

***1P - Report Period: APR 1999***  
***Status Of Reported Tests***

**1**

| STATUS               | COUNT | PERCENT |
|----------------------|-------|---------|
| Aborted              | 15    | 25.424  |
| Cancelled            | 9     | 15.254  |
| Valid                | 35    | 59.322  |
| Total Reported Tests | 59    | 100.000 |



***1P - Report Period: APR 1999  
Itemized Lost Test Report***

| Obs | Date     | TESTKEY    | REASON   |
|-----|----------|------------|--|
| 1   | 19981002 | RSI-257131 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 2   | 19981005 | RSI-257140 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 3   | 19981006 | RSI-257153 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 4   | 19981012 | RSI-257197 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 5   | 19981012 | RSI-257198 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 6   | 19981014 | RSI-257221 | Prior To Completion At Sponsor Request                     |
| 7   | 19981023 | RSI-257302 | Prior To Completion At Sponsor Request                     |
| 8   | 19981027 | RSI-257318 | Prior To Completion At Sponsor Request                     |
| 9   | 19981106 | RSI-257399 | Prior To Completion At Sponsor Request                     |
| 10  | 19981124 | RSI-257525 | Prior To Completion At Sponsor Request                     |
| 11  | 19981125 | RSI-257563 | Prior To Completion At Sponsor Request                     |
| 12  | 19981202 | RSI-257595 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 13  | 19981207 | RSI-257628 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 14  | 19981214 | RSI-257662 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 15  | 19981215 | RSI-257675 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 16  | 19981217 | RSI-257692 | Operationally Invalid,by Lab                               |
| 17  | 19990104 | RSI-257760 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 18  | 19990105 | RSI-257764 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 19  | 19990111 | RSI-257805 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 20  | 19990115 | RSI-257822 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 21  | 19990203 | RSI-257920 | Prior To Completion At Sponsor Request                     |
| 22  | 19990203 | RSI-257926 | Prior To Completion At Sponsor Request                     |
| 23  | 19990302 | RSI-258046 | Prior To Completion,reason Being Beyond Control Of The Lab |
| 24  | 19990305 | RSI-258060 | Prior To Completion At Sponsor Request                     |



***1P - Report Period: APR 1999***  
***Replicate Database Report***

| Components of<br>Replicate<br>Database | APR<br>1999 | All<br>Periods |
|--|-------------|----------------|
| Number of Tests                        | .           | 8              |
| Formulations                           | .           | 4              |
| Labs                                   | .           | 3              |
| Stands                                 | .           | 8              |



***1P - Report Period: APR 1999***  
***by-Formulation Pooled s and Reproducibility of Replicate Data***

| Report Period | Parameter          | Degrees of Freedom | Pooled s | R       |
|---------------|--------------------|--------------------|----------|---------|
| All           | TGC                | 4                  | 6.0220   | 16.862  |
| All           | TLC                | 4                  | 11.0039  | 30.811  |
| All           | WD                 | 4                  | 39.3061  | 110.057 |
| All           | OC                 | 4                  | 0.0955   | 0.267   |
| All           | EOTOC              | 4                  | 0.0521   | 0.146   |
| All           | TGC (Without SA)   | 4                  | 5.4011   | 15.123  |
| All           | TLC (Without SA)   | 4                  | 11.0039  | 30.811  |
| All           | WD (Without SA)    | 4                  | 37.5755  | 105.211 |
| All           | OC (Without SA)    | 4                  | 0.0521   | 0.146   |
| All           | EOTOC (Without SA) | 4                  | 0.0521   | 0.146   |



**IP - Report Period: APR 1999**  
**Pass/Fail**

| Report Period | API Category                   | N   | Number Passed | % Passed |
|---------------|--------------------------------|-----|---------------|----------|
| APR 1999      | All Categories, All Parameters | 35  | 25            | 71.429   |
| APR 1999      | CI-4 - All Parameters          | 35  | 25            | 71.429   |
| APR 1999      | CI-4, EOTOC                    | 35  | 30            | 85.714   |
| APR 1999      | CI-4, EOTOC (Without SA)       | 35  | 30            | 85.714   |
| APR 1999      | CI-4, OC                       | 35  | 33            | 94.286   |
| APR 1999      | CI-4, OC (Without SA)          | 35  | 33            | 94.286   |
| APR 1999      | CI-4, SCUFFING                 | 35  | 35            | 100.000  |
| APR 1999      | CI-4, STUCK_RINGS              | 35  | 35            | 100.000  |
| APR 1999      | CI-4, TGC                      | 35  | 32            | 91.429   |
| APR 1999      | CI-4, TGC (Without SA)         | 35  | 30            | 85.714   |
| APR 1999      | CI-4, TLC                      | 35  | 28            | 80.000   |
| APR 1999      | CI-4, TLC (Without SA)         | 35  | 28            | 80.000   |
| APR 1999      | CI-4, WD                       | 35  | 31            | 88.571   |
| APR 1999      | CI-4, WD (Without SA)          | 35  | 31            | 88.571   |
| All           | All Categories, All Parameters | 136 | 51            | 37.500   |
| All           | CI-4 - All Parameters          | 136 | 51            | 37.500   |
| All           | CI-4, EOTOC                    | 136 | 89            | 65.441   |
| All           | CI-4, EOTOC (Without SA)       | 136 | 89            | 65.441   |
| All           | CI-4, OC                       | 136 | 109           | 80.147   |
| All           | CI-4, OC (Without SA)          | 136 | 108           | 79.412   |
| All           | CI-4, SCUFFING                 | 136 | 83            | 61.029   |
| All           | CI-4, STUCK_RINGS              | 136 | 136           | 100.000  |
| All           | CI-4, TGC                      | 136 | 94            | 69.118   |
| All           | CI-4, TGC (Without SA)         | 136 | 91            | 66.912   |
| All           | CI-4, TLC                      | 136 | 85            | 62.500   |
| All           | CI-4, TLC (Without SA)         | 136 | 85            | 62.500   |



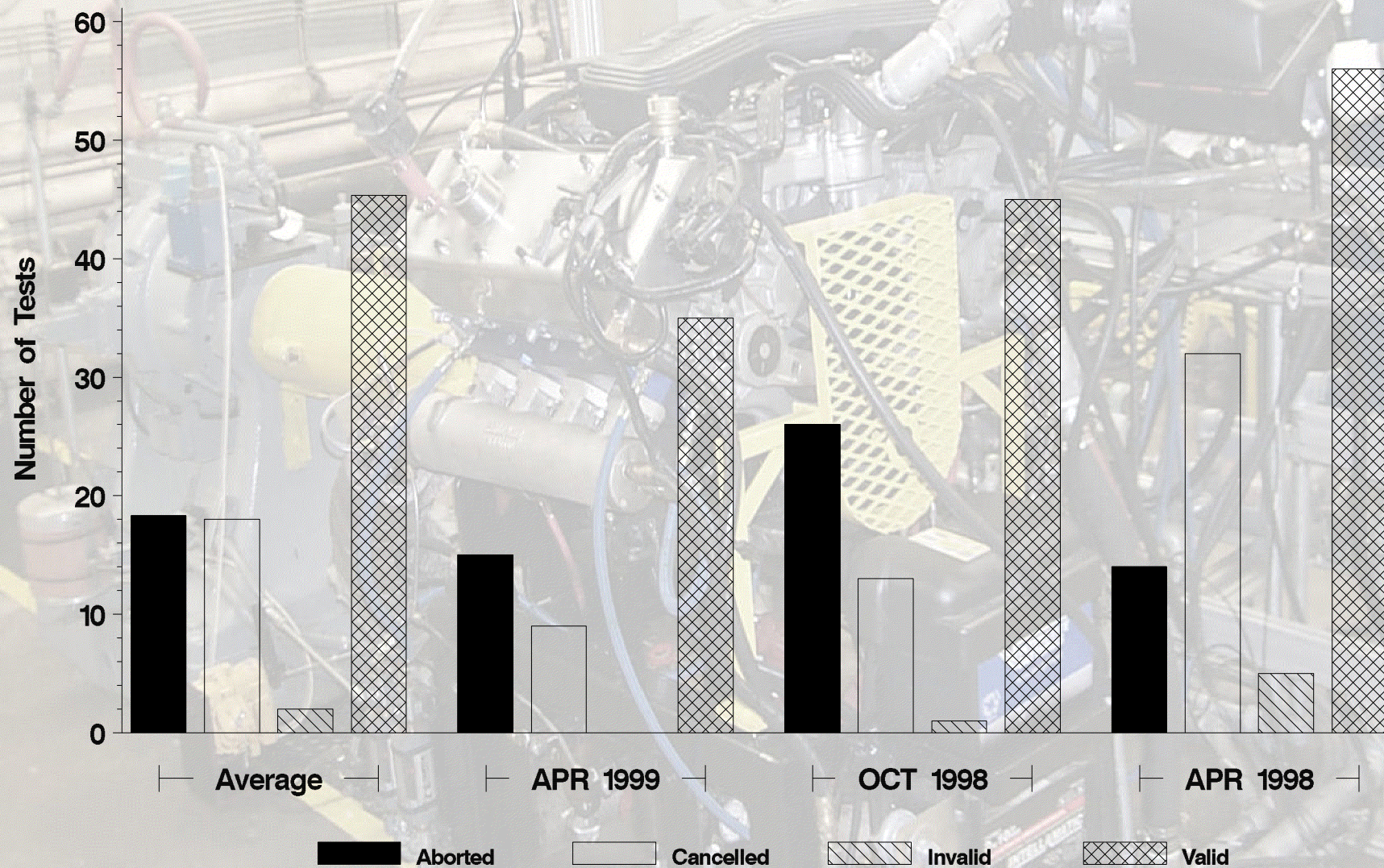
***IP - Report Period: APR 1999***  
***Pass/Fail***

| Report Period | API Category          | N   | Number Passed | % Passed |
|---------------|-----------------------|-----|---------------|----------|
| All           | CI-4, WD              | 136 | 101           | 74.265   |
| All           | CI-4, WD (Without SA) | 136 | 97            | 71.324   |



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## Status of Reported Tests

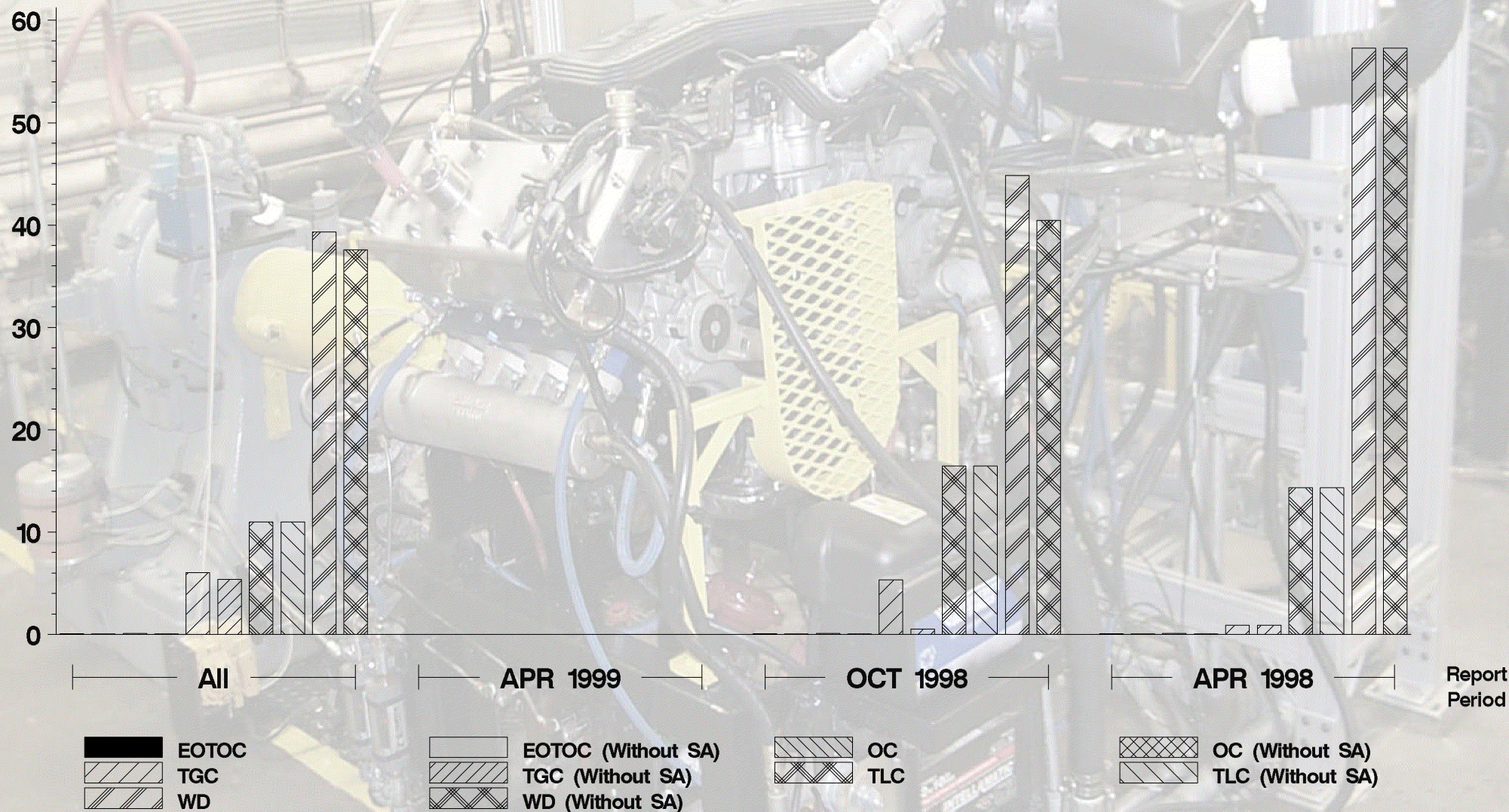


Report  
Period



**1P**

**Candidate Precision as Represented by Pooled S**





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