# Less Than 1% Variation in the Fill Accuracy of the SAFS-100 CellSeal® Semi-Automated Filling System

Chad Johnson, Ph.D. & Eric Rodenberg, Ph.D.

**Summary:**

As cell therapies gain wide acceptance as a clinically valuable tool, methods of efficiently preparing, packaging and storing biologics at commercial scale become of vital importance. Performing this task manually can be tedious, time consuming, inaccurate, expensive, and introduce potential sources of contamination.

The SAFS-100 CellSeal® Semi-Automated Filling System, an alternative to manual methods, was evaluated for fill accuracy using CellSeal Closed-System Cryogenic Vials and two solutions of differing viscosities. **This study demonstrates that the SAFS-100 CellSeal® Semi-Automated Filling System has a very high fill accuracy – less than 1% variation.**

## Introduction:

The SAFS-100 is a semi-automated filling system tailored to work with the CellSeal Closed-System Cryogenic Vial, a container-closure system intended for cryogenic storage. The SAFS-100 is a biosafety hood-compatible or bench-top instrument that can dispense cell suspensions in an aseptic, volume-controlled manner for hundreds of vials per hour. The fill settings are customizable, allowing for either of two size CellSeal Vials (2 mL and 5 mL) over a range of fill volumes up to 5 mL and various suspension fluid viscosities. To be effective, it is important that the manufacturer be able to capture appropriate sample/therapy volumes to minimize waste and ensure accurate dosing. This study evaluates the accuracy of closed-system fill volumes using the system.

## Method:

In order to characterize the accuracy of fluid fill volumes using the SAFS-100, two target fill volumes were tested—0.8 mL (low volume) using the 2 mL CellSeal Vial and 5.0 mL (high volume) using the 5 mL CellSeal Vial. Additionally, two fluids with different viscosities were tested at each volume—0.9% saline (low viscosity) and CryoStor® CS-10, a commercial grade cryopreservation solution (medium viscosity). A 5% variation of the target fill was chosen as an acceptable limit.

CellSeal vials were labeled and loaded for testing. Half of the vials for each run were sampled, with 30 of 60 used for each saline volume and 20 of 40 vials for each CryoStor volume. The SAFS-100 fills vials in sets of 10. Sampling was performed on a blocked analysis to ensure that each of the 10 possible vial positions were assayed the same number of times. Initial unfilled vial weights were recorded. After performing the automated fill, final weights were recorded. Fluid fill volume was calculated as (final weight – initial weight) / fluid density.

## Results – Fill Accuracy:

For cell banking or cell therapy cryopreservation, cell suspensions must be dispensed into appropriate vials accurately and consistently. In this series of experiments, the SAFS-100 accurately filled and sealed all of the CellSeal Vials. The SAFS-100 was set to dispense either saline or CryoStor at 0.8 mL into the 2 mL CellSeal Vials or 5.0 mL into the 5 mL CellSeal Vials.

As is indicated in figures 1-4, all results (diamonds) were well within the 5% accuracy limit (dotted lines) for all vials tested. Figures 1-4 also illustrate the high level of consistency in the filling volumes. Coefficients of variation are <1% for all groups and a low 0.02% for the CryoStor at the 5.0 mL target fill volume.

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## Fill Accuracy for 2 mL CellSeal® Closed-System Cryogenic Vials

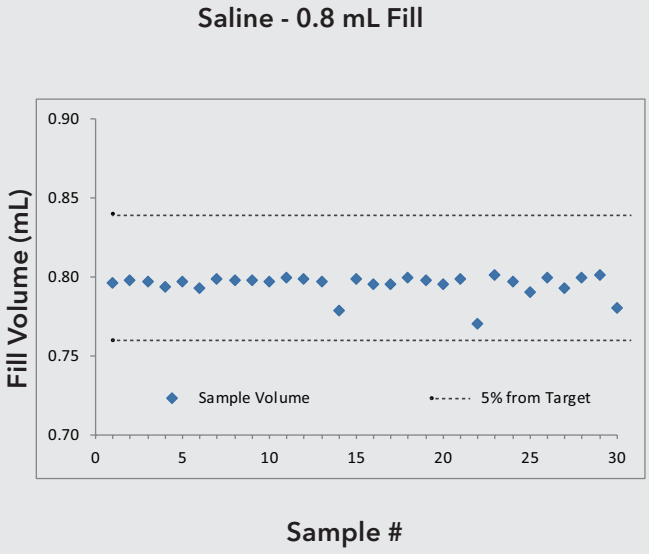


Figure 1

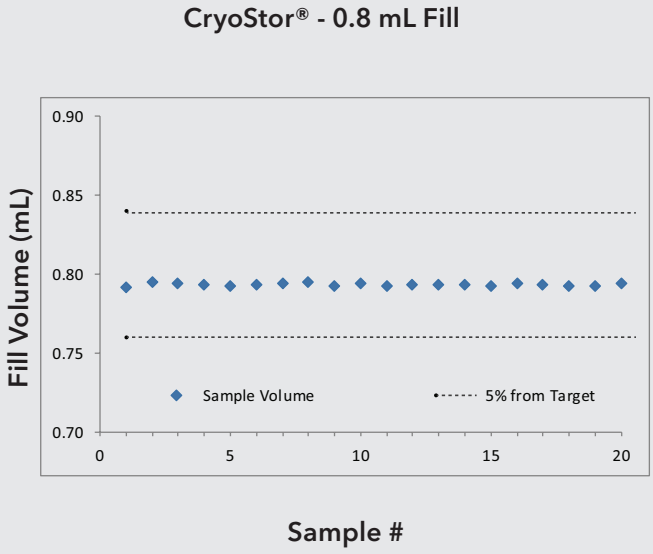


Figure 2

## Fill Accuracy for 5 mL CellSeal® Closed-System Cryogenic Vials

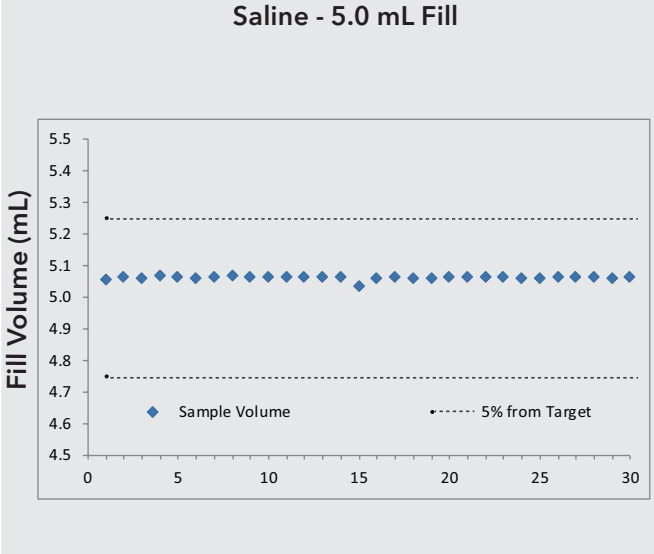


Figure 3

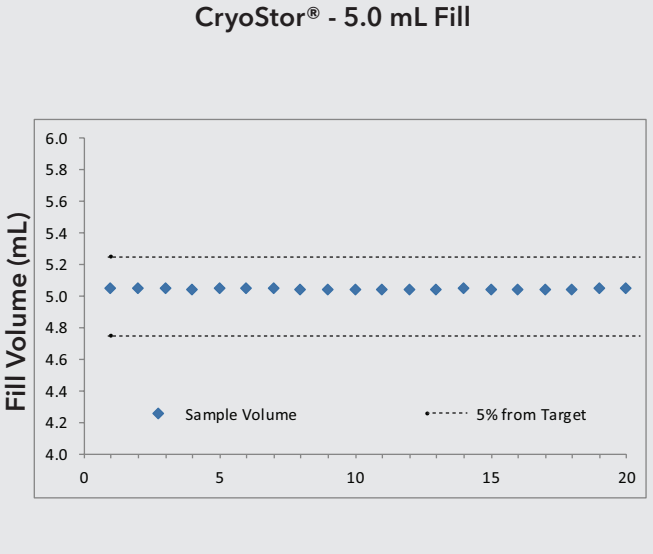


Figure 4

CellSeal Cryogenic Vials are available in a 10Set of 2 mL or 5 mL prepackaged vials for use with the Semi-Automated Filling System. With the additional adjustable settings for the SAFS-100, the fill volumes may be selected to match the requirements of the manufacturer for their specific cell and cryopreservation media.

| CellSeal® Vial Size (mL) | Volume Set (mL) | Fluid | Average Volume ± SD (mL) | Range (mL) | CV% |
|---|---|---|---|---|---|
| 2 ( Fig. 1) | 0.8 | Saline | 0.800 ± 0.010 | 0.77 – 0.80 | 0.87% |
| 2 ( Fig. 2) | 0.8 | CryoStor® | 0.790 ± 0.001 | 0.79 – 0.80 | 0.13% |
| 5 (Fig. 3) | 5.0 | Saline | 5.060 ± 0.005 | 5.04 – 5.07 | 0.11% |
| 5 (Fig. 4) | 5.0 | CryoStor® | 5.050 ± 0.001 | 5.05 – 5.05 | 0.02% |

**The CellSeal® SAFS-100 Semi-Automated Filling System in operation under a biosafety hood.**

## Conclusion

- SAFS-100 accurately filled two relevant fluids into either 2 mL or 5 mL CellSeal® Closed-System Cryogenic Vials
- Variation with each filling volume was low with coefficient of variation less than 1%
- With fully-adjustable settings, the fill volume can be fine-tuned to match the manufacturer requirements
- Filling accuracy was well within the acceptable parameters

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# About The Authors


### Chad Johnson, Ph.D.

Chad joined Cook Biotech Incorporated as a research engineer in December 2003. As a member of the Research Department, he was in charge of biomaterial assessment and improvement efforts. In 2007, Chad was promoted to research manager and led a team in the discovery, identification and feasibility testing of new biomaterials along with responsibilities for biocompatibility testing, scientific presentations to doctors, and authoring information for regulatory submissions. In September 2015, Chad transitioned to Cook Regentec as a senior research scientist where, as part of a larger team of engineers and scientists, he is focused on development and commercialization of device-based regenerative medicine therapies.

### Eric Rodenberg, Ph.D.

Eric began his association with Cook companies in 2010. As a member of the Research Department biomaterials team, Eric was responsible for leading and coordinating pre-clinical small animal studies; evaluating external technologies; conducting early-phase biomaterials characterizations and base material improvement experimentation; and serving as a scientific CME presenter. In September 2015, Eric transitioned to Cook Regentec as a research scientist where, as part of a larger team of engineers and scientists, Eric is focused on the development and commercialization of device-based regenerative medicine therapies.



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