

Status Of Reported Tests

STATUS	COUNT	PERCENT
Cancelled	1	25
Valid	3	75
Total Reported Tests	4	100

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20250407	ACC-38690	Test Terminated At Sponsor Request

Replicate Database Report

Components of Replicate Database	OCT 2025	All Periods
Number of Tests	.	44
Formulations	.	21
Labs	.	4
Stands	.	17

by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
All	TGC	23	5.6146	15.721
All	EOTOC (Without SA)	23	0.2127	0.596
All	TLC	23	8.8457	24.768
All	WD	23	40.0810	112.227
All	OC	23	0.2013	0.564
All	EOTOC	23	0.1213	0.340
All	TGC (Without SA)	23	5.9127	16.556
All	TLC (Without SA)	23	8.5002	23.800
All	WD (Without SA)	23	40.6552	113.834
All	OC (Without SA)	23	0.2127	0.596

1P - Report Period: OCT 2025

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Pass/Fail

TGC <=36 SCUFFING ='NO' STUCK_RINGS ='NO' TLC <=40 WD <=350 OC <=12.4 EOTOC <=14.6

Report Period	API Category	N	Number Passed	% Passed
OCT 2025	All Categories, All Parameters	3	3	100.000
OCT 2025	CI-4 - All Parameters	3	3	100.000
OCT 2025	CI-4, EOTOC	3	3	100.000
OCT 2025	CI-4, EOTOC (Without SA)	3	3	100.000
OCT 2025	CI-4, OC	3	3	100.000
OCT 2025	CI-4, OC (Without SA)	3	3	100.000
OCT 2025	CI-4, SCUFFING	3	3	100.000
OCT 2025	CI-4, STUCK_RINGS	3	3	100.000
OCT 2025	CI-4, TGC	3	3	100.000
OCT 2025	CI-4, TGC (Without SA)	3	3	100.000
OCT 2025	CI-4, TLC	3	3	100.000
OCT 2025	CI-4, TLC (Without SA)	3	3	100.000
OCT 2025	CI-4, WD	3	3	100.000
OCT 2025	CI-4, WD (Without SA)	3	3	100.000
All	All Categories, All Parameters	406	252	62.069
All	CI-4 - All Parameters	406	252	62.069
All	CI-4, EOTOC	406	334	82.266
All	CI-4, EOTOC (Without SA)	406	318	78.325
All	CI-4, OC	406	369	90.887
All	CI-4, OC (Without SA)	406	361	88.916
All	CI-4, SCUFFING	406	349	85.961
All	CI-4, STUCK_RINGS	406	405	99.754
All	CI-4, TGC	406	335	82.512
All	CI-4, TGC (Without SA)	406	326	80.296
All	CI-4, TLC	406	308	75.862

Pass/Fail

TGC <=36 SCUFFING ='NO' STUCK_RINGS ='NO' TLC <=40 WD <=350 OC <=12.4 EOTOC <=14.6

Report Period	API Category	N	Number Passed	% Passed
All	CI-4, TLC (Without SA)	406	308	75.862
All	CI-4, WD	406	320	78.818
All	CI-4, WD (Without SA)	406	312	76.847

ACC Monitoring Agency

203 Armstrong Drive, Freeport, PA 16229, USA

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

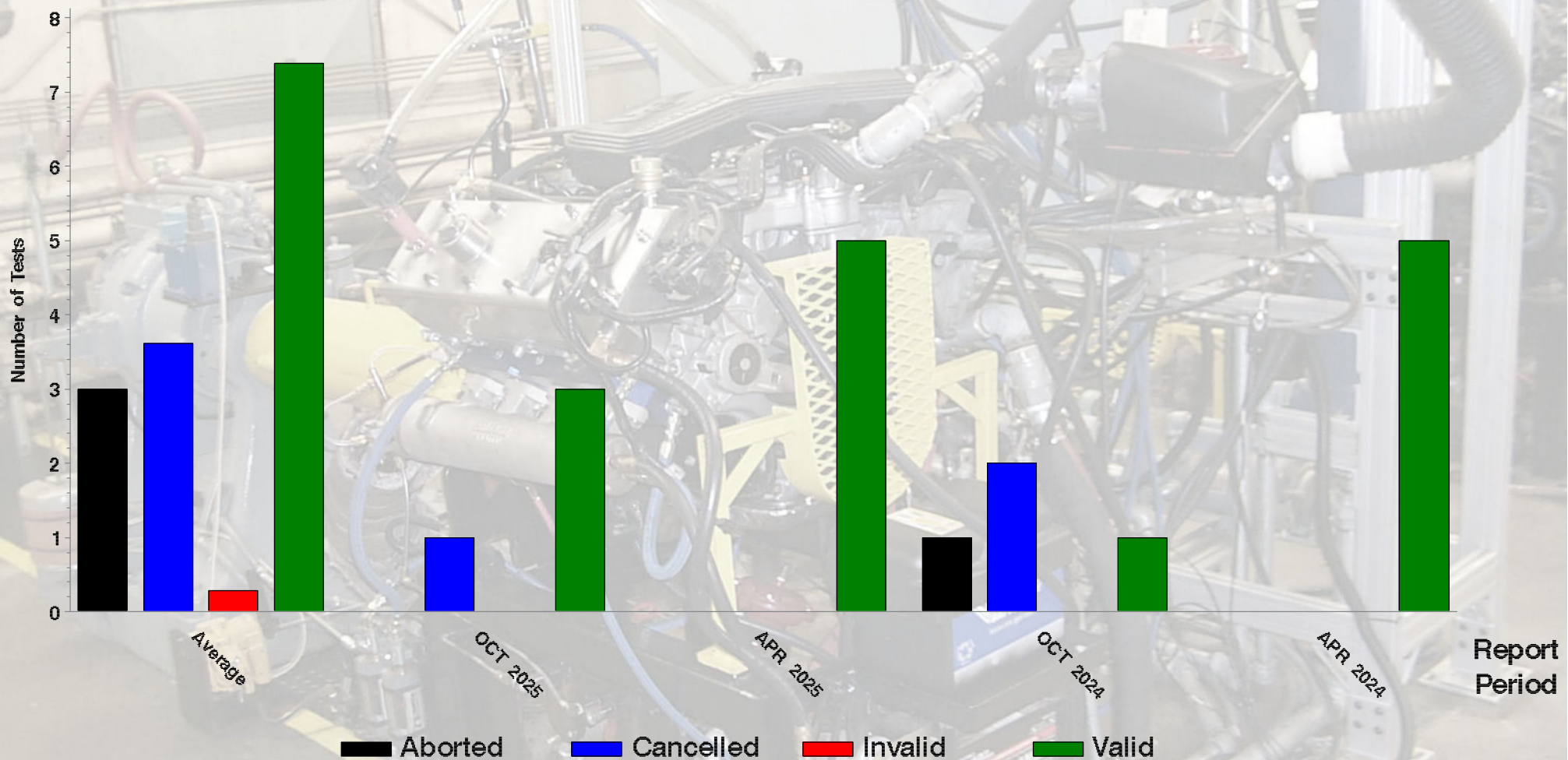
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Candidate Precision as Represented by Pooled S

