

# Thirty-Second Disinfection Study for SwabCap™

Report of a study commissioned by ICU Medical, Inc. and conducted by Toxikon

## OBJECTIVE

A protocol was developed and executed by Toxikon (Toxikon Corporation, Bedford, MA), a leading preclinical contract research organization (CRO) to characterize the antimicrobial efficacy of the SwabCap against four strains of bacteria: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterobacter cloacae*, and *Candida albicans*.

## OVERVIEW

For each organism, 10 test articles were utilized. A total of three needlefree connectors were inoculated and not subjected to SwabCap treatment to establish a comparative, positive control baseline. A single SwabCap with a needlefree connector was not challenged but subjected to the same recovery procedure and used as a negative control.

The septum of each needlefree connector was challenged, and the SwabCaps were then applied. The test system was incubated under ambient conditions for a period of 30 seconds, and surviving organisms were determined.

## TEST ORGANISM PREPARATION

Individual cultures of *P. aeruginosa*, *S. aureus*, and *E. cloacae* were grown in Trypticase Soy Broth (TSB) and incubated aerobically for 43 hours and 30 minutes at 30–35°C. *C. albicans* was grown in TSB and incubated aerobically for 71 hours at 20–25°C.

Saturated cultures were standardized to  $\geq 10^7$  CFU/mL and used for the microbial challenge.

Inoculation verification of the above suspension was performed in duplicate to confirm the culture concentrations. The bacterial plates were incubated aerobically at 30–35°C for five days. Upon completion, the plates were enumerated for colony count determination. The number of microorganisms deposited on each test article was converted for  $\log_{10}$  reduction determination.

The antimicrobial efficacy of the SwabCap was characterized against four strains—*P. aeruginosa*, *S. aureus*, *E. cloacae*, and *C. albicans*—after challenge of the needlefree connector septum.

## TEST PROCEDURE

For each organism, a 10  $\mu$ L droplet of  $\geq 10^7$  CFU/mL ( $\geq 10^5$  CFU/sample) was deposited on the septum of the needlefree connectors. A SwabCap was secured to 10 samples (for each strain and time point). During SwabCap application to the needlefree connector, the cap was turned until snug on the needlefree connector. Positive control samples (needlefree connectors) were challenged and recovered after 30 seconds.

Samples were allowed to incubate under ambient conditions for 30 seconds within a laminar flow hood. During incubation, samples were maintained in the upright position.

TABLE 1: STUDY MATRIX

Sample	Needlefree Connector Challenge	SwabCap Application	Number of Samples/Conditions			
			P. aeruginosa	S. aureus	E. cloacae	C. albicans
Positive	+	-	3	3	3	3
Test	+	+	10	10	10	10
Negative	-	+	1	1	1	1

“+” indicates process inclusion, “-” indicates step omitted.

## DESCRIPTION OF TEST ORGANISM QUANTIFICATION

Upon completion of the ambient incubation period, the number of surviving microorganisms from each test article was determined by separating the SwabCap from the needlefree connectors and subjecting the connectors to two fluid flushes, each of a 10 mL volume (total flush volume = 20 mL). Serial dilution, spread plating, and membrane filtration determined the number of surviving organisms. Enumeration was performed on Trypticase Soy Agar (TSA) plates after incubation at 30–35° C for up to five days.

All test samples exceeded the minimum 4-log reduction after 30 seconds.

## TEST RESULTS

Data in Table 2 below demonstrate antimicrobial efficacy against all strains after 30 seconds of exposure time, and the average  $\log_{10}$  reduction to control for all strains was  $\geq 4$ . These data results satisfy the acceptance criteria for antimicrobial efficacy of the SwabCap when applied to needlefree connectors contaminated with P. aeruginosa, S. aureus, E. cloacae, and C. albicans.

TABLE 2: ANTIMICROBIAL EFFICACY

Challenge Strain	Log <sub>10</sub> Reduction to Initial Challenge		Average Result
	Acceptance Criteria	Observed*	
P. aeruginosa	$\geq 4.0$	5.2	Pass
S. aureus	$\geq 4.0$	5.3	Pass
E. cloacae	$\geq 4.0$	4.9	Pass
C. albicans	$\geq 4.0$	4.3	Pass

\*Observed result value is the average  $\log_{10}$  Reduction to Control.

## CONCLUSION

All test samples exceeded the minimum 4-log reduction after 30 seconds.