



# Charter Medical Products

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# Objectives

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- To describe our validation using the Cell-Freeze® cryogenic storage containers



# Cell-Freeze® Bag

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- In 2009 our purchasing department would not sign the agreement with our then current bag manufacturer so we were forced to change to a different vendor earlier than most Cell Therapy labs.
- There were very few options at that time
- We chose Charter Medical to validate because they were willing to work with us and provide samples of bags at no cost for our validation

# Validation

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- We performed 3 runs using buffy coats from the local blood center with a side by side comparison of the freezing bags that we were currently using.
- We did 3 runs at the lowest volume of the manufacturer recommendation and then 3 runs at the maximum volume for the bag per manufacture recommendation.
- Parameters tested with each run:
  - Cell Count
  - Viability (Trypan Blue and 7AAD)
  - Sterility
  - Confirm that bag did not break or crack during the freezing and thawing



# Validation Results

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- The ease of use and overall handling of the bags was similar between both brands compared
- Mean post-thaw viability and cell counts were determined to be equivalent between the previously validated and Charter Medical bags

# Validation Results cont.

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- When comparing mean viabilities of the thawed buffy coats frozen in both bags it was found that with a 95% confidence, there was no significant difference in either one of the runs
- **High Volume:**
  - Old bag = 88.9 % Viable
  - Charter Medical = 88.03 % Viable
  - p-value = 0.8
- **Low Volume:**
  - Old bag = 97.75 % Viable
  - Charter Medical = 97.43 % Viable
  - p-value = 1.00

# Validation Results cont.

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- When comparing mean cell counts of the thawed buffy coats frozen in both bags it was found that with a 95% confidence, there was no significant difference in either one of the runs
- **High Volume:**
  - Old bag =  $3.08 \times 10^7$  cells/mL
  - Charter Medical =  $2.86 \times 10^7$  cells/mL
  - p-value = 0.8
- **Low Volume:**
  - Old bag =  $2.14 \times 10^7$  cells/mL
  - Charter Medical =  $2.15 \times 10^7$  cells/mL
  - p-value = 0.8

## Low Volume Run

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<b>Product</b>	<b>Cell Count/mL</b>	<b>Viability (Trypan)</b>	<b>Viable Recovery</b>
Pooled Buffy Coats (Pre freezing)	8.77E+07	100%	
Old bag 1	2.88E+07	97.9	0.32
Old bag 2	3.28E+07	97.6	0.37
<b>Charter Medical 1</b>	<b>2.44E+07</b>	<b>98.4</b>	<b>0.27</b>
<b>Charter Medical 2</b>	<b>2.64E+07</b>	<b>96.2</b>	<b>0.29</b>
<b>Charter Medical 3</b>	<b>3.50E+07</b>	<b>97.7</b>	<b>0.39</b>

## High Volume Run

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<b>Product</b>	<b>Cell Count/mL</b>	<b>Viability (Trypan)</b>	<b>Viable Recovery</b>
Pooled Buffy Coats (Pre freezing)	5.54E+07	100%	
Old bag 1	2.48E+07	91.1	0.41
Old bag 2	1.80E+07	86.7	0.28
<b>Charter Medical</b>	<b>2.56E+07</b>	<b>89.8</b>	<b>0.41</b>
<b>Charter Medical</b>	<b>1.90E+07</b>	<b>88.4</b>	<b>0.30</b>
<b>Charter Medical</b>	<b>1.98E+07</b>	<b>85.9</b>	<b>0.31</b>

# Cell-Freeze® Bag

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