

Nexus TKO[®]-5 & Nexus Cannula: Microbial Barrier Performance Study

Methods

In 2008, Nexus commissioned Apptec Laboratory Services in St. Paul MN to execute a GLP study on the TKO-5 and various Nexus Cannulas. A total of 24 TKO-5 devices were challenged along with positive and negative controls. *S. auerus* (Gram positive) and *E. coli* (gram negative) were chosen as the challenge organisms as they are common causes of blood stream infections. The concentration of the microbial suspensions was adjusted to 10⁸ CFU/mL to create an appropriate challenge level in order to meet the FDA recommendation, which is a minimum of 10³ CFU/mL. New inoculum suspensions were prepared each test day.

Prior to the microbial challenge, each test device was activated a total of 100 times when using a non-locking straight cannula or 27 activations when using a locking cannula. An alcohol prep pad (70% IPA) was used every 10th activation.

At the beginning of the test and each subsequent test day, each sample was disinfected using a 15 second circular swab technique with a standard individually packaged Becton Dickinson 70% IPA prep pad. The device was then allowed to dry for at least 1 minute. Each sample was then inoculated with 0.01mL of the challenge organism and the inoculum was allowed to remain on the septum for a minimum of 1 minute. Each challenge device was then disinfected following the same swabbing procedure as listed above. Following the disinfection, the test devices were then flushed using saline. The eluate was collected on a 0.45µ filter media and placed on SCDA plates. The plates were then incubated at 30-35°C for 48-72 hours prior to counting. This cycle of inoculation, disinfection and flushing/plating was repeated three more times for a total of 4 activations cycles on each test device. The last flush of the day was done using SCDB/BSA instead of saline.

Cannula	# of Pre-activations	# of Test Day Activations	# of Total Activations
Nexus Straight Blunt Cannula	100	4	104
Nexus Conical Tip Straight Cannula	100	4	104
Nexus Lever Locking Cannula	27	4	31
Nexus Barrel Locking Cannula	27	4	31

Positive and negative controls were run concurrently with the study. The negative controls were not inoculated and the positive controls were inoculated, but not disinfected.

Results

All positive controls showed growth and all negative controls had no growth. The TKO-5 had reported results of < 2 recovered CFU/device for both test organisms on all samples.

Conclusions

Overall, the data demonstrates the TKO-5 prevents passage of organisms through the septum following a high number of insertions using the Nexus straight and locking cannulas.