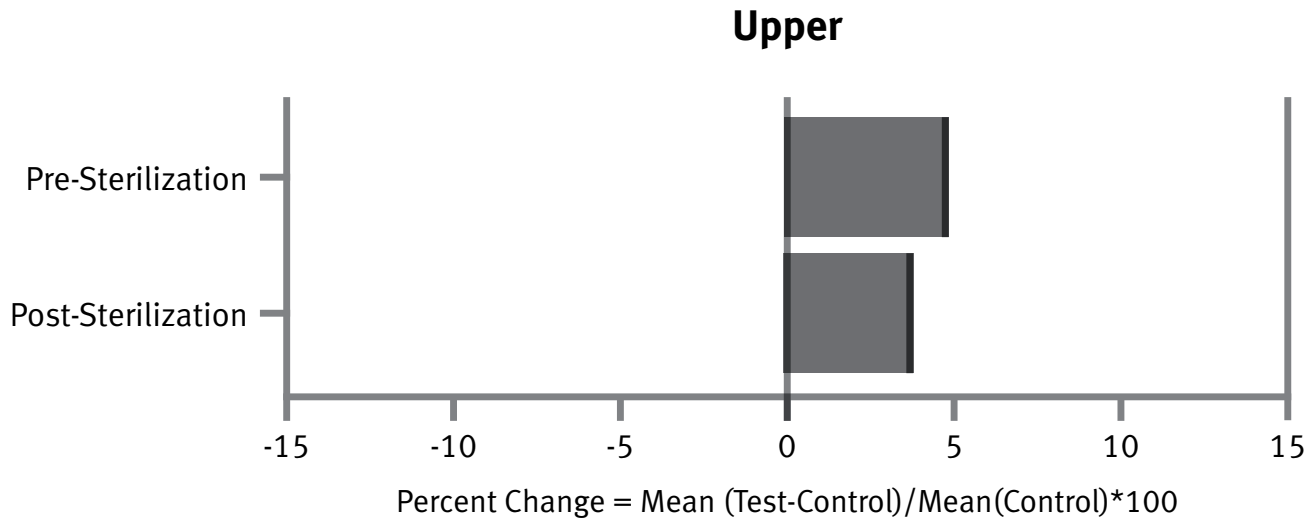


Percent Change in Seal Strength Relative to the Control for Maximum Load – ASTM F88

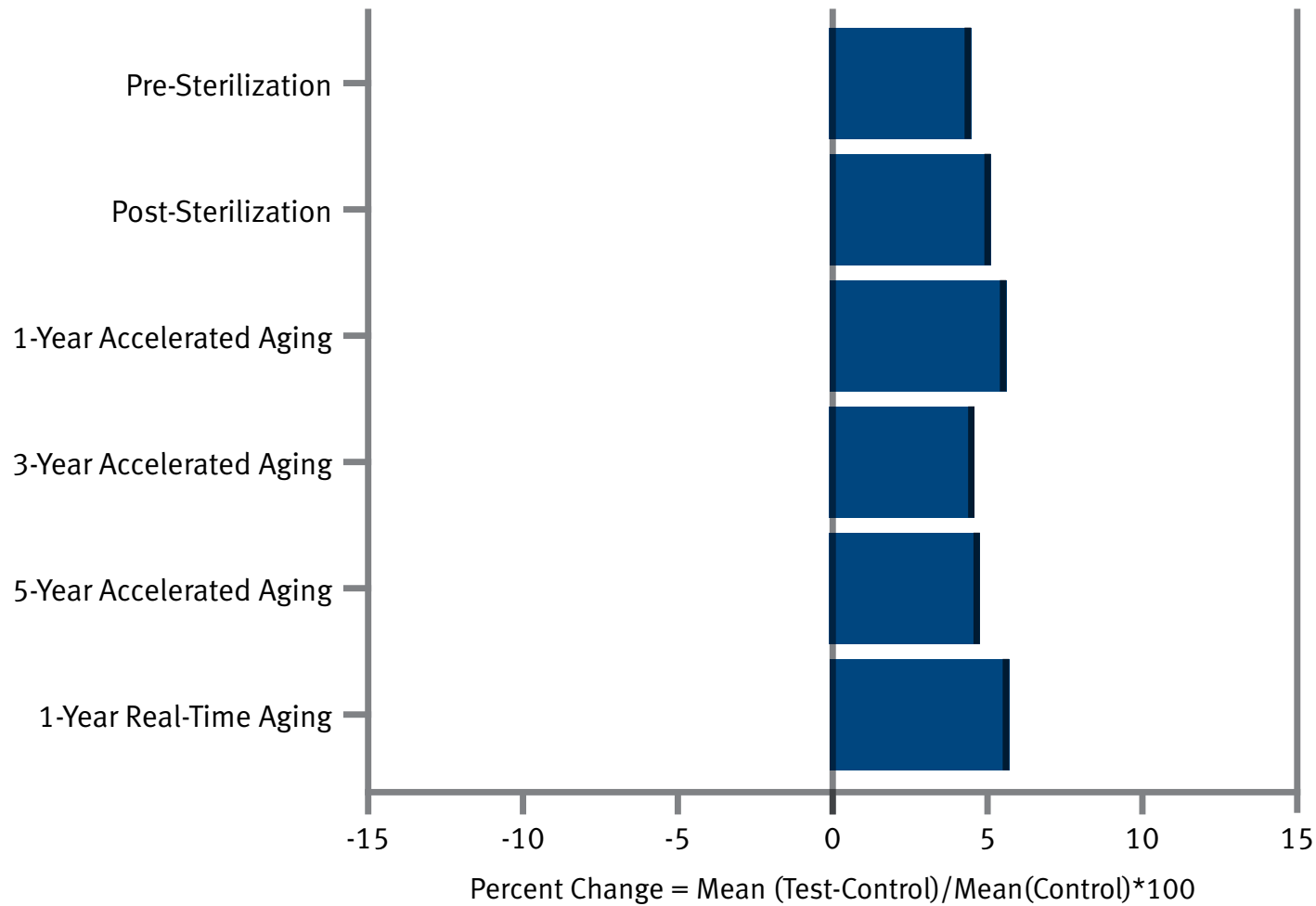


Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Maximum Load – ASTM F88



Nominal

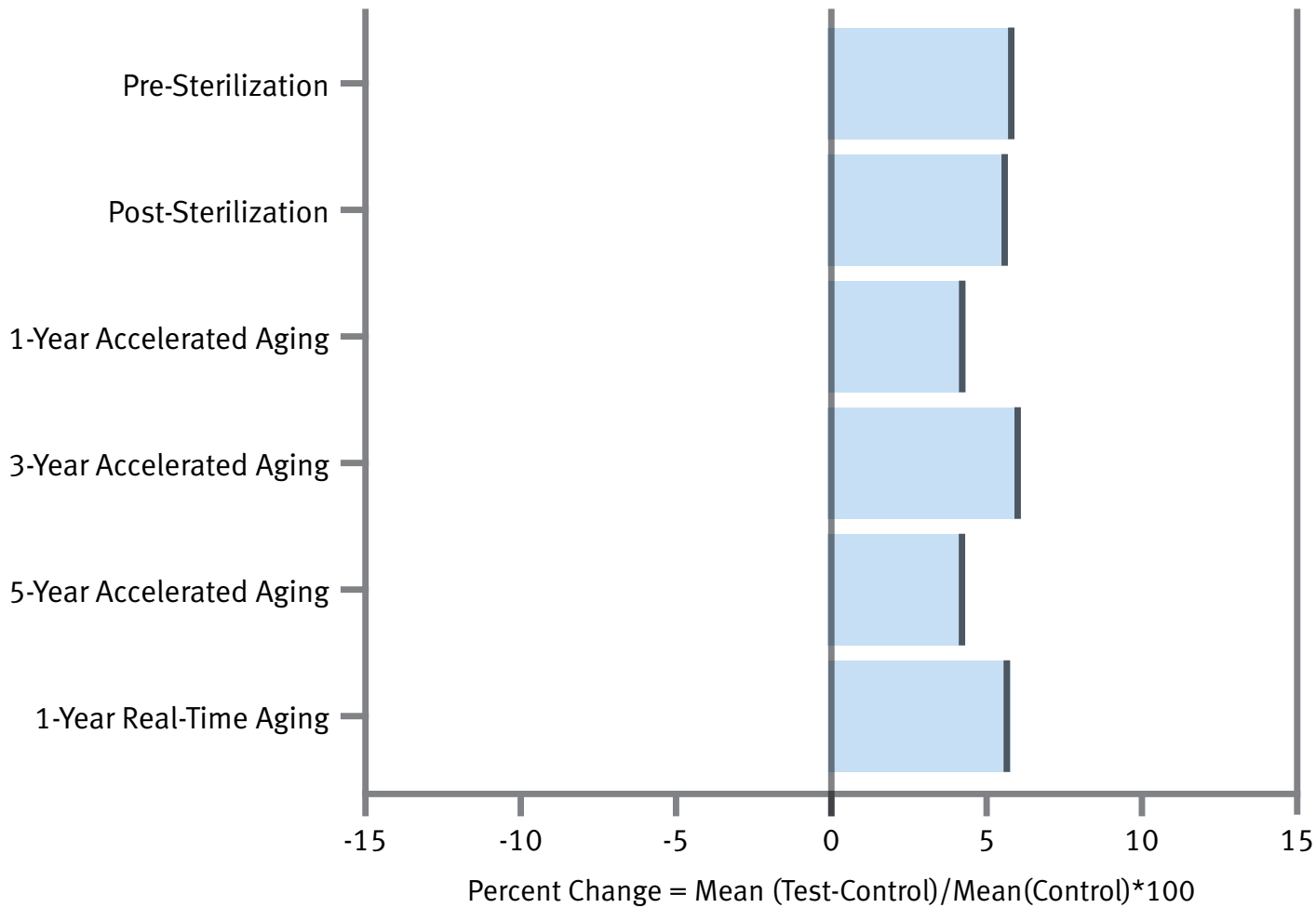


Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Maximum Load – ASTM F88

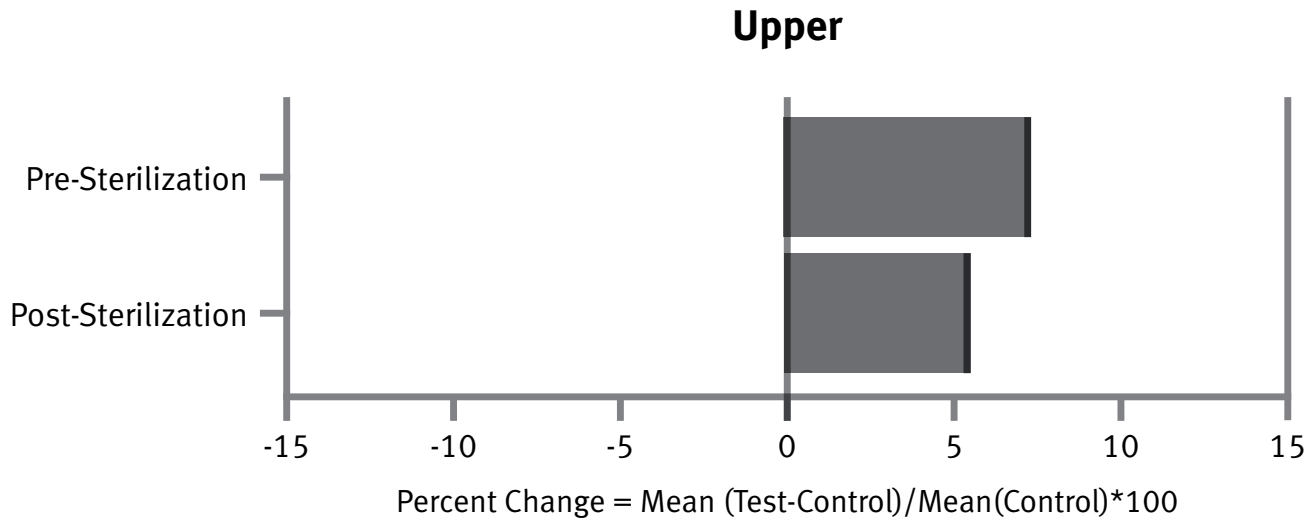


Lower



Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Average Load — ASTM F88

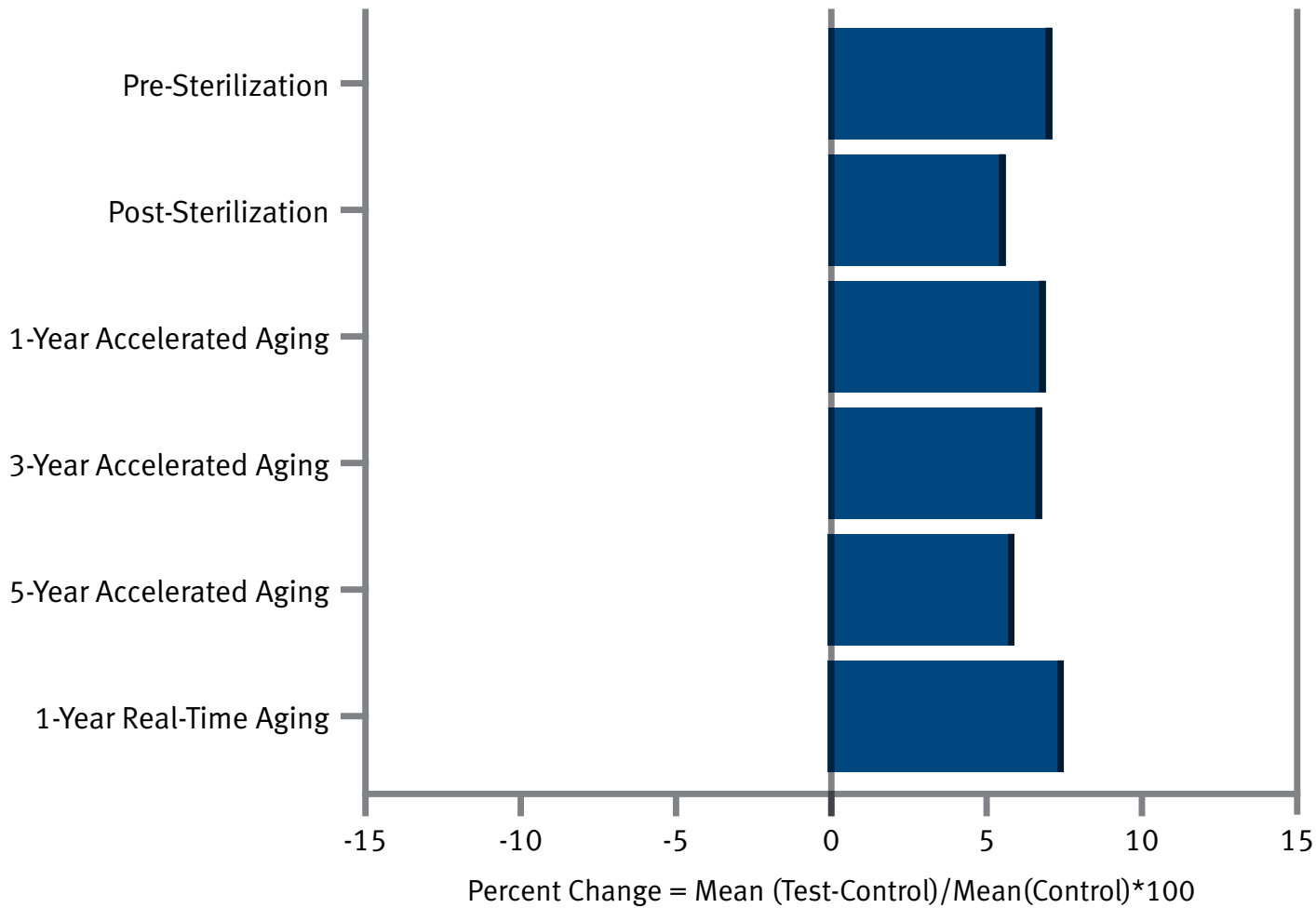


Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Average Load — ASTM F88



Nominal

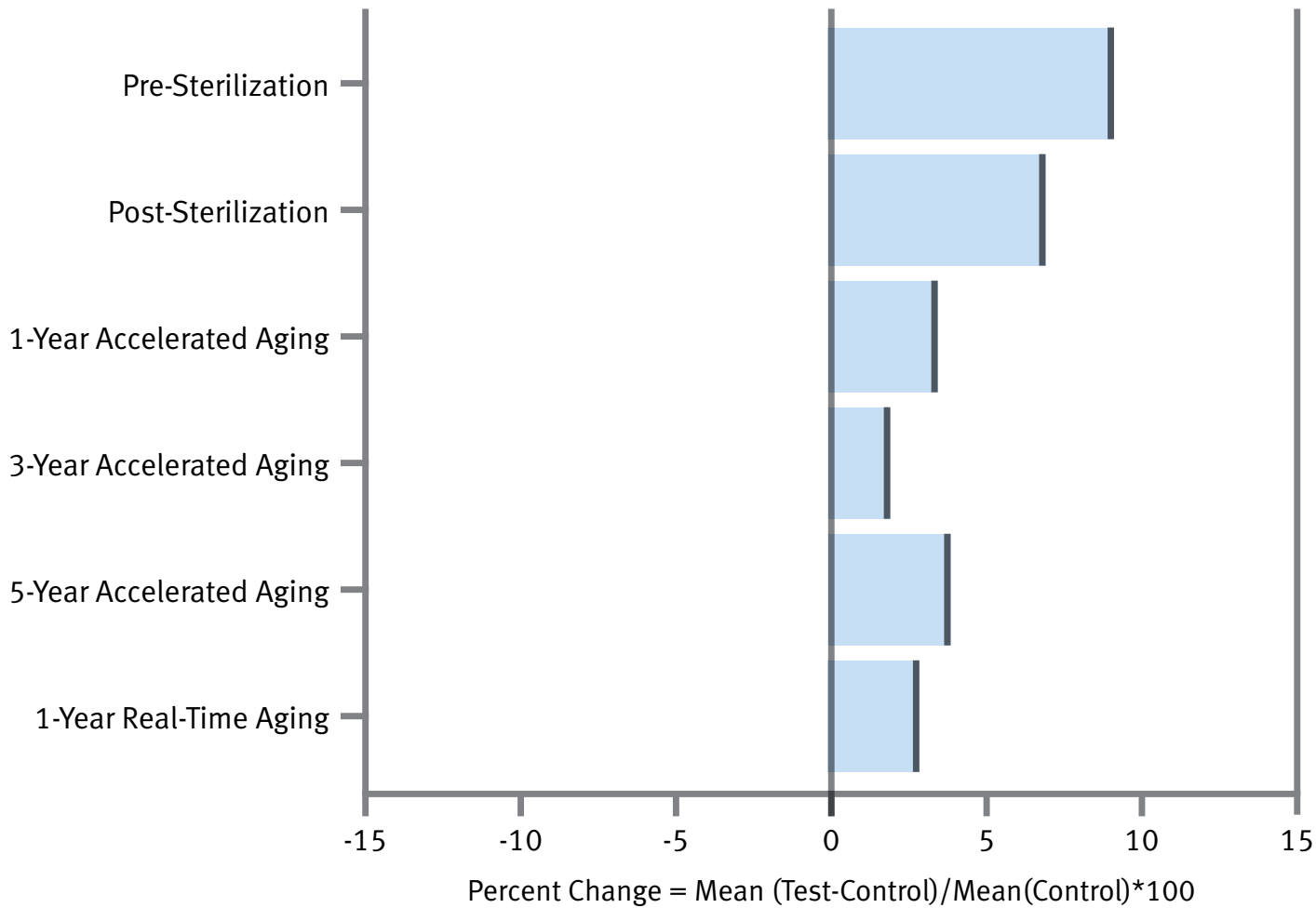


Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Average Load — ASTM F88



Lower



Test=Transition Protocol Material
Control=Current Tyvek®

Cumulative Pass/Fail Summary for Seal Strength through 1-Year Real-Time Aging* – ASTM F88



Tyvek.

Tyvek® Style	Coating Type	Sterilization Type	Pouches and Bags		Form-Fill-Seal		Rigid Trays	
			Pass	Fail	Pass	Fail	Pass	Fail
1073B	Coated	Pre-Sterilization	11	0	13	0	24	0
		EO	35	0	35	0	55	0
		Gamma	15	0	15	0	38**	0
		Electron-beam			15	0		
		Steam					15	0
		Dry Heat					5	0
		Low Temp. H ₂ O ₂	5	0				
		Low Temp. C ₂ H ₄ O ₃					5	0
	Uncoated	Pre-Sterilization	14	0				
		EO	34	1***				
		Gamma	15	0				
		Electron-beam	15	0				
		Steam	5	0				
	1059B	Coated	Pre-Sterilization			5	0	
EO					15	0		
Gamma					5	0		
Electron-beam					5	0		
Uncoated		Pre-Sterilization	5	0	2	1****		
		EO	25	0	15	0		

THERE ARE NO CELLS IN THE MPTP FOR THIS CATEGORY

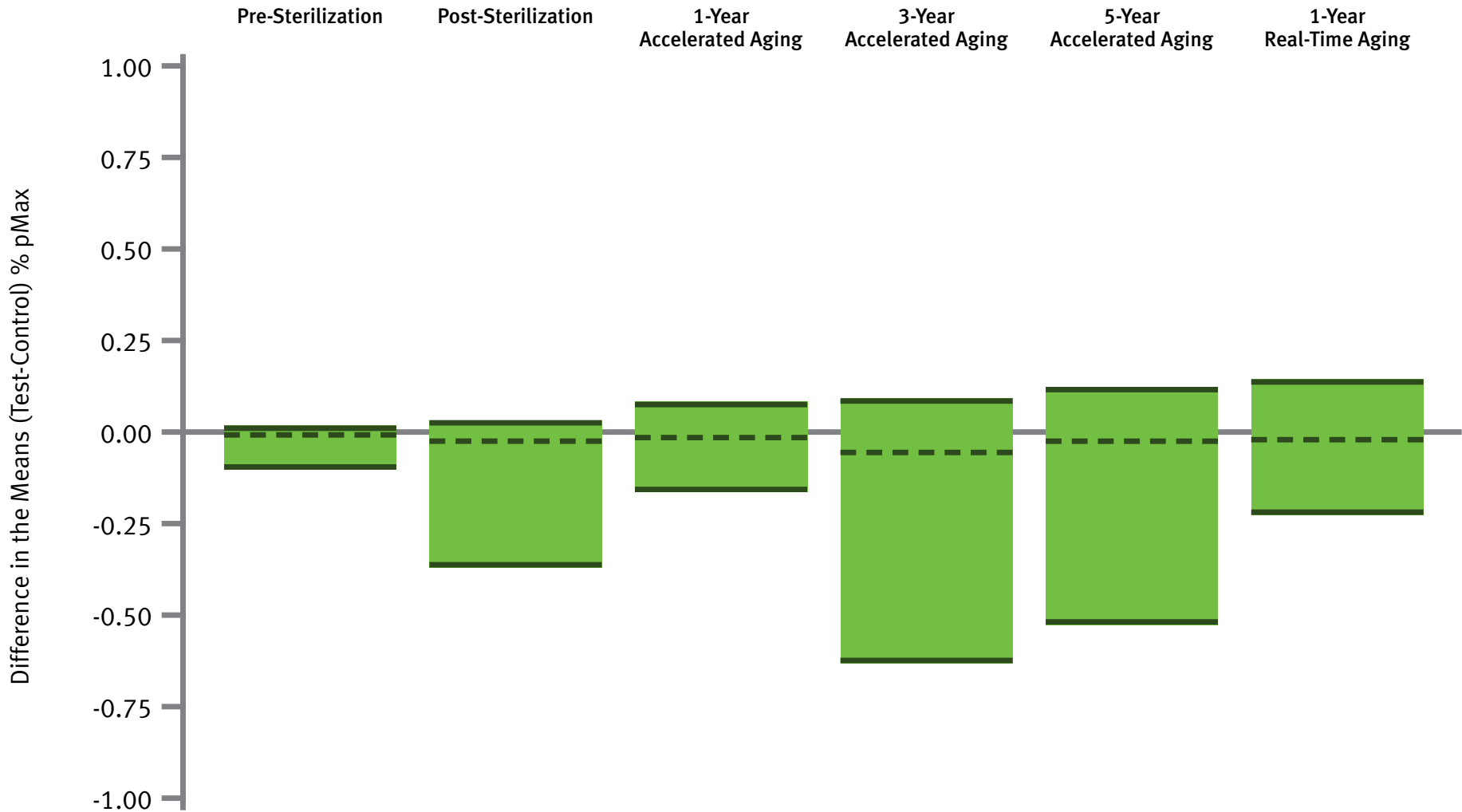
* At all time points, vent bag, Kwikbreathe™ True Header bag and weld seal bag seal strengths are not included; the failure modes were non-peelable seals. (3 cells)

** For one Cell at two time points, Transition Protocol material and Current material exhibited a majority of seal failures which were not peel failures; thus the seal strength results were not included in the final analysis.

*** For one Cell at one time point, the package configuration exceeded the upper end of the equivalence limit by 0.06 lb/in., implying that the Transition Protocol material seal strength was stronger than the Current material.

**** For one Cell, the package configuration exceeded the upper end of the equivalence limit by 0.05 lb/in. at the upper sealing condition, implying that the Transition Protocol material seal strength was stronger than the Current material.

Microbial Barrier Summary for Coated 1073B – ASTM F2638

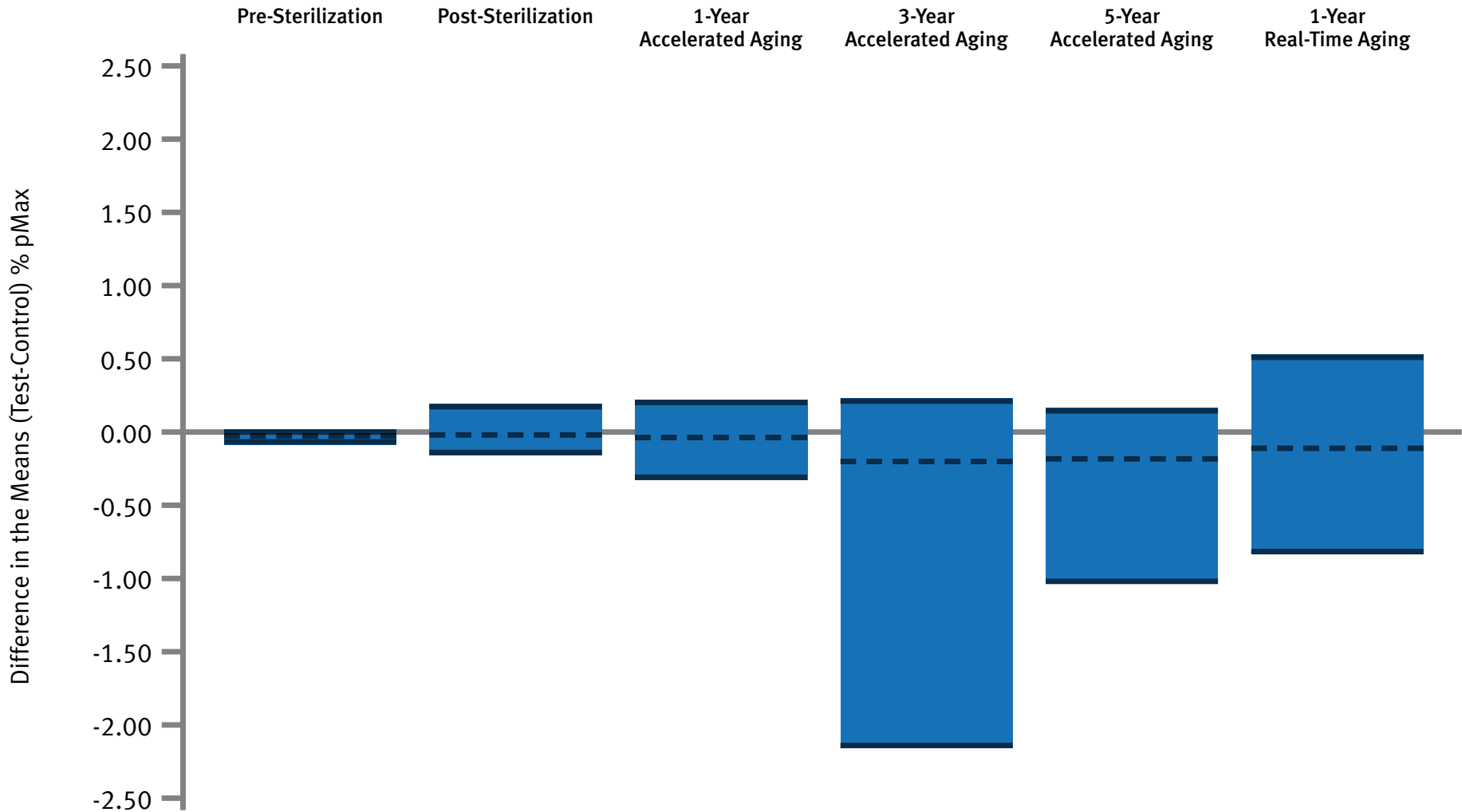


Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Microbial Barrier Summary for Uncoated 1073B – ASTM F2638



Tyvek.

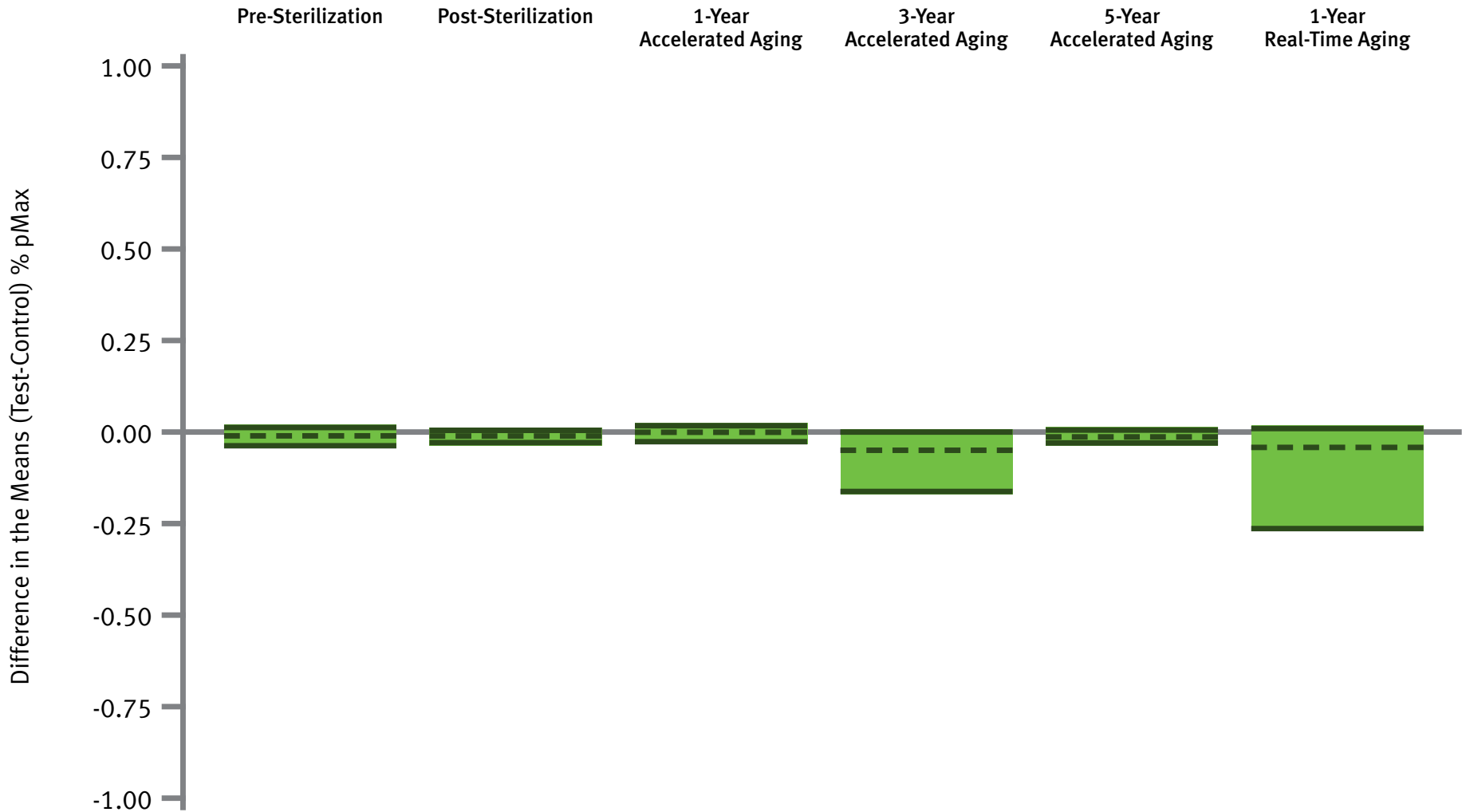


Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Microbial Barrier Summary for Coated 1059B – ASTM F2638

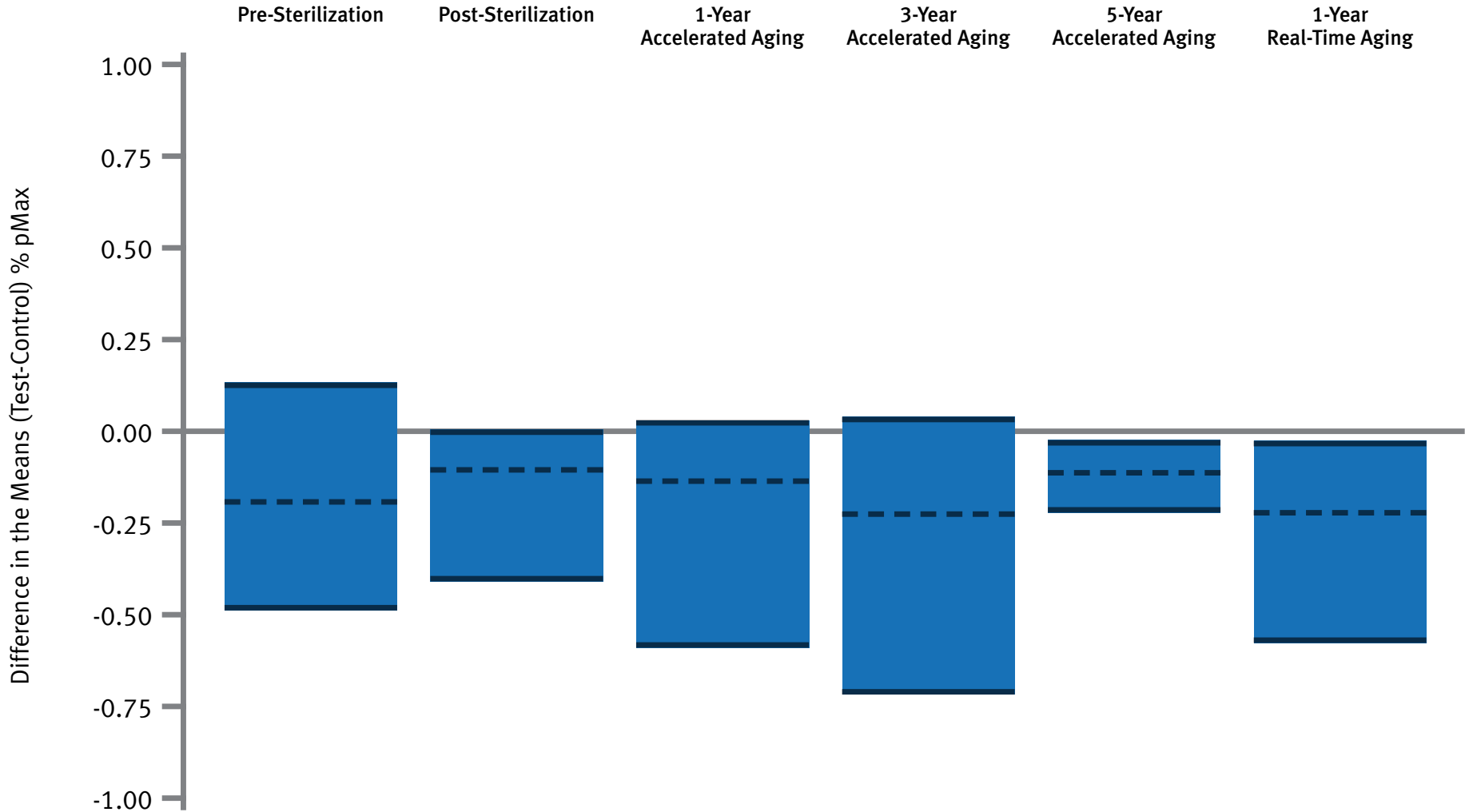


Tyvek.



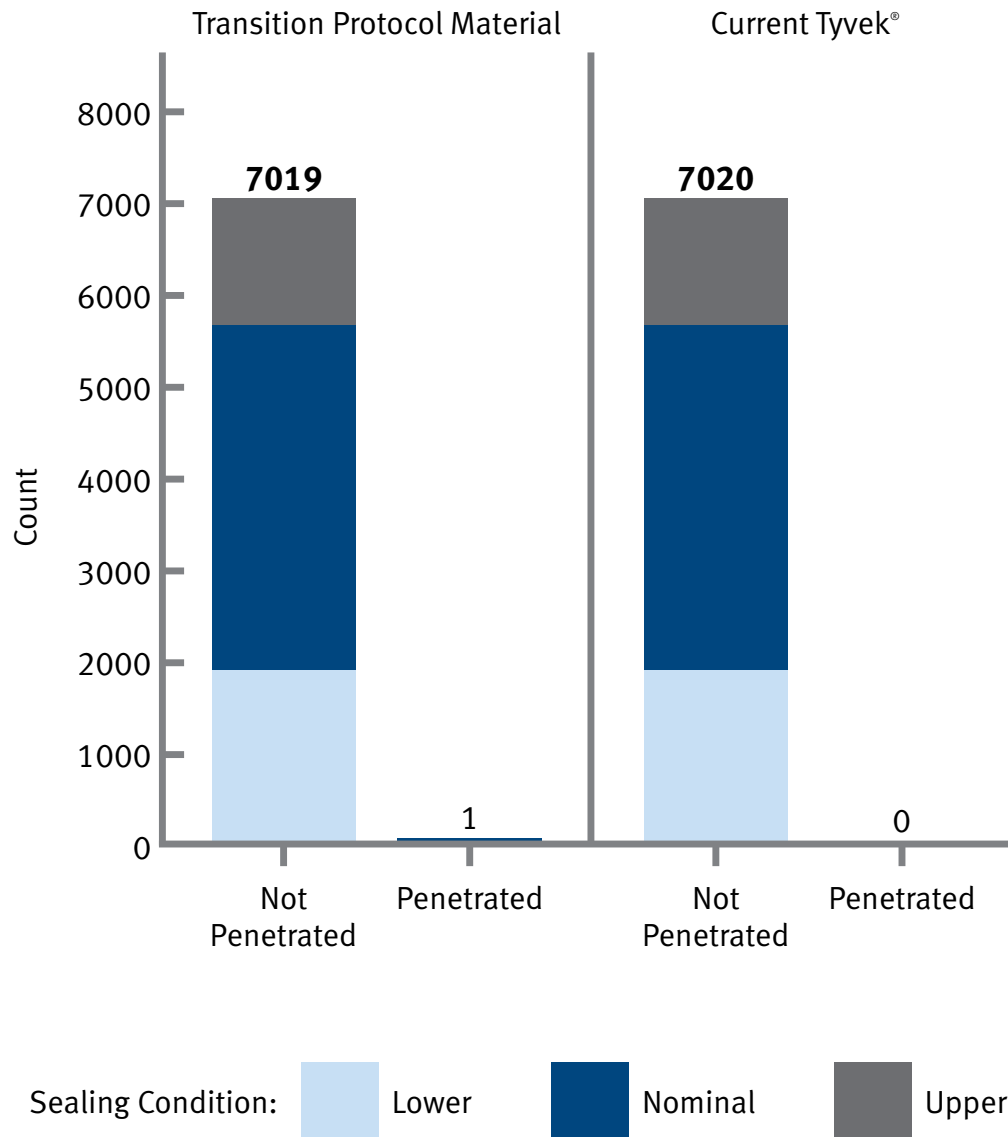
Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Microbial Barrier Summary for Uncoated 1059B – ASTM F2638



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Package Integrity Testing Summary through 1-Year Real-Time Aging – ASTM F1929



Pre- & Post-Sterilization Visual Inspection Summary – ASTM F1886M



Pre-Sterilization

Post-Sterilization

