

Status Of Reported Tests

STATUS	COUNT	PERCENT
Cancelled	2	12.5
Valid	14	87.5
Total Reported Tests	16	100.0

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20240506	ACC-35794	Test Terminated At Sponsor Request
2	20240923	ACC-36838	Test Terminated At Sponsor Request

Replicate Database Report

Components of Replicate Database	OCT 2024	All Periods
Number of Tests	.	13
Formulations	.	7
Labs	.	4
Stands	.	11

by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
All	IRPH360	6	26.6576	74.6414
All	KV40PC	6	23.9782	67.1390
All	IRPH360 (Without SA)	6	25.0961	70.2691
All	KV40PC (Without SA)	6	19.0652	53.3824

Pass/Fail

Report Period	API Category	N	Number Passed	% Passed
OCT 2024	All Categories, All Parameters	14	13	92.857
OCT 2024	CK - All Parameters	14	13	92.857
OCT 2024	CK, IRPH360	14	13	92.857
OCT 2024	CK, IRPH360 (Without SA)	14	13	92.857
OCT 2024	CK, KV40PC	14	13	92.857
OCT 2024	CK, KV40PC (Without SA)	14	14	100.000
All	All Categories, All Parameters	510	418	81.961
All	CK - All Parameters	510	418	81.961
All	CK, IRPH360	510	431	84.510
All	CK, IRPH360 (Without SA)	510	452	88.627
All	CK, KV40PC	510	446	87.451
All	CK, KV40PC (Without SA)	510	479	93.922

ACC Monitoring Agency

203 Armstrong Drive, Freeport, PA 16229, USA

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

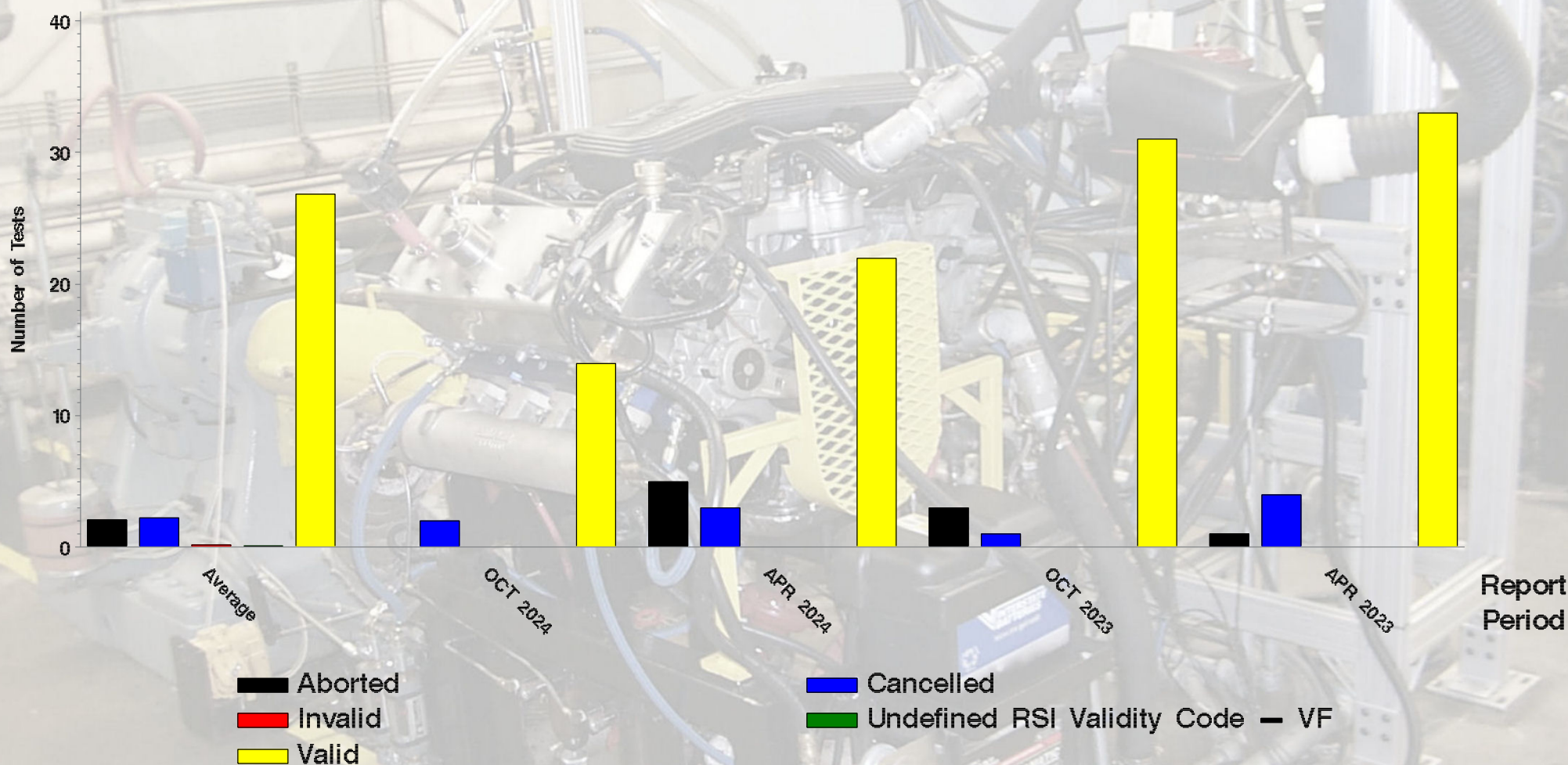
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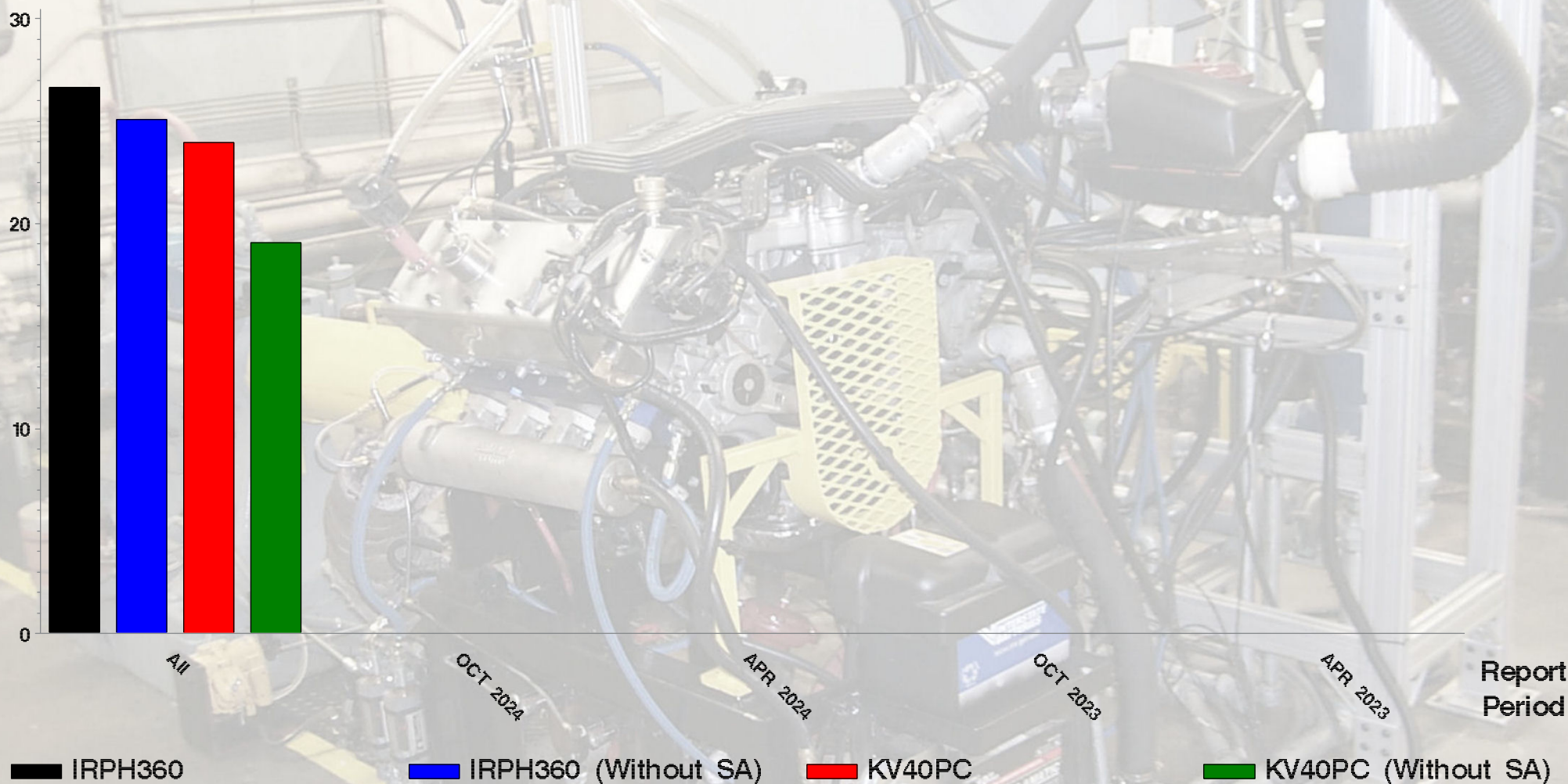
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Candidate Precision as Represented by Pooled S



Thursday, October 31, 2024