A comparative test for fluid containment between Corvida Halo® and BD PhaSeal® Closed System Transfer Devices

OBJECTIVE:

Evaluate the effectiveness of a novel CSTD, the Halo®, in comparison to PhaSeal® in containing fluid when using the CSTD to transfer a drug surrogate (0.05% fluorescein) from a drug vial to syringe to IV bag.

TEST METHOD:

Fluorescein solution is commonly used to train health care providers in the sterile preparation of hazardous drugs and to document hazardous drug egress into the environment. In similar fashion a fluorescein solution was utilized to evaluate the ability of the Halo® devices to maintain liquid containment during fluid transfer across the dry to dry compression fit seal connections that are made between the CSTD components. A benchmark test was also performed using the BD PhaSeal® CSTD.

- Testing was performed by an independent third party lab.
- To evaluate containment when transferring liquid from a drug vial to syringe, the Halo® Closed Syringe Adaptors and Closed Vial Adaptors were attached to syringes and drug vials respectively, following the Instruction for Use (IFU). Similarly, the PhaSeal® Injectors and Protectors were connected to syringes and drug vials respectively following the IFU.
- To evaluate containment when transferring liquid from a syringe to IV bag, the Halo® Closed Syringe Adaptors and Closed Bag Adaptors were attached to syringes and IV bags respectively, following the Instruction for Use (IFU). Similarly, the PhaSeal® Injectors and Infusion Adaptors were connected to syringes and IV bags respectively following the IFU.
- Each set of components was challenged to a total of fourteen (14) transfers between each set of components. Following each transfer, the respective components were disconnected and the dry-to-dry seal connections were inspected using a UV light to identify any fluorescein escapes into the environment.
- 30 sets of Corvida Halo® components were subjected to one year accelerated aging per ASTM F1980-07 prior to testing.
- 30 sets of PhaSeal® components were non-expired, commercially available components.

RESULTS:

There were no fluid leaks observed on any of the fluid transfers between any of the Halo® components vs the PhaSeal® system that leaked in as little as 5 transfers.

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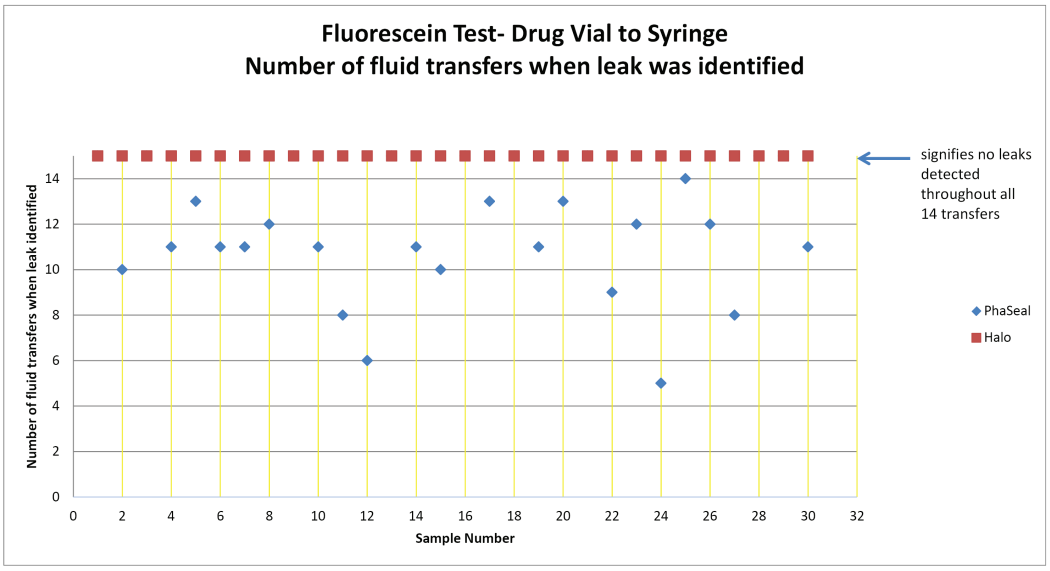

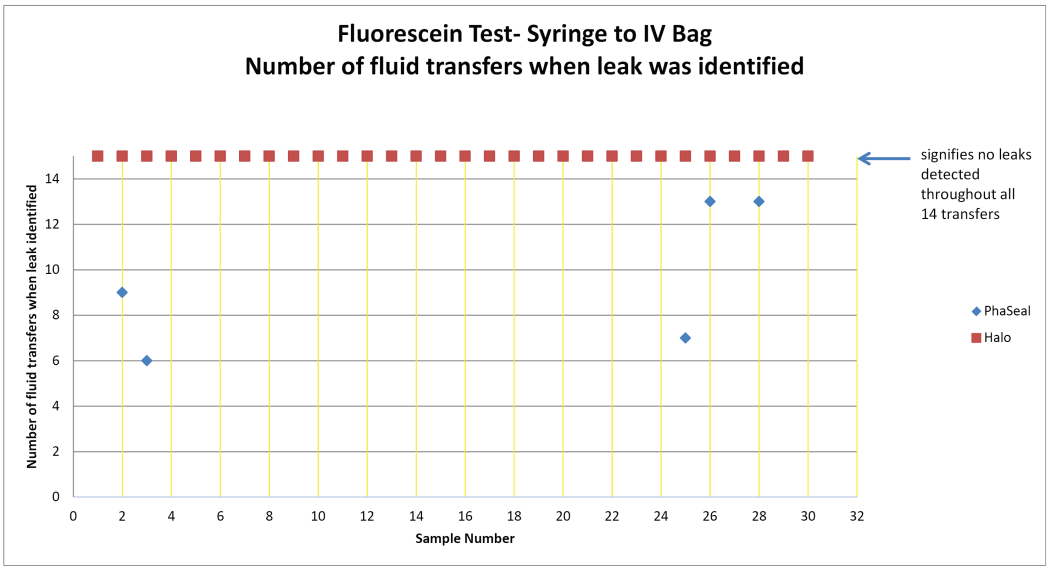

CONCLUSION:

Corvida Halo® provides superior fluid containment as compared to BD PhaSeal® when subjected to multiple uses of the devices. The Halo® seal system has been designed to assure a high level, even when challenged to extreme conditions, such as 14 fluid transfers. This is especially important in protecting clinicians when multiple vial accesses and drug transfers are involved.

Reference:

1. TPR2002 - Fluorescein Test Report (Halo T=0) – Legend Technical Services Report #1404940, February 2015
2. TPR2003 - Fluorescein Test Report (Halo T=1 yr) – Legend Technical Services Report #1405368, February 2015
3. TPR2004 - Fluorescein Test Report (BD Phaseal CSTD System) – Legend Technical Services Report #1404973, February 2015
4. Corvida Medical® Comparison Test Report, February 2015

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