

SwiftX Virus: High-Performance RNA/DNA Extraction for Blood-Borne Pathogens – A Multicenter Validation Study

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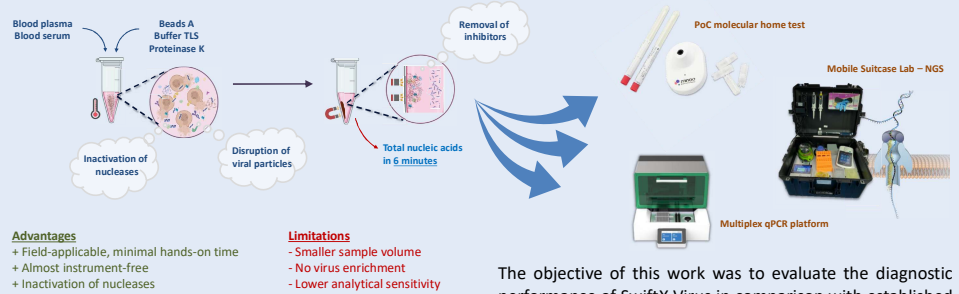
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Background and Objectives

Molecular diagnostics relies on accurate nucleic acid extraction as a prerequisite for pathogen detection. The EU project **Prepare-TID** aims at the development and validation of an integrated molecular analysis workflow. The objective is to provide **field-ready DNA/RNA extraction tools** that can be applied for multiple molecular detection technologies, such as **isothermal home tests**, **multiplex real-time PCR**, and **mobile NGS analyses**.

SwiftX Virus (SXV) was developed as a rapid, manual extraction kit for RNA and DNA from blood plasma and serum, aiming to simplify workflows compared to conventional bind-wash-elute methods.



The objective of this work was to evaluate the diagnostic performance of SwiftX Virus in comparison with established RNA extraction kits across multiple blood-borne pathogens.

Material & Methods

Study 1 was conducted in Italy as well as Türkiye. A total of 175 samples from local population were analyzed: 143 clinical specimens (77 positive, 66 negative) and 32 spiked samples. The SwiftX Virus extraction protocol was tested head-to-head with Qiagen QIAamp RNA Mini and Roche MagnaPure 96. All extracted RNA was quantified using in-house real-time PCR assays at the study site or and CE-IVD marked PCR kits.

Main objective: benchmarking of rapid extraction method against conventional purification methods.

Study 2 was conducted in India. A total of 146 clinical specimens (68 positives, 78 negatives) from local population were analyzed. SXV-RNAs were detected with an in-house RT-RAA assay targeting Dengue RNA. This “rapid workflow” was benchmarked against Qiagen QIAamp Viral RNA Mini & Altona Diagnostics RealStar Dengue 3.0 as a conventional time- & resource-consuming workflow.

Main objective: benchmarking of a rapid detection workflow against a conventional molecular workflow.

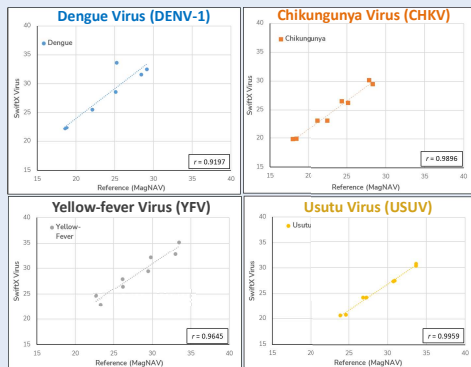
Both studies were conducted in 2025 by partners from the EU Horizon project Prepare-TID as well as from a capacity-building project partially sponsored by the Indian funds.

The data gathered in the performance evaluation was leveraged for completing the Technical File of SwiftX Virus for making it available as a CE-IVD marked product for routine diagnostic use.

Results

Study 1 encompassed clinically pre-characterized sera and plasma samples positive for various viruses such as Dengue Virus (DENV-1,-2,-3), West Nile Virus (WNV-1,-2), Crimean-Congo Hemorrhagic Fever Virus (CCHFV), and Leptospira.

Clinically negative plasma & sera were spiked with:



Reference: Roche MagnaPure 96 (Cts normalized for compar. of extraction efficiency)

Diagnostic performance with clinical plasma & serum:

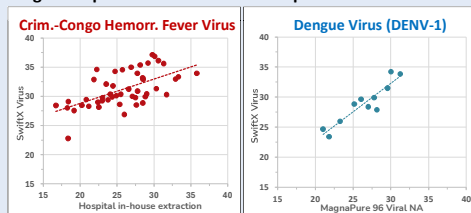


Table 1. Performance of the SwiftX Virus extraction

	Diagn. sensitivity	Diagn. specificity
SwiftX Virus	98.04%	100%

SwiftX Virus achieved 98.04% sensitivity (95% CI: 93.10–99.76%) and 100% specificity (95% CI: 95.07–100%). Positive predictive value was 100%, negative predictive value 99.51%, and overall accuracy 99.61%. Performance was consistent across six viral pathogens (CCHFV, Dengue, WNV, Chikungunya, Yellow Fever, Usutu) and one bacterial pathogen (Leptospira).

Study 2 encompassed 146 clinical sera, which originated from suspected Dengue patients. All samples were pre-characterized by NS1 ELISA.

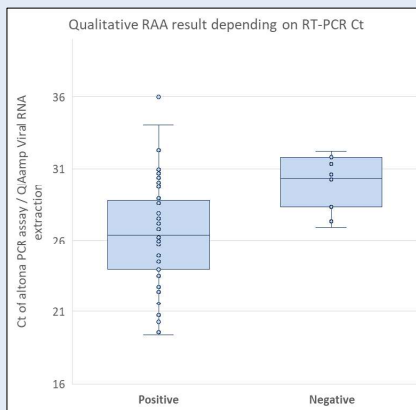


Table 2. Performances of RAA-based detection versus qPCR-based detection

RAA vs PCR	Diagn. sensitivity	Diagn. specificity
All samples	85.29%	100%
All with Ct<30	92.16%	100%
All with Ct<25	100%	100%

The focus of Study 2 was to evaluate how well a combination of rapid extraction and detection method performance compared to established laboratory kits. Thus, SwiftX Virus extracted RNA was amplified with an isothermal assay based on RAA technology.

While RAA detection is incredibly fast, such assays are also known to have a lower analytical sensitivity compared to PCR assays. Study 2 prove that SwiftX Virus extraction in combination with RAA detection offers a fast, simple-to-perform workflow, which has a slightly lower diagnostic sensitivity.

Conclusion

SwiftX Virus demonstrated excellent diagnostic performance for RNA/DNA extraction from blood plasma and serum, meeting and exceeding predefined sensitivity and specificity criteria. Its simplified workflow offers a robust alternative to conventional extraction methods for molecular diagnostics.



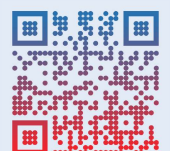
Key take aways:

- One-step protocol for RNA/DNA extraction
- Efficient removal of blood plasma inhibitors
- Total extraction time: 6 minutes
- Batch-processing in PCR cycle possible
- Validated with 300+ samples, mostly clinical specimens
- 98% diagnostic sensitivity, 100% diagnostic specificity
- Available as CE-IVD kit for routine use in diagnostics

Outlook

Future work will evaluate if SwiftX™ Virus can be combined with ClassiX™ CleanUp to allow for concentration and further purification of RNA.

The combination of both may provide a simple and fully-field compatible extraction method enabling advanced molecular analyses such as Oxford Nanopore sequencing.



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