

Status Of Reported Tests

| STATUS               | COUNT | PERCENT |
|----------------------|-------|---------|
| Cancelled            | 1     | 12.5    |
| Valid                | 7     | 87.5    |
| Total Reported Tests | 8     | 100.0   |

Itemized Lost Test Report

| Obs | Date     | TESTKEY   | REASON                             |
|-----|----------|-----------|------------------------------------|
| 1   | 20231219 | ACC-34928 | Test Terminated At Sponsor Request |

Replicate Database Report

| Components of Replicate Database | APR 2024 | All Periods |
|----------------------------------|----------|-------------|
| Number of Tests                  | .        | 12          |
| Formulations                     | .        | 6           |
| Labs                             | .        | 4           |
| Stands                           | .        | 8           |

by-Formulation Pooled s and Reproducibility of Replicate Data

| Report Period | Parameter | Degrees of Freedom | Pooled s | R       |
|---------------|-----------|--------------------|----------|---------|
| All           | DPBFNL    | 6                  | 0.9390   | 2.6292  |
| All           | CLWFLNL   | 6                  | 2.9635   | 8.2979  |
| All           | ATRWLFNL  | 6                  | 29.2147  | 81.8012 |

Pass/Fail  
DPBFNL <=30.0 CLWFNL <=120

| Report Period | API Category                   | N   | Number Passed | % Passed |
|---------------|--------------------------------|-----|---------------|----------|
| APR 2024      | All Categories, All Parameters | 7   | 0             | 0.000    |
| APR 2024      | CH-4 - All Parameters          | 7   | 0             | 0.000    |
| APR 2024      | CH-4, ATRWLFNL                 | 7   | 0             | 0.000    |
| APR 2024      | CH-4, CLWFNL                   | 7   | 7             | 100.000  |
| APR 2024      | CH-4, DPBFNL                   | 7   | 6             | 85.714   |
| All           | All Categories, All Parameters | 817 | 226           | 27.662   |
| All           | CH-4 - All Parameters          | 817 | 226           | 27.662   |
| All           | CH-4, ATRWLFNL                 | 817 | 398           | 48.715   |
| All           | CH-4, CLWFNL                   | 817 | 817           | 100.000  |
| All           | CH-4, DPBFNL                   | 817 | 445           | 54.468   |

# ACC Monitoring Agency

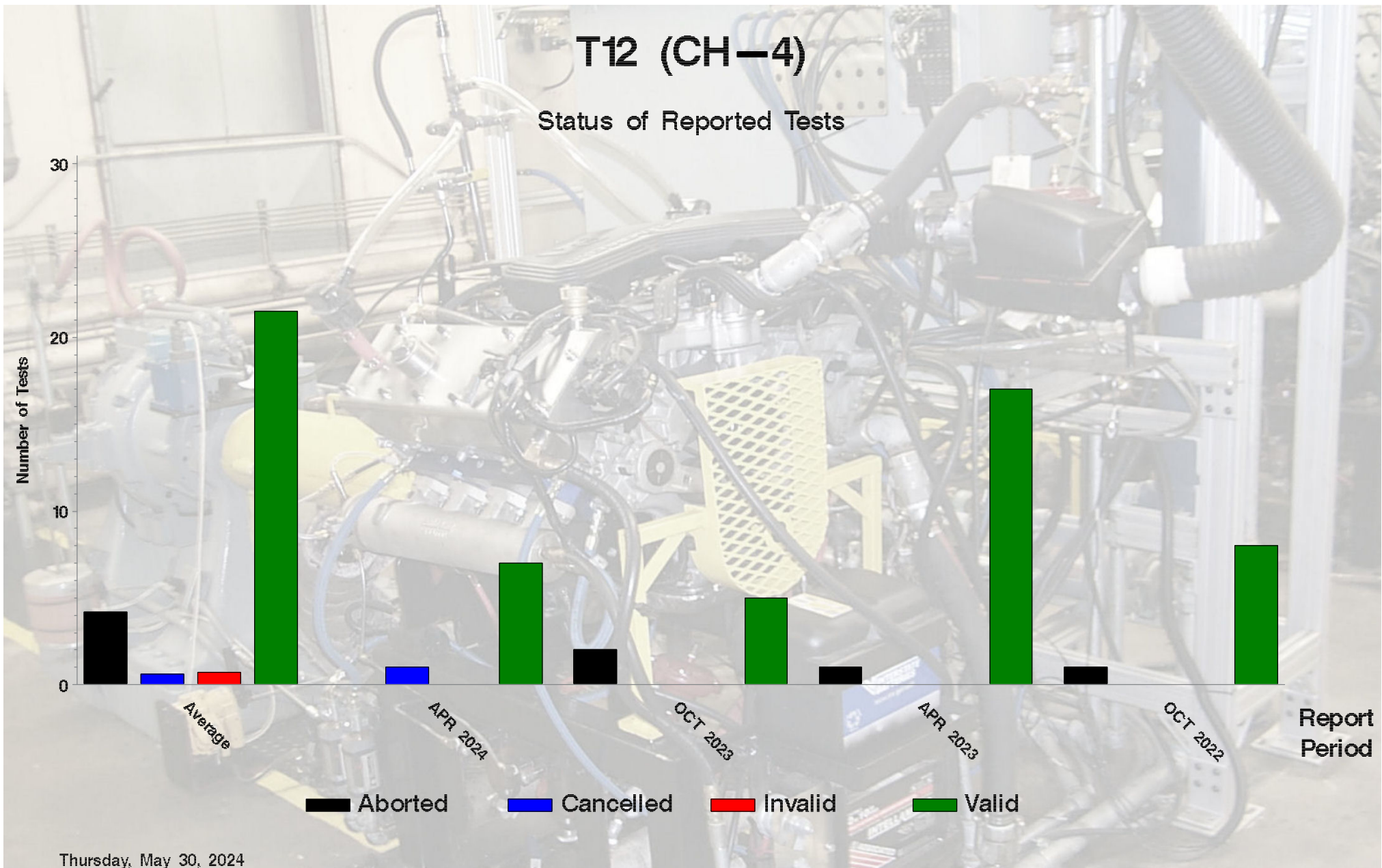
203 Armstrong Drive, Freeport, PA 16229, USA

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412-365-1000

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# ACC Monitoring Agency

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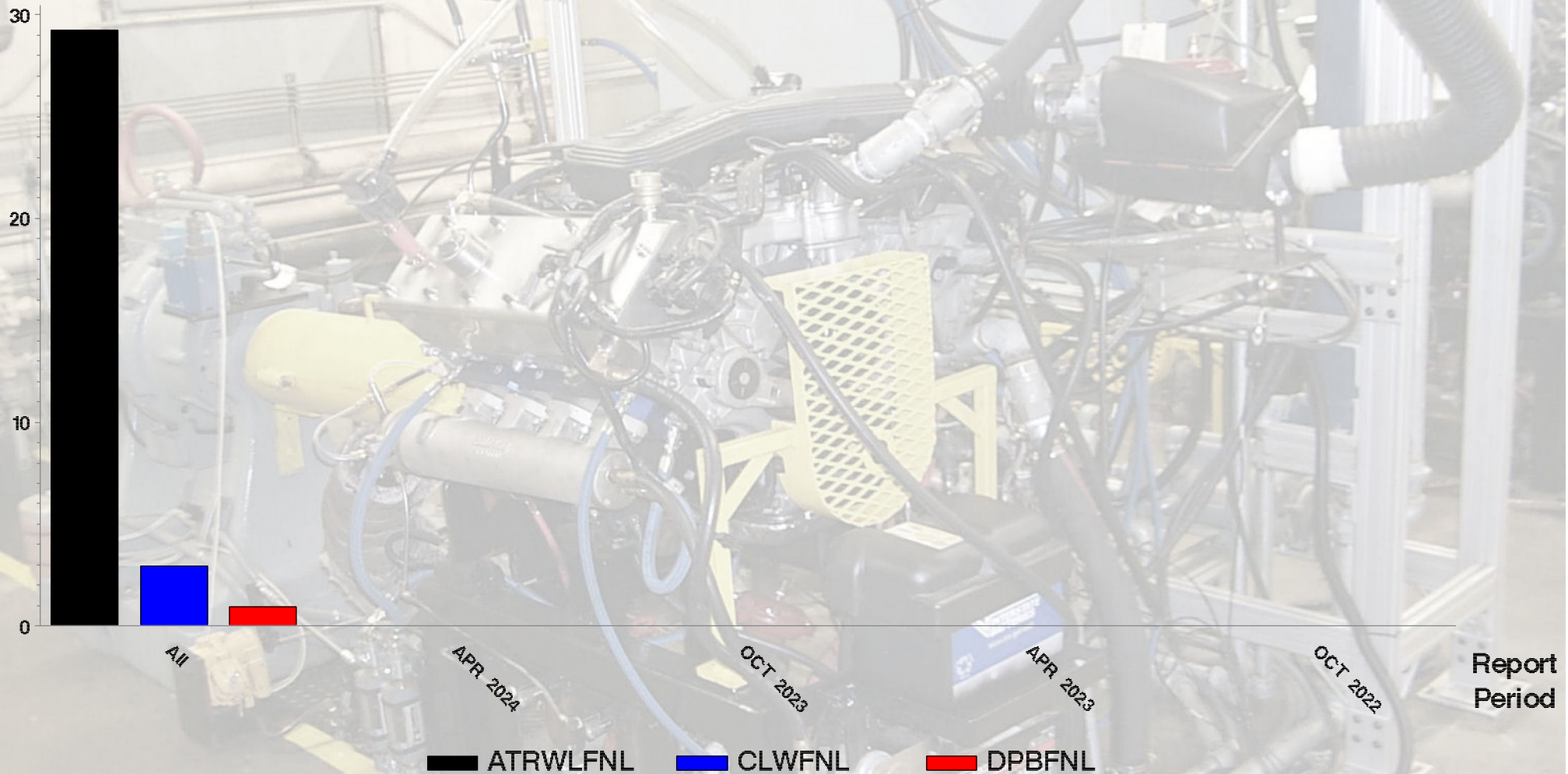
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## T12 (CH-4)

Candidate Precision as Represented by Pooled S



Thursday, May 30, 2024