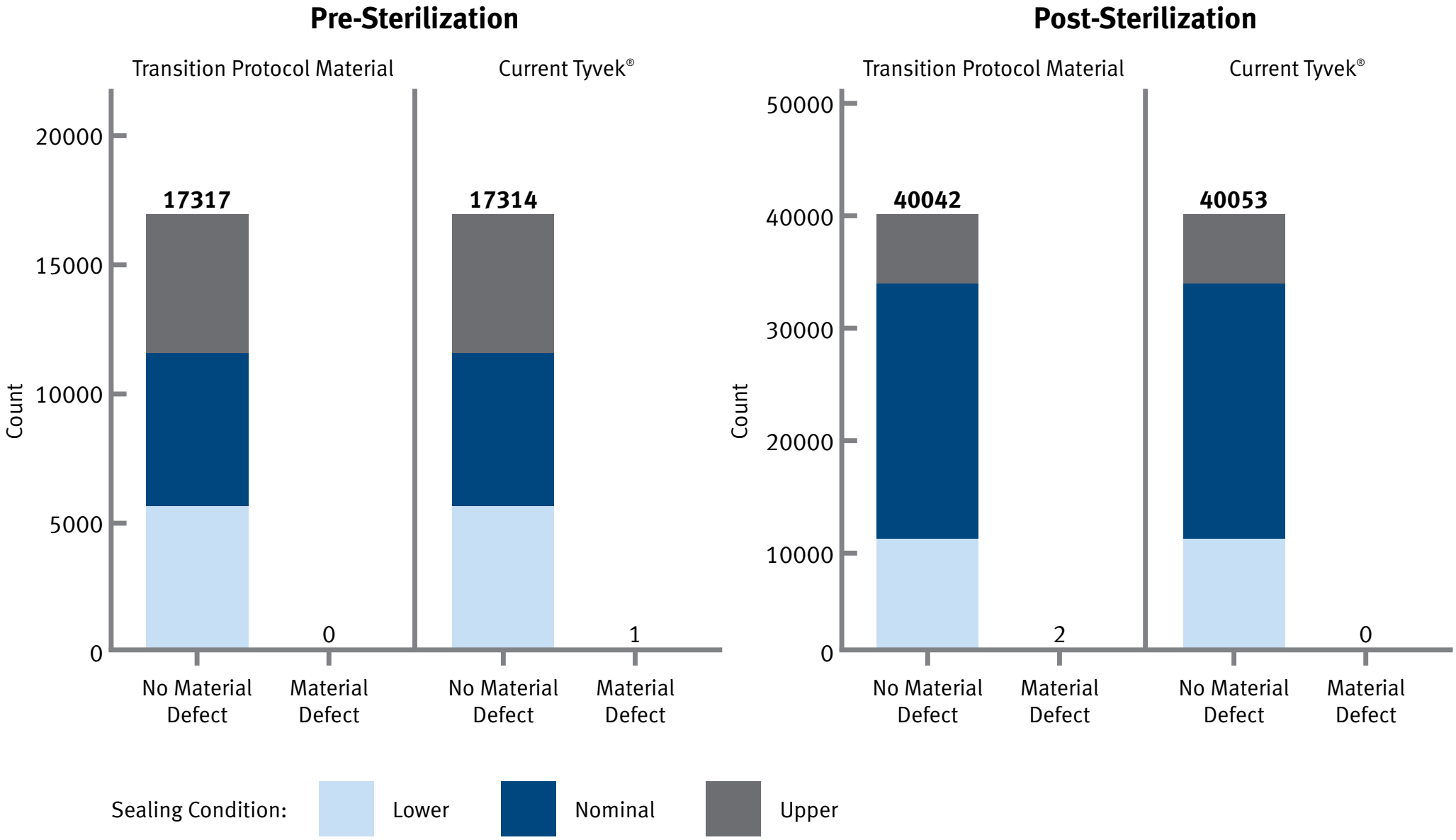
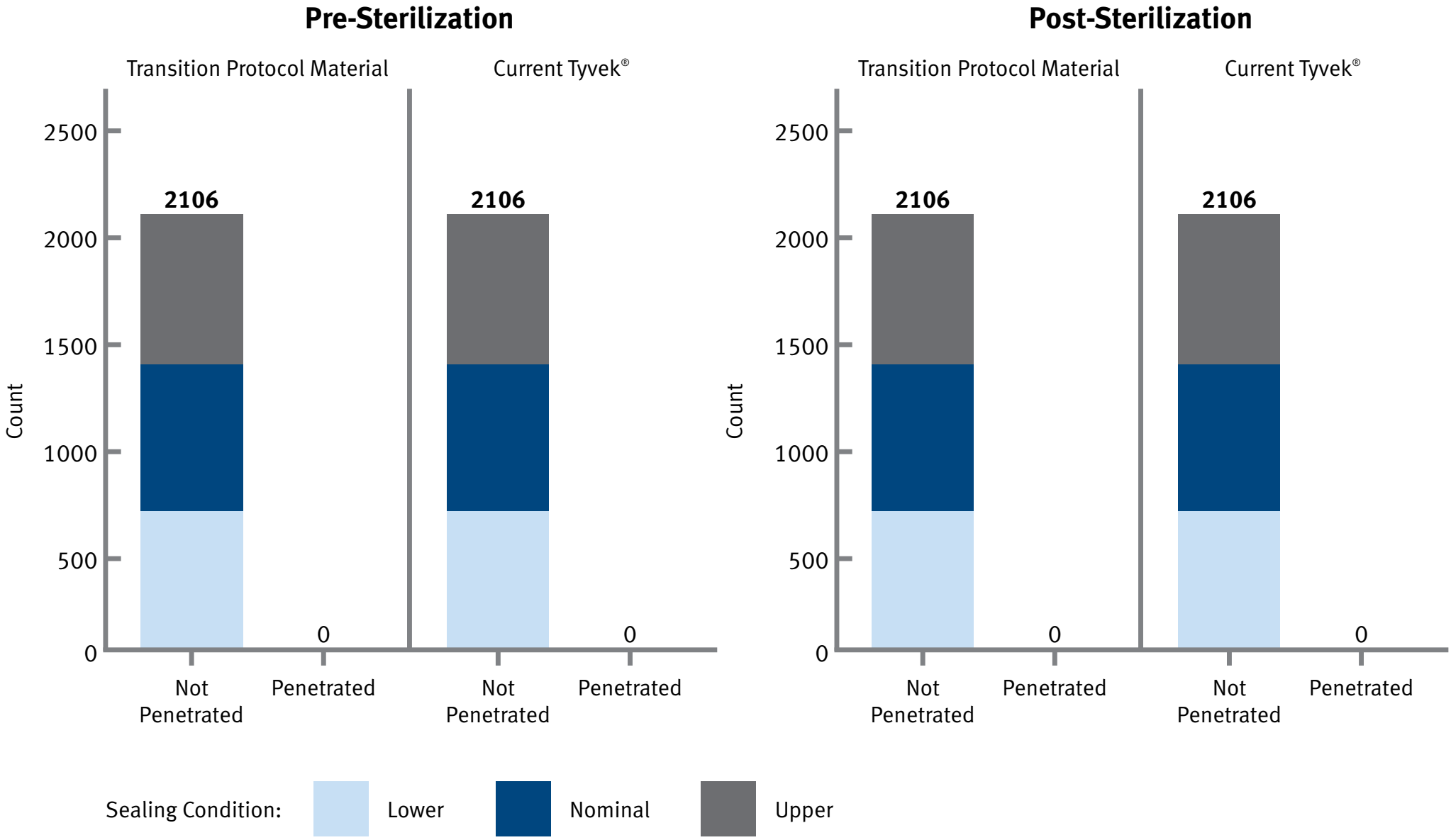
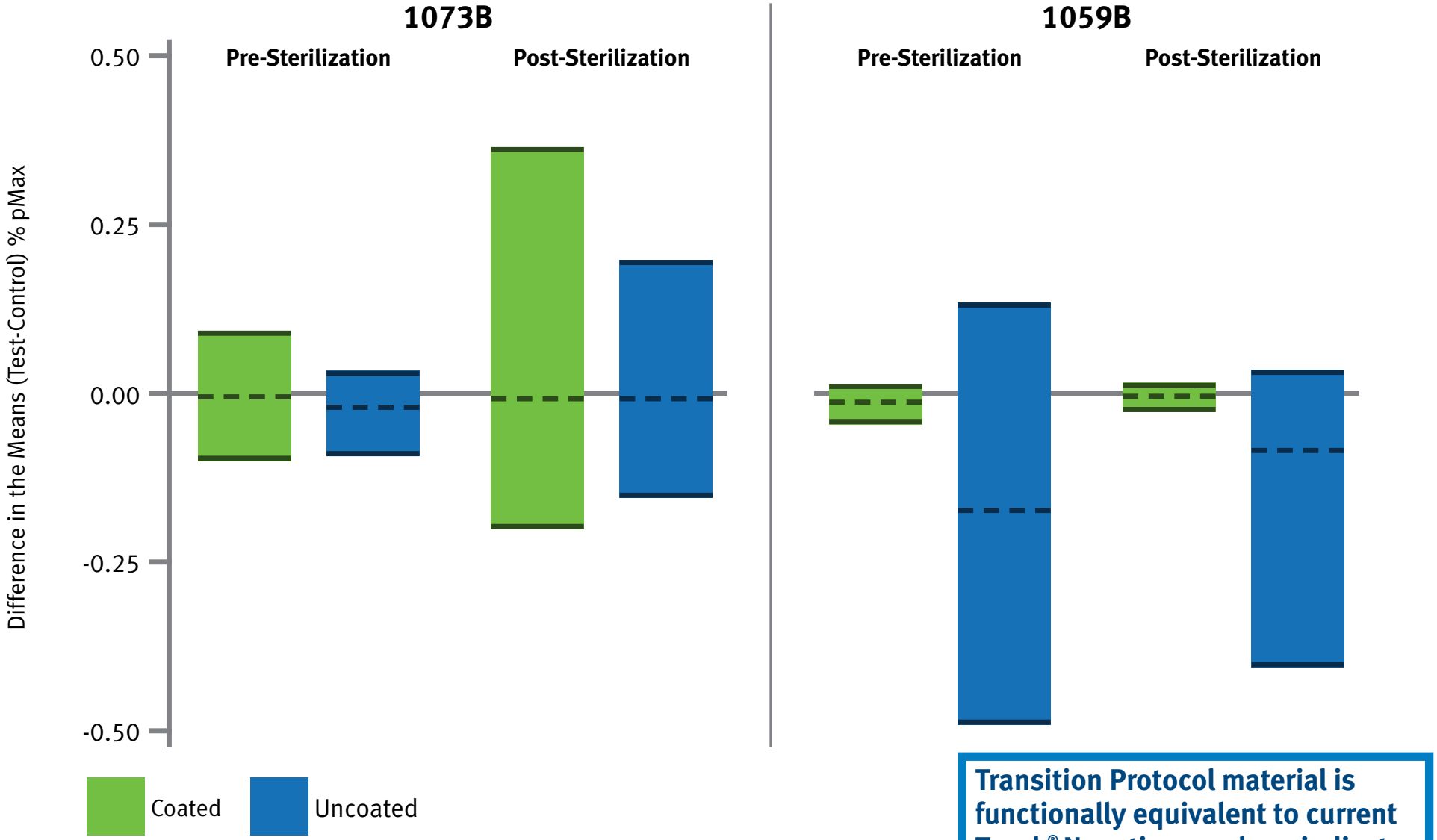
Pre- & Post-Sterilization Visual Inspection Summary — ASTM F1886M



Pre- & Post-Sterilization Package Integrity Summary — ASTM F1929



Pre- & Post-Sterilization Microbial Barrier Summary for Coated and Uncoated 1073B and 1059B — ASTM F2638



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

Transition Protocol material is functionally equivalent to current Tyvek®. Negative numbers indicate test performed better than control, as evidenced by ALL dashed lines (which fall below zero).

Industry Summary: MPTP Test Results at Pre- and Post-Sterilization, Pass/Fail Summary for Seal Strength* — ASTM F88

DUPONT Tyvek.

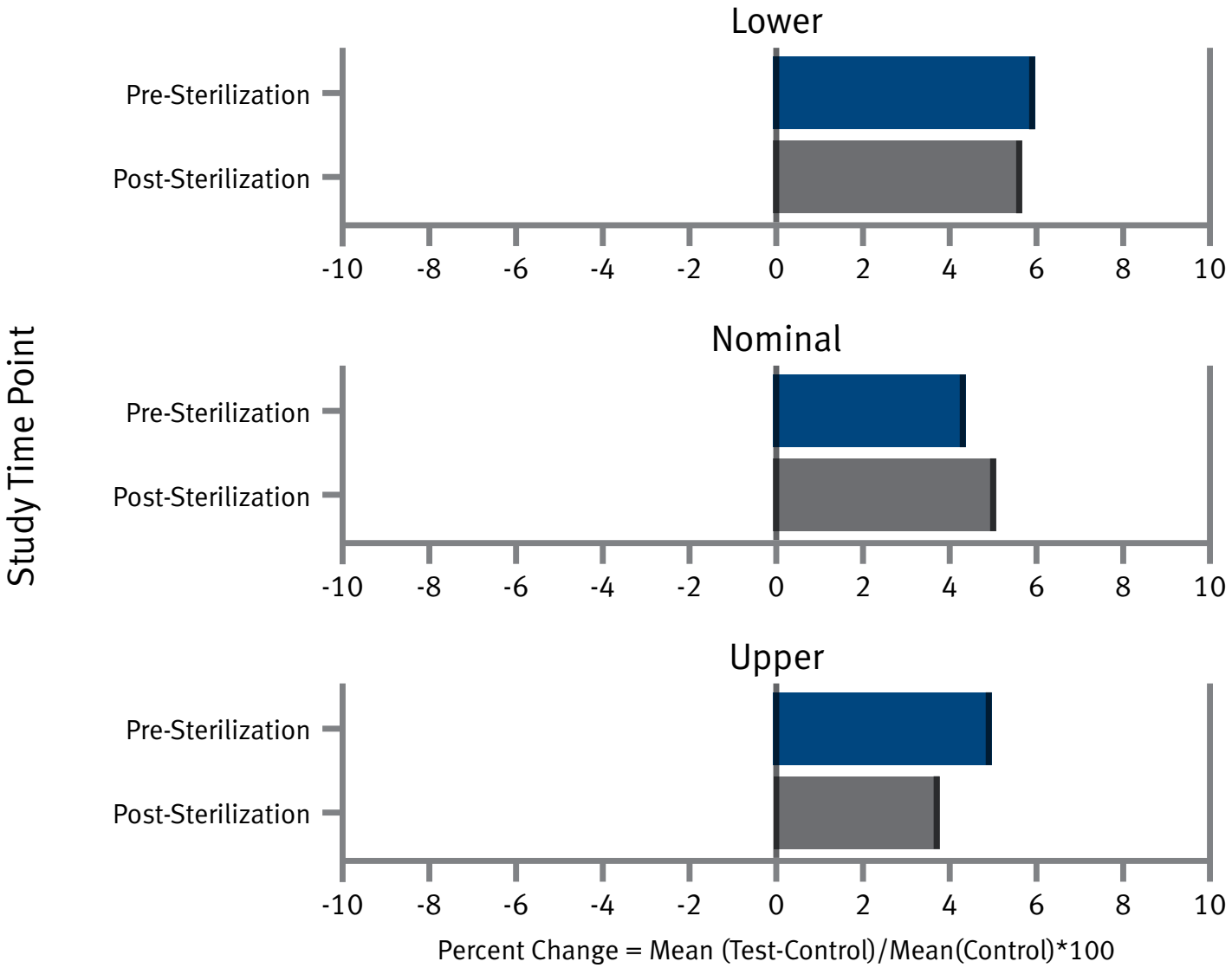
Tyvek® Style	Coating Type	Sterilization Type	Pouches and Bags		Form-Fill-Seal		Rigid Trays	
			Pass	Fail	Pass	Fail	Pass	Fail
1073B	Coated	Pre-sterilization	11	0	13	0	24	0
		EO	7	0	7	0	11	0
		Gamma	3	0	3	0	8	0
		Electron-beam			3	0		
		Steam					3	0
		Dry Heat					1	0
		Low Temp. H_2O_2	1	0				
		Low Temp. $C_2H_4O_3$					1	0
	Uncoated	Pre-sterilization	14	0				
		EO	7	0				
		Gamma	3	0				
		Electron-beam	3	0				
		Steam	1	0				
1059B	Coated	Pre-sterilization			5	0		
		EO			3	0		
		Gamma			1	0		
		Electron-beam			1	0		
	Uncoated	Pre-sterilization	5	0	2	1**		
		EO	5	0	3	0		

There are no cells in the MPTP for this category

*Vent bag, Kwikbreathe™ True Header bag and weld seal bag seal strengths are not included; the failure modes were non-peelable seals.

A high sealing condition for one package configuration exceeded the high end of the equivalence limit by 0.05 lb/in., implying that the Transition Protocol material seal strength was stronger than the current material. A root cause failure analysis (RCFA) is underway. ***This anomaly was not duplicated with post-sterilization data.*

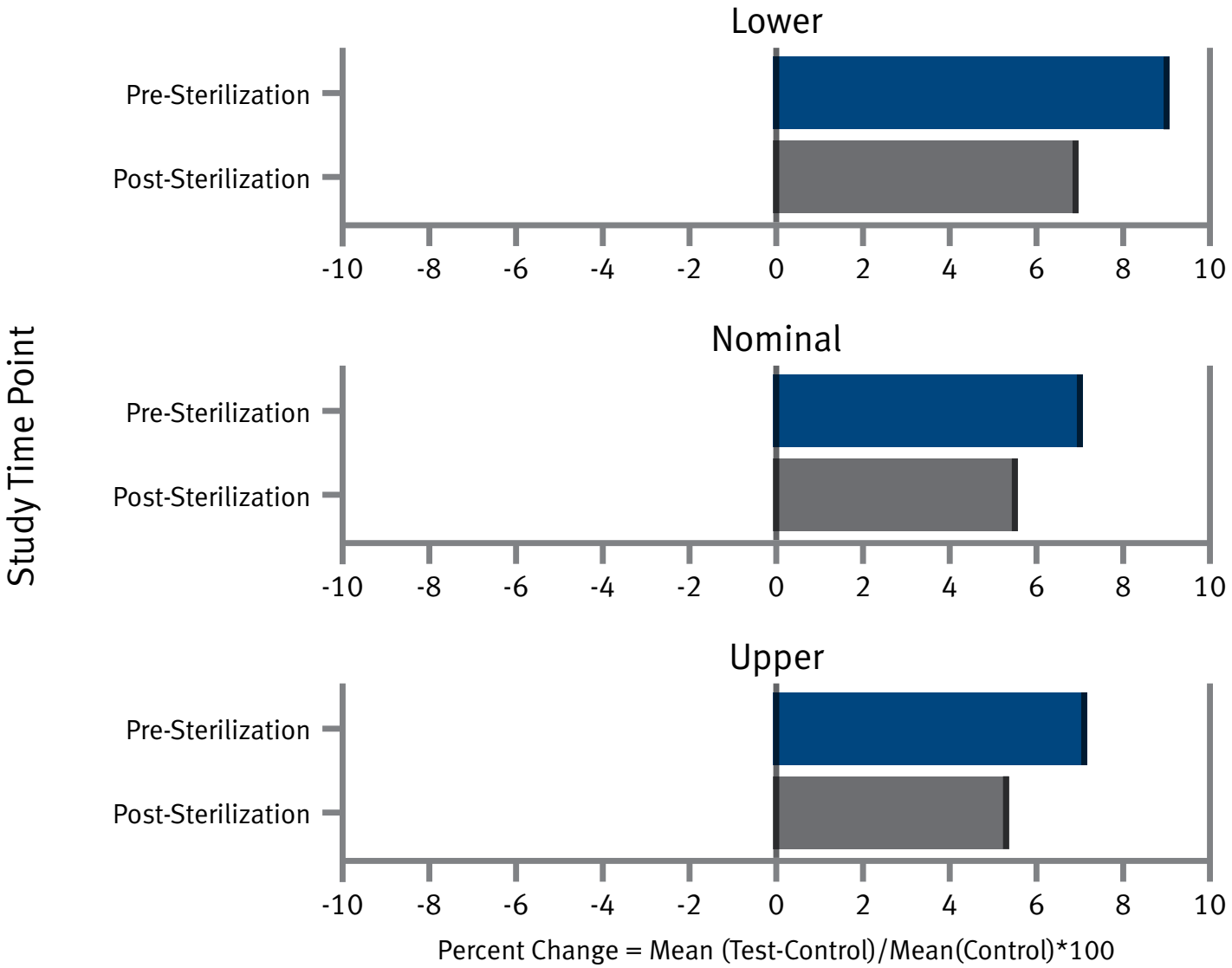
Percent Change in Seal Strength Relative to the Control for Maximum Load — ASTM F88



Test=Transition Protocol Material
Control=Current Tyvek®

As a population, maximum load seal strengths for test are ~4-6% higher than control.

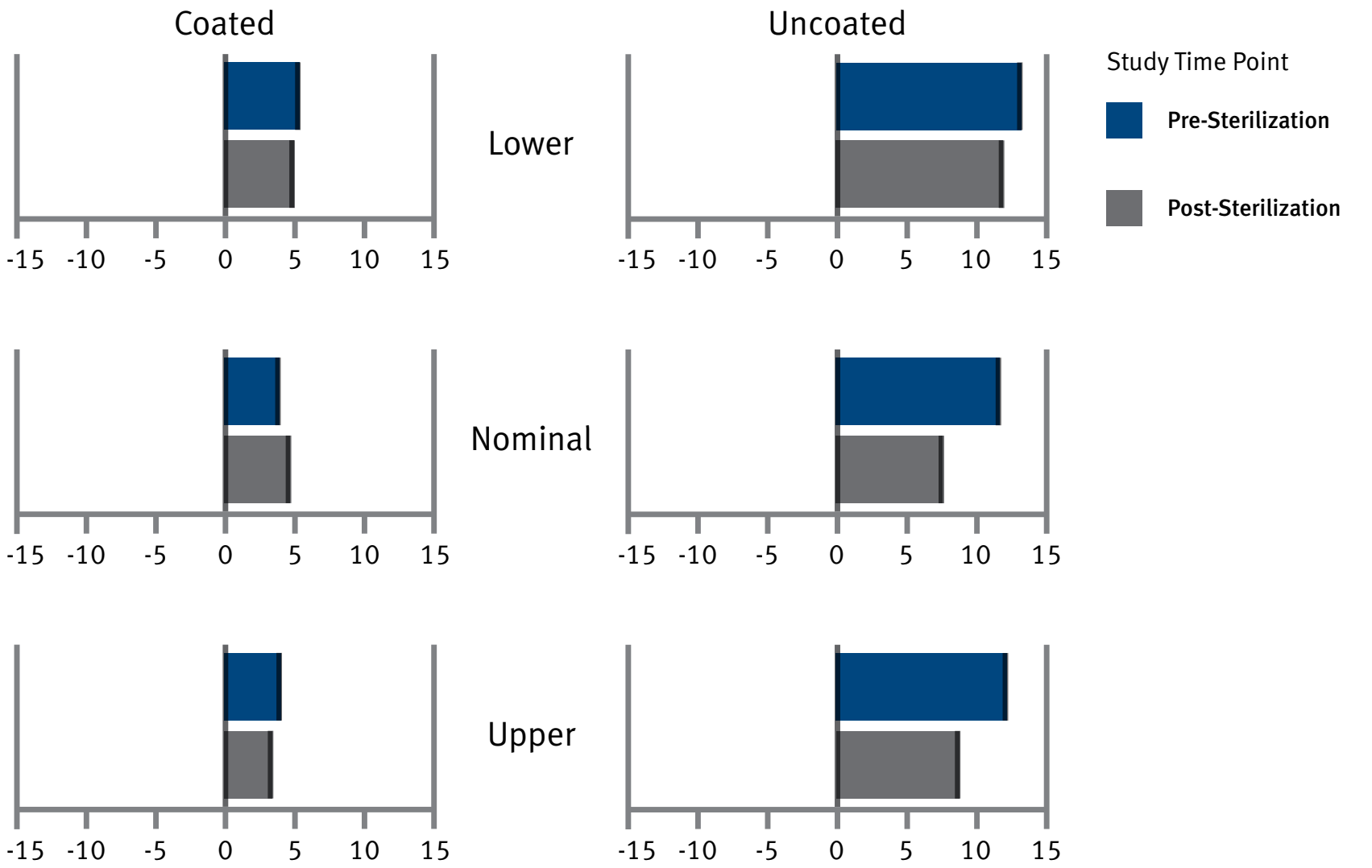
Percent Change in Seal Strength Relative to the Control for Average Load — ASTM F88



Test=Transition Protocol Material
Control=Current Tyvek®

As a population, average load seal strengths for test are ~5-9% higher than control.

Percent Change in Seal Strength Relative to the Control for Coated and Uncoated 1073B Cells — ASTM F88

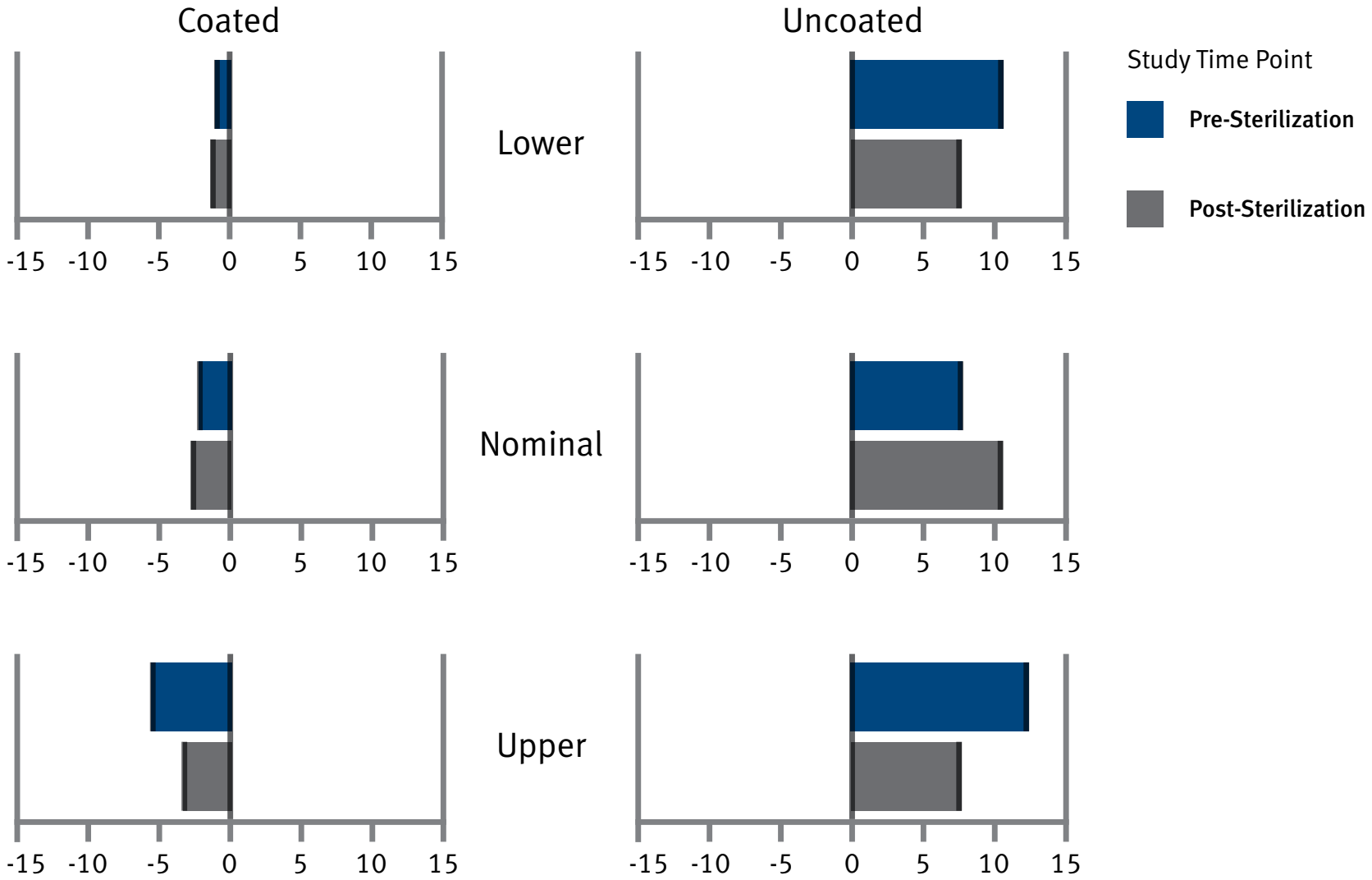


Percent Change = Mean (Test-Control)/Mean(Control)*100

Test=Transition Protocol Material
Control=Current Tyvek®

As a population, the percent change in seal strength for coated 1073B cells is less than uncoated cells.

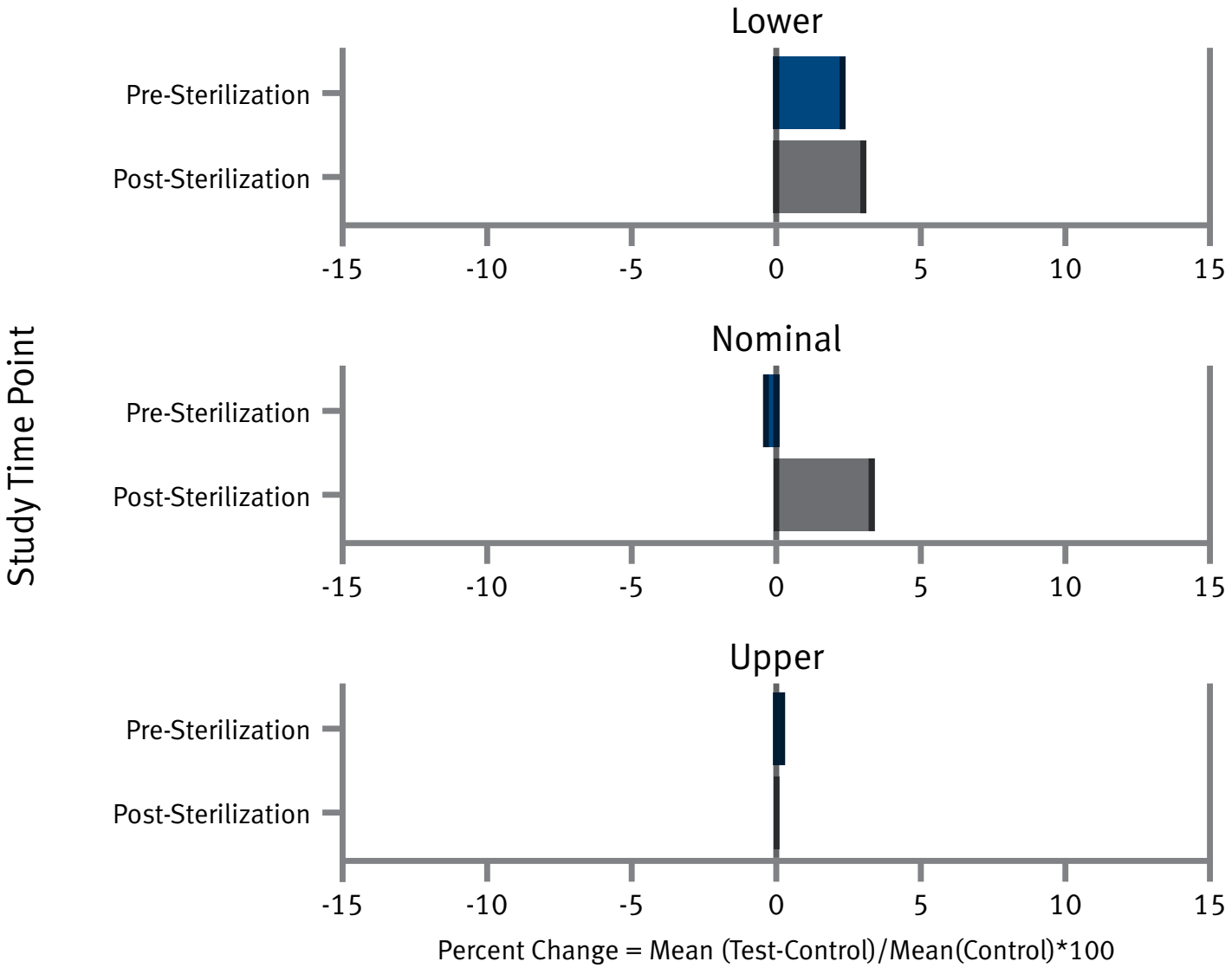
Percent Change in Seal Strength Relative to the Control for Coated and Uncoated 1059B Cells — ASTM F88



Percent Change = Mean (Test-Control)/Mean(Control)*100

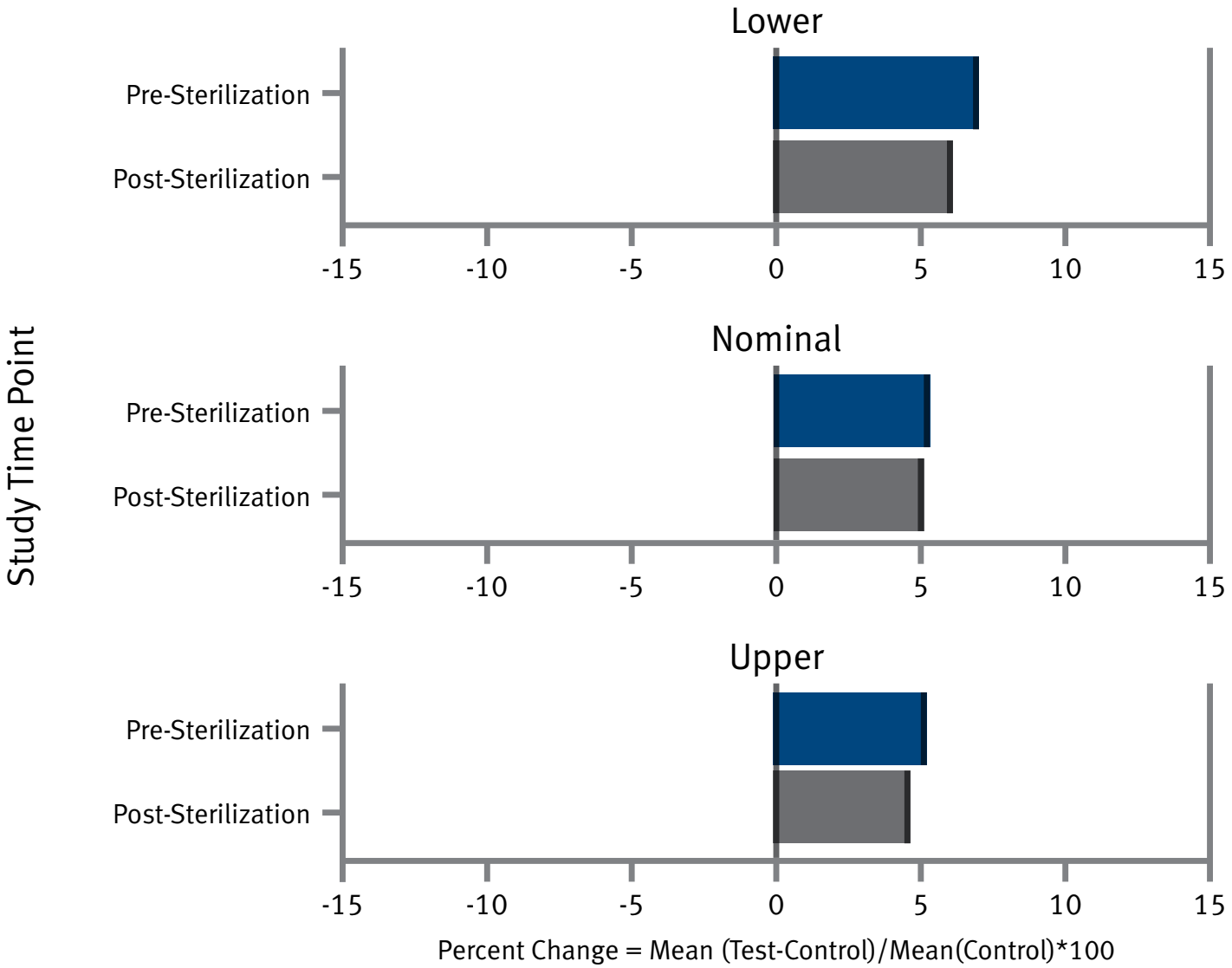
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Coated 1073B FFS — ASTM F88



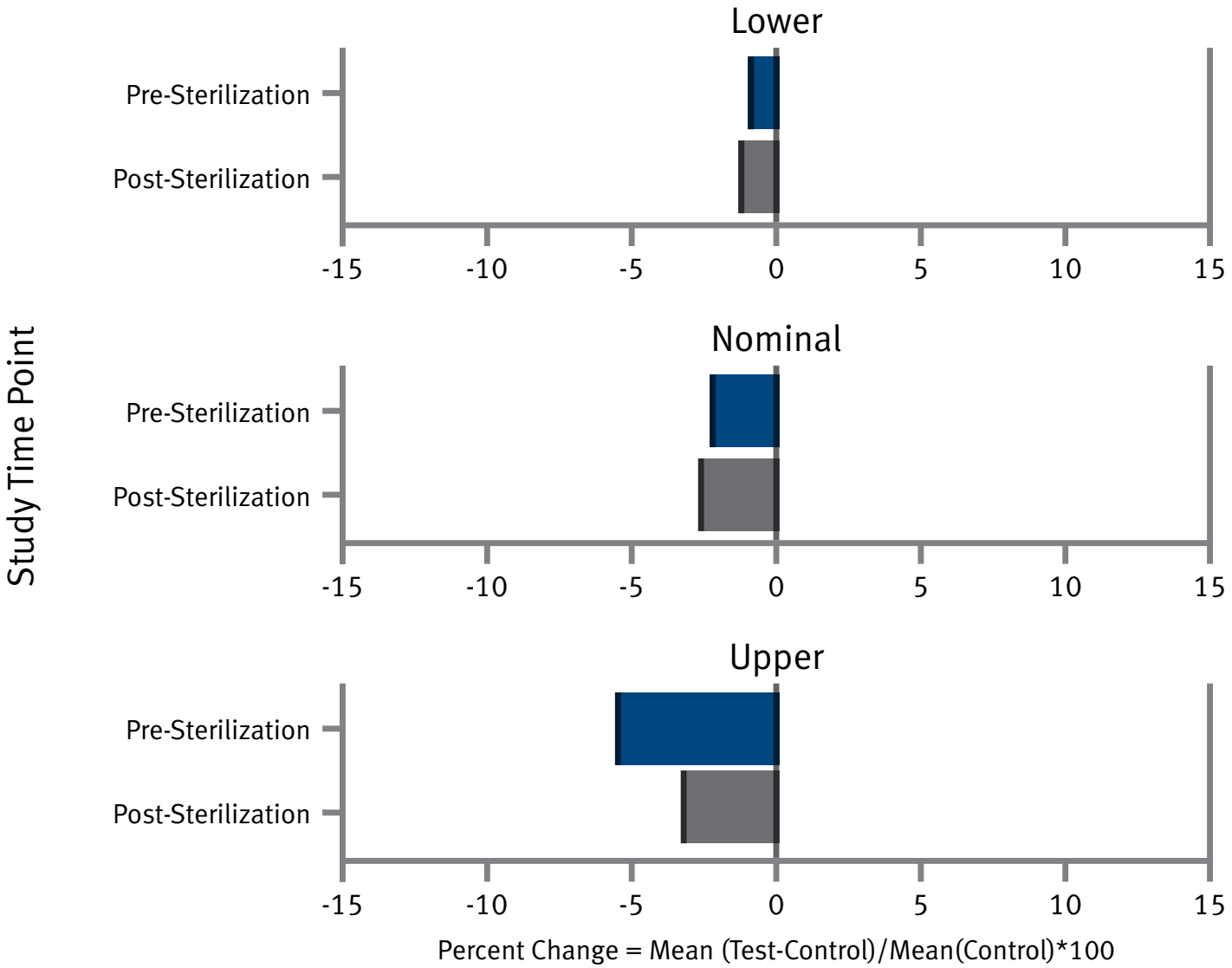
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Coated 1073B Lids/Rigid Trays—ASTM F88



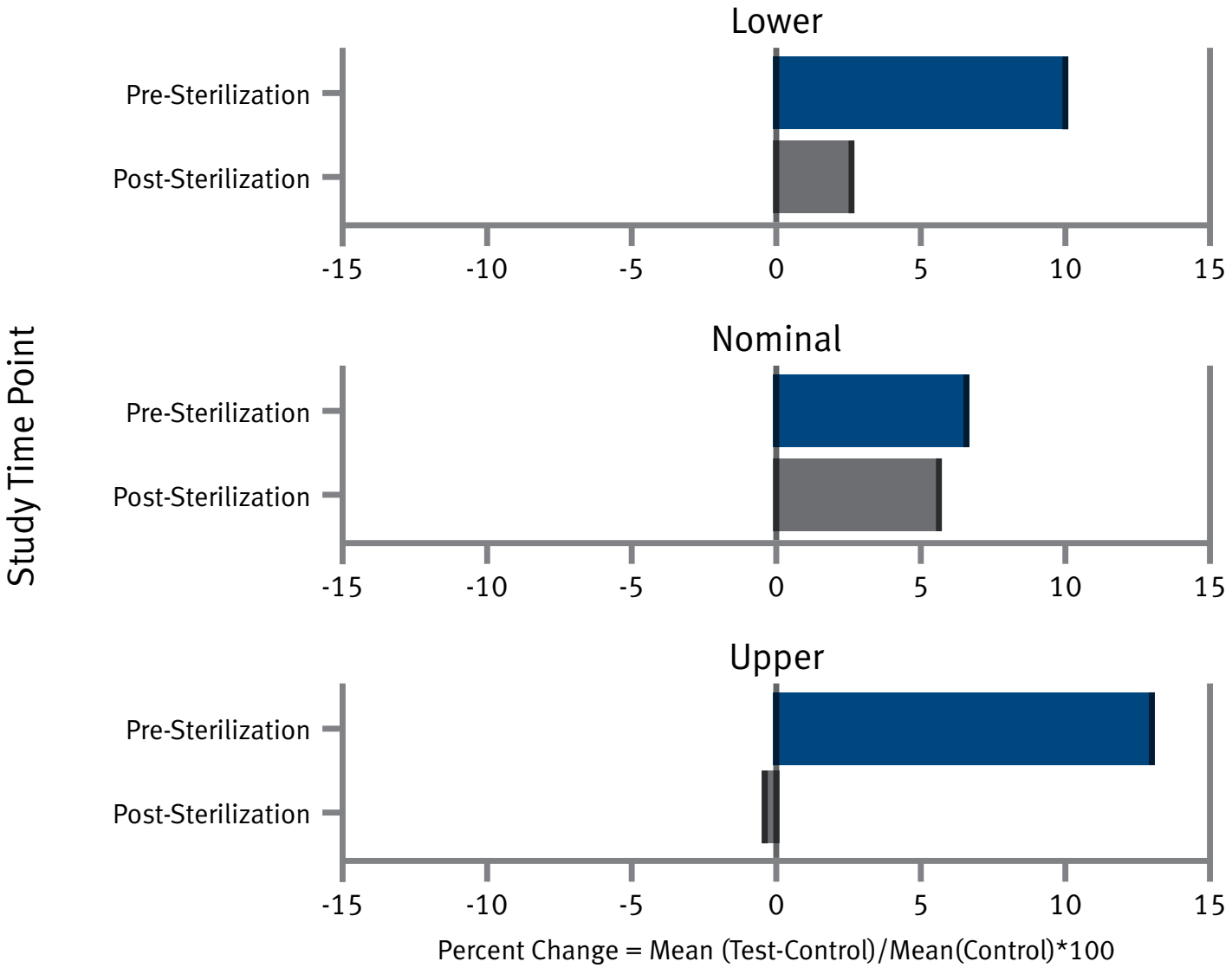
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Coated 1059B FFS — ASTM F88



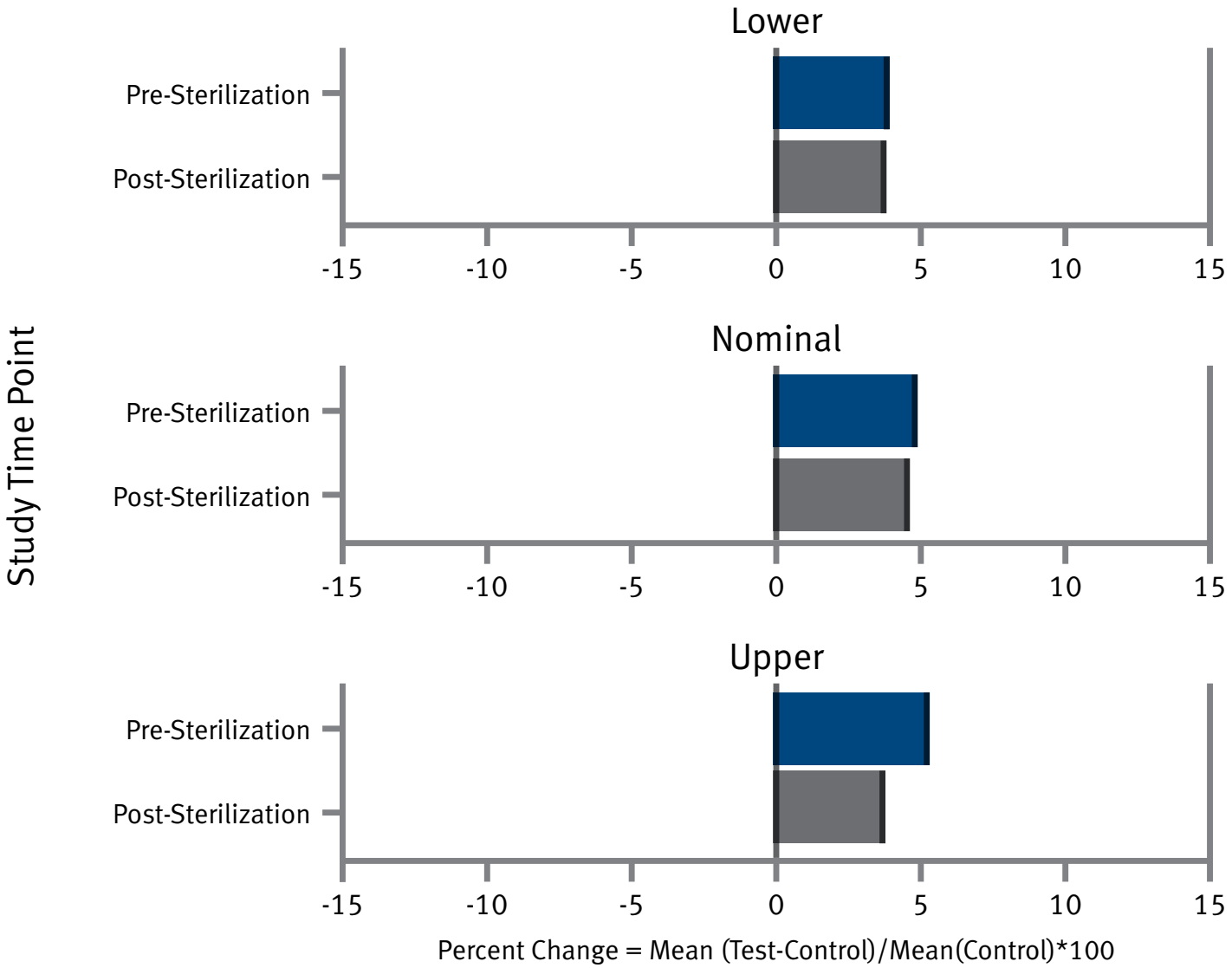
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Uncoated 1059B FFS — ASTM F88



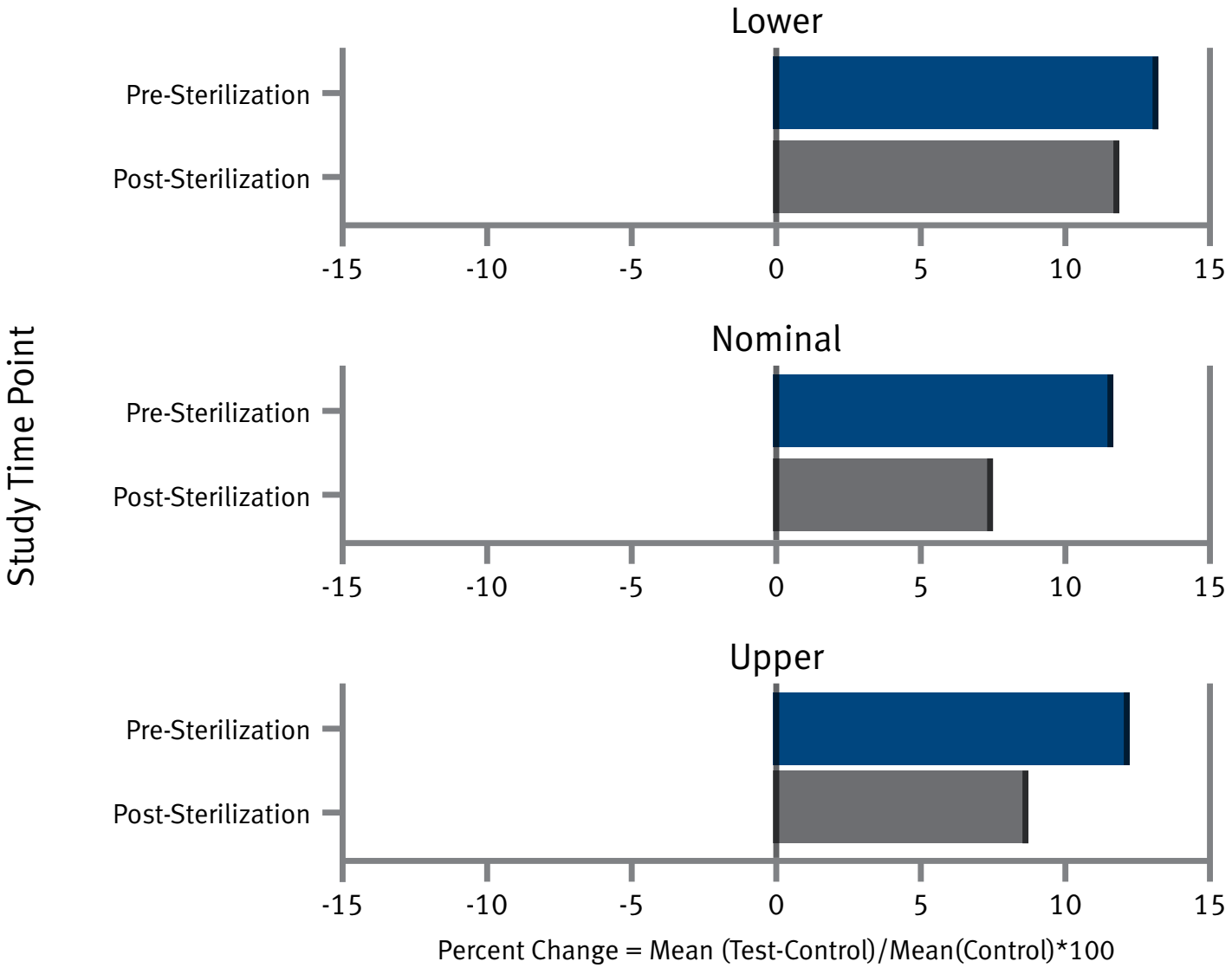
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Coated 1073B Pouches/Bags — ASTM F88



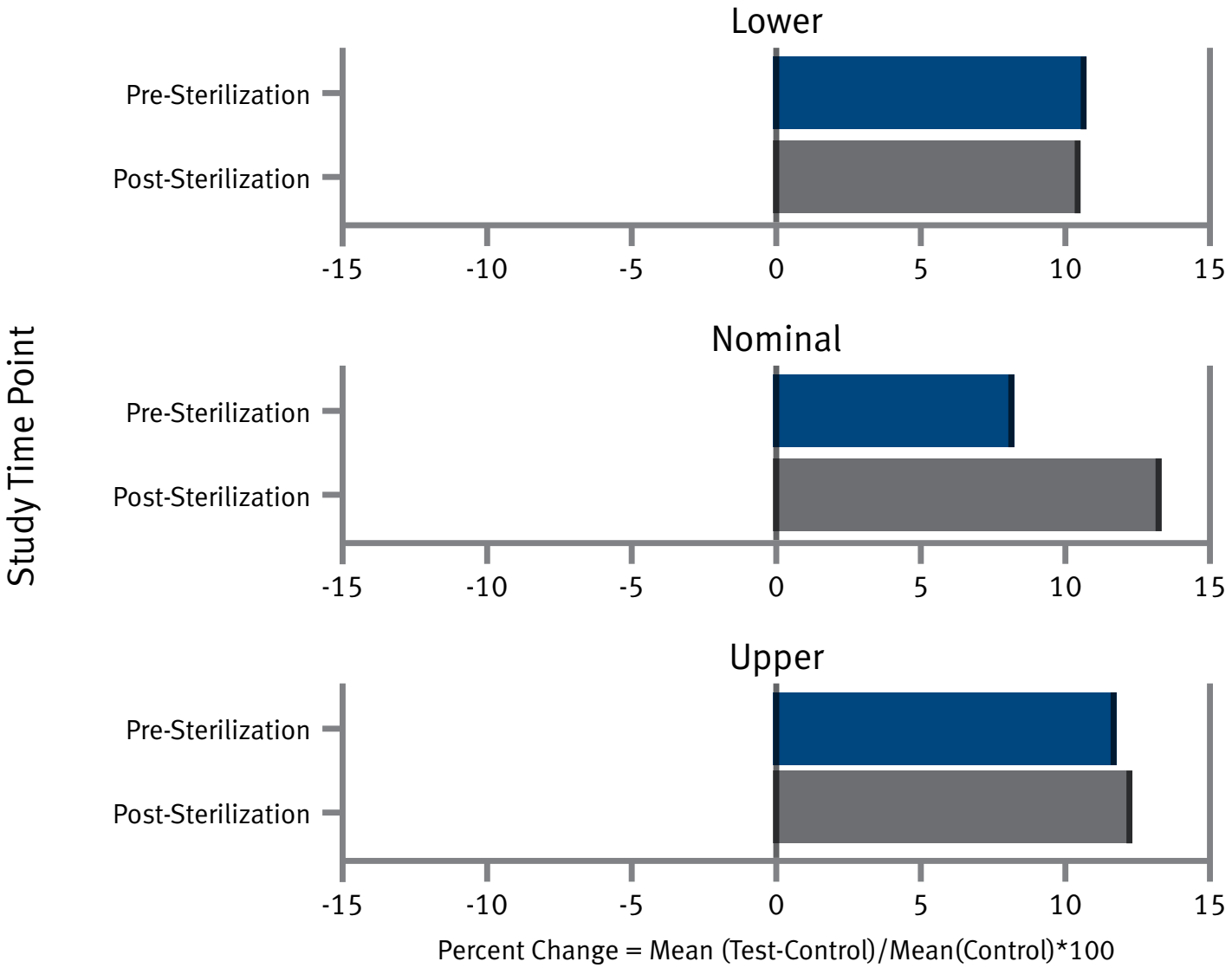
Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Uncoated 1073B Pouches/Bags — ASTM F88



Test=Transition Protocol Material
Control=Current Tyvek®

Percent Change in Seal Strength Relative to the Control for Uncoated 1059B Pouches/Bags — ASTM F88



Test=Transition Protocol Material
Control=Current Tyvek®