

Status Of Reported Tests

STATUS	COUNT	PERCENT
Aborted	1	8.333
Invalid	1	8.333
Valid	10	83.333
Total Reported Tests	12	100.000

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20191206	ACC-27232	No Explanation Available
2	20191219	ACC-27343	No Explanation Available

Replicate Database Report

Components of Replicate Database	APR 2020	All Periods
Number of Tests	.	8
Formulations	.	4
Labs	.	3
Stands	.	7

by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
All	IRPH360	4	32.0770	89.8156
All	KV40PC	4	28.9540	81.0712
All	IRPH360 (Without SA)	4	30.5978	85.6737
All	KV40PC (Without SA)	4	23.0910	64.6548

Pass/Fail
 IRPH360 <=125 KV40PC <=75

Report Period	API Category	N	Number Passed	% Passed
APR 2020	All Categories, All Parameters	10	10	100.000
APR 2020	CK - All Parameters	10	10	100.000
APR 2020	CK, IRPH360	10	10	100.000
APR 2020	CK, IRPH360 (Without SA)	10	10	100.000
APR 2020	CK, KV40PC	10	10	100.000
APR 2020	CK, KV40PC (Without SA)	10	10	100.000
All	All Categories, All Parameters	293	217	74.061
All	CK - All Parameters	293	217	74.061
All	CK, IRPH360	293	227	77.474
All	CK, IRPH360 (Without SA)	293	246	83.959
All	CK, KV40PC	293	240	81.911
All	CK, KV40PC (Without SA)	293	265	90.444



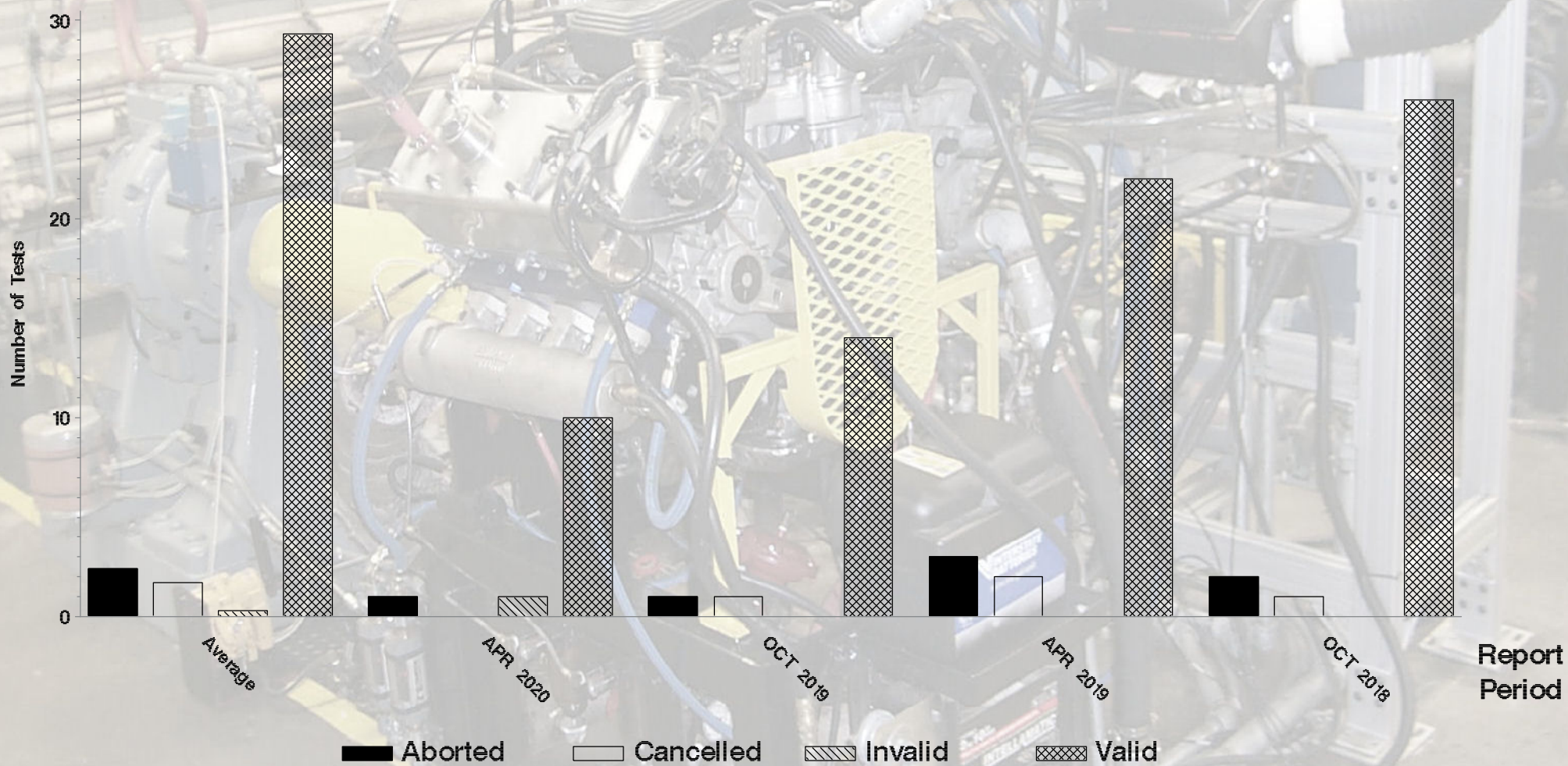
Monitoring Agency

6555 Penn Avenue, Pittsburgh, PA 15206

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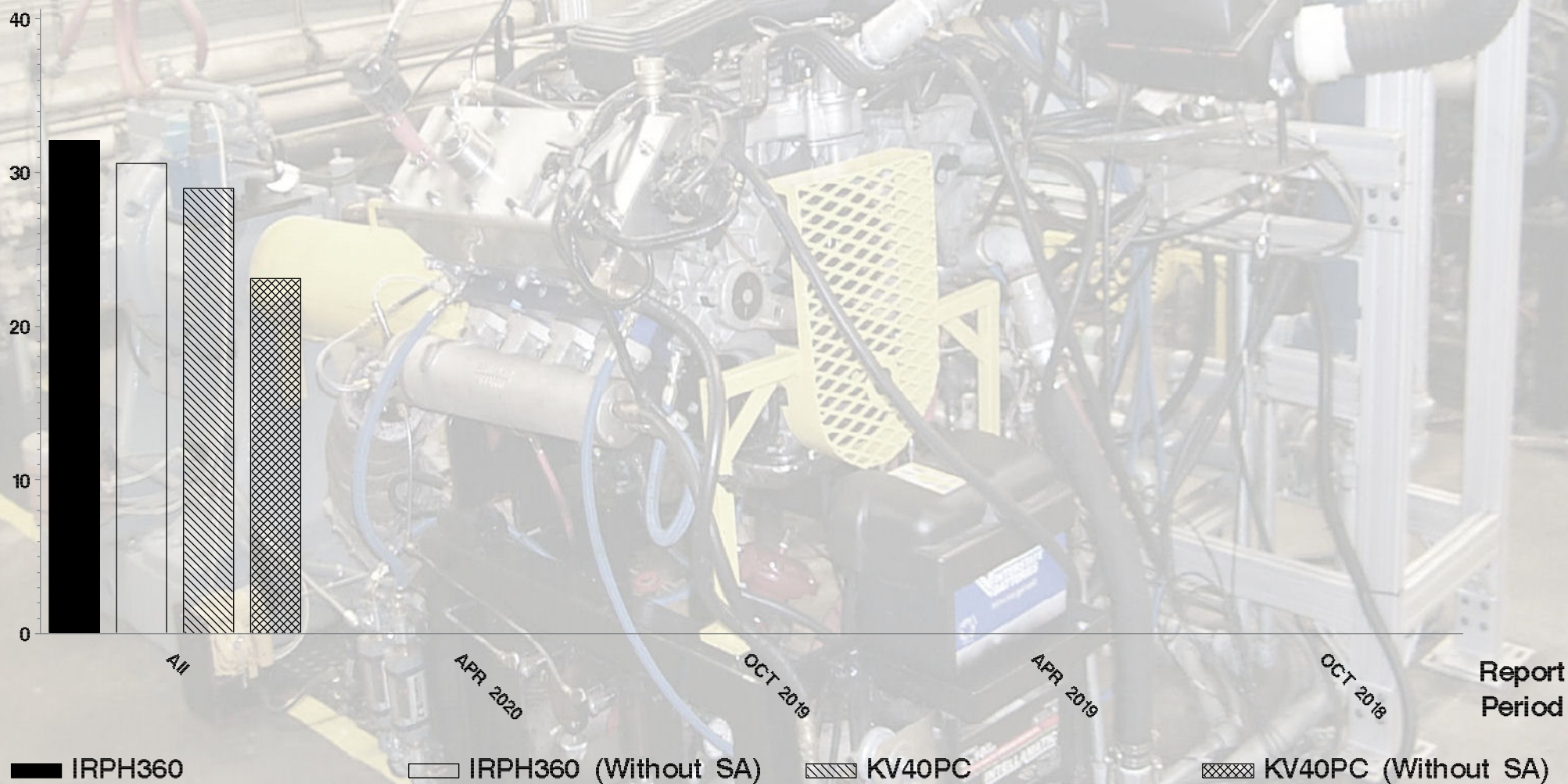
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Candidate Precision as Represented by Pooled S



Monday, July 20, 2020