

1P - Report Period: OCT 2006
Status Of Reported Tests

1

STATUS	COUNT	PERCENT
Cancelled	1	20
Invalid	1	20
Valid	3	60
Total Reported Tests	5	100

1P - Report Period: OCT 2006
Itemized Lost Test Report

Obs	Date	TESTKEY	REASON
1	20060508	RSI-293508	Prior To Completion At Sponsor Request
2	20060816	RSI-294869	Operationally Invalid,lab Declares Invalid

1P - Report Period: OCT 2006
Replicate Database Report

Components of Replicate Database	OCT 2006	All Periods
Number of Tests	2	32
Formulations	1	15
Labs	1	4
Stands	1	14

1P - Report Period: OCT 2006
by-Formulation Pooled s and Reproducibility of Replicate Data

Report Period	Parameter	Degrees of Freedom	Pooled s	R
OCT 2006	TGC	1	3.5355	9.899
OCT 2006	TLC	1	4.4194	12.374
OCT 2006	WD	1	3.3941	9.504
OCT 2006	OC	1	0.1623	0.455
OCT 2006	EOTOC	1	0.0838	0.235
OCT 2006	TGC (Without SA)	1	3.5355	9.899
OCT 2006	TLC (Without SA)	1	4.4194	12.374
OCT 2006	WD (Without SA)	1	3.3941	9.504
OCT 2006	OC (Without SA)	1	0.0838	0.235
OCT 2006	EOTOC (Without SA)	1	0.0838	0.235
All	TGC	17	6.0234	16.866
All	TLC	17	8.9008	24.922
All	WD	17	40.0761	112.213
All	OC	17	0.1754	0.491
All	EOTOC	17	0.1076	0.301
All	TGC (Without SA)	17	6.3978	17.914
All	TLC (Without SA)	17	8.9008	24.922
All	WD (Without SA)	17	40.8511	114.383
All	OC (Without SA)	17	0.1076	0.301
All	EOTOC (Without SA)	17	0.1076	0.301

1P - Report Period: OCT 2006
Pass/Fail

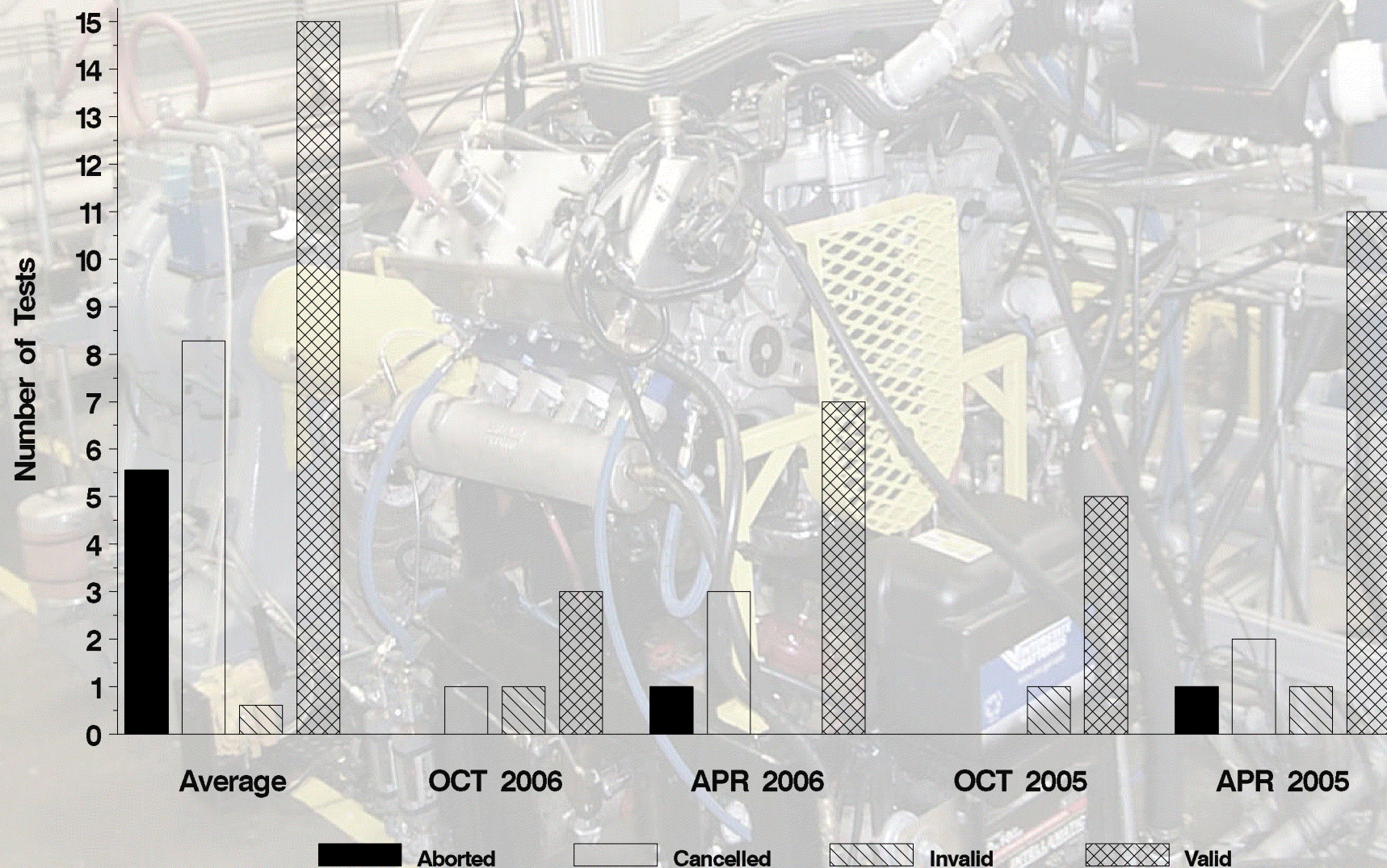
Report Period	API Category	N	Number Passed	% Passed
OCT 2006	All Categories, All Parameters	3	2	66.667
OCT 2006	CI-4 - All Parameters	3	2	66.667
OCT 2006	CI-4, EOTOC	3	3	100.000
OCT 2006	CI-4, EOTOC (Without SA)	3	2	66.667
OCT 2006	CI-4, OC	3	3	100.000
OCT 2006	CI-4, OC (Without SA)	3	3	100.000
OCT 2006	CI-4, SCUFFING	3	3	100.000
OCT 2006	CI-4, STUCK_RINGS	3	3	100.000
OCT 2006	CI-4, TGC	3	3	100.000
OCT 2006	CI-4, TGC (Without SA)	3	3	100.000
OCT 2006	CI-4, TLC	3	2	66.667
OCT 2006	CI-4, TLC (Without SA)	3	2	66.667
OCT 2006	CI-4, WD	3	3	100.000
OCT 2006	CI-4, WD (Without SA)	3	3	100.000
All	All Categories, All Parameters	270	153	56.667
All	CI-4 - All Parameters	270	153	56.667
All	CI-4, EOTOC	270	215	79.630
All	CI-4, EOTOC (Without SA)	270	208	77.037
All	CI-4, OC	270	239	88.519
All	CI-4, OC (Without SA)	270	237	87.778
All	CI-4, SCUFFING	270	216	80.000
All	CI-4, STUCK_RINGS	270	270	100.000
All	CI-4, TGC	270	212	78.519
All	CI-4, TGC (Without SA)	270	203	75.185
All	CI-4, TLC	270	193	71.481
All	CI-4, TLC (Without SA)	270	193	71.481

1P - Report Period: OCT 2006
Pass/Fail

Report Period	API Category	N	Number Passed	% Passed
All	CI-4, WD	270	214	79.259
All	CI-4, WD (Without SA)	270	207	76.667

1P

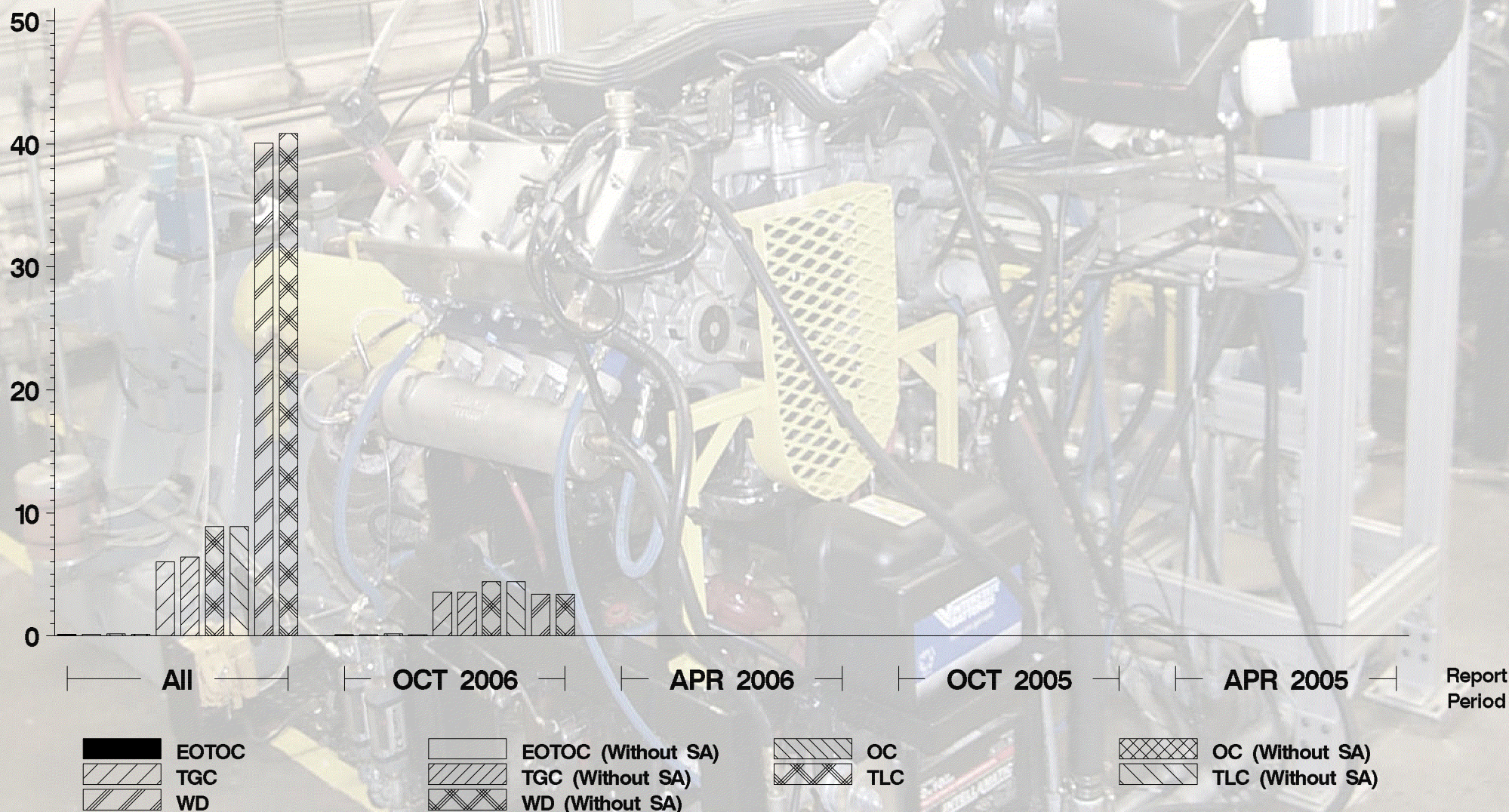
Status of Reported Tests



Report
Period

1P

Candidate Precision as Represented by Pooled S



1P

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