

**1K - Report Period: OCT 2003**  
**Status Of Reported Tests**

**1**

| STATUS               | COUNT | PERCENT |
|----------------------|-------|---------|
| Aborted              | 1     | 6.25    |
| Cancelled            | 1     | 6.25    |
| Invalid              | 1     | 6.25    |
| Valid                | 13    | 81.25   |
| Total Reported Tests | 16    | 100.00  |

**1K - Report Period: OCT 2003**  
**Itemized Lost Test Report**

| Obs | Date     | TESTKEY    | REASON                                                                |
|-----|----------|------------|-----------------------------------------------------------------------|
| 1   | 20030404 | RSI-268820 | Lab Declaration Of Invalid Test,reason Being Beyondcontrol Of The Lab |
| 2   | 20030604 | RSI-269291 | Prior To Completion,reason Being Beyond Control Of The Lab            |
| 3   | 20030918 | RSI-270115 | Prior To Completion At Sponsor Request                                |

**1K - Report Period: OCT 2003**  
**Replicate Database Report**

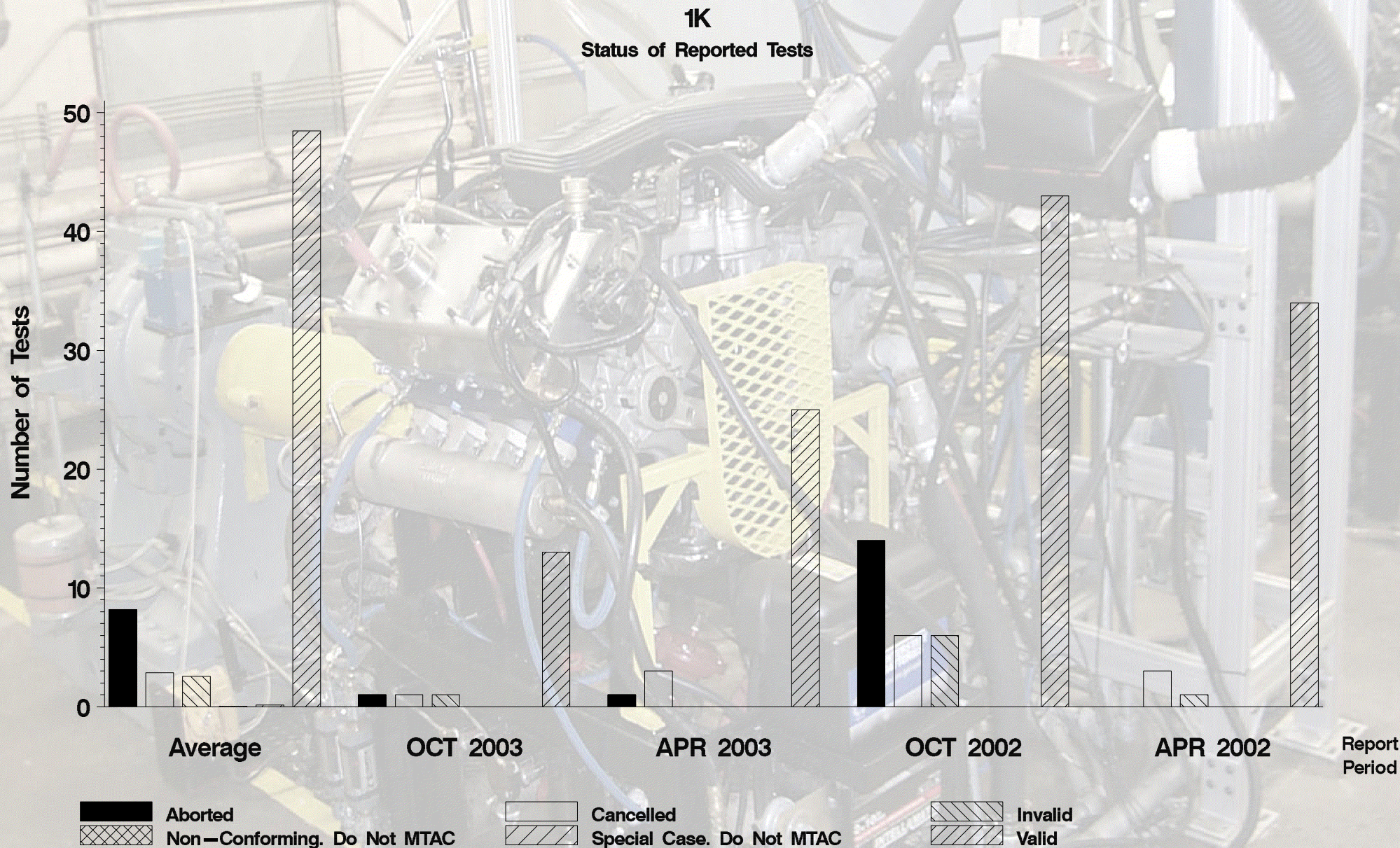
| Components of Replicate Database | OCT 2003 | All Periods |
|----------------------------------|----------|-------------|
| Number of Tests                  | 2        | 237         |
| Formulations                     | 2        | 104         |
| Labs                             | 1        | 8           |
| Stands                           | 2        | 45          |

**1K - Report Period: OCT 2003**  
**by-Formulation Pooled s and Reproducibility of Replicate Data**

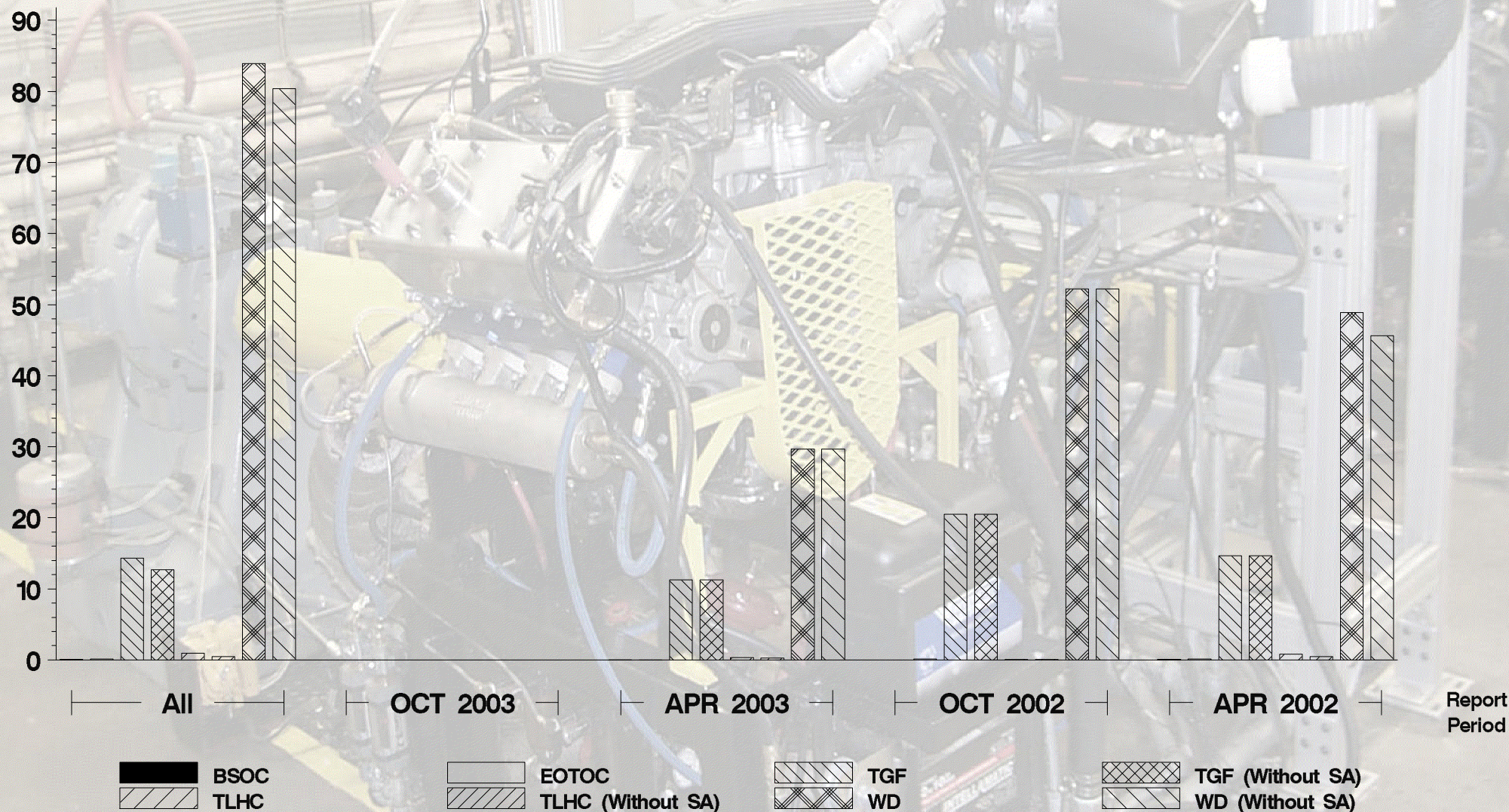
| Report Period | Parameter         | Degrees of Freedom | Pooled s | R       |
|---------------|-------------------|--------------------|----------|---------|
| OCT 2003      | TGF               | 0                  | 0.0000   | 0.000   |
| OCT 2003      | WD                | 0                  | 0.0000   | 0.000   |
| OCT 2003      | TLHC              | 0                  | 0.0000   | 0.000   |
| OCT 2003      | BSOC              | 0                  | 0.0000   | 0.000   |
| OCT 2003      | EOTOC             | 0                  | 0.0000   | 0.000   |
| OCT 2003      | TGF (Without SA)  | 0                  | 0.0000   | 0.000   |
| OCT 2003      | WD (Without SA)   | 0                  | 0.0000   | 0.000   |
| OCT 2003      | TLHC (Without SA) | 0                  | 0.0000   | 0.000   |
| All           | TGF               | 133                | 14.3177  | 40.090  |
| All           | WD                | 133                | 83.9183  | 234.971 |
| All           | TLHC              | 133                | 0.9192   | 2.574   |
| All           | BSOC              | 133                | 0.0652   | 0.182   |
| All           | TGF (Without SA)  | 133                | 12.6568  | 35.439  |
| All           | WD (Without SA)   | 133                | 80.3735  | 225.046 |
| All           | TLHC (Without SA) | 133                | 0.4619   | 1.293   |
| All           | EOTOC             | 132                | 0.1256   | 0.352   |

**1K - Report Period: OCT 2003**  
**Pass/Fail**

| Report Period | API Category                   | N   | Number Passed | % Passed |
|---------------|--------------------------------|-----|---------------|----------|
| OCT 2003      | All Categories, All Parameters | 13  | 10            | 76.923   |
| OCT 2003      | CI-4 - All Parameters          | 13  | 10            | 76.923   |
| OCT 2003      | CI-4, BSOC                     | 13  | 13            | 100.000  |
| OCT 2003      | CI-4, EOTOC                    | 13  | 12            | 92.308   |
| OCT 2003      | CI-4, SCUFFING                 | 13  | 13            | 100.000  |
| OCT 2003      | CI-4, STUCK_RINGS              | 13  | 13            | 100.000  |
| OCT 2003      | CI-4, TGF                      | 13  | 12            | 92.308   |
| OCT 2003      | CI-4, TGF (Without SA)         | 13  | 12            | 92.308   |
| OCT 2003      | CI-4, TLHC                     | 13  | 10            | 76.923   |
| OCT 2003      | CI-4, TLHC (Without SA)        | 13  | 10            | 76.923   |
| OCT 2003      | CI-4, WD                       | 13  | 11            | 84.615   |
| OCT 2003      | CI-4, WD (Without SA)          | 13  | 11            | 84.615   |
| All           | All Categories, All Parameters | 969 | 256           | 26.419   |
| All           | CI-4 - All Parameters          | 969 | 256           | 26.419   |
| All           | CI-4, BSOC                     | 969 | 955           | 98.555   |
| All           | CI-4, EOTOC                    | 969 | 912           | 94.118   |
| All           | CI-4, SCUFFING                 | 969 | 497           | 51.290   |
| All           | CI-4, STUCK_RINGS              | 969 | 501           | 51.703   |
| All           | CI-4, TGF                      | 969 | 642           | 66.254   |
| All           | CI-4, TGF (Without SA)         | 969 | 793           | 81.837   |
| All           | CI-4, TLHC                     | 969 | 746           | 76.987   |
| All           | CI-4, TLHC (Without SA)        | 969 | 865           | 89.267   |
| All           | CI-4, WD                       | 969 | 838           | 86.481   |
| All           | CI-4, WD (Without SA)          | 969 | 886           | 91.434   |



**1K**  
**Candidate Precision as Represented by Pooled S**



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