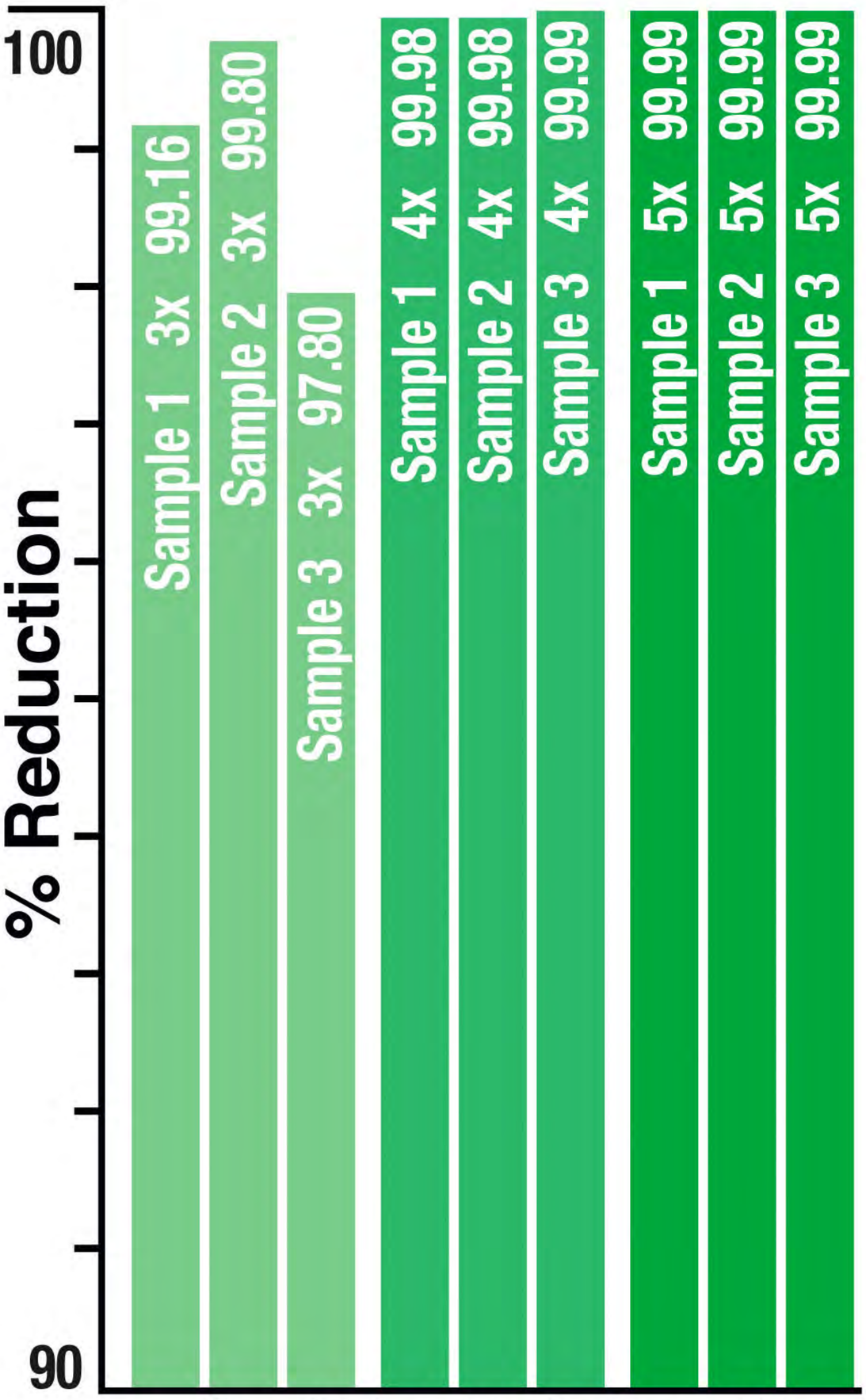
Disinfection Swabbing Study

Laboratory Nos. 395445 and 398575

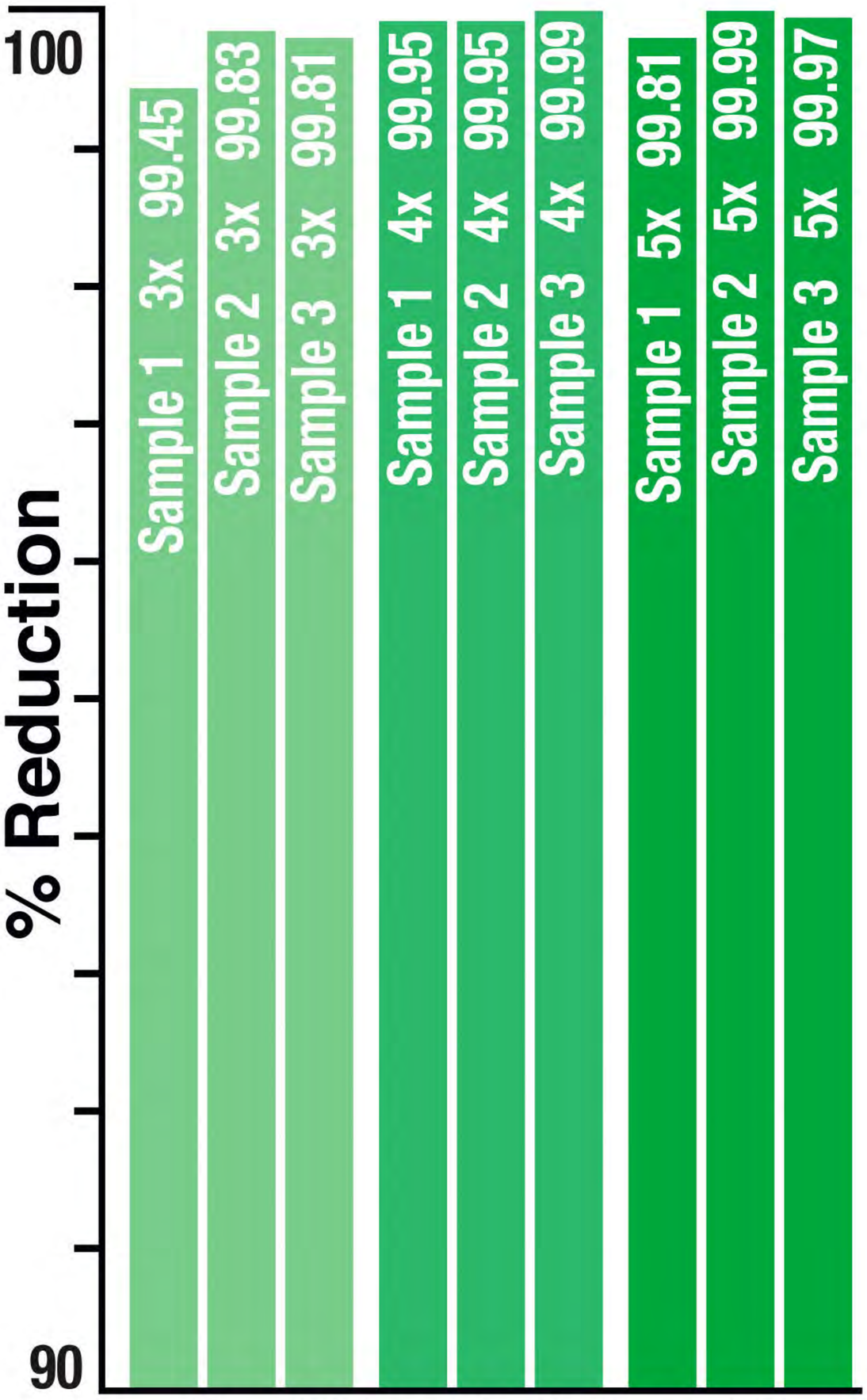
Intraluminal Protection System

InVision-Plus®

with Neutral Advantage Technology



Swabbing Technique #1
Back and Forth



Swabbing Technique #2
Clockwise/Counter-clockwise

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT Sept-Oct 2007

*No statistical difference between any data sets.

RyMed Technologies, LLC

Disinfection Swabbing Study for the InVision-Plus® with Neutral Advantage Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to conduct a disinfection swabbing study on the **InVision-Plus® with Neutral Advantage Technology,** manufactured by RyMed Technologies, LLC.

OBJECTIVE: Effective disinfection or swabbing of catheter hubs, needleless I.V. connectors, and injection surfaces prior to access is a critical catheter care and maintenance practice. Swabbing protocol within facilities generally consists of back and forth or rotational application of a 70% isopropyl alcohol (IPA) prep pad to the access surface with a combination of force and friction for a period of time. It has been suggested that inadequate surface swabbing can be the result or combination of poor I.V. connector access surface design, an insufficient swabbing protocol, or practitioner compliance. In order to demonstrate that the **InVision-Plus® with Neutral Advantage Technology** can be effectively swabbed in accordance with an acceptable swabbing technique, this test procedure was designed to validate the effectiveness of two different swabbing methods, (1) back and forth and (2) clockwise/counter-clockwise, each being performed with 3, 4, or 5 passes or rotations.

METHODS: Eighteen samples were contaminated with an organic material containing a minimum of 1.0 x 10(4) CFU/mL *Staphylococcus aureus*, ATCC #6538 through direct inoculation and allowed to stand for one (1) minute. The samples were then disinfected using the specified disinfection procedure and bioburden assays were performed to determine the bioload reduction.

PROCEDURE:

Swabbing Technique #1: A 70% IPA prep pad was passed back and forth across the surface of the septum three times in each direction for a total of six times while applying slight pressure to the pad. Using a thumb and finger, the pad was then twisted back and forth over the threads three times in each direction. The units were allowed to dry at ambient temperature. Three samples were disinfected using this method. The swabbing technique was repeated again on the same number of newly inoculated samples in the same manner but using four, then five back and forth motions.

Swabbing Technique #2: A 70% IPA prep pad was placed on the surface of the septum and rotated clockwise and counter-clockwise a total of three times in each direction while applying slight thumb pressure. Using a thumb and finger, the pad was then twisted back and forth over the threads three times in each direction. The units were allowed to dry at ambient temperature. Three samples were disinfected using this method. The swabbing technique was repeated again on the same number of newly inoculated samples in the same manner but using four, then five clockwise and counter-clockwise rotations.

RESULTS: The percentage reduction of *S. aureus* bioburden is reflected in the table.

CONCLUSION: The data demonstrate that there is no statistical difference between the data sets and that the **InVision-Plus® with Neutral Advantage Technology** can be effectively disinfected with either three to five back and forth motions or three to five clockwise and counter-clockwise rotations as described by the swabbing techniques.

The complete study protocols and final reports on file at RyMed Technologies, LLC.

RyMed TECHNOLOGIES, LLC