RNA and DNA from swab samples. It can be applied to dry swabs, swabs eluted in transport media, or saliva.

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.

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.

Equipment provided by the user

- Appropriate personal protective equipment
- Pipets and disposable pipet tips (aerosol barriers recommended)
- 1.5ml microcentrifuge tubes (locked-caps or screw-caps recommended) or a deep-well plate
- Heat source (water bath, dry heat bath, thermo shaker)

Before start: Activation of Component E

It is of highest importance that SwiftX™ Component E is activated by addition of Component C and Component P before use. Follow these 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. Turn bottle with activated Component E upside down 10 times to prepare a homogeneous solution. Mark the activation date on the bottle.**

Activated Component E must be stored at 2-8°C. It is recommended to use it directly after activation. If required, activated Component E can be stored without loss in functionality for up to 5 days at the indicated storage temperature.

It shall be noted here, that according to CLP regulations, activated Component E is not considered a hazardous mixture due to the low concentration of the resuspended enzyme blends.

Extraction Procedure (Swab Protocol)

This protocol describes the workflow of extraction of viral RNA and DNA from swab specimen. The swabs can be transported in dry state (highest concentration of specimen) or in transport medium (human sample could be partially eluted from swab).

Make sure you have activated SwiftX™ Component E before starting the extraction procedure.

- 1. Swirl swab for 5 seconds in 500µL activated SwiftX™ Component E.**
- 2. Cut off swab tip to release it into the reaction tube. Close the reaction tube securely to prevent opening during lysis step.**
- 3. Incubate lysis mixture for 15 minutes at 90°C.**
- 4. Cool down, e.g. on ice, 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.**

Application notes:

- SwiftX™ *Swabs* has been validated with flocked swabs, polyester-woven swabs, and cotton swabs.
- If swabs with a small sampling head are used, such as nasopharyngeal swabs, then the volume of activated Component E can be reduced to 300µL.
- It has been reported that use of Component P for activation of Component E is not compatible with the isothermal amplification technologies RPA and RAA.

Extraction Procedure (Media Protocol)

This protocol describes the workflow of extraction of viral RNA and DNA from liquid specimens. This can be transport media containing swabbed specimens or saliva as a specimen itself.

Make sure you have activated SwiftX™ Component E before starting the extraction procedure.

- 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 lysis mixture for 15 minutes at 90°C.**
- 3. Cool down, e.g. on ice, 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.**

Application notes:

- The following transport media have been validated: Saline, PBS, UTM, VTM. Some VTM show precipitation during the extraction procedure. This does not influence the extraction efficiency.
- Samples containing a high amount of salt, e.g. guanidine hydrochloride, such as certain transport media and conservation media are not compatible with SwiftX™ Swabs, because the extracted nucleic acids will show a strong inhibitory effect on the downstream amplification reaction.

Contacts and disclaimer

This product is owned by:

Xpedite Diagnostics GmbH

An der Halde 15

86807 Buchloe

Germany

www.xpedite-dx.com

info@xpedite-dx.com

This product may be used solely in accordance with the provided protocol. Every step deviating from this protocol must be validated by the user.

This product shall not be reused or resold without license by Xpedite Diagnostics.