Clinical and Analytical Evaluation of the 15-Minute, FDA-Cleared, CLIA-Waived, DASH® SARS-CoV-2 & Flu A/B Test Performed on the Point-of-Care DASH® Rapid PCR System

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The DASH® SARS-CoV-2 & Flu A/B Test is a rapid, reverse transcription polymerase chain reaction (RT-PCR) assay performed on the point-of-care DASH® Rapid PCR Instrument and is intended for simultaneous *in vitro* qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus ribonucleic acid (RNA) in anterior nasal (AN) swab specimens from patients with signs and symptoms of respiratory tract infection. The DASH® SARS-CoV-2 & Flu A/B Test received dual FDA 510(k) clearance and CLIA waiver. Here we present data from the clinical trial and analytical studies that supported the regulatory submission.

PURPOSE / OBJECTIVES

- The DASH® SARS-CoV-2 & Flu A/B Test combines the technologies of sequence-specific capture and RT-PCR amplification. The target RNA molecules from AN swab specimens are captured by sequence-specific biotinylated oligomers and enriched via streptavidin-coated paramagnetic particles. Fluorescent-based RT-PCR reaction enables the highly sensitive target detection on DASH® Rapid PCR system.
- A clinical study was conducted to compare the DASH® SARS-CoV-2 & Flu A/B Test to FDA-cleared RT-PCR assays by testing clinical specimens at CLIA-waived sites.
- Analytical sensitivity, specificity, and reproducibility of the DASH® SARS-CoV-2 & Flu A/B Test was evaluated by using contrived samples prepared in the laboratory.

MATERIALS & METHODS

- Clinical performance was established in a multi-center study conducted from January to March 2024 using AN swab specimens collected from individuals with signs and symptoms of respiratory infection. Seven geographically diverse CLIA-waived testing sites within the United States participated in the study. AN swabs were collected by either a healthcare provider or an adult from individuals below 14 years or were self-collected from individuals aged 14 years or older. Additional AN swabs were collected in transport media for comparator testing.
- Positive percent agreement (PPA) and negative percent agreement (NPA) were calculated against FDA cleared RT-PCR tests to determine clinical sensitivity and specificity. All discordant results between the DASH® SARS-CoV-2 & Flu A/B Test and the comparator were investigated using a third, highly-sensitive FDA-cleared test.
- Analytical evaluation was performed following FDA guidance and CLSI guidelines. Reproducibility was evaluated at three CLIA-waived sites by three previously untrained operators, across five days, and three lots of cartridges.

RESULTS

- Clinical trial: A total of 817 eligible subjects were enrolled, 22 were excluded due to protocol deviations (e.g., specimen shipping concerns causing the comparator sample to be ineligible for testing within the test IFU stability window, etc.). In total, 795 specimens were included in performance calculations for SARS-CoV-2, and 792 specimens in performance calculations for Flu A and Flu B when tested on the DASH® SARS-CoV-2 & Flu A/B Test (Table 1).
- Reproducibility: The DASH® SARS-CoV-2 & Flu A/B Test demonstrated 99.6% overall concordance from 3 clinical sites by untrained operators (Table 2).
- The DASH® SARS-CoV-2 & Flu A/B Test is demonstrated to be highly sensitive and specific, and can accurately detect common strains and lineages for SARS-CoV-2, influenza A and influenza B in clinical specimens.

RESULTS

Table 1. Clinical Evaluation Summary

Test Targets	PPA		NPA	
	TP/(TP+FN)	PPA (95% CI)	TN/(TN+FP)	NPA (95% CI)
SARS-CoV-2	160/168	95.2% (90.9% - 97.6%)	624/627	99.5% (98.6% - 99.8%)
Flu A	50/53	94.3% (84.6% - 98.1%)	725/739	98.1% (96.8% - 98.9%)
Flu B	36/37	97.3% (86.2% - 99.9%)	749/755	99.2% (98.3% - 99.6%)

Table 2. Reproducibility Study Summary

Sample Type	# Samples Tested	# Correct Results	% Concordance (95% CI)
Low Positive	270	268	99.3% (97.3% - 99.8%)
Moderate Positive	269	268	99.6% (97.9% - 100.0%)
Negative	270	270	100% (98.6% - 100.0%)
Total	809	806	99.6% (98.9% - 99.9%)

SUMMARY / CONCLUSION

The FDA-cleared, CLIA-waived, DASH® SARS-CoV-2 & Flu A/B Test is a rapid and robust molecular diagnostic assay that is suitable for point-of-care use. Its analytical and clinical performance is substantially equivalent to existing FDA-cleared molecular diagnostic tests for SARS-CoV-2, Flu A, and Flu B. The DASH® Rapid PCR system delivers the benefits of simple, affordable, rapid, and accurate testing to respiratory patients at the point of care.