

***VG - Report Period: OCT 2003***  
***Status Of Reported Tests***

**1**

| STATUS               | COUNT | PERCENT |
|----------------------|-------|---------|
| Aborted              | 7     | 8.235   |
| Cancelled            | 3     | 3.529   |
| Invalid              | 3     | 3.529   |
| Valid                | 72    | 84.706  |
| Total Reported Tests | 85    | 100.000 |

***VG - Report Period: OCT 2003  
Itemized Lost Test Report***

| Obs | Date     | TESTKEY    | REASON                                                                |
|-----|----------|------------|-----------------------------------------------------------------------|
| 1   | 20030423 | RSI-268982 | Operationally Invalid,by Lab                                          |
| 2   | 20030425 | RSI-269005 | Operationally Invalid,lab Declares Invalid                            |
| 3   | 20030512 | RSI-269120 | Operationally Invalid,by Lab                                          |
| 4   | 20030523 | RSI-269163 | Operationally Invalid,by Lab                                          |
| 5   | 20030530 | RSI-269258 | Lab Declaration Of Invalid Test,reason Being Beyondcontrol Of The Lab |
| 6   | 20030603 | RSI-269300 | Operationally Invalid,by Lab                                          |
| 7   | 20030604 | RSI-269313 | Operationally Invalid,by Lab                                          |
| 8   | 20030630 | RSI-269501 | Prior To Completion At Sponsor Request                                |
| 9   | 20030701 | RSI-269462 | Prior To Completion At Sponsor Request                                |
| 10  | 20030714 | RSI-269527 | Prior To Completion At Sponsor Request                                |
| 11  | 20030725 | RSI-269575 | Operationally Invalid,by Lab                                          |
| 12  | 20030904 | RSI-269994 | Operationally Invalid,lab Declares Invalid                            |
| 13  | 20030911 | RSI-270062 | Operationally Invalid,by Lab                                          |

***VG - Report Period: OCT 2003***  
***Replicate Database Report***

| Components of<br>Replicate<br>Database | OCT<br>2003 | All<br>Periods |
|----------------------------------------|-------------|----------------|
| Number of Tests                        | 2           | 19             |
| Formulations                           | 1           | 9              |
| Labs                                   | 1           | 4              |
| Stands                                 | 2           | 12             |

**VG - Report Period: OCT 2003**  
**by-Formulation Pooled s and Reproducibility of Replicate Data**

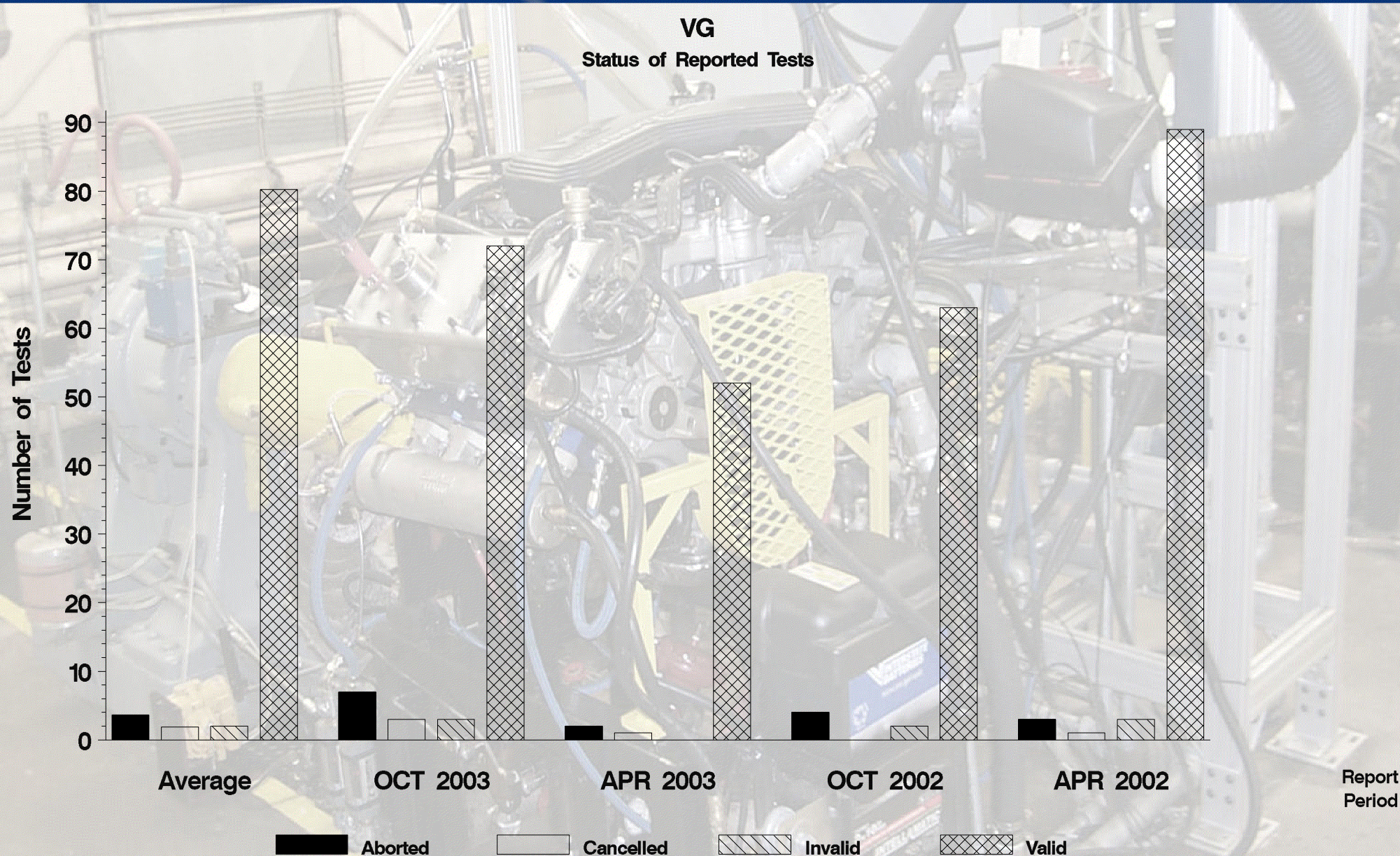
| Report Period | Parameter         | Degrees of Freedom | Pooled s | R       |
|---------------|-------------------|--------------------|----------|---------|
| OCT 2003      | AES               | 1                  | 1.51321  | 4.23698 |
| OCT 2003      | RACS              | 1                  | 0.65054  | 1.82151 |
| OCT 2003      | AEVB              | 1                  | 0.03536  | 0.09899 |
| OCT 2003      | APV               | 1                  | 0.02121  | 0.05940 |
| OCT 2003      | OSCR              | 1                  | 3.10734  | 8.70057 |
| OCT 2003      | AES (Without SA)  | 1                  | 1.51321  | 4.23698 |
| OCT 2003      | RACS (Without SA) | 1                  | 0.65054  | 1.82151 |
| OCT 2003      | AEVB (Without SA) | 1                  | 0.03536  | 0.09899 |
| OCT 2003      | APV (Without SA)  | 1                  | 0.02121  | 0.05940 |
| OCT 2003      | OSCR (Without SA) | 1                  | 1.19174  | 3.33686 |
| All           | AES               | 10                 | 0.69619  | 1.94934 |
| All           | RACS              | 10                 | 0.28299  | 0.79236 |
| All           | AEVB              | 10                 | 0.14052  | 0.39345 |
| All           | APV               | 10                 | 0.26761  | 0.74932 |
| All           | OSCR              | 10                 | 1.26870  | 3.55236 |
| All           | AES (Without SA)  | 10                 | 0.64431  | 1.80408 |
| All           | RACS (Without SA) | 10                 | 0.24124  | 0.67546 |
| All           | AEVB (Without SA) | 10                 | 0.11007  | 0.30819 |
| All           | APV (Without SA)  | 10                 | 0.25607  | 0.71700 |
| All           | OSCR (Without SA) | 10                 | 0.47263  | 1.32336 |



**VG - Report Period: OCT 2003**  
**Pass/Fail**

| Report Period | API Category                   | N   | Number Passed | % Passed |
|---------------|--------------------------------|-----|---------------|----------|
| OCT 2003      | All Categories, All Parameters | 72  | 41            | 56.944   |
| OCT 2003      | GF-4 - All Parameters          | 72  | 41            | 56.944   |
| OCT 2003      | GF-4, AES                      | 72  | 50            | 69.444   |
| OCT 2003      | GF-4, AES (Without SA)         | 72  | 51            | 70.833   |
| OCT 2003      | GF-4, AEVB                     | 72  | 59            | 81.944   |
| OCT 2003      | GF-4, AEVB (Without SA)        | 72  | 60            | 83.333   |
| OCT 2003      | GF-4, APV                      | 72  | 61            | 84.722   |
| OCT 2003      | GF-4, APV (Without SA)         | 72  | 62            | 86.111   |
| OCT 2003      | GF-4, OSCR                     | 72  | 60            | 83.333   |
| OCT 2003      | GF-4, OSCR (Without SA)        | 72  | 59            | 81.944   |
| OCT 2003      | GF-4, RACS                     | 72  | 72            | 100.000  |
| OCT 2003      | GF-4, RACS (Without SA)        | 72  | 72            | 100.000  |
| OCT 2003      | GF-4, STUCK_RINGS              | 72  | 72            | 100.000  |
| All           | All Categories, All Parameters | 642 | 443           | 69.003   |
| All           | GF-4 - All Parameters          | 642 | 443           | 69.003   |
| All           | GF-4, AES                      | 642 | 481           | 74.922   |
| All           | GF-4, AES (Without SA)         | 642 | 480           | 74.766   |
| All           | GF-4, AEVB                     | 642 | 579           | 90.187   |
| All           | GF-4, AEVB (Without SA)        | 642 | 131           | 20.405   |
| All           | GF-4, APV                      | 642 | 600           | 93.458   |
| All           | GF-4, APV (Without SA)         | 642 | 606           | 94.393   |
| All           | GF-4, OSCR                     | 642 | 544           | 84.735   |
| All           | GF-4, OSCR (Without SA)        | 642 | 538           | 83.801   |
| All           | GF-4, RACS                     | 642 | 621           | 96.729   |
| All           | GF-4, RACS (Without SA)        | 642 | 620           | 96.573   |
| All           | GF-4, STUCK_RINGS              | 642 | 641           | 99.844   |

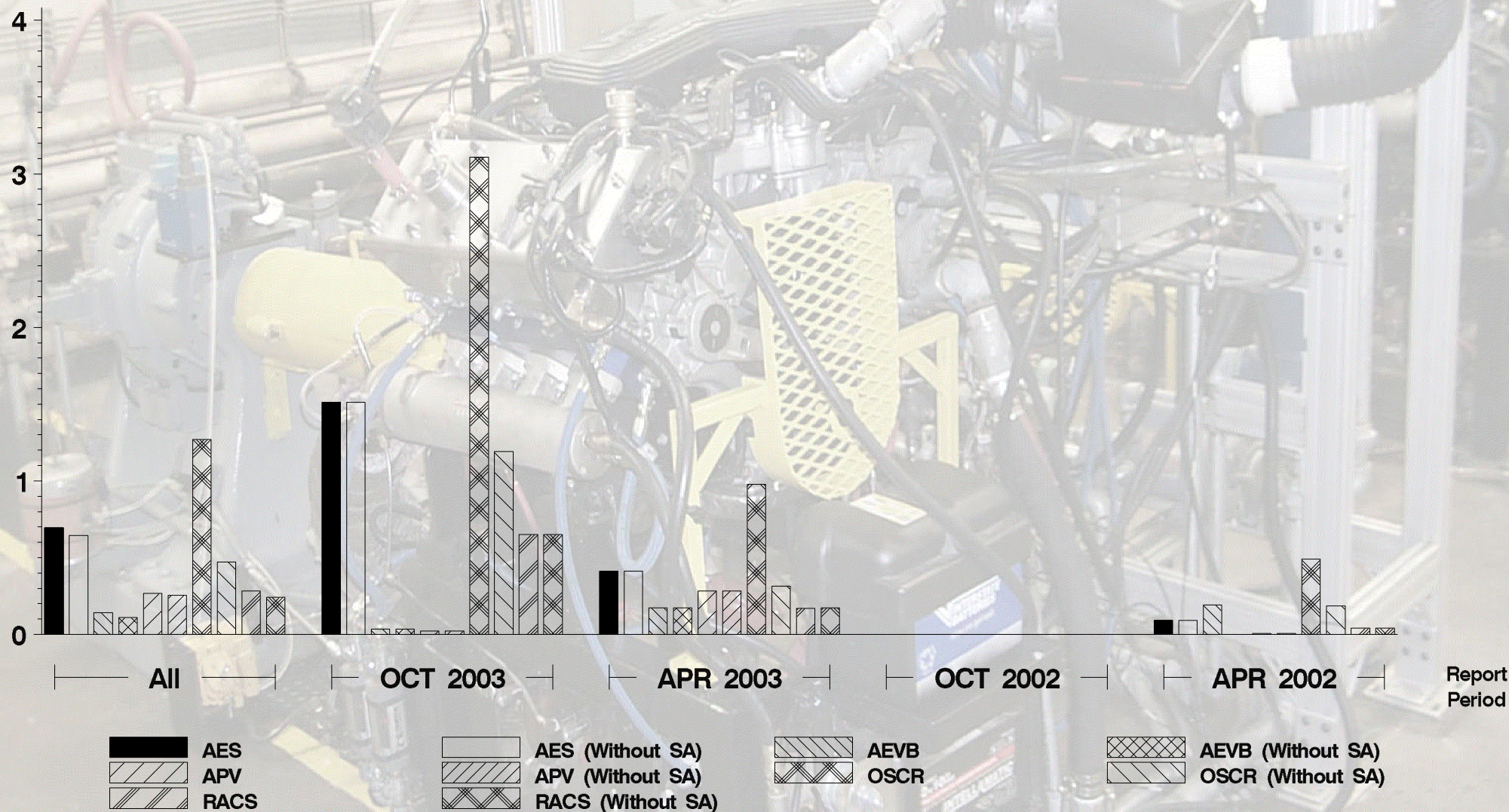






**VG**

**Candidate Precision as Represented by Pooled S**





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