CE IVD

SwiftX™ Virus

(REF: SXV-50-IVD)

Instructions for Use

Content

Intended use

SwiftX™ Virus is intended to be used for manual extraction of RNA and DNA of viruses and bacteria from human blood serum and blood plasma. For professional use only.

Principles of the method

SwiftX™ Virus is designed for rapid one-step extraction of DNA and RNA of viruses as well as bacteria. The validated sample types are blood plasma and blood serum. The different components of SwiftX™ Virus have specific functionalities within the workflow of DNA/RNA extraction.

Buffer TLS enables an efficient lysis of viruses and bacteria. Buffer TLS is fully compatible with PCR methods and next-generation sequencing methods.

The use of **Proteinase K** enhances the cell and virus lysis efficiency of Buffer TLS and ensures irreversible inactivation of nucleases.

During and after heat lysis, the paramagnetic particles **Beads A** bind cell debris and other particulate matter. After magnetic separation, the lysate is cleared from those potentially inhibiting substances.

Content of the kit

Buffer TLS
Proteinase K
Beads A

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 screwcaps recommended)
- 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™ Virus 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™ Virus kits are good to be used within 3 months.

Warnings and precautions

SwiftX™ Virus comprises a Proteinase K solution, which is considered a hazardous substance. The Safety Data Sheet (SDS) is available upon request. The following hazard and precaution statements apply:

Proteinase K:

Danger.

H315	Causes skin irritation.
H319	Causes serious eye irritation.
P264	Wash respective body parts after accidental contact.
P280	Wear protective gloves, eyes, and face 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.

Be aware that the sample mixture remains potentially infectious until the heat lysis is conducted.

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

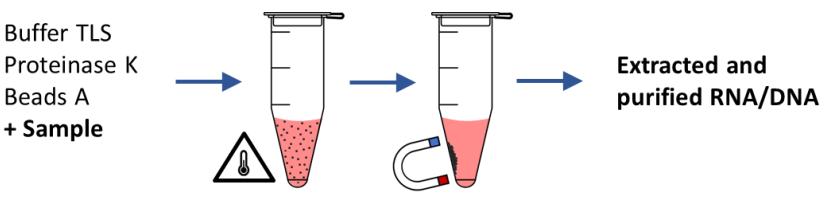
Make sure to work with clean equipment and use pipette tips with aerosol barriers to avoid carryover of specimens or nucleic acid extracts between samples.

Sample types and their collection, handling, and storage

SwiftX™ Virus has been validated for plasma as well as serum prepared from venous blood draws. For sample collection, handling and storage, follow established phlebotomy guidelines.

If blood plasma is used for DNA/RNA extraction, it is advised to avoid heparin as an anticoagulant due to its known inhibitory potential to enzymatic amplification reactions.

Graphical representation of the extraction procedure



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Protocol for extraction of RNA and DNA

To do before starting

- Set the heating block to 95 °C.
- Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.

1. **Shake or vortex Beads A for 30 seconds to ensure homogeneous suspension. Pipet 15µL of Beads A into a 1.5 mL microtube.**
2. **Add 3µl Proteinase K.**
3. **Add 100µL Buffer TLS.**
4. **Add 20µL of your serum or plasma sample. Mix well by vortexing or pipetting up and down.**
5. **Tightly close the microtube.**
6. **Incubate lysis mixture at 95°C for 5 minutes.**
7. **Remove the sample from the heating device and mix well for 5 seconds.**
8. **Remove condensate from the lid by short-spinning or tapping the tube on the work bench.**
9. **Place the sample in a magnetic stand at room temperature for 1 minute to let the magnetic particles separate.**
10. **Open the lid while the sample remains in the magnetic stand and transfer the supernatant into a new microtube for storage or use in downstream applications.**

Extracted DNA can be stored for 2 weeks at -20°C or for 6 months at -80°C.

Extracted RNA can be stored for 2 days at -20°C or for 1 month at -80°C.

Note: If extracted nucleic acids are not directly used, mix them by vortexing for 2 seconds before use for RNA/DNA analysis.

Performance data

A total of 175 samples has been analyzed for the performance evaluation. Among those were 143 clinical specimens (77 samples positive for various pathogens, 66 samples negative for the tested pathogen), and an additional 32 negative specimens spiked with various pathogens. The successful detection of the following viral and bacterial infections had been validated in the studies: Dengue Virus, West-Nile Virus, Chikungunya Virus, Crimean-Congo Hemorrhagic Fever Virus, Yellow-Fever Virus, Usutu Virus, Leptospira.

In a few cases, the use of frozen left-over samples showed limitations as it was evident that the samples did not contain the original concentration of viral particles anymore, which they used to contain at the time of the first tests before freezing. In such cases, discordant results were resolved using the original clinical information on the sample. Based on all validation data available, the below diagnostic performance has been calculated. For PPV, NPV, and Accuracy, a prevalence of 20% has been assumed for the infection that a specimen was tested for.

	Value	95% confidence interval
Sensitivity	98.04%	93.10% to 99.76%
Specificity	100%	95.07% to 100%
Positive predictive value	100%	96.38% to 100%
Negative predictive value	99.51%	98.10% to 99.88%
Accuracy	99.61%	97.17% to 100%

Limitations

- SwiftX™ Virus is not intended for detection of very low concentrations viruses and bacteria. The extraction protocol does not include a pathogen concentration step. Instead, the specimen is diluted by mixing with the extraction reagents. Thus, the diagnostic sensitivity for very low viremic samples may be lower than the overall sensitivity calculated from the performance studies.
- It is not recommended to use heparin as anti-coagulant for plasma preparation. It was not assessed how well the reverse purification step in SwiftX™ Virus removes heparin from the lysate.
- Long-term frozen storage of samples and repeated freeze-thaw events can have a negative impact on the integrity of viral particles and bacterial cells. Thus, it is recommended to extract RNA/DNA from specimens as soon as possible after sampling.
- Low-titer samples

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

	For in-vitro diagnostic use
	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™ Virus 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

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