

SwiftX™ cfDNA

(REF: SXCF-50, SXCF-12)

Instructions for Use

Content

Intended use.....	2
Principles of the method	2
Content of the kit	2
Equipment to be provided by the user	2
Storage and shelf life	3
Warnings and precautions	3
Sample types and their collection, handling, and storage	3
Graphical representation of the extraction procedure.....	4
Step-by-step protocol for DNA extraction	5
Literature references.....	6
Key to symbols.....	6

Intended use

SwiftX™ cfDNA is intended to be used for manual purification of cell-free DNA from blood plasma, blood serum, cerebrospinal fluid, and urine samples. For research use only.

The extracted DNA samples can be applied to a wide range of analytical methods, such as spectrophotometric and fluorometric analyses, real-time quantitative PCR, digital PCR, isothermal amplification, microarray analysis, and next-generation sequencing.

Principles of the method

SwiftX™ cfDNA is designed for rapid purification of cell-free DNA from cell-free specimens such as blood serum, blood plasma, cerebrospinal fluid, and urine. The different components of SwiftX™ cfDNA have specific functionalities within the workflow of DNA extraction.

Buffer CFB provides optimal conditions for binding DNA to the paramagnetic particles Beads C.

Buffer CFW keeps DNA bound to Beads C, while facilitating the removal of contaminants such as proteins and low-molecular weight compounds.

Buffer CFE enables the efficient elution of DNA from Beads C leading to a maximized yield of cell-free DNA in the eluate.

Beads C are paramagnetic particles with fast and strong magnetic response utilized for binding and concentration of DNA during the purification process.

Content of the kit

Buffer CFB

Buffer CFW

Buffer CFE

Beads C

Equipment to be provided by the user

For performing 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 microcentrifuge tubes (safe-lock-caps or screw-caps recommended)
- Samples tubes with appropriate volume
- Magnetic stand (Xpedite Diagnostics REF: MAG-12)
- Vortexer (Xpedite Diagnostics REF: VOR-01)
- Heating block (Xpedite Diagnostics REF: ACC-15)
- Mini spin centrifuge (Xpedite Diagnostics REF: CEN-01)

Storage and shelf life

SwiftX™ cfDNA kits 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™ cfDNA kits are good to be used within 3 months.

Warnings and precautions

SwiftX™ cfDNA comprises of 3 buffers and paramagnetic particles. All components of the kit are free of hazardous substances. The safety data sheets (SDS) for SwiftX™ cfDNA 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.

Nucleic acid extracts can be disposed of 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

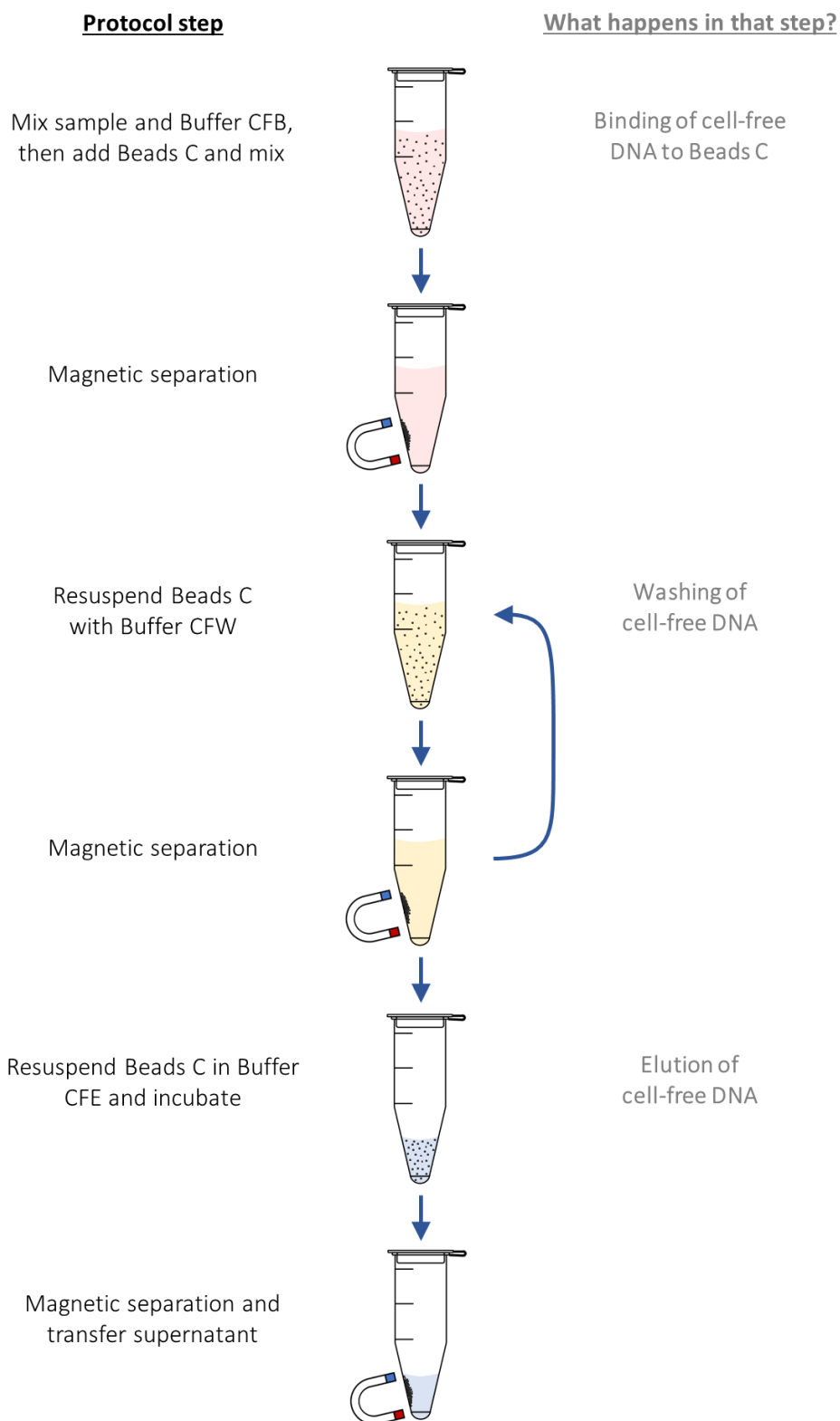
Venous whole blood should be collected using sterile equipment according to established phlebotomy procedures. SwiftX™ cfDNA was validated for venous whole blood. The anticoagulants K₂ EDTA and Na₃ Citrate have been validated. Lithium Heparin, however, shall not be used as a blood coagulant because it is not compatible with SwiftX cfDNA. Blood samples should be processed without delay to avoid degradation of cell-free DNA. For that, blood samples should be centrifuged for 10 minutes 1900 x g. A second centrifugation for 10 minutes at 16000 x g is recommended to remove any traces of remaining cells or cell debris.

Urine and also cerebrospinal fluid should be processed without delay to avoid degradation of cell-free DNA. It is recommended to remove cell remnants by centrifugation for 10 minutes at 16000 x g. SwiftX cfDNA is compatible with the use of Streck® Urine Preserve as stabilization additive in urine samples.

The optimal **sample input volume** is 2 mL of liquid specimen. However, the user can process as little as 0.5 mL to up to 5 mL.

The standard **elution volume** is 100 µL but can be chosen as low as 15µL according to the user's requirements.

Graphical representation of the purification procedure



Step-by-step protocol for cell-free DNA purification

To do before starting

- Set the heating block to 70 °C.
- Shake or vortex Beads C for 30 seconds to homogenize the particle suspension.

1. **Add 2 mL of Buffer CFB to 2 mL sample in a tube with sufficient volume capacity.**
2. **Add 20 µL of Beads C and mix well by pipetting up and down or by vortexing for 10 seconds. Ensure that no liquid is resting at the tube lid.**

Note: The sample volume can be chosen from 0.5 mL to 5 mL. Always use the same volume of Buffer CFB compared to the sample volume. Do not change the volume of Beads C (20 µL).

3. **Incubate the sample tube at room temperature for 5 minutes.**
4. **Place the tube in a magnetic stand for 2 minutes.**
5. **Open the tube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
6. **Add 500 µL of Buffer CFW 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 the tube in a magnetic stand for 1 minute.**
8. **Open the tube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
9. **Add 500 µL of Buffer CFW and mix well by pipetting up and down or by vortexing for 2 seconds. Transfer bead suspension to a microtube for further processing.**
10. **Place the tube in a magnetic stand for 1 minute.**
11. **Open the tube while remaining in the magnetic stand. Completely remove and discard the supernatant by pipetting.**
12. **Add 100 µL of Buffer CFE to the microtube and resuspend the Beads C by vortexing for 5 seconds. Ensure all liquid is collected at the bottom of the tube.**

Note: For higher concentration of DNA, as little as 15µL Buffer CFE can be used.

13. **Incubate microtube in a heating block at 70 °C for 3 minutes.**
14. **Remove microtube from heating block and place in a magnetic stand for 1 minute.**
15. **Do not remove the microtube from the magnetic stand! Use the supernatant directly for molecular analysis or transfer to a new microtube.**

Extracts can be stored for up to 7 days at 4 - 8 °C or up to 4 weeks at -20 °C.

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

Literature references

- Hu *et al.*, 2024. Cell-free DNA: a promising biomarker in infectious diseases. *Trends in Microbiology*.
- Dudley *et al.*, 2021. Detection and diagnostic utilization of cellular and cell-free tumor DNA. Annual Review of Pathology: *Mechanisms of Disease* 16(1): 199-222.
- Adhit *et al.*, 2023. Liquid biopsy: An evolving paradigm for non-invasive disease diagnosis and monitoring in medicine. *Cureus* 15(12): e50176.

Key to symbols

	Catalog number
	Number of extractions
	Storage temperature
	Batch number
	Expiry date
	Read Instructions for Use
	Legal manufacturer

Legal manufacturer

Xpedit Diagnostics GmbH

Lilienthalstr. 2a
85399 Hallbergmoos
Germany

Phone: +49-811-998538-10

E-Mail: info@xpedit-dx.com

Web: www.xpedit-dx.com