

Status Of Reported Tests

STATUS	COUNT	PERCENT
Cancelled	1	12.5
Valid	7	87.5
Total Reported Tests	8	100.0

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20240802	ACC-36540	Test Terminated At Sponsor Request

Replicate Database Report

Components of Replicate Database	OCT 2024	All Periods
Number of Tests	1	7
Formulations	1	3
Labs	1	2
Stands	1	2

by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
OCT 2024	AAVE4050	0	0.00000	0.00000
OCT 2024	AAEV4050 (Without SA)	0	0.00000	0.00000
All	AAVE4050	4	0.68860	1.92807
All	AAEV4050 (Without SA)	4	0.86505	2.42214

Pass/Fail
AAVE4050 <=11.8

Report Period	API Category	N	Number Passed	% Passed
OCT 2024	All Categories, All Parameters	7	6	85.7143
OCT 2024	CK - All Parameters	7	6	85.7143
OCT 2024	CK, AAEV4050 (Without SA)	7	4	57.1429
OCT 2024	CK, AAVE4050	7	6	85.7143
All	All Categories, All Parameters	234	206	88.0342
All	CK - All Parameters	234	206	88.0342
All	CK, AAEV4050 (Without SA)	234	187	79.9145
All	CK, AAVE4050	234	206	88.0342

ACC Monitoring Agency

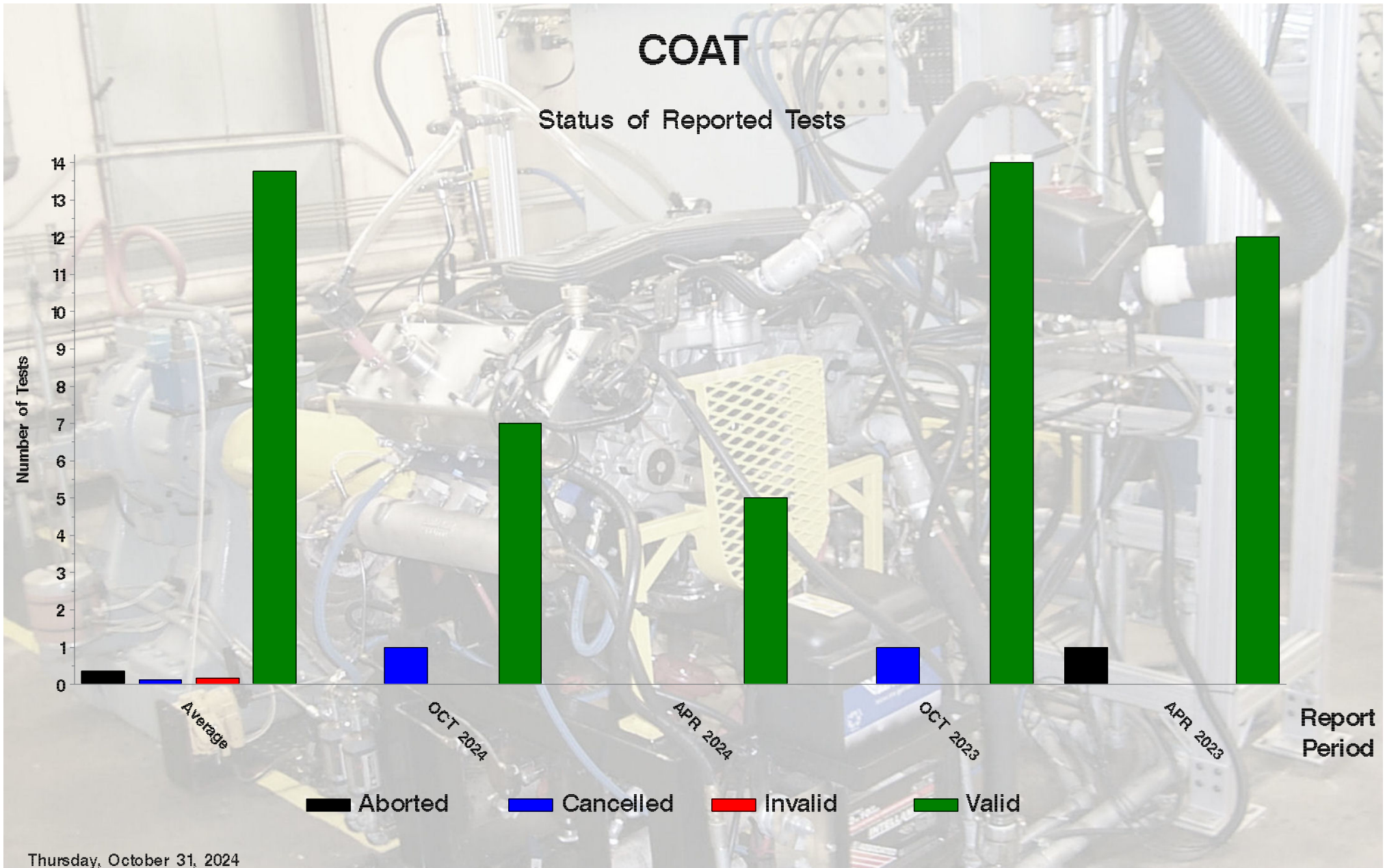
203 Armstrong Drive, Freeport, PA 16229, USA

<https://www.acc-ma.org>
412-365-1000

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ACC Monitoring Agency

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Candidate Precision as Represented by Pooled S

