

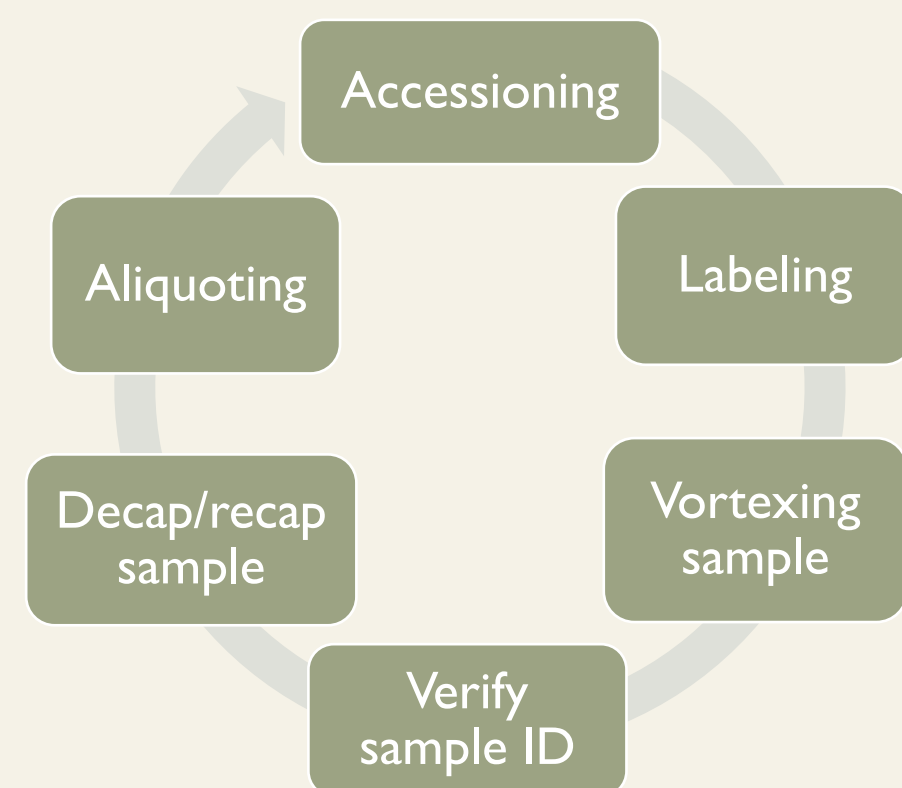
WORKFLOW COMPARISON AND EVALUATION OF AN AUTOMATED INSTRUMENT FOR HANDLING SAMPLE PREPARATION IN CLINICAL LABORATORY

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Introduction

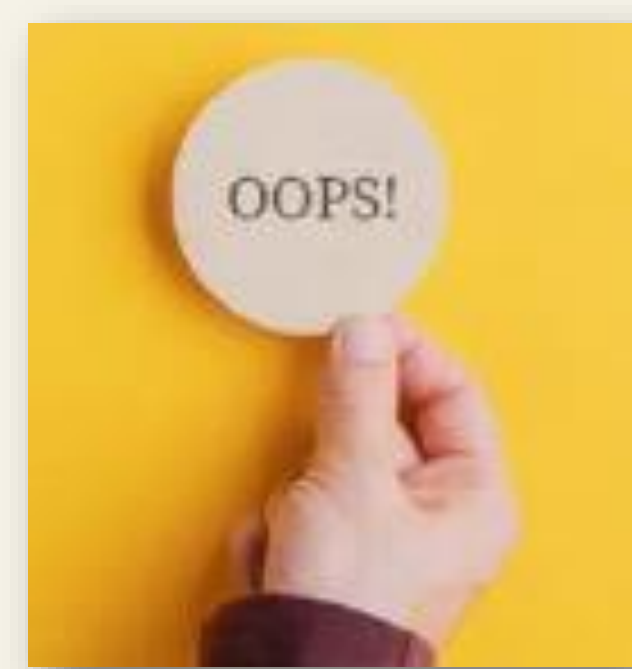
Laboratory testing:



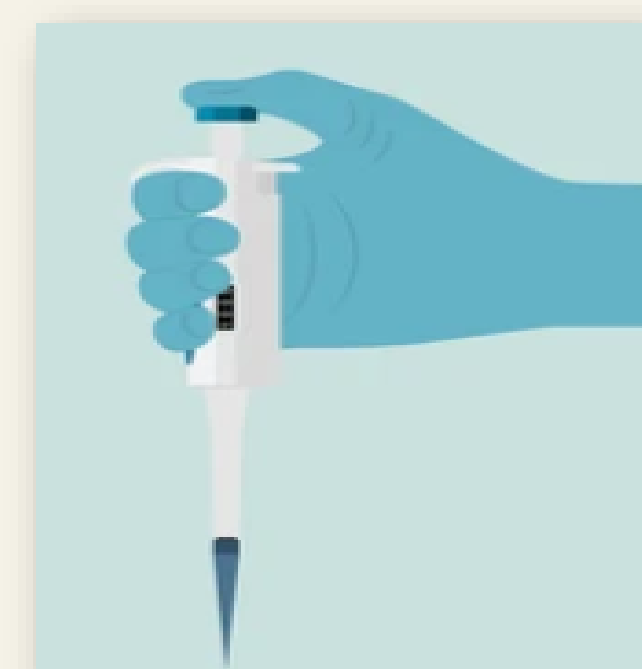
Multi-step process



Accurate & precise



Quality control



Manual & Repetitive



Ergonomic issues

Objectives

- To evaluate the performance of an automated instrument, Copan UniVerse, for pre-analytical processing of clinical samples
- To assess the potential workflow improvements

Methods

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

Protocols under evaluation:

- Copan UTM tube with nasopharyngeal swab to Hologic Fusion lysis tube
- Oral saline gargle tube to Hologic Fusion lysis tube

- Clinical Copan UTM samples and saline gargle samples were each divided into two categories:

- Positive – inoculated with SARS-CoV-2 culture
- Negative – uninoculated (negative for SARS-CoV-2)

n = 24 per sample type
(12 positive, 12 negative)

- Clinical samples were initially manual aliquoted into Hologic Fusion lysis tubes, followed by processing on the UniVerse in a checkerboard format, and then all aliquoted samples were tested using the Hologic Panther Fusion SARS-CoV-2 assay. PCR results from the UniVerse method were compared with the manual method for accuracy.

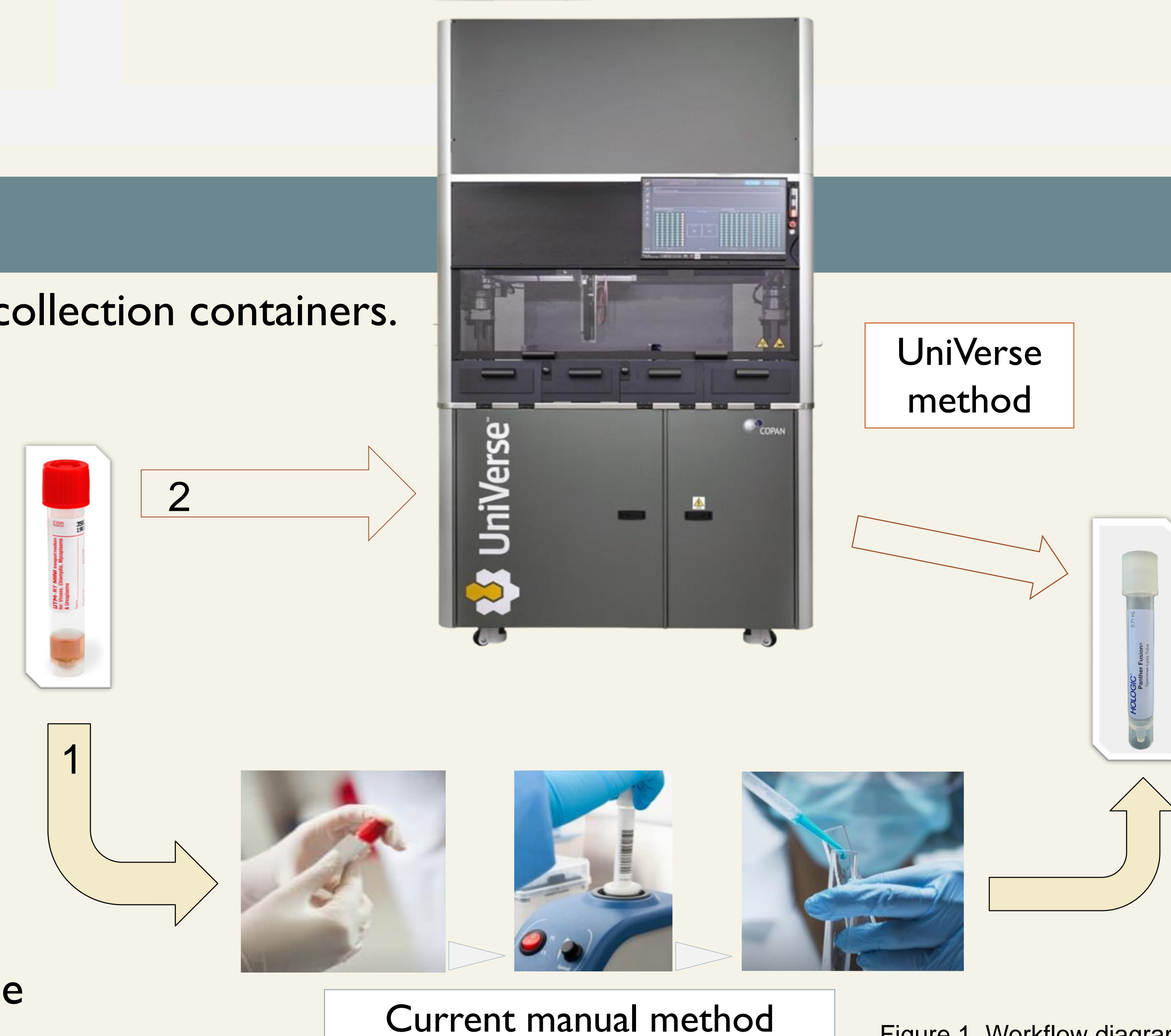


Figure 1. Workflow diagram for manual and UniVerse processing

Results

Method Comparison

- Results obtained from the UniVerse methods were concordance with those from the manual method, no cross-contamination was observed from the checkerboard experiment.

UniVerse protocol	Accuracy	Average Δ Ct
Copan UTM to Fusion tube	100%	0.15 ± 0.553
Saline gargle to Fusion tube	100%	0.18 ± 0.580

Figure 2. SARS-CoV-2 NAT results comparison between samples processed by the manual method and the UniVerse method.

Workflow comparison

- Hands-on time was reduced by 50% with UniVerse method

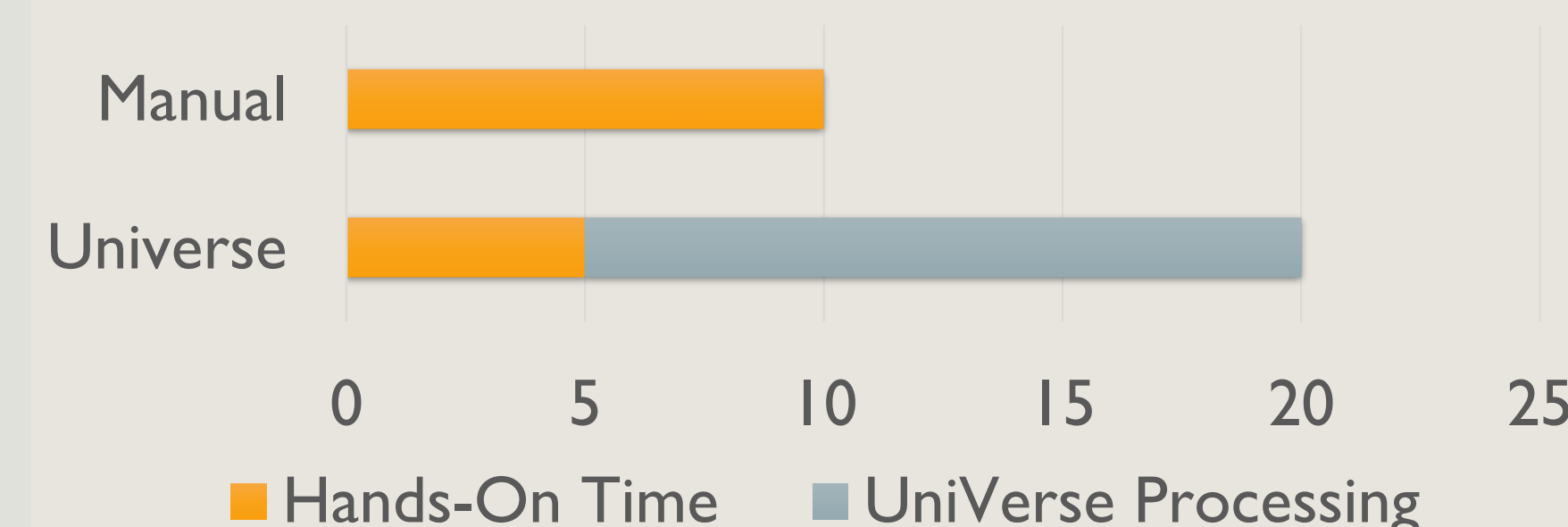


Figure 3. Time analysis for processing 24 samples. Turnaround time in minutes.

- Verified UniVerse's functionalities:

- ✓ Barcode scanning
- ✓ Labeling of secondary container
- ✓ Volume aliquoted
- ✓ Decap/recap sample container

Conclusion

- Copan UniVerse instrument aliquoted samples from primary container to secondary container accurately
- It improved laboratory's pre-analytical workflow by automating repetitive manual procedures
- It 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
- Clinical validation is ongoing

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