Validation of an automated instrument for handling specimen preparation

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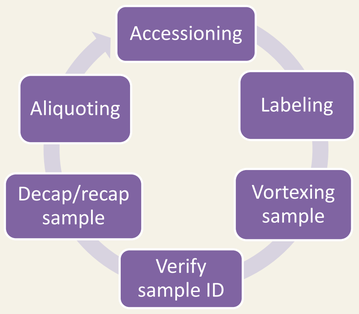
Introduction

Laboratory testing:



Multi-step process

Accurate

Precise

Quality control

Manual

Repetitive

Ergonomic issues

Objectives

- To validate an automated instrument, Copan UniVerse, for pre-analytical processing of clinical samples
- To assess the potential enhancements in workflow efficiency through the integration of the UniVerse instrument

Methods

- Custom protocols are programmed on the UniVerse instrument for processing specific sample collection containers.

  Protocols under evaluation:

  Copan UTM tube with regular swab to secondary containers (Fig. 1)

- Accuracy and precision were evaluated using lab prepared samples. Copan 2ml UTM swabs were inoculated with MEM media to serve as the negative control, and for positive control, Copan UTM were inoculated with SARS-CoV-2/HSV1 virus at two distinct concentrations. Samples were organized in checkerboard format for testing.
- Prospective clinical validation was performed on the Copan UTM to deep well plate protocol using previously tested HSV/VZV patient samples.
- Copan UTM samples were split for manual processing and UniVerse processing by manually aliquoting into an aliquot tube and then processing the remaining sample in the Copan UTM on the UniVerse. All aliquoted samples were tested using the Hologic Panther Fusion SARS-CoV-2 assay or the LDT HSV/VZV qPCR assay.

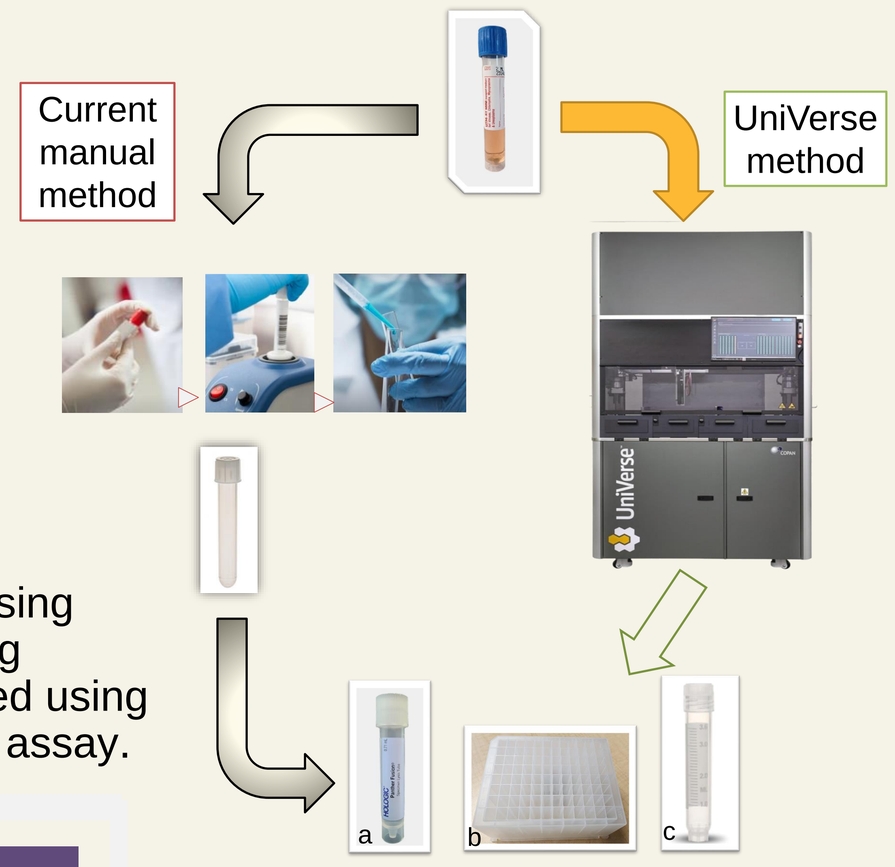


Figure 1. Workflow diagram for manual method and UniVerse method for pre-analytical processing of Copan UTM sample to secondary containers: a) Hologic Fusion lysis tube, b) KingFisher deep well plate and c) Simport 4ml cryovial.

Results

UniVerse protocol	Accuracy	Precision % cv	Ct range of viral culture
Copan UTM to Fusion tube n=120	99.20%	0.23	28
		1.32	31
Copan UTM to deep well plate n=275	100%	1.19	20
		2.43	30
Copan UTM to Simport tube n=92	100%	1.38	20
		1.63	30

Figure 2. Comparison of lab prepared samples processed by the manual method and the UniVerse method. Three UniVerse protocols were validated against the manual method. Precision experiment for Fusion tube and deep well plate protocols were conducted over three successive days.

PCR target	Accuracy	Mean ΔCt (UniVerse-Manual)
HSV1	99.43%*	-0.330 ± 0.722
HSV2	99.72%	-0.533 ± 0.886
VZV	99.43%	-0.708 ± 0.983
Human β-globin	93.15%	-0.276 ± 0.958

Figure 3. Clinical validation of the Copan UTM to deep well plate protocol using patient HSV/VZV samples (n=352). One notable discordant result for HSV1 was false positive by the UniVerse method, this sample might have been contaminated during the initial splitting process.

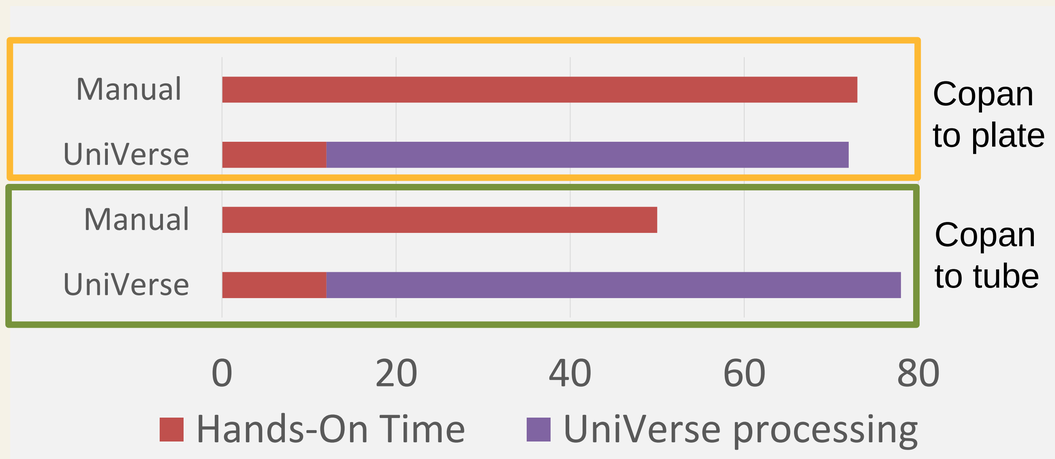


Figure 4. Time analysis for processing 96 samples. Turnaround time in minutes. Significant reduction in hands-on time using the UniVerse method, eliminating the need of aliquoting sample to an aliquot tube prior to testing.

Conclusion

- Samples handled by the Copan UniVerse instrument produced results similar to those of manually processed samples, with an accuracy exceeding 99% across all three validated UniVerse protocols.
- UniVerse instrument helped reduce hands-on time, possible human errors and staff's ergonomic issues.
- Standardizing the collection kits is crucial for maximizing the instrument's efficiency.

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