

Status Of Reported Tests

STATUS	COUNT	PERCENT
Aborted	1	25
Cancelled	2	50
Valid	1	25
Total Reported Tests	4	100

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20240529	ACC-35938	Test Terminated At Sponsor Request
2	20240711	ACC-36299	Test Aborted Due To Excessive Downtime
3	20240812	ACC-36600	Test Terminated At Sponsor Request

Replicate Database Report

Components of Replicate Database	OCT 2024	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

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 2024	All Categories, All Parameters	1	1	100.000
OCT 2024	CI-4 - All Parameters	1	1	100.000
OCT 2024	CI-4, EOTOC	1	1	100.000
OCT 2024	CI-4, EOTOC (Without SA)	1	1	100.000
OCT 2024	CI-4, OC	1	1	100.000
OCT 2024	CI-4, OC (Without SA)	1	1	100.000
OCT 2024	CI-4, SCUFFING	1	1	100.000
OCT 2024	CI-4, STUCK_RINGS	1	1	100.000
OCT 2024	CI-4, TGC	1	1	100.000
OCT 2024	CI-4, TGC (Without SA)	1	1	100.000
OCT 2024	CI-4, TLC	1	1	100.000
OCT 2024	CI-4, TLC (Without SA)	1	1	100.000
OCT 2024	CI-4, WD	1	1	100.000
OCT 2024	CI-4, WD (Without SA)	1	0	0.000
All	All Categories, All Parameters	398	246	61.809
All	CI-4 - All Parameters	398	246	61.809
All	CI-4, EOTOC	398	328	82.412
All	CI-4, EOTOC (Without SA)	398	312	78.392
All	CI-4, OC	398	363	91.206
All	CI-4, OC (Without SA)	398	355	89.196
All	CI-4, SCUFFING	398	342	85.930
All	CI-4, STUCK_RINGS	398	397	99.749
All	CI-4, TGC	398	329	82.663
All	CI-4, TGC (Without SA)	398	320	80.402
All	CI-4, TLC	398	302	75.879

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)	398	302	75.879
All	CI-4, WD	398	314	78.894
All	CI-4, WD (Without SA)	398	306	76.884

ACC Monitoring Agency

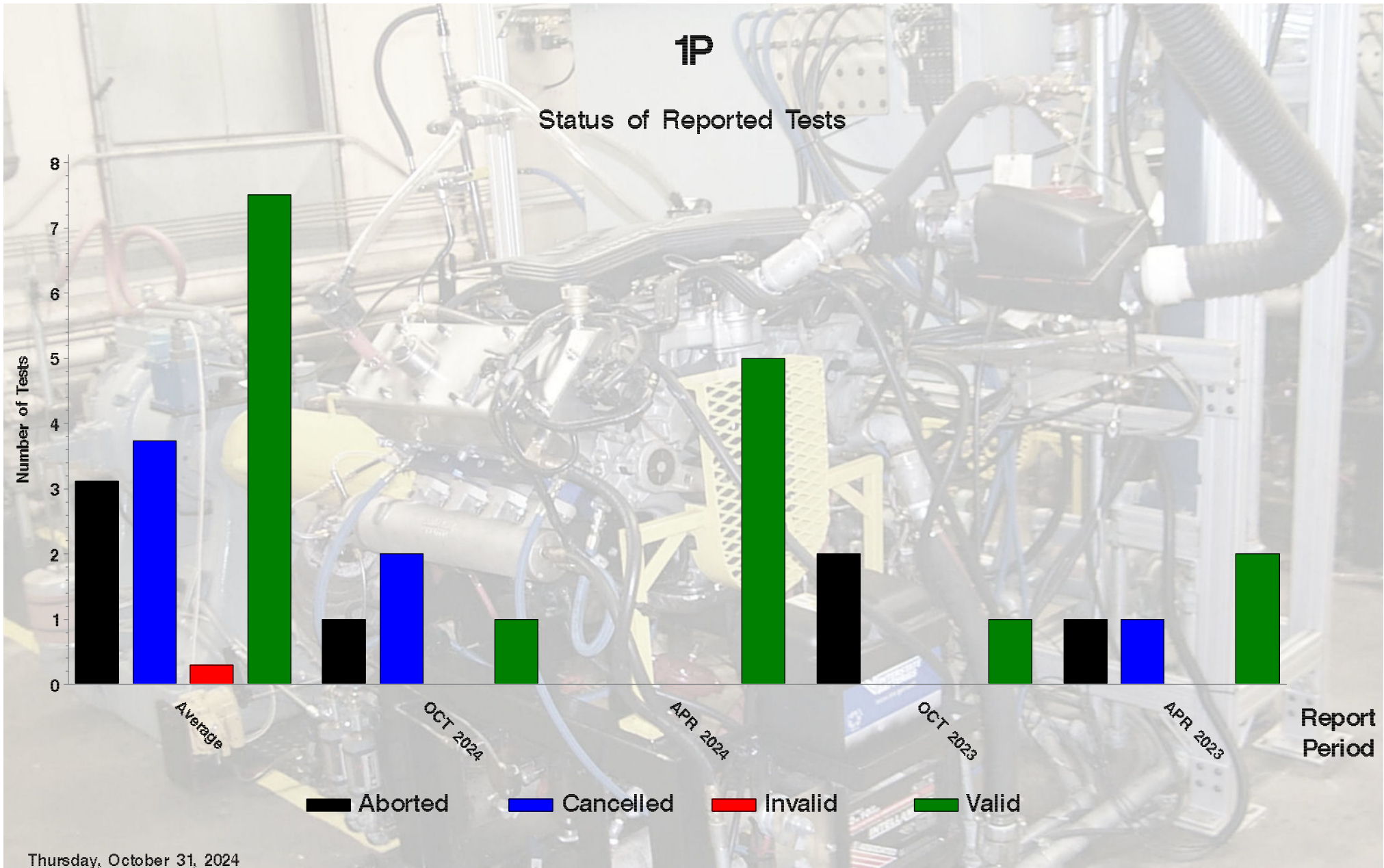
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Candidate Precision as Represented by Pooled S

