CE IVD

SwiftX™ DNA

(REF: SXD-25-IVD)

Instructions for Use

Content

Intended use

SwiftX™ DNA is intended to be used for manual extraction of DNA of fungi, bacteria, parasites, viruses and human cells from various human samples. For professional use.

Principles of the method

SwiftX™ DNA is designed for rapid extraction of DNA from a wide range of biological samples. The different components of SwiftX™ DNA have specific functionalities within the workflow of DNA extraction.

Buffer EN stabilizes biological cells such as bacteria, epithelial cells, white blood cells, protozoa during cell capturing and enables efficient binding of biological cells to the magnetic particles.

The magnetic particles **Beads A** show a broad binding property to cells and proteins. This effect is leveraged in two ways during SwiftX™ DNA-based extraction. Firstly, Beads A enable a species-independent concentration of cells from liquid specimens. Secondly, during and after heat lysis, Beads A are utilized to remove cell debris and other particulate matter from the lysis mixture.

In conjunction with application of heat, **Buffer DL** enables an efficient lysis of viruses, bacteria, protozoa, and animal cells. Buffer DL is fully compatible with a wide range of amplification chemistries.

Content of the kit

Buffer EN
Buffer DL
Beads A

Storage and shelf life

SwiftX™ DNA reagents must be stored at 2°C to 8°C. Reagents are good to be used until the expiry date indicated on the label. Do not use reagents after their indicated expiry date.

After first use, SwiftX™ DNA reagents are good to be used within 3 months.

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 barriers recommended)
- 1.5mL and 2mL microcentrifuge tubes (safe-lock-caps or screw-caps recommended)
- Magnetic stand (e.g. Xpedite Diagnostics REF: MAG-12)
- Vortexer (e.g. Xpedite Diagnostics REF: VOR-01)
- Heating block (e.g. Xpedite Diagnostics REF: ACC-12)
- Mini spin centrifuge (e.g. Xpedite Diagnostics REF: CEN-01)
- optional: Proteinase K, 20mg/mL (Xpedite Diagnostics REF: PRK-1mL)

Warnings and precautions

SwiftX™ DNA comprises of two buffers (Buffer EN and DL) and paramagnetic particles (Beads A). All components of the kit are free of hazardous substances. The safety data sheets (SDS) for SwiftX™ DNA components are available upon request.

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

Be aware that the sample remains potentially infectious during the extraction process until the heat lysis was conducted. Consequently, supernatants of the cell capturing step must be treated as potentially infectious.

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.

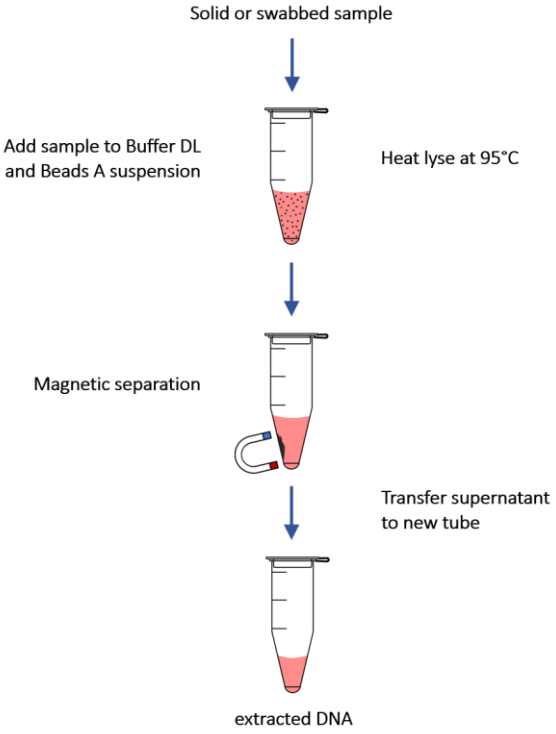
Sample types and their collection, handling, and storage

SwiftX™ DNA can be applied for nucleic acid extraction from a multitude of different sample types. The following sample types have been validated during the development of the kit: swabs (oral, nasal, skin, rectal, vaginal), whole blood (venous, peripheral), tissue homogenates, skin biopsies, skin scrapings, nails, hair bulbs, urine, saliva, sputum, transport media (saline, PBS, liquid amies), liquid-based cytology media, cell cultures, dried blood spots, blood spots on FTA paper, FFPE samples.

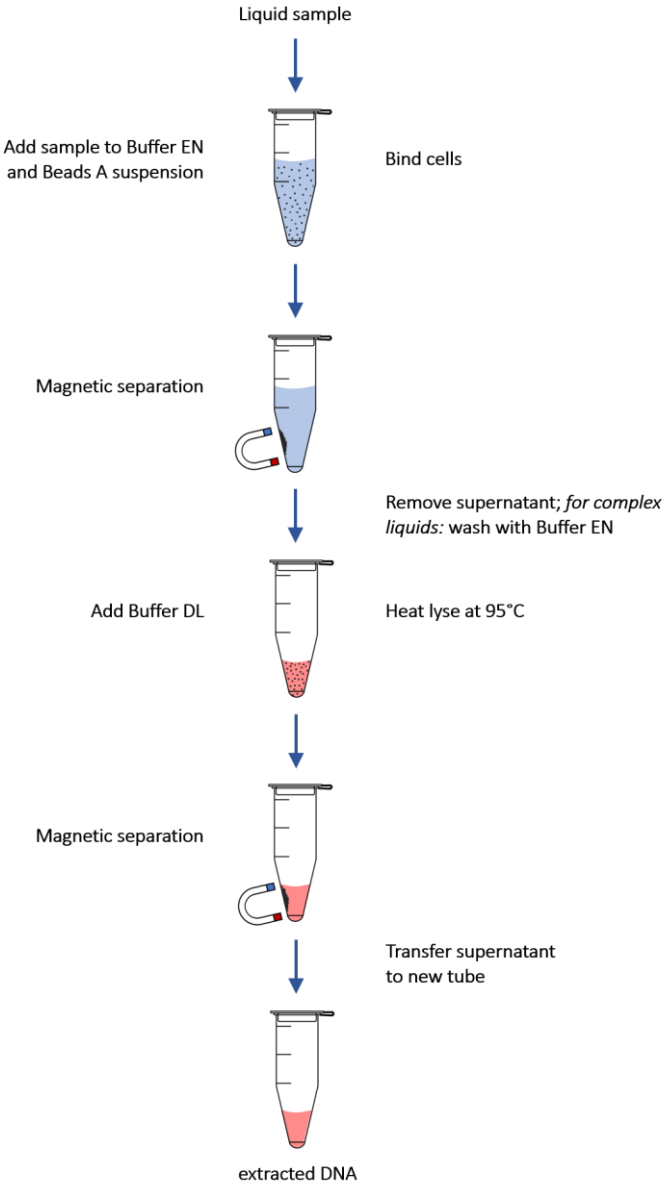
Specific advice on sample collection and storage cannot be given because of the wide applicability of SwiftX™ DNA. In general, it is recommended to store specimens at 2°C to 8°C and to process them as soon as possible after collection.

Overview of the extraction procedure

Direct extraction procedure with reverse purification



Cell capturing with subsequent extraction procedure and reverse purification



Protocols recommended for different sample types

Protocol 1 is recommended for processing of the following solid sample types:

- Swabs (oral, nasal, skin)
- Skin scrapings
- Skin biopsies
- Hair bulbs
- Dried blood spots
- Fingernails, toenails
- Blood spots on FTA paper
- FFPE samples

Protocol 2 is recommended for processing of the following liquid sample types:

- Urine
- Saliva
- Cell cultures
- cerebrospinal fluid
- fine-needle aspirates
- Swabbed material (incl. vaginal, rectal) in transport media (saline, PBS, amies)

Protocol 3 is recommended for processing of the following complex liquid sample types:

- Whole blood (venous, peripheral)
- Liquid-based cytology media
- Tissue homogenates
- Sputum

Extraction of DNA from Fungi and Staphylococci:

An additional Proteinase K digestion step can increase the lysis efficiency for fungal and staphylococcal cells, which leads to a higher yield of pathogen DNA. See section "Additional advice and application notes" for advice on the use of Proteinase K and further information.

Protocol 1: DNA extraction from solid specimens

To do before starting

- Set the heating block to 95°C.
- Set a second heating block to 60°C if you intend to perform a Proteinase K incubation step (see separate section on Additional advice and application notes).
- Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.

1. **Place your sample material in a 1.5 mL microtube with safe lock-cap.**

2. **Depending on the sample material to be extracted, perform one of the following steps:**

    a. **Swabs:** add 300 µL (flocked swabs) or 500µL (woven swabs) of Buffer DL to the microtube and elute swabbed material by swirling against the tube wall for 10 seconds. Dispose of the swab.

    b. **All others:** add 100 µL of Buffer DL to the microtube.

3. **Incubate microtube in a heating block at 95 °C for 15 minutes.**

4. **Remove microtube from heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**

5. **Place microtube in a magnetic stand for 1 minute.**

6. **Open the microtube while remaining in the magnetic stand.**

7. **Transfer the supernatant to a new microtube for storage (up to 4 weeks at -20 °C) or use it directly for analysis.**

    Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for your analysis.

Protocol 2: DNA extraction from liquid specimens

To do before starting

- Set the heating block to 95°C.
- Set a second heating block to 60°C if you intend to perform a Proteinase K incubation step (see separate section on Additional advice and application notes).
- Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.

- Prepare enough **"binding mix"** of Buffer EN and Beads A for your extractions as follows:
  - Determine the volume of sample you want to process (200µL – 1mL)
  - Pipette an equal volume of Buffer EN into a tube, e.g. 500µL of Buffer EN if you want to process 500µL of liquid sample)
  - Add 30µL of Beads A to the Buffer EN
    Note: do not modify the volume of Beads A, it must always be 30µL independent of the volume of Buffer EN
  - Mix well for 5 seconds by vortexing or inverting the tube.

1. **Add the prepared "binding mix" (see above) to a microtube.**

2. **Add the desired volume of liquid sample (200µL – 1mL) to the "binding mix". Mix well by pipetting up and down or by vortexing for 5 seconds. Ensure all liquid is removed from the tube lid. Spin the microtube briefly if necessary.**

3. **Incubate microtube at room temperature for 3 minutes.**

4. **Place microtube in a magnetic stand for 1 minute.**

5. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**

6. **Add 100µL of Buffer DL to the microtube and resuspend the magnetic particles by vortexing for 5 seconds. Ensure all liquid is collected at the bottom of the tube. Spin briefly if necessary.**

7. **Incubate microtube at 95°C for 15 minutes.**

8. **Remove microtube from the heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**

9. **Place microtube in a magnetic stand for 1 minute.**

10. **Open the microtube while remaining in the magnetic stand.**

11. **Transfer the supernatant to a new microtube for storage (up to 4 weeks at -20 °C) or use it directly for analysis.**

    Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for your analysis.

Protocol 3: DNA extraction from complex liquid specimens

To do before starting

- Set the heating block to 95°C.
- Set a second heating block to 60°C if you intend to perform a Proteinase K incubation step (see separate section on Additional advice and application notes).
- Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.

- Prepare enough **"binding mix"** of Buffer EN and Beads A for your extractions as follows:
  - Determine the volume of sample you want to process (50µL to 200µL)
  - Pipette **two** volumes of Buffer EN into a tube, e.g. 400µL of Buffer EN if you want to process 200µL of complex liquid sample)
  - Add 30µL of Beads A to the Buffer EN; **Note:** do not modify the volume of Beads A, it must always be 30µL independent of the volume of Buffer EN
  - Mix well for 5 seconds by vortexing or inverting the tube.

1. **Add the required volume of "binding mix" (100µL to 400µL, see above) to a microtube.**
2. **Add the desired volume of liquid sample (50µL to 200µL) to the "binding mix". Mix well by pipetting up and down or by vortexing for 5 seconds. Ensure all liquid is removed from the tube lid. Spin the microtube briefly if necessary.**
3. **Incubate microtube at room temperature for 3 minutes.**
4. **Place microtube in a magnetic stand for 2 minutes.**
5. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
6. **Add 500 µL of Buffer EN and mix well by pipetting up and down or by vortexing for 2 seconds. Ensure that no liquid is sitting at the tube lid. Spin the tube briefly if necessary.**
7. **Place microtube in a magnetic stand for 1 minute.**
8. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
9. **Add 100 µL of Buffer DL to the microtube and resuspend the Beads A by vortexing for 5 seconds. Ensure all liquid is collected at the bottom of the tube. Spin briefly if necessary.**
10. **Incubate microtube in a heating block at 95 °C for 15 minutes.**
11. **Remove microtube from heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**
12. **Place microtube in a magnetic stand for 1 minute.**
13. **Open the microtube while remaining in the magnetic stand.**

14. **Transfer the supernatant to a new microtube for storage (up to 4 weeks at -20 °C) or use it directly for analysis.**

    Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for your analysis.

Additional advice and application notes

Processing of tissue, fingernails, hair follicles, and swabs from mucous specimens

To increase the yield of extracted DNA from these sample types, a Proteinase K treatment before the heat lysis step is recommended. For that, perform the following step before the incubation at 95°C: add 5µl of Proteinase K (20mg/mL) to the lysis mixture, mix again, and incubate at 60°C for 10 minutes. If the tissue is not completely dissolved by then, you may incubate another 10 minutes at 60°C. Afterwards, continue as advised in the protocol.

Extraction of DNA from fungi, dermatophytes, and bacteria

The yield of DNA extracted from these cell types can benefit from the use of a Proteinase K treatment before the heat lysis step. For that, perform the following step before the incubation at 95°C: add 5µl of Proteinase K (20mg/mL) to the lysis mixture, mix again, and incubate at 60°C for 10 minutes. Continue as advised in the protocol.

Processing of complex samples

It has been reported that an increase in time for the capturing of cells to up to 10 minutes can lead to a higher sensitivity of the DNA extraction procedure.

Always give enough time for magnetic separation of Beads A to allow for optimal cell capture and reverse purification, respectively.

Processing of viscous samples such as sputum

Very viscous samples are recommended to be liquefied before specimens should be liquefied by a product or method that is not based on sodium hydroxide or guanidinium salts. Suitable methods are DTT- or other sulfide-based products, e.g. SL Solution (Copan Diagnostics) or Sigma-SP (Medical Wire & Equipment).

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-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.

See also the section “Limitations” for further information.

Control procedure

Detection of a control target next to the diagnostic target is state-of-the-art in molecular diagnostics. 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™ DNA enables extraction of all DNA in a given sample, the user is flexible in the choice of the control target.

In general, the user is responsible for selecting the appropriate control target, for determining appropriate quality control procedures in the laboratory, and for complying with applicable laboratory regulations.

Diagnostic performance characteristics

The performance of SwiftX™ DNA has been extensively validated internally as well as by external groups. The majority of the data was published in peer-reviewed scientific journals. All publications and application notes can be found on the SwiftX™ DNA product webpage.

SwiftX™ DNA has been validated for DNA extraction from the following specimens:

- swabs (oral, nasal, skin, rectal, vaginal)
- tissue homogenates
- skin scrapings
- hair bulbs
- saliva
- liquid-based cytology media
- cell cultures
- blood spots on FTA paper
- whole blood (venous, peripheral)
- skin biopsies
- fingernails, toenails
- urine
- sputum
- transport media (saline, PBS, amies)
- dried blood spots
- FFPE samples

SwiftX™ DNA has been validated for DNA extraction from the following pathogens and cells:

- Gram-negative bacteria (Escherichia, Bordetella, Proteus, Klebsiella, Leptospira, Borrelia, Neoehrlichia, Rickettsia, Salmonella)
- Gram-positive bacteria (Streptococcus, Staphylococcus, Mycobacterium)
- Fungi (Trichophyton, Microsporum, Nannizia, Aspergillus, Candida)
- Parasites (Schistosoma, Leishmania, Cryptosporidium, Babesia)
- Viruses (Human Papilloma Virus)
- Host cells (leukocytes, epithelial cells)

Limitations

Specimens stored in inactivating media

The cell capturing function of SwiftX™ DNA (see Protocols 2 and 3) cannot be utilized if the cells in the specimen have already been lysed. This is the case if the sample has been transported or stored in an inactivating buffer with high concentration of chaotropic salt, because they tend to lyse biological cells and may reduce the number of intact cells available for capturing. Examples for such transport media are eNAT®, PrimeStore® MTM, and DNA/RNA Shield™. In such case, you need to test whether the target cells are still intact, so they can be captured with Beads A.

Photometric determination of DNA concentrations, e.g. using NanoDrop

Although the reverse purification mechanism actively removes impurities and inhibitors, DNA extracted with SwiftX™ DNA is not as pure as nucleic acids extracted with silica-based purification kits. Thus, photometric determination of A260/A280 ratios and quantification by A260 measurement is of limited use. This is due to the lower limit of quantification of the Nanodrop method, which leads to wrong analysis data especially in samples with low cell count or DNA concentration. Thus, Nanodrop measurements may generally lead to misinterpretation of the extraction efficiency. However, if you still wish to perform a photometric analysis, do not forget to blank your measurement with Buffer DL instead of water or other buffers, because Buffer DL itself absorbs light around a wavelength of 280nm.

Analysis of extracted DNA using digital PCR

Buffer DL contains low concentrations of detergents. It was observed that DNA samples extracted with SwiftX™ DNA should only be applied to digital PCR analysis if the dPCR system does not require droplet generation, because Buffer DL interferes with droplet stability. If you still wish to use SwiftX™ DNA extracts for digital PCR, we recommend diluting the extracted DNA with water or another detergent-free buffer.

Literature references

- Dairawan & Shetty (2020) Am J Biomed Sci & Res Article 8:39
- Ali *et al.* (2017) Biomed Res Int Article ID 9306564
- Schmitz *et al.* (2022) J Clin Microbiol 60: e0244621
- Kurkela & Brown (2009) Medicine 37: 535
- Liu *et al.* (2023) Mol Med Reports 27: 104

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 SwiftX™ DNA 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.

Legal manufacturer

Xpedite Diagnostics GmbH
Lilienthalstr. 2a
85399 Hallbergmoos
Germany

Phone: +49-811-998538-10
E-Mail: info@xpedite-dx.com
Web: www.xpedite-dx.com