

Public Master File 006555
(submission A-0000)

PMF006555_Drouillard_2025_abscess figures

Results of Study
1U01FD006804-01: visual of
primary and secondary
variables

P-VALUE FOR OVERALL TREATMENT EFFECT

ENDPOINT	EVENT	P-VALUE
LA CONDITION	PRESENT	0.940
LA SEVERITY	MODERATE OR SEVERE	0.473
	SEVERE	0.117
FINAL ULTRASOUND	PRESENT	0.154
FINAL YIELD GRADE	--	0.318
USDA QUALITY GRADE	--	0.499
HCW (LB)	--	0.407
CALCULATED YIELD GRADE	--	0.312
RIB EYE AREA (IN ²)	--	0.301
MARBLING SCORE	--	0.997
12TH RIB BODY FAT THICKNESS (IN)	--	0.114
KPH	--	0.915

ANALYSIS RESULTS: BINARY ENDPOINTS

					P-VALUE COMPARED TO	
ENDPOINT	EVENT	TREATMENT	PROB. OF EVENT+/-SE		Y	Z
LA CONDITION	PRESENT	X	43.6%+/-4.1%	A	0.947	0.739
		Y	43.2%+/-4.1%	A	.	0.790
		Z	41.7%+/-4.0%	A	.	.
LA SEVERITY	MODERATE OR SEVERE	X	35.6%+/-3.9%	A	0.412	0.234
		Y	31.1%+/-3.8%	A	.	0.714
		Z	29.1%+/-3.7%	A	.	.
	SEVERE	X	22.1%+/-3.6%	A	0.107	0.064
		Y	14.8%+/-3.0%	A	.	0.813
		Z	13.8%+/-2.9%	A	.	.
FINAL ULTRASOUND	PRESENT	X	6.0%+/-2.0%	A	0.094	0.160
		Y	2.0%+/-1.2%	A	.	0.723
		Z	2.6%+/-1.3%	A	.	.

ANALYSIS RESULTS: MULTINOMIAL ENDPOINTS

			P-VALUE COMPARED TO		RATE OF EVENT+/-SE			
ENDPOINT	TREATMENT		Y	Z	=1	<=2	<=3	=4
FINAL YIELD GRADE	X	A	0.309	0.641	2.6%+/-0.9%	37.9%+/-4.3%	89.2%+/-2.1%	10.8%+/-2.1%
	Y	A	.	0.138	2.1%+/-0.7%	32.2%+/-4.1%	86.6%+/-2.5%	13.4%+/-2.5%
	Z	A	.	.	2.9%+/-0.9%	40.5%+/-4.4%	90.2%+/-1.9%	9.8%+/-1.9%

ANALYSIS RESULTS: MULTINOMIAL ENDPOINTS

			P-VALUE COMPARED TO		RATE OF EVENT+/-SE			
ENDPOINT	TREATMENT		Y	Z	PRIME	CHOICE OR PRIME	SELECT, CHOICE OR PRIME	OTHERS
USDA QUALITY GRADE	X	A	0.243	0.659	10.4%+/-2.2%	93.7%+/-1.5%	99.2%+/-0.4%	0.8%+/-0.4%
	Y	A	.	0.463	7.4%+/-1.8%	91.2%+/-2.0%	98.9%+/-0.6%	1.1%+/-0.6%
	Z	A	.	.	9.2%+/-2.0%	92.9%+/-1.7%	99.1%+/-0.5%	0.9%+/-0.5%

ANALYSIS RESULTS: NUMERICAL ENDPOINTS

				P-VALUE COMPARED TO	
ENDPOINT	TREATMENT	LSM+/-SE		Y	Z
HCW (LB)	X	903+/-7	A	0.234	0.262
	Y	914+/-7	A	.	0.940
	Z	913+/-7	A	.	.
CALCULATED YIELD GRADE	X	3.16+/-0.06	A	0.214	0.885
	Y	3.25+/-0.06	A	.	0.166
	Z	3.15+/-0.06	A	.	.
RIB EYE AREA (IN ²)	X	14.02+/-0.13	A	0.320	0.129
	Y	14.17+/-0.13	A	.	0.594
	Z	14.25+/-0.13	A	.	.
MARBLING SCORE	X	532+/-9	A	0.940	0.965
	Y	531+/-9	A	.	0.975
	Z	531+/-9	A	.	.
12TH RIB BODY FAT THICKNESS (IN)	X	0.536+/-0.013	A	0.056	0.798
	Y	0.572+/-0.013	A	.	0.093
	Z	0.540+/-0.013	A	.	.
KPH	X	1.827+/-0.016	A	0.676	0.862
	Y	1.836+/-0.016	A	.	0.806
	Z	1.830+/-0.016	A	.	.

VALIDATION OF THERMOGRAPHIC IMAGING OF LIVERS FOR DETECTING LA

Statistic	Estimate	95% Lower Confidence Limit	95% Upper Confidence Limit
Simple Kappa	0.0632	0.0204	0.1060

Statistic	Value
Cramer's V	0.1493

McNemar's Test for Disagreement	Pr > ChiSq
170.1978	<.0001

SENSITIVITY	Type of Confidence Limits	95% Lower Confidence Limit	95% Upper Confidence Limit
0.067708	Likelihood Ratio	0.0378	0.1090

SPECIFICITY	Type of Confidence Limits	95% Lower Confidence Limit	95% Upper Confidence Limit
0.98828	Likelihood Ratio	0.9699	0.9971