

Evaluation and implementation of an innovative urine collection and transport device

with full laboratory automation in a high-volume reference laboratory setting

CLINICAL BACKGROUND

Quest Diagnostics operates large reference laboratories in the United States, Puerto Rico, Mexico, and Brazil. Each year, Quest laboratories serve a third of the adults and half of the physicians and hospitals in the United States, processing hundreds to thousands of urine cultures each night at each site. To manage this testing volume, Quest implemented microbiology laboratory automation WASP-FLO and WASPLab (Copan Diagnostics, Inc., Murrieta, CA) at four of their high-volume locations starting in 2018.

The Copan UriSponge™ is designed for the collection, transport, and preservation of urine specimens from the collection site to the testing laboratory. Boric acid has recently been included in the Candidate List of substances of very high concern for Authorization, published under Article 59(10) of the REACH Regulation, due to its reproductive toxicity. A new UriSponge™ formulation was developed using sodium propionate and potassium sorbate as alternative preservatives.

Urine collected in the newly formulated UriSponge™ can be stored at room temperature or refrigerated for up to 48 hours and can be processed manually or with microbiology laboratory automation according to the manufacturer. This study was undertaken to evaluate the performance of the new preservative formulation used in UriSponge™ for both manual cultures and those performed using WASP-FLO and WASPLab.

METHODS

The UriSponge evaluation study was designed in 2 phases and conducted at one Quest facility in July of 2023.

Phase I – Urine from donors not currently taking antibiotics was pooled and filtered to remove any bacteria or yeast. Twenty-two urine aliquots were inoculated with representative urinary pathogens including *Escherichia coli*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Staphylococcus saprophyticus*, *Enterococcus faecalis*, and *Candida albicans*, at a final concentration of 1.5×10^4 CFU/mL. Six UriSponge devices were collected from each urine following the manufacturer collection instructions. The prepared UriSponge samples were plated using 1uL of sample onto a blood and MacConkey bi-plate at Time 0 (T0) manually and using the WASPLab automation. Plates were incubated in ambient atmosphere at 33-37°C for 18-24 hours. The remaining UriSponge devices were then stored at 4-8°C (2 devices) and 20-25°C (2 devices) for 48 hours and plated and incubated again as above both manually and with WASPLab.

Phase II – A total of 512 unpreserved patient urine specimens were included in the study. Three UriSponge devices were collected from each urine following the manufacturer collection

instructions. Time 0 cultures were prepared for each urine by immediately plating 1uL of the UriSponge preserved urine specimen onto a blood and MacConkey bi-plate and incubating in the WASPLab in ambient atmosphere at 33-37°C. One of the 2 remaining UriSponge devices from each urine was stored at 4-8°C for 48 hours, while the remaining UriSponge devices were stored at 20-25°C for 48 hours. After this storage period, the UriSponge specimens were again sampled by plating 1uL onto a blood and MacConkey bi-plate and incubating in the WASPLab in ambient atmosphere at 33-37°C.

Acceptance Criteria for both phases of study were $\geq 90\%$ acceptable growth defined as follows:

- growth within 1 quantitation category of corresponding T0 culture.
- recovery of $\geq 95\%$ of all clinically significant organisms recovered as compared to T0 cultures (within 1 quantitation category).
- $\leq 5\%$ recovery of additional organisms in clinically significant quantities beyond 1 quantitation category as compared to T0 cultures.

RESULTS

Phase I: There was 100% (22/22) agreement with UriSponge devices stored at 4-8°C and 20-25°C for 48 hours as compared to T0 cultures for both manual and automated methods.

Phase II: There was 96.5% (494/512) agreement with UriSponge devices stored at 4-8°C and 20-25°C for 48 hours as compared to T0 cultures using automated methods. 18/512 (3.5%) specimens showed clinically significant discrepancies as compared to T0 cultures as follows:

- 16/18 results were the same for both ambient and refrigerated temperatures.
- 2 had results where ambient or refrigerated stored devices matched the T0 culture, but other temperature was discrepant.

Quantitation categories are as follows:

Quantitation Categories	
1x	1,000-9,000 CFU/mL
10x	10,000-49,000 CFU/mL
50x	50,000-100,000 CFU/mL
100x	> 100,000 CFU/mL

Details of discrepant results are shown below for both 4-8°C (refrigerated – **Chart 1**) and 20-25°C (ambient – **Chart 2**) for 48 hours as compared to T0 cultures.

All patient specimens stored in UriSponge at 4-8°C and 20-25°C for 48 hours exceeded acceptance criteria as compared to their corresponding T0 cultures.

ADVANTAGES AND CHALLENGES

New specimen pallets were needed to fully integrate UriSponge into our automated specimen sorter, WASP-FLO, and on the WASPLab enabling us to maintain a fully automated workflow. For our sites without automation, manually eluting urine from the sponge was problematic. Standalone centrifuges were used to extract the urine from the UriSponge device so that manual cultures could be performed. In addition, some clinics struggled with appropriate specimen submission and additional education was performed to ensure appropriate use of the UriSponge.

Examples of two re-education efforts included: 1) not decanting urines into the UriSponge tube, and 2) allowing the sponge to remain in the urine specimens for 5 seconds to appropriately saturate the sponge with urine prior to placing it back into the UriSponge tube.

DISCUSSION

Copan Urisponge is a robust collection/transportation/preservative device for urine cultures. Excellent results were achieved when evaluating urine specimens stored at room temperature or at refrigerated temperatures for up to 48 hours as compared to results from the corresponding initially cultured urine. The Copan UriSponge device can be used for manual culture or with WASP-FLO and/or WASPLab for full automation of urine cultures. It is important to note that education of specimen collectors is critical due to the unique nature of this transport system.

Chart 1

Refrigerated vs Baseline	ENTERO	GNB	LF GNB	NLF GNB
Discordant	9	5	8	12
Number of Tests	512	512	512	512
Discordant %	1.8%	1.0%	1.6%	2.3%
Poisson Distribution (Lower bound)	0.0089	0.003	0.007	0.021
Poisson Distribution (Observed)	0.018	0.01	0.016	0.023
Poisson Distribution (Upper bound)	0.033	0.023	0.03	0.041
% Pass (Max)	99%	100%	99%	98%
% Pass (Observed)	98%	99%	98%	98%
% Pass (Min)	0.967	0.977	0.97	0.959

Chart 2

Refrigerated vs Baseline	ENTERO	GNB	LF GNB	NLF GNB
Discordant	10	5	8	12
Number of Tests	512	512	512	512
Discordant %	2.0%	1.0%	1.6%	2.3%
Poisson Distribution (Lower bound)	0.009	0.003	0.007	0.021
Poisson Distribution (Observed)	0.02	0.01	0.016	0.023
Poisson Distribution (Upper bound)	0.036	0.023	0.03	0.041
% Pass (Max)	99%	100%	99%	98%
% Pass (Observed)	98%	99%	98%	98%
% Pass (Min)	0.964	0.977	0.97	0.959

KEY: ENTERO=Enterococcus, GNB=Gram negative bacilli (LF not specified), LF=lactose fermenting; NLF=non-lactose fermenting