

***1P - Report Period: OCT 2016***  
***Status Of Reported Tests***

| STATUS               | COUNT | PERCENT |
|----------------------|-------|---------|
| Valid                | 6     | 100     |
| Total Reported Tests | 6     | 100     |

***1P - Report Period: OCT 2016***  
***Replicate Database Report***

| Components of<br>Replicate<br>Database | OCT<br>2016 | All<br>Periods |
|----------------------------------------|-------------|----------------|
| Number of Tests                        | .           | 40             |
| Formulations                           | .           | 19             |
| Labs                                   | .           | 4              |
| Stands                                 | .           | 15             |

**1P - Report Period: OCT 2016**  
**by-Formulation Pooled s and Reproducibility of Replicate Data**

| Report Period | Parameter          | Degrees of Freedom | Pooled s | R       |
|---------------|--------------------|--------------------|----------|---------|
| All           | TGC                | 21                 | 5.8417   | 16.357  |
| All           | TLC                | 21                 | 9.0181   | 25.251  |
| All           | WD                 | 21                 | 40.6875  | 113.925 |
| All           | OC                 | 21                 | 0.2033   | 0.569   |
| All           | EOTOC              | 21                 | 0.1203   | 0.337   |
| All           | TGC (Without SA)   | 21                 | 6.1554   | 17.235  |
| All           | TLC (Without SA)   | 21                 | 8.6465   | 24.210  |
| All           | WD (Without SA)    | 21                 | 41.3067  | 115.659 |
| All           | OC (Without SA)    | 21                 | 0.2035   | 0.570   |
| All           | EOTOC (Without SA) | 21                 | 0.1044   | 0.292   |

**1P - Report Period: OCT 2016**  
**Pass/Fail**

| Report Period | API Category                   | N   | Number Passed | % Passed |
|---------------|--------------------------------|-----|---------------|----------|
| OCT 2016      | All Categories, All Parameters | 6   | 5             | 83.333   |
| OCT 2016      | CI-4 - All Parameters          | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, EOTOC                    | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, EOTOC (Without SA)       | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, OC                       | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, OC (Without SA)          | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, SCUFFING                 | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, STUCK_RINGS              | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, TGC                      | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, TGC (Without SA)         | 6   | 6             | 100.000  |
| OCT 2016      | CI-4, TLC                      | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, TLC (Without SA)         | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, WD                       | 6   | 5             | 83.333   |
| OCT 2016      | CI-4, WD (Without SA)          | 6   | 5             | 83.333   |
| All           | All Categories, All Parameters | 370 | 226           | 61.081   |
| All           | CI-4 - All Parameters          | 370 | 226           | 61.081   |
| All           | CI-4, EOTOC                    | 370 | 304           | 82.162   |
| All           | CI-4, EOTOC (Without SA)       | 370 | 290           | 78.378   |
| All           | CI-4, OC                       | 370 | 337           | 91.081   |
| All           | CI-4, OC (Without SA)          | 370 | 329           | 88.919   |
| All           | CI-4, SCUFFING                 | 370 | 314           | 84.865   |
| All           | CI-4, STUCK_RINGS              | 370 | 369           | 99.730   |
| All           | CI-4, TGC                      | 370 | 303           | 81.892   |
| All           | CI-4, TGC (Without SA)         | 370 | 294           | 79.459   |
| All           | CI-4, TLC                      | 370 | 279           | 75.405   |

***1P - Report Period: OCT 2016***  
***Pass/Fail***

| Report Period | API Category           | N   | Number Passed | % Passed |
|---------------|------------------------|-----|---------------|----------|
| All           | CI-4, TLC (Without SA) | 370 | 279           | 75.405   |
| All           | CI-4, WD               | 370 | 294           | 79.459   |
| All           | CI-4, WD (Without SA)  | 370 | 287           | 77.568   |



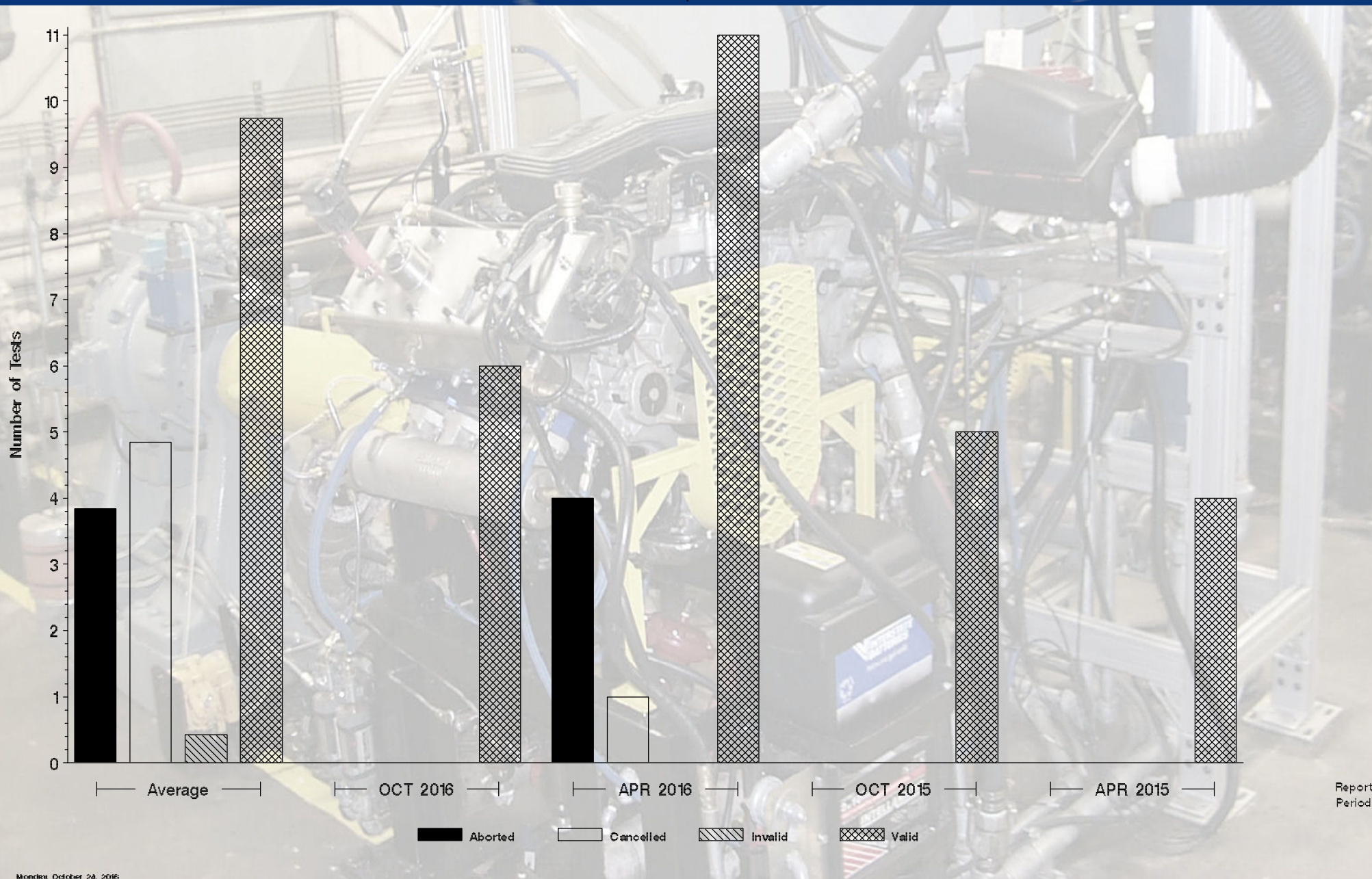
# Monitoring Agency

6555 Penn Avenue, Pittsburgh, PA 15206

<https://acc-ma.org>

1P

Status of Reported Tests







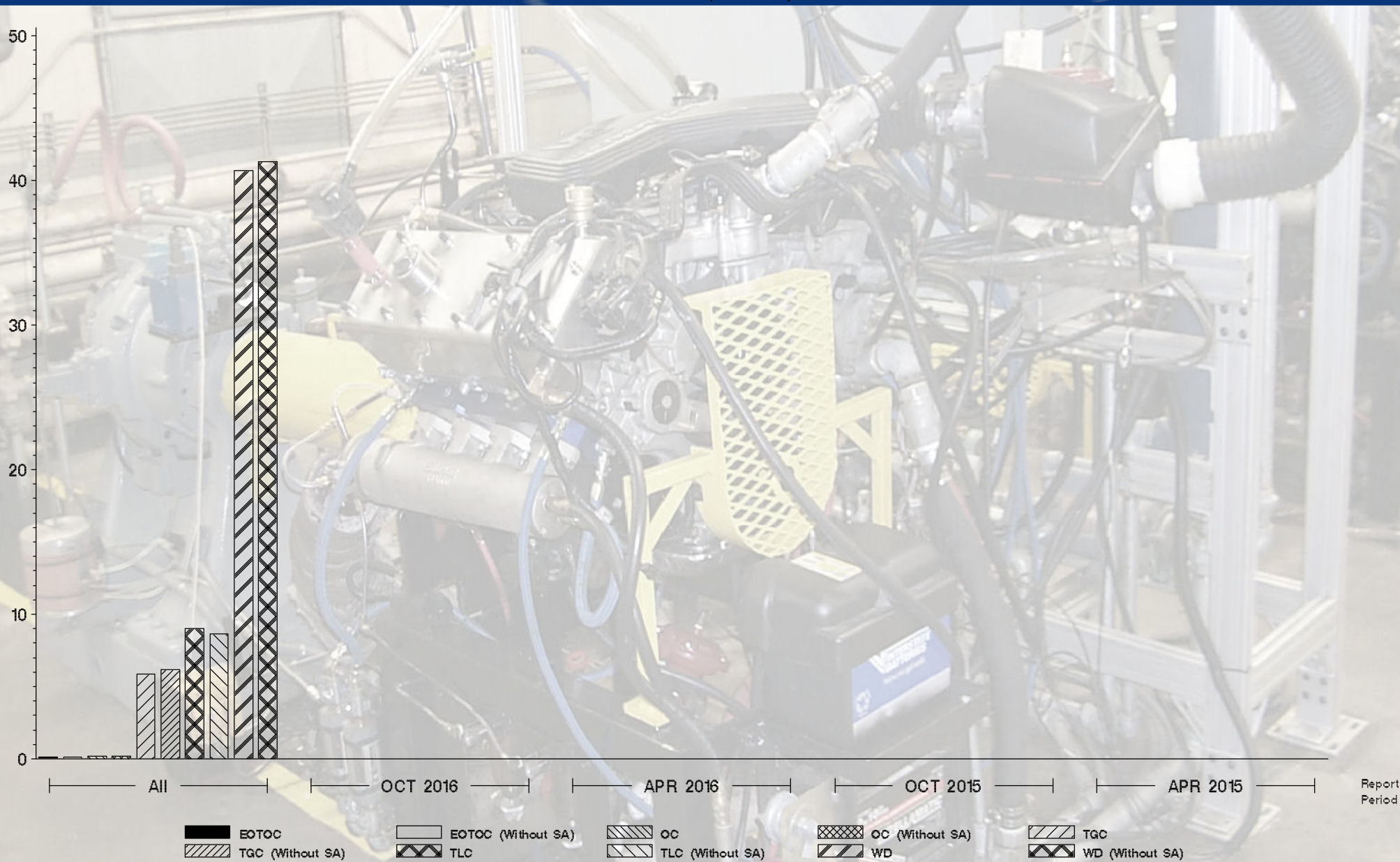
# Monitoring Agency

6555 Penn Avenue, Pittsburgh, PA 15206

<https://acc-ma.org>

1P

Candidate Precision as Represented by Pooled S





# Monitoring Agency

6555 Penn Avenue, Pittsburgh, PA 15206

<https://acc-ma.org>

1P

Candidate Precision as Represented by Pooled S

