Status Of Reported Tests

STATUS	COUNT	PERCENT
Cancelled	3	9.375
Valid	29	90.625
Total Reported Tests	32	100.000

Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20211101	ACC-31171	Test Terminated At Sponsor Request
2	20220307	ACC-31751	Test Terminated At Sponsor Request.
3	20220318	ACC-31850	Test Terminated At Sponsor Request.

Replicate Database Report

Components of Replicate Database	APR 2022	All Periods
Number of Tests	1	10
Formulations	1	5
Labs	1	3
Stands	1	8

by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
APR 2022	IRPH360	0	0.0000	0.0000
APR 2022	KV40PC	0	0.0000	0.0000
APR 2022	IRPH360 (Without SA)	0	0.0000	0.0000
APR 2022	KV40PC (Without SA)	0	0.0000	0.0000
All	IRPH360	5	28.6910	80.3347
All	KV40PC	5	25.9381	72.6266
All	IRPH360 (Without SA)	5	27.3862	76.6813
All	KV40PC (Without SA)	5	20.6900	57.9320

Pass/Fail
IRPH360 <=125   KV40PC <=75

Report Period	API Category	N	Number Passed	% Passed
APR 2022	All Categories, All Parameters	29	28	96.552
APR 2022	CK - All Parameters	29	28	96.552
APR 2022	CK, IRPH360	29	28	96.552
APR 2022	CK, IRPH360 (Without SA)	29	28	96.552
APR 2022	CK, KV40PC	29	28	96.552
APR 2022	CK, KV40PC (Without SA)	29	29	100.000
All	All Categories, All Parameters	392	312	79.592
All	CK - All Parameters	392	312	79.592
All	CK, IRPH360	392	324	82.653
All	CK, IRPH360 (Without SA)	392	343	87.500
All	CK, KV40PC	392	335	85.459
All	CK, KV40PC (Without SA)	392	362	92.347

T13

Status of Reported Tests

Friday, October 14, 2022
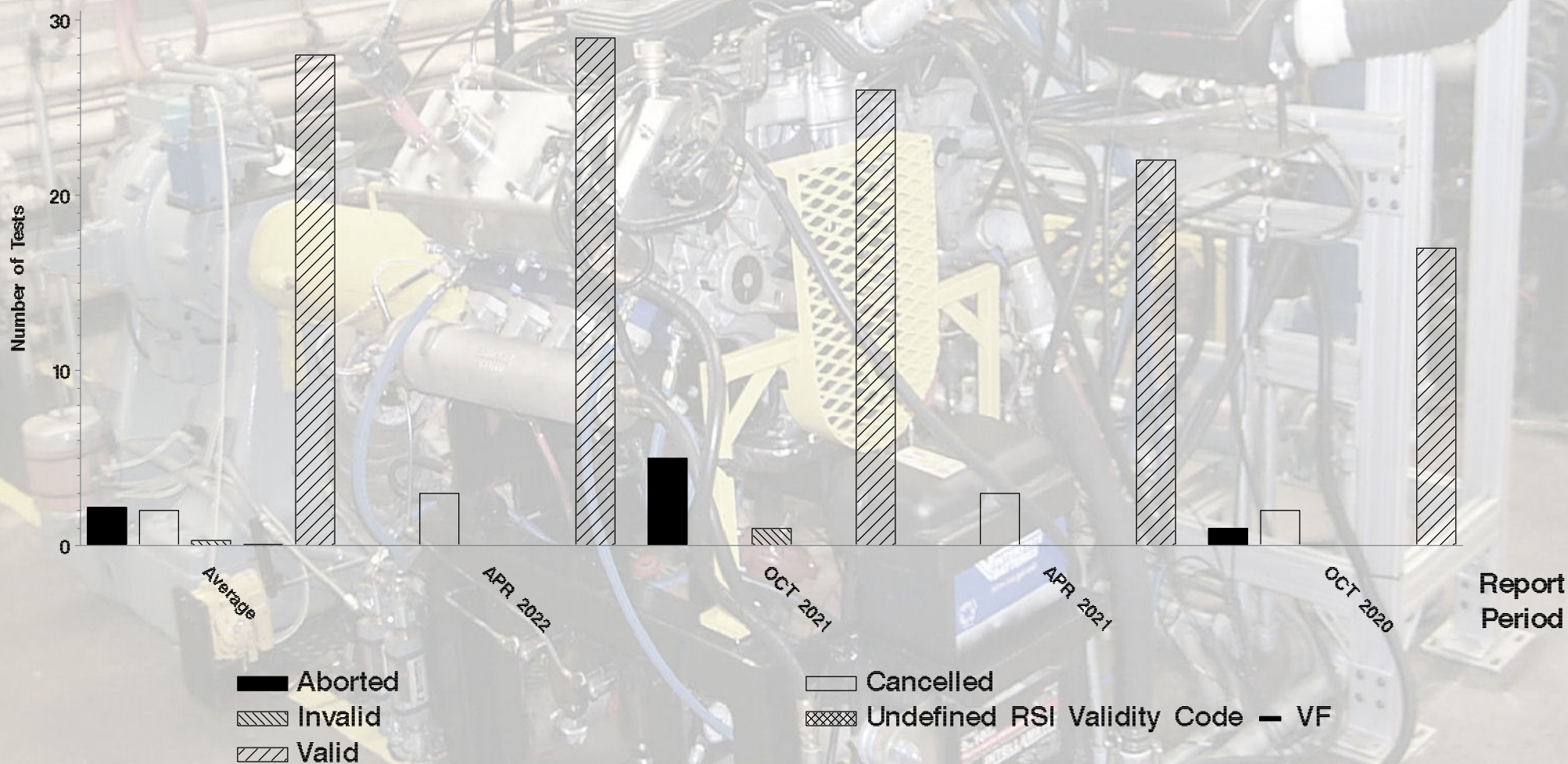
T13

Candidate Precision as Represented by Pooled S

Friday, October 14, 2022