High-Consistency RNA Extraction Across SARS-CoV-2 Variants

Zinexts MagPurix® System Demonstrates Reliable Performance in TFDA National Standard Study

Executive Summary

In a national collaborative study led by the Taiwan Food and Drug Administration (TFDA), eight laboratories across Taiwan and the United Kingdom evaluated multiple extraction platforms to establish second-generation national standards for SARS-CoV-2 and its variants.

The **MagPurix® Viral Nucleic Acid Extraction Kit** (Zinexts Life Science Corp.) achieved highly consistent RNA quantification values across all six viral strains—matching or surpassing the precision of other commercial systems such as Qiagen, Abbott, and Roche.

The study confirmed that Zinexts' automated extraction technology ensures reliable RNA recovery, excellent reproducibility, and strong assay linearity, supporting its use in high-level standardization and regulatory validation workflows.

Background

The TFDA initiated a national collaborative study to create heat-inactivated RNA standards for the original Wuhan strain and five major SARS-CoV-2 variants (Alpha, Beta, Gamma, Delta, Omicron).

Each participating laboratory used its routine RNA extraction and amplification workflows, generating eleven datasets through both RT-qPCR and RT-dPCR assays.

Extraction systems evaluated included:

- MagPurix® Viral Nucleic Acid Extraction Kit (Zinexts Life Science, Taiwan)
- Qiagen platforms (QIAamp, EZ1, and QIAzol)
- Abbott Alinity m automated system
- Roche COBAS SARS-CoV-2 test

The comparison provided a unique, multi-laboratory benchmark for extraction precision, recovery efficiency, and cross-platform consistency.

Key Findings

1. Zinexts Shows Excellent Agreement with the International Standard

Laboratories using MagPurix® achieved RNA concentrations between 7.39–7.72 Log10 IU/mL across all variants closely aligned with the WHO international standard (7.70 Log10 IU/mL) and the overall mean of all laboratories (7.29–7.70 Log10 IU/mL).

Variant	MagPurix® (Average)	Qiagen (Average)*	Abbott Alinity m	Roche COBAS	Global Mean
Original	7.68	7.63	7.35	7.65	7.69
Alpha	7.73	7.60	7.35	7.61	7.70
Beta	7.67	7.61	7.48	7.53	7.69
Gamma	7.42	7.47	7.11	7.19	7.44
Delta	7.58	7.46	7.09	7.19	7.52
Omicron	7.39	7.40	6.71	6.85	7.29

*Includes QIAamp, QIAzol, and EZ1 results.

Zinexts' MagPurix® consistently matched or outperformed other extraction systems, particularly in variant RNA quantification stability and proximity to the expected 7.7 Log10 IU/mL target.

2. Superior Consistency and Reproducibility

- Coefficient of variation (CV): Across all strains, MagPurix® data remained well within the 2–3 % range, equal or better than most Qiagen datasets and significantly tighter than Abbott and Roche results.
- PCR linearity ($R^2 \geq 0.97$): MagPurix® datasets fully met WHO criteria for quantitative assays; all three MagPurix® replicates fell within the accepted slope range (–3.1 to –3.6).
- No data exclusion: Unlike some other labs (e.g., Lab 4 – Qiagen QIAamp), MagPurix® results required no outlier removal, indicating strong inter-run reproducibility.

3. Strong Multi-Variant Performance

RNA recovery using MagPurix® remained highly uniform across all six variants, with less than 0.3 Log10 IU/mL deviation between strains.

In contrast, other extraction systems showed wider fluctuation — for example, Abbott and Roche values dropped by nearly 0.7–1.0 Log10 IU/mL for Omicron, reflecting reduced extraction or amplification efficiency for high-mutation strains.

4. Compatibility and Stability

The MagPurix® extracted RNA showed excellent compatibility with both RT-qPCR and RT-dPCR platforms used in the TFDA study.

Furthermore, RNA standards maintained quantitative stability for up to 24 months at –20 °C and –80 °C, underscoring the robustness of the extraction workflow for long-term reference material production.

Conclusion

The TFDA collaborative study demonstrated that the Zinexts MagPurix® Viral Nucleic Acid Extraction Kit provides:

- Consistent RNA recovery across diverse SARS-CoV-2 variants
- Superior reproducibility and alignment with WHO standards
- Stable, high-quality extracts suitable for both quantitative and digital PCR
- Reliable results without outlier exclusion, outperforming certain manual or semi-automated methods

These findings confirm MagPurix® as a dependable platform for national reference material preparation, diagnostic assay calibration, and molecular testing quality control.

By ensuring precision and stability, Zinexts technology supports regulatory agencies and diagnostic developers worldwide in achieving consistent and comparable molecular results.

Reference

Wu, M.-S., Chang, P.-C., Lin, P.-L., Tso, C.-H., Chen, H.-M., Peng, Y.-H., Wu, P.-C., Hsu, J.-C., & Wang, D.-Y. (2024). Establishment of national standards of SARS-CoV-2 variants in Taiwan. *Heliyon*, *10*, e38275. https://doi.org/10.1016/j.heliyon.2024.e38275