**USDA/GIPSA Proficiency Program**
**Testing for the Presence of Biotechnology Events in Corn and Soybeans**
**May 2008 Sample Distribution Results**

**Purpose of USDA/GIPSA Proficiency Program**
Through the USDA/GIPSA Proficiency Program, USDA seeks to improve the overall performance of testing for biotechnology-derived grains and oil seeds. The USDA/GIPSA Proficiency Program helps organizations identify areas of concern and take corrective actions to improve testing accuracy, capability and reliability.

**Program Description**

In this round of the USDA/GIPSA Proficiency Program one set of samples was used for both qualitative and quantitative analyses. The samples were fortified with various combinations and concentrations of transgenic traits, and participants had the choice of providing qualitative and/or quantitative results. Scoring of the participant's qualitative results was done by computing the "percentage of correctly reported transgenic traits" in the samples (Tables 1 to 34, and Figure 1). The "percentage false positive" and "percentage false negative" were calculated by dividing the number of incorrectly reported results by the number of "provided negatives" or "provided positives" that were distributed to the participants. To assess accuracy of individual participant's submitted quantitative results for a tested transgenic event, z-scores (based on: reported value – fortification value / standard deviation) were computed for each reported quantification result (Tables 35 to 47). Prior to computing the z-scores, outliers in the distribution of values were eliminated by use of the Grubb's Test for Outliers. To evaluate the performance as a group (i.e., inter-laboratory variation), a summary table (Table 48) was prepared to show the accuracy and precision of the composite quantification results at each fortification level for the various transgenic events.

**Sample Composition**
The corn samples contained various combinations and concentrations of the following transgenic traits: T25, CBH351, MON810, GA21, E176, Bt11, NK603, Herculex, MON863, Herculex RW, and MIR 604; or, no events (i.e., negative corn sample). The various transgenic concentration levels were produced on a percentage weight-weight basis (%w/w). A calculated amount of ground transgenic corn was blended to homogeniety with a calculated amount of non-transgenic corn to produce concentrations from 0.1%w/w to 5.0%w/w of the event. The soybean samples were either non-transgenic soybeans, or fortified soybean samples containing 0.5%w/w or 2.5%w/w of the transgenic glyphosate-tolerant soybeans (RoundUp Ready®). Each participant received six corn and three soybean samples. Each sample contained approximately 20 grams of ground material.

**Program Participants**
Participants included organizations from Africa, Asia, Europe, North America, and South America. Each participant received a study description and a data report form by electronic mail, and included with the samples. Participants submitted results by electronic mail, FAX, or regular mail. No analytical methodologies were specified, and organizations used both DNA- and protein-based testing technologies. Forty-seven organizations participated in the May 2008 round of proficiency testing.

- Seventeen participants submitted **qualitative** results only,
- Eighteen submitted **quantitative** results only, and
- Twenty-eight participants submitted a combination of **qualitative** and **quantitative** results.

In this report, participating organizations are identified by a confidential "Participant Identification Number." Appendix I identifies those organizations who gave GIPSA permission to list them as participants in the USDA/GIPSA Proficiency Program; some organizations participated but requested their identity to remain confidential.

**Data Summary Results**

Data submitted by the participants are summarized in this report primarily in tables and figures. Participants reported their results on a qualitative basis, quantitative basis, or a combination of both qualitative and quantitative bases. Qualitative results were reported as the presence or absence of a particular event in each sample. Quantitative results were reported as the concentration of a particular event in the sample. Due to the complexity of the data, this report summarizes the data as follows:

**Qualitative Data Summaries.** This section summarizes qualitative sample analysis data:

- Table 1: Qualitative results for corn fortified with 35S for all participants (DNA-based assays).

- Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants.

- Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays).

- Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.

- Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays).

- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T25 for all participants.

- Table 7: Qualitative results for corn fortified CBH351 with for all participants (DNA-based assays).

- Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports for CBH351 for all participants.

- Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays).

- Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports for MON810 for all participants.

- Table 11: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays).

- Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports for GA21 for all participants.

- Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays).

- Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt176 for all participants.

- Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays).

- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt11 for all participants.

- Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays).

- Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports for NK603 for all participants.

- Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays).

- Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex for all participants.

- Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays).

- Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports for MON863 for all participants.

- Table 23: Qualitative results for soybeans fortified with Herculex RW for all participants (DNA-based assays).

- Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex RW for all participants.

- Table 25: Qualitative results for soybeans fortified with MIR604 for all participants (DNA-based assays).

- Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR604 for all participants.

- Table 27: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).

- Table 28: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays).

- Table 29: Percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays).

- Figure 1: Group average of percentage correct for Qualitative reports on each event (DNA-based assays).

- Table 30: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) for Participant #1843 (only this participant submitted results).

- Table 31: Qualitative results for soybeans fortified with CP4EPSPS (RUR) for all participants using Lateral Flow Strip (LFS) Testing.

- Table 32: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing.

- Table 33: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

- Table 34: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).


**Quantitative Data Summaries.** This section summarizes quantitative sample analysis data:

- Table 35: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).

- Table 36: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).

**Table 1: Qualitative results for corn fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| 35S Participant Number | Sample 1 N | Sample 2 P | Sample 3 P | Sample 4 P | Sample 5 P | Sample 6 P |
|---|---|---|---|---|---|---|
| 1752 | N | P | P | P | P | P |
| 1754 | N | P | P | P | P | P |
| 1755 | N | P | P | P | P | P |
| 1764 | N | P | P | P | P | P |
| 1774 | N | P | P | P | P | P |
| 1778 | N | P | P | P | P | P |
| 1785 | N | P | P | P | P | P |
| 1844 | N | P | P | P | P | P |
| 1847 | N | P | P | P | P | P |
| 1858 | N | P | P | P | P | P |
| 1870 | N | P | P | P | P | P |
| 1891 | N | P | P | P | P | P |
| 1892 | N | P | P | P | P | P |
| 2032 | N | P | P | P | P | P |
| 2034 | N | P | P | P | P | P |
| 2044 | N | P | P | P | P | P |
| 2045 | N | P | P | P | P | P |
| 2057 | N | P | P | P | P | P |
| 2075 | N | P | P | P | P | P |
| 2076 | **P** | **N** | P | P | P | P |
| 2095 | N | P | P | P | P | P |
| 2100 | N | P | P | P | P | P |
| 2108 | N | P | P | P | P | P |
| 2112 | N | P | P | P | P | P |
| 2126 | N | P | P | P | P | P |
| 2132 | N | P | P | P | P | P |
| 2675 | N | P | P | P | P | P |
| 2691 | N | P | P | P | P | P |
| 2692 | N | P | P | P | P | P |
| 2694 | N | P | P | P | P | P |
| 2716 | N | P | P | P | P | P |
| 2717 | N | P | P | P | P | P |
| 2719 | N | P | P | P | P | P |
| 2720 | **P** | P | P | P | P | **N** |
| 2723 | N | P | P | P | P | P |
| 2724 | N | P | P | P | P | P |
| 2808 | **P** | **N** | **N** | P | P | P |
|  |  |  |  |  |  |  |
| N, Results | 37 | 37 | 37 | 37 | 37 | 37 |
| # Negative | 34 | 2 | 1 | 0 | 0 | 1 |
| # Positive | 3 | 35 | 36 | 37 | 37 | 36 |
| % Correct | 91.9% | 94.6% | 97.3% | 100.0% | 100.0% | 97.3% |
| % Incorrect | 8.1% | 5.4% | 2.7% | 0.0% | 0.0% | 2.7% |

**Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports for 35S for all participants.**

| | |
|---|---|
| **Total # Reported results** | 222 |
| **# Incorrect** | 7 |
| **% Correct** | 96.8% |
| **# Provided Positives (P)** | 185 |
| **# False Negative** | 4 |
| **% False Negative** | 2.2% |
| **# Provided Negatives (N)** | 37 |
| **# False Positive** | 3 |
| **% False Positive** | 8.1% |

**Table 3: Qualitative results for corn fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| NOS | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| **Participant Number** | **N** | **P** | **P** | **P** | **P** | **P** |
| **1752** | N | P | P | P | P | P |
| **1754** | N | P | P | P | P | P |
| **1755** | N | P | P | P | P | P |
| **1764** | N | P | P | P | P | P |
| **1774** | N | P | P | P | P | P |
| **1778** | N | P | P | P | P | P |
| **1785** | N | P | P | P | P | P |
| **1844** | N | P | P | P | P | P |
| **1847** | N | P | P | P | P | P |
| **1858** | N | P | P | P | P | P |
| **1870** | N | P | P | P | P | P |
| **1891** | N | P | P | P | P | P |
| **1892** | N | P | P | P | P | P |
| **2032** | N | P | P | P | P | P |
| **2034** | N | P | P | P | P | P |
| **2044** | N | P | P | P | P | P |
| **2057** | N | P | P | P | P | P |
| **2095** | N | P | P | P | P | P |
| **2100** | N | P | P | P | P | P |
| **2108** | N | P | P | P | P | P |
| **2112** | N | P | P | P | P | P |
| **2126** | N | P | P | P | P | P |
| **2132** | N | P | P | P | P | P |
| **2675** | N | P | P | P | P | P |
| **2691** | N | P | P | P | P | P |
| **2692** | N | P | P | P | P | P |
| **2694** | N | P | P | P | P | P |
| **2716** | N | P | P | P | P | P |
| **2717** | N | P | P | P | P | P |
| **2719** | N | P | P | P | P | P |
| **2723** | N | P | P | P | P | P |
| **2724** | N | P | P | P | P | P |
| **2808** | **P** | P | P | **N** | P | **N** |
| | | | | | | |
| **N, Results** | 33 | 33 | 33 | 33 | 33 | 33 |
| **# Negative** | 32 | 0 | 0 | 1 | 0 | 1 |
| **# Positive** | 1 | 33 | 33 | 32 | 33 | 32 |
| **% Correct** | 97.0% | 100.0% | 100.0% | 97.0% | 100.0% | 97.0% |
| **% Incorrect** | 3.0% | 0.0% | 0.0% | 3.0% | 0.0% | 3.0% |

**Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports for NOS for all participants.**

| | |
|---|---|
| Total # Reported results | 198 |
| # Incorrect | 3 |
| % Correct | 98.5% |
| # Provided Positives (P) | 165 |
| # False Negative | 2 |
| % False Negative | 1.2% |
| # Provided Negatives (N) | 33 |
| # False Positive | 1 |
| % False Positive | 3.0% |

**Table 5: Qualitative results for corn fortified with T25 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| T25 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| Participant Number | 0.0% | 0.0% | 0.0% | 0.1% | 1.5% | 0.4% |
| 1752 | N | N | N | P | P | P |
| 1773 | N | N | N | P | P | P |
| 1774 | N | **P** | N | P | P | P |
| 1785 | N | N | N | P | P | P |
| 1844 | N | N | N | P | P | P |
| 1859 | N | N | N | P | P | P |
| 1892 | N | N | N | P | P | P |
| 2032 | N | **P** | N | P | P | P |
| 2034 | N | **P** | **P** | **N** | P | P |
| 2060 | N | **P** | N | **N** | P | P |
| 2075 | N | **P** | N | **N** | P | P |
| 2126 | N | N | N | **N** | **N** | P |
| 2132 | N | N | N | P | P | P |
| 2692 | N | N | N | P | P | P |
| 2694 | N | N | N | P | P | P |
| | | | | | | |
| N, Results | 15 | 15 | 15 | 15 | 15 | 15 |
| # Negative | 15 | 10 | 14 | 4 | 1 | 0 |
| # Positive | 0 | 5 | 1 | 11 | 14 | 15 |
| % Correct | 100.0% | 66.7% | 93.3% | 73.3% | 93.3% | 100.0% |
| % Incorrect | 0.0% | 33.3% | 6.7% | 26.7% | 6.7% | 0.0% |

**Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T25 for all participants.**

| | |
|---|---|
| Total # Reported results | 90 |
| # Incorrect | 11 |
| % Correct | 87.8% |
| # Provided Positives | 45 |
| # False Negative | 5 |
| % False Negative | 11.1% |
| # Provided Negatives | 45 |
| # False Positive | 6 |
| % False Positive | 13.3% |

**Table 7: Qualitative results for corn fortified CBH351 with for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| CBH351 | Sample 1 | Sample 3 | Sample 4 | Sample 5 |
|---|---|---|---|---|
| **Participant Number** | **0.0%** | **3.0%** | **0.0%** | **0.5%** |
| **1752** | N | P | N | P |
| **1773** | N | P | N | P |
| **1774** | N | P | N | P |
| **1785** | N | P | N | P |
| **1844** | N | P | N | P |
| **1859** | N | P | N | P |
| **1891** | N | P | N | P |
| **1892** | N | P | N | P |
| **2032** | N | P | N | P |
| **2034** | N | P | N | **N** |
| **2675** | N | P | N | P |
| **2692** | N | P | N | P |
| **2692** | N | P | N | P |
| | | | | |
| **N, Results** | 13 | 13 | 13 | 13 |
| **# Negative** | 13 | 0 | 0 | 1 |
| **# Positive** | 0 | 13 | 13 | 12 |
| **% Correct** | 100.0% | 100.0% | 100.0% | 92.3% |
| **% Incorrect** | 0.0% | 0.0% | 0.0% | 7.7% |

*Data from Sample 2 (0.4% fortification) and Sample 6 (0.4% fortification) have been eliminated from the table and from the analysis of data due to inconsistencies in the reported quantifications.*

**Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports for CBH351 for all participants.**

| | |
|---|---|
| **Total # Reported results** | 52 |
| **# Incorrect** | 1 |
| **% Correct** | 98.1% |
| **# Provided Positives** | 26 |
| **# False Negative** | 1 |
| **% False Negative** | 3.8% |
| **# Provided Negatives** | 26 |
| **# False Positive** | 0 |
| **% False Positive** | 0.0% |

**Table 9: Qualitative results for corn fortified with MON810 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| MON810 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| Participant Number | 0.0% | 0.0% | 1.5% | 5.0% | 0.1% | 0.4% |
| 1752 | N | N | P | P | P | P |
| 1773 | N | N | P | P | P | P |
| 1774 | N | N | P | P | P | P |
| 1785 | N | N | P | P | P | P |
| 1844 | N | N | P | P | P | P |
| 1859 | N | N | P | P | P | P |
| 1862 | N | N | P | P | **N** | P |
| 1892 | N | N | P | P | P | P |
| 2032 | N | N | P | P | **N** | P |
| 2034 | N | N | P | P | P | P |
| 2060 | N | N | P | P | P | P |
| 2075 | N | **P** | P | P | P | P |
| 2126 | N | N | P | P | P | P |
| 2132 | N | N | P | P | P | P |
| 2675 | N | N | P | P | P | P |
| 2692 | N | N | P | P | P | P |
| 2724 | N | N | P | P | P | P |
| 2808 | N | N | P | P | P | P |
| | | | | | | |
| N, Results | 18 | 18 | 18 | 18 | 18 | 18 |
| # Negative | 18 | 17 | 0 | 0 | 2 | 0 |
| # Positive | 0 | 1 | 18 | 18 | 16 | 18 |
| % Correct | 100.0% | 94.4% | 100.0% | 100.0% | 88.9% | 100.0% |
| % Incorrect | 0.0% | 5.6% | 0.0% | 0.0% | 11.1% | 0.0% |

**Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports for MON810 for all participants.**

| | |
|---|---|
| Total # Reported results | 108 |
| # Incorrect | 3 |
| % Correct | 97.2% |
| # Provided Positives | 72 |
| # False Negative | 2 |
| % False Negative | 2.8% |
| # Provided Negatives | 36 |
| # False Positive | 1 |
| % False Positive | 2.8% |

**Table 11: Qualitative results for corn fortified with GA21 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| GA21 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| **Participant Number** | **0.0%** | **0.8%** | **0.5%** | **1.5%** | **0.0%** | **0.0%** |
| **1752** | N | P | P | P | N | N |
| **1773** | N | P | P | P | N | **P** |
| **1774** | N | P | P | P | **P** | N |
| **1785** | N | P | P | P | N | N |
| **1844** | N | P | P | P | N | N |
| **1859** | N | P | P | P | N | N |
| **1862** | N | P | P | P | N | N |
| **1892** | N | P | P | P | N | N |
| **2032** | N | P | P | P | N | N |
| **2034** | N | P | P | P | N | N |
| **2060** | N | P | P | P | N | N |
| **2075** | N | P | P | P | N | N |
| **2126** | N | P | P | P | N | N |
| **2675** | N | P | P | P | N | N |
| **2692** | N | P | P | P | N | N |
| | | | | | | |
| **N, Results** | 15 | 15 | 15 | 15 | 15 | 15 |
| **# Negative** | 15 | 0 | 0 | 0 | 14 | 14 |
| **# Positive** | 0 | 15 | 15 | 15 | 1 | 1 |
| **% Correct** | 100.0% | 100.0% | 100.0% | 100.0% | 93.3% | 93.3% |
| **% Incorrect** | 0.0% | 0.0% | 0.0% | 0.0% | 6.7% | 6.7% |

**Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports for GA21 for all participants.**

| | |
|---|---|
| **Total # Reported results** | 90 |
| **# Incorrect** | 2 |
| **% Correct** | 97.8% |
| **# Provided Positives** | 45 |
| **# False Negative** | 0 |
| **% False Negative** | 0.0% |
| **# Provided Negatives** | 45 |
| **# False Positive** | 2 |
| **% False Positive** | 4.4% |

**Table 13: Qualitative results for corn fortified with Bt176 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| Bt176 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| **Participant Number** | **0.0%** | **0.8%** | **0.1%** | **0.5%** | **3.0%** | **0.4%** |
| **1752** | N | P | P | P | P | P |
| **1773** | N | P | P | P | P | P |
| **1774** | N | P | P | P | P | P |
| **1785** | N | P | P | P | P | P |
| **1844** | N | P | P | P | P | P |
| **1858** | N | P | P | P | P | P |
| **1859** | N | P | P | P | P | P |
| **1862** | N | P | P | P | P | P |
| **1892** | N | P | P | P | P | P |
| **2032** | N | P | P | P | P | P |
| **2034** | N | P | P | P | P | P |
| **2060** | N | P | P | P | P | P |
| **2126** | N | P | P | P | P | P |
| **2132** | N | P | P | P | P | P |
| **2692** | N | P | P | P | P | P |
| **2724** | N | P | P | P | P | P |
| **2808** | N | **N** | **N** | P | P | P |
| | | | | | | |
| **N, Results** | 17 | 17 | 17 | 17 | 17 | 17 |
| **# Negative** | 17 | 1 | 1 | 0 | 0 | 0 |
| **# Positive** | 0 | 16 | 16 | 17 | 17 | 17 |
| **% Correct** | 100.0% | 94.1% | 94.1% | 100.0% | 100.0% | 100.0% |
| **% Incorrect** | 0.0% | 5.9% | 5.9% | 0.0% | 0.0% | 0.0% |

**Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt176 for all participants.**

| | |
|---|---|
| **Total # Reported results** | 102 |
| **# Incorrect** | 2 |
| **% Correct** | 98.0% |
| **# Provided Positives** | 85 |
| **# False Negative** | 2 |
| **% False Negative** | 2.3% |
| **# Provided Negatives** | 17 |
| **# False Positive** | 0 |
| **% False Positive** | 0.0% |

**Table 15: Qualitative results for corn fortified with Bt11 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| Bt11 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| Participant Number | 0.0% | 0.4% | 0.0% | 1.5% | 1.5% | 0.0% |
| 1752 | N | P | N | P | P | N |
| 1773 | N | P | N | P | P | N |
| 1774 | N | P | N | P | P | N |
| 1785 | N | P | N | P | P | N |
| 1844 | N | P | N | P | P | N |
| 1858 | N | P | N | P | P | N |
| 1859 | N | P | N | P | P | N |
| 1862 | N | **N** | N | P | **N** | N |
| 1892 | N | P | N | P | P | N |
| 2032 | N | **N** | N | **N** | P | N |
| 2034 | N | P | N | P | P | N |
| 2060 | N | P | N | P | P | N |
| 2075 | N | P | N | P | P | N |
| 2132 | N | P | N | P | P | N |
| 2692 | N | P | N | P | P | N |
| 2724 | N | P | N | P | P | N |
| 2808 | N | **N** | N | **N** | P | N |
| | | | | | | |
| N, Results | 17 | 17 | 17 | 17 | 17 | 17 |
| # Negative | 17 | 3 | 17 | 2 | 1 | 17 |
| # Positive | 0 | 14 | 0 | 15 | 16 | 0 |
| % Correct | 100.0% | 82.4% | 100.0% | 88.2% | 94.1% | 100.0% |
| % Incorrect | 0.0% | 17.6% | 0.0% | 11.8% | 5.9% | 0.0% |

**Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt11 for all participants.**

| | |
|---|---|
| Total # Reported results | 102 |
| # Incorrect | 6 |
| % Correct | 94.1% |
| # Provided Positives | 51 |
| # False Negative | 6 |
| % False Negative | 11.8% |
| # Provided Negatives | 51 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays) (N = negative; P = positive)**.

| NK603 Participant Number | Sample 1 0.0% | Sample 2 0.4% | Sample 3 3.0% | Sample 4 0.5% | Sample 5 0.5% | Sample 6 0.0% |
|---|---|---|---|---|---|---|
| 1752 | N | P | P | P | P | N |
| 1773 | N | P | P | P | P | N |
| 1774 | N | P | P | P | P | N |
| 1785 | N | P | P | P | P | N |
| 1788 | N | P | P | P | P | N |
| 1844 | N | P | P | P | P | N |
| 1859 | N | P | P | P | P | N |
| 1862 | N | P | P | P | P | N |
| 2032 | N | P | P | P | P | N |
| 2034 | N | P | P | P | P | N |
| 2060 | N | P | P | P | P | N |
| 2075 | N | P | P | P | P | N |
| 2126 | N | P | P | P | P | N |
| 2692 | N | P | P | P | P | N |
| | | | | | | |
| N, Results | 14 | 14 | 14 | 14 | 14 | 14 |
| # Negative | 14 | 0 | 0 | 0 | 0 | 14 |
| # Positive | 0 | 14 | 14 | 14 | 14 | 0 |
| % Correct | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| % Incorrect | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

**Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports for NK603 for all participants.**

| | |
|---|---|
| Total # Reported results | 84 |
| # Incorrect | 0 |
| % Correct | 100.0% |
| # Provided Positives | 56 |
| # False Negative | 0 |
| % False Negative | 0.0% |
| # Provided Negatives | 28 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 19: Qualitative results for corn fortified with Herculex for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| Herculex | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| Participant Number | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.1% |
| 1752 | N | N | N | N | N | P |
| 1773 | N | N | N | N | N | P |
| 1774 | N | N | N | N | N | P |
| 1785 | N | N | N | N | N | P |
| 1844 | N | N | N | N | N | P |
| 1859 | N | N | N | N | N | P |
| 2032 | N | N | N | N | N | P |
| 2034 | N | N | N | N | N | P |
| 2060 | N | N | N | N | N | P |
| 2126 | N | N | N | N | **P** | P |
| 2675 | N | N | N | N | N | P |
| 2692 | N | N | N | N | N | P |
| | | | | | | |
| N, Results | 12 | 12 | 12 | 12 | 12 | 12 |
| # Negative | 12 | 12 | 12 | 12 | 11 | 0 |
| # Positive | 0 | 0 | 0 | 0 | 1 | 12 |
| % Correct | 100.0% | 100.0% | 100.0% | 100.0% | 91.7% | 100.0% |
| % Incorrect | 0.0% | 0.0% | 0.0% | 0.0% | 8.3% | 0.0% |

**Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex for all participants.**

| | |
|---|---|
| Total # Reported results | 72 |
| # Incorrect | 1 |
| % Correct | 98.6% |
| # Provided Positives | 12 |
| # False Negative | 0 |
| % False Negative | 0 |
| # Provided Negatives | 60 |
| # False Positive | 1 |
| % False Positive | 1.7% |

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**Table 21: Qualitative results for corn fortified with MON863 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).**

| MON863 Participant Number | Sample 1 0.0% | Sample 2 1.5% | Sample 3 0.0% | Sample 4 0.0% | Sample 5 0.0% | Sample 6 0.8% |
|---|---|---|---|---|---|---|
| 1752 | N | P | N | N | N | P |
| 1773 | N | P | N | N | N | P |
| 1774 | N | P | N | N | N | P |
| 1785 | N | P | N | N | N | P |
| 1788 | N | P | N | N | N | P |
| 1844 | N | P | N | N | N | P |
| 1859 | N | P | N | N | N | P |
| 2032 | N | P | N | N | N | P |
| 2034 | N | P | N | N | N | **N** |
| 2060 | N | P | N | N | N | P |
| 2075 | N | P | N | N | N | P |
| 2112 | N | P | N | N | N | P |
| 2126 | N | P | N | N | N | P |
| 2675 | N | P | N | N | N | P |
| 2692 | N | P | N | N | N | P |
| | | | | | | |
| N, Results | 15 | 15 | 15 | 15 | 15 | 15 |
| # Negative | 15 | 0 | 15 | 15 | 15 | 1 |
| # Positive | 0 | 15 | 0 | 0 | 0 | 14 |
| % Correct | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 93.3% |
| % Incorrect | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 6.7% |

**Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports for MON863 for all participants.**

| | |
|---|---|
| Total # Reported results | 90 |
| # Incorrect | 1 |
| % Correct | 98.9% |
| # Provided Positives | 30 |
| # False Negative | 1 |
| % False Negative | 3.3% |
| # Provided Negatives | 60 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 23: Qualitative results for corn fortified with Herculex RW for all participants (DNA-based assays) (N = negative; P = positive)**.

| Herculex RW | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| Participant Number | 0.0% | 0.8% | 0.0% | 0.0% | 0.0% | 0.0% |
| 1752 | N | P | N | N | N | N |
| 1773 | N | P | N | N | N | N |
| 1774 | N | P | N | N | N | N |
| 1785 | N | P | N | N | N | N |
| 1844 | N | P | N | N | N | N |
| 1859 | N | P | N | N | N | N |
| 2032 | N | P | N | N | N | N |
| 2034 | N | P | N | N | N | N |
| 2060 | N | P | N | N | N | N |
| 2112 | N | P | N | N | N | N |
| 2126 | N | P | N | N | N | N |
| 2716 | N | P | N | N | N | N |
|  |  |  |  |  |  |  |
| N, Results | 12 | 12 | 12 | 12 | 12 | 12 |
| # Negative | 12 | 0 | 12 | 12 | 12 | 12 |
| # Positive | 0 | 12 | 0 | 0 | 0 | 0 |
| % Correct | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| % Incorrect | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

**Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports for Herculex RW for all participants.**

| | |
|---|---|
| Total # Reported results | 72 |
| # Incorrect | 0 |
| % Correct | 100.0% |
| # Provided Positives | 12 |
| # False Negative | 0 |
| % False Negative | 0.0% |
| # Provided Negatives | 60 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 25: Qualitative results for soybeans fortified with MIR604 for all participants (DNA-based assays).**

| MIR604 | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 | Sample 6 |
|---|---|---|---|---|---|---|
| **Participant Number** | **0.0%** | **0.5%** | **0.0%** | **0.0%** | **0.0%** | **0.0%** |
| 1752 | N | P | N | N | N | N |
| 1773 | N | P | N | N | N | N |
| 1774 | N | P | N | N | N | N |
| 1785 | N | P | N | N | N | N |
| 1844 | N | P | N | N | N | N |
| 1859 | N | P | N | N | N | N |
| 2032 | N | P | N | N | N | N |
| 2034 | N | P | N | N | N | N |
| 2060 | N | P | N | N | N | N |
| | | | | | | |
| N, Results | 9 | 9 | 9 | 9 | 9 | 9 |
| # Negative | 9 | 0 | 9 | 9 | 9 | 9 |
| # Positive | 0 | 9 | 0 | 0 | 0 | 0 |
| % Correct | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| % Incorrect | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

**Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports for MIR604 for all participants.**

| | |
|---|---|
| # Reported results | 72 |
| # Incorrect | 0 |
| % Correct | 100.0% |
| # Provided Positives | 9 |
| # False Negative | 0 |
| % False Negative | 0.0% |
| # Provided Negatives | 60 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 27: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface)**.

| CP4 EPSPS | Sample 1 | Sample 2 | Sample 3 |
|---|---|---|---|
| **Participant Number** | **0.0%** | **2.5%** | **0.5%** |
| **1752** | N | P | P |
| **1774** | N | P | P |
| **1785** | N | P | P |
| **1788** | N | P | P |
| **1844** | N | P | P |
| **1858** | N | P | P |
| **1859** | N | P | P |
| **1892** | N | P | P |
| **2032** | N | P | P |
| **2034** | N | P | P |
| **2076** | N | P | P |
| **2100** | **P** | P | P |
| **2108** | N | **N** | P |
| **2675** | **P** | P | P |
| **2692** | N | P | P |
| **2717** | N | P | P |
|  |  |  |  |
| **N, Results** | 16 | 16 | 16 |
| **# Negative** | 14 | 1 | 0 |
| **# Positive** | 2 | 15 | 16 |
| **% Correct** | 87.5% | 93.8% | 100.0% |
| **% Incorrect** | 12.5% | 6.2% | 0.0% |

**Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS (Roundup Ready) for all participants.**

| | |
|---|---|
| **Total # Reported results** | 48 |
| **# Incorrect** | 3 |
| **% Correct** | 93.8% |
| **# Provided Positives** | 32 |
| **# False Negative** | 1 |
| **% False Negative** | 3.1% |
| **# Provided Negatives** | 16 |
| **# False Positive** | 2 |
| **% False Positive** | 12.5% |

**Table 29: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays).**

N = total number of results submitted for an event; %False Negative = [# False Negatives / # Provided Positives] x 100; %False Positives = [#False Positives / # Provided Negatives] x100.

| Event | 35S | NOS | T25 | CBH351 | MON810 | GA21 | Bt176 |
|---|---|---|---|---|---|---|---|
| N, Results | 222 | 198 | 90 | 52 | 108 | 90 | 102 |
| Reported Incorrect | 7 | 3 | 11 | 1 | 3 | 2 | 2 |
| % Correct | 96.8% | 98.5% | 87.7% | 98.1% | 97.2% | 97.8% | 98.0% |
| N, Provided Positives | 185 | 165 | 45 | 26 | 72 | 45 | 85 |
| N, False Negatives | 4 | 2 | 5 | 1 | 2 | 0 | 2 |
| % False Negative | 2.1% | 1.2% | 11.1% | 3.8% | 2.8% | 0.0% | 2.3% |
| N, Provided Negatives | 37 | 33 | 45 | 26 | 36 | 45 | 17 |
| N, False Positives | 3 | 1 | 6 | 0 | 1 | 2 | 0 |
| % False Positives | 8.1% | 3.0% | 13.3% | 0.0% | 2.8% | 4.4% | 0.0% |

| Event | Bt11 | NK603 | Herculex | MON863 | HerculexRW | MIR604 | RUR |
|---|---|---|---|---|---|---|---|
| N, Results | 102 | 84 | 72 | 90 | 72 | 54 | 48 |
| Reported Incorrect | 6 | 0 | 1 | 1 | 0 | 0 | 3 |
| % Correct | 94.1% | 100.0% | 98.6% | 98.8% | 100.0% | 100.0% | 93.8% |
| N, Provided Positives | 51 | 56 | 12 | 30 | 12 | 9 | 32 |
| N, False Negatives | 6 | 0 | 0 | 1 | 0 | 0 | 1 |
| % False Negative | 11.8% | 0.0% | 0 | 3.3% | 0.0% | 0.0% | 3.1% |
| N, Provided Negatives | 51 | 28 | 60 | 60 | 60 | 45 | 16 |
| N, False Positives | 0 | 0 | 1 | 0 | 0 | 0 | 2 |
| % False Positives | 0.0% | 0.0% | 1.7% | 0.0% | 0.0% | 0.0% | 12.5% |

**Figure 1: Group average of percentage correct for Qualitative reports on each event (DNA-based assays).** Embedded numbers represent the total number of reported results for that event. Data are shown on a composite basis (i.e., all participants results combined) extracted from the percentage correct scores in Table 29.
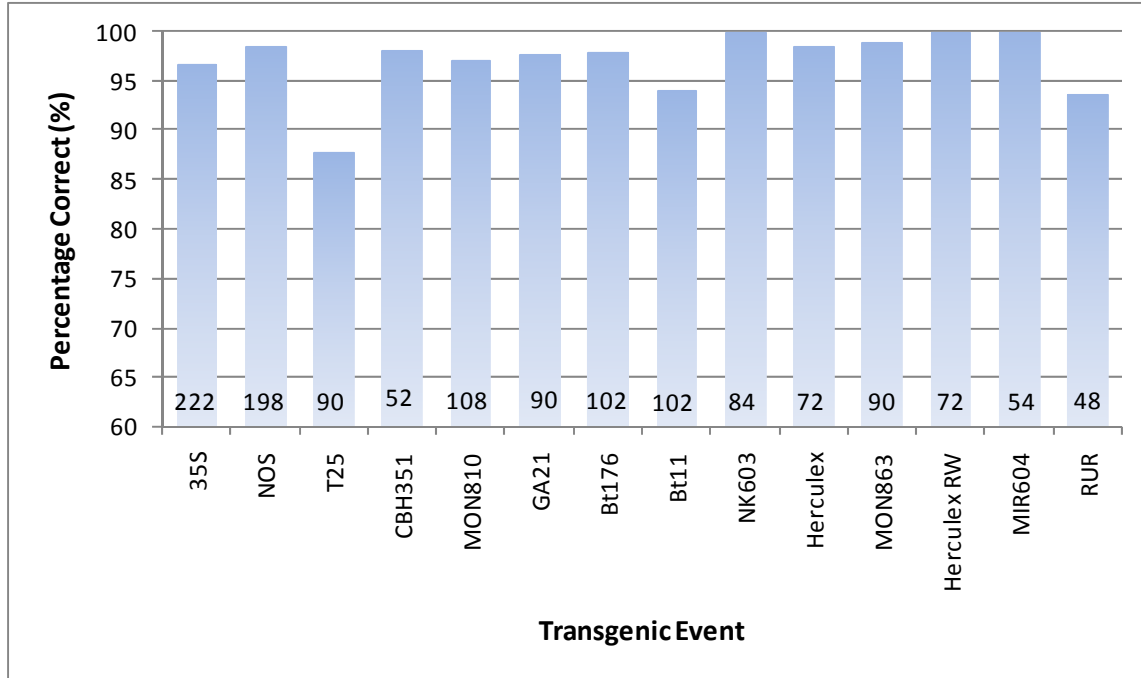
**Table 30: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) for Participant #1843 (only this participant submitted such results).**

| Participant Number 1843 | Transgenic Event | | | | | | |
|---|---|---|---|---|---|---|---|
| Sample Number | T25 | CBH351 | NK603 | Cry 1 Ab | Herculex | Mon863 | Herculex RW |
| 1 | N | N | N | N | N | N | N |
| 2 | N | *N | P | N | N | P | P |
| 3 | N | P | P | **N | N | N | N |
| 4 | N | N | N | †N | N | N | N |
| 5 | P | P | P | N | N | N | N |
| 6 | N | P | N | N | ‡N | P | N |
| | | | | | | | |
| Total # Reported results | 6 | 6 | 6 | 5 | 5 | 6 | 6 |
| # Incorrect | 0 | 1 | 0 | 1 | 0 | 0 | 0 |
| % Correct | 100.0% | 83.3% | 100.0% | 80.0% | 100.0% | 100.0% | 100.0% |
| # Provided Positives | 1 | 4 | 3 | 1 | 0 | 2 | 1 |
| # False Negative | 0 | 1 | 0 | 1 | 0 | 0 | 0 |
| % False Negative | 0.0% | 25.0% | 0.0% | 100.0% | 0.0% | 0.0% | 0.0% |
| # Provided Negatives | 5 | 2 | 3 | 4 | 5 | 4 | 5 |
| # False Positive | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| % False Positive | 0.0% | 0.0% | 0.0% | 100.0% | 0.0% | 0.0% | 0.0% |

*The Participant's stated MDL for **CBH351** was 0.125%, the unknown sample #2 was fortified with CBH351 at 0.4% which was greater than their MDL; therefore, the result was scored as incorrect.
**The Participant's stated MDL for **Cry1Ab** was 1%, the unknown sample #3 was fortified at 1.5% MON810 and 0% Bt11; result was not included in the performance analysis.
†The Participant's stated MDL for **Cry1Ab** was 1%, the unknown sample #4 was fortified at 5% MON810 and 1.5% Bt11; result was scored as incorrect.
‡The Participant's stated MDL for **Herculex** was 0.5%, the unknown sample #6 was fortified at 0.1% which was less than their MDL; therefore, the result was not included in the performance analysis.

**Table 31: Qualitative results for soybeans fortified with CP4EPSPS (RUR) for all participants using Lateral Flow Strip (LFS) Testing (N = negative; P = positive).**

| CP4 EPSPS (RUR) | Sample 1 | Sample 2 | Sample 3 |
|---|---|---|---|
| Participant Number | 0.0% | 2.5% | 0.5% |
| 1764 | N | P | P |
| 1843 | N | P | P |
| 2126 | N | P | P |
| | | | |
| N, Results | 3 | 3 | 3 |
| # Negative | 3 | 0 | 0 |
| # Positive | 0 | 3 | 3 |
| % Correct | 100.0% | 100.0% | 100.0% |
| % Incorrect | 0.0% | 0.0% | 0.0% |

**Table 32:  Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Lateral Flow Strip (LFS) Testing.**

| | |
|---|---|
| Total # Reported results | 9 |
| # Incorrect | 0 |
| % Correct | 100.0% |
| # Provided Positives | 6 |
| # False Negative | 0 |
| % False Negative | 0.0% |
| # Provided Negatives | 3 |
| # False Positive | 0 |
| % False Positive | 0.0% |

**Table 33:  Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).**

| CP4 EPSPS (RUR) | Sample 1 | Sample 2 | Sample 3 |
|---|---|---|---|
| Participant Number | 0.0% | 2.5% | 0.5% |
| 1754 | N | P | P |
| 2126 | N | P | P |
| 2817 | N | P | P |

**Table 34:  Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).**

| Total # Reported results | 9 |
|---|---|
| # Incorrect | 0 |
| % Correct | 100.0% |
| # Provided Positives | 6 |
| # False Negative | 0 |
| % False Negative | 0.0% |
| # Provided Negatives | 3 |
| # False Positive | 0 |
| % False Positive | 0.0% |

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**Table 35: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range, i.e., z > 2 and quantifications marked with asterisk (*) indicate values determined to outliers by the Grubb's Test for Outliers.

| | Event: T25 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.1% | | 0.4% | | 1.5% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.4 | 0.0 | 1.4 | -0.2 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.3 | -0.7 | 0.6 | -1.9 |
| 1764 | 0.0 | 0.0 | *0.6 | - | 0.0 | 0.0 | 0.1 | 0.0 | 0.5 | 0.7 | 1.0 | -1.1 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.5 | 0.7 | 1.0 | -1.1 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.11 | 1.3 | 0.63 | 1.7 | 1.5 | 0.1 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.08 | **-2.7** | 0.5 | 0.7 | 1.6 | 0.2 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.15 | **6.7** | 0.5 | 0.7 | 1.0 | -1.1 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.5 | 0.7 | 1.0 | -1.1 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | **13.6** | 0.49 | 0.6 | 1.6 | 0.2 |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.42 | 0.2 | 1.4 | -0.2 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.49 | 0.6 | 1.0 | -1.1 |
| 2719 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.1 | **-2.2** | 0.0 | **-3.2** |

**Table 36: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: CBH351 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.5% | | 3.0% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.4 | 1.8 | -0.8 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.5 | 1.1 | -1.3 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.5 | 3.1 | 0.1 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.5 | 1.9 | -0.7 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | **-2.4** | 0.3 | -1.8 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.52 | 0.1 | 4.7 | 1.1 |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.57 | 0.3 | 3.0 | 0.0 |

*Data from Sample 2 (0.4% fortification) and Sample 6 (0.4% fortification) have been eliminated from the table and from the analysis of data due to inconsistencies in the reported quantifications.*

**Table 37: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: MON810 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.1% | | 0.4% | | 1.5% | | 5.0% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.2 | -1.4 | 0.6 | -0.8 | 1.2 | **-3.2** |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.3 | -0.7 | 1.5 | 0.0 | 3.0 | -1.7 |
| 1764 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.4 | 0.0 | 1.6 | 0.1 | 4.4 | -0.5 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.3 | -0.7 | 0.8 | -0.6 | 3.2 | -1.5 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.09 | -0.1 | 0.39 | -0.1 | 1.44 | -0.1 | 4.6 | -0.3 |
| 1783 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.11 | **-2.1** | 0.26 | -1.1 | 1.3 | **-3.2** |
| 1847 | 0.0 | 0.0 | 0.0 | 0.0 | 0.02 | -0.6 | 0.13 | -1.9 | 0.63 | -0.8 | 2.4 | **-2.2** |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.04 | -0.4 | 0.25 | -1.1 | 0.9 | -0.5 | 2.7 | -1.9 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.2 | -1.4 | 0.62 | -0.8 | 2.1 | **-2.4** |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.5 | **2.8** | 0.0 | **-2.9** | 0.6 | -0.8 | 1.0 | **-3.4** |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.22 | -1.3 | 1.0 | -0.4 | 3.3 | -1.4 |
| 2095 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | -0.7 | 0.15 | -1.8 | 0.5 | -0.9 | 1.5 | **-2.9** |
| 2112 | 0.0 | 0.0 | 0.0 | 0.0 | 0.05 | -0.4 | 0.26 | -1.1 | 0.58 | -0.9 | 2.08 | **-2.5** |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.04 | -0.4 | 0.3 | -0.7 | 1.0 | -0.4 | 3.1 | -1.6 |
| 2691 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.35 | -0.3 | 0.73 | -0.7 | 2.8 | -1.8 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.03 | -0.5 | 0.19 | -1.5 | 0.54 | -0.9 | 1.9 | **-2.6** |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.3 | -0.7 | 5.0 | **3.3** | 1.48 | **-3.0** |
| 2719 | 0.0 | 0.0 | *1.08 | - | 0.1 | 0.0 | 0.0 | **-2.9** | 0.42 | -1.0 | 0.0 | **-4.2** |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.48 | **2.7** | 0.52 | 0.8 | 1.4 | -0.1 | 2.6 | -2.0 |

**Table 38: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: GA21 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.5% | | 0.8% | | 1.5% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | *0.1 | - | 0.8 | 1.3 | 1.2 | 0.8 | 1.9 | 0.8 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.3 | 0.3 | -1.0 | 0.8 | -1.4 |
| 1764 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.6 | 0.4 | 0.7 | -0.2 | 1.5 | 0.0 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.4 | 0.5 | -0.6 | 1.2 | -0.6 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.47 | -0.1 | 0.54 | -0.5 | 1.34 | -0.3 |
| 1783 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.15 | -1.5 | 0.38 | -0.8 | 0.6 | -1.8 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.4 | 0.5 | -0.6 | 1.0 | -1.0 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -0.8 | 0.5 | -0.6 | 1.1 | -0.8 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.6 | 0.4 | 1.4 | 1.2 | 2.0 | 1.0 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -0.8 | 0.5 | -0.6 | 1.2 | -0.6 |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.36 | -0.6 | 0.74 | -0.1 | 1.1 | -0.8 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.33 | -0.7 | 0.55 | -0.5 | 0.87 | -1.2 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.48 | -0.1 | 1.53 | 1.4 | 1.02 | -0.9 |
| 2719 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | -1.7 | 0.12 | -1.3 | 0.1 | **-2.8** |
| 2720 | 0.0 | 0.0 | *0.96 | - | *1.12 | - | 0.15 | -1.5 | *4.53 | **7.5** | 0.48 | -2.0 |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.9 | 1.7 | 1.8 | 2.0 | 1.6 | 0.2 |

**Table 39: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| Event: Bt176 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.1% | | 0.4% | | 0.5% | | 0.8% | | 3.0% | |
| Participant Number | Result | Z-score | Result | Z-score | Result | Z-score | Result | Z-score | Result | Z-score | Result | Z-score |
| 1754 | 0.0 | 0.0 | 0.1 | 0.0 | 0.2 | -1.6 | 0.2 | -1.7 | 0.3 | **-2.6** | 1.3 | **-2.8** |
| 1755 | 0.0 | 0.0 | 0.00 | **-2.2** | 0.2 | -1.6 | 0.2 | -1.7 | 0.3 | **-2.6** | 1.3 | **-2.8** |
| 1764 | 0.0 | 0.0 | 0.1 | 0.0 | 0.4 | 0 | 0.5 | 0.0 | 0.7 | -0.5 | 3.4 | 0.6 |
| 1778 | 0.0 | 0.0 | *0.4 | **6.6** | 0.3 | -0.8 | 0.7 | 1.1 | 0.7 | -0.5 | 1.8 | -1.9 |
| 1780 | 0.0 | 0.0 | 0.1 | 0 | 0.55 | 1.2 | 0.44 | -0.3 | 0.59 | -1.1 | 2.5 | -0.8 |
| 1870 | 0.0 | 0.0 | 0.07 | -0.6 | 0.3 | -0.8 | 0.4 | -0.6 | 0.7 | -0.5 | 3.0 | 0.0 |
| 1891 | 0.0 | 0.0 | 0.1 | 0.0 | 0.5 | 0.8 | 0.5 | 0.0 | 0.8 | 0.0 | 2.9 | -0.1 |
| 2044 | 0.0 | 0.0 | 0.1 | 0.0 | 0.4 | 0.0 | 0.3 | -1.1 | 0.3 | **-2.6** | 1.4 | **-2.6** |
| 2057 | 0.0 | 0.0 | 0.1 | 0.0 | 0.24 | -1.2 | 0.3 | -1.1 | 0.5 | -1.6 | 1.8 | -1.9 |
| 2128 | 0.0 | 0.0 | 0.11 | 0.2 | 0.35 | -0.4 | 0.46 | -0.2 | NR | - | NR | - |
| 2691 | 0.0 | 0.0 | 0.12 | 0.4 | 0.4 | 0.0 | 0.35 | -0.9 | 0.49 | -1.6 | 1.74 | **-2.1** |
| 2694 | 0.0 | 0.0 | 0.04 | -1.3 | 0.41 | 0.1 | 0.28 | -1.3 | 0.64 | -0.8 | 1.92 | -1.8 |
| 2716 | 0.0 | 0.0 | 0.11 | 0.2 | 0.4 | 0.0 | 0.5 | 0.0 | *4.8 | **21.0** | 1.52 | **-2.4** |
| 2719 | 0.0 | 0.0 | 0.0 | **-2.2** | 0.64 | 1.9 | 0.8 | 1.7 | 0.45 | -1.8 | 2.5 | -0.8 |
| 2723 | 0.0 | 0.0 | 0.16 | 1.3 | 0.46 | 0.4 | 0.46 | -0.2 | 0.82 | 0.1 | 2.6 | -0.6 |

**Table 40: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| Event: Bt11 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.4% | | 1.5% | | 1.5% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | **-2.2** | 1.4 | **-2.4** | 1.6 | 0.2 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.5 | 0.7 | -1.9 | 1.0 | -1.0 |
| 1764 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.5 | 0.7 | -1.9 | 0.8 | -1.4 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | 0.0 | 1.6 | 0.2 | 1.4 | -0.2 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.32 | -0.6 | 1.47 | -0.1 | 1.5 | 0.0 |
| 1783 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.17 | -1.7 | 0.53 | **-2.3** | 0.7 | -1.6 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.25 | -1.1 | 1.2 | -0.7 | 1.3 | -0.4 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -0.7 | 1.3 | -0.4 | 1.1 | -0.8 |
| 2044 | 0.0 | 0.0 | *0.9 | - | 0.0 | 0.0 | 0.4 | 0.0 | 0.6 | **-2.1** | 2.0 | 1.0 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.5 | 0.8 | -1.6 | 0.7 | -1.6 |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -0.7 | 1.09 | -0.9 | 1.04 | -0.9 |
| 2691 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.43 | 0.2 | 1.21 | -0.7 | 1.62 | 0.2 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.28 | -0.9 | 1.61 | 0.2 | 1.51 | 0.0 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | *1.00 | **4.5** | *3.05 | **3.7** | 1.47 | -0.1 |
| 2719 | 0.0 | 0.0 | *2.08 | - | 0.0 | 0.0 | 0.28 | -0.9 | 0.32 | **-2.8** | 0.0 | **-3.1** |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.65 | 1.8 | 1.3 | -0.4 | 1.5 | 0.0 |

**Table 41: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: NK603 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.4% | | 0.5% | | 0.5% | | 3.0% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -2.0 | 0.3 | -1.4 | 0.3 | -0.9 | 2.1 | -1.0 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -2.0 | 0.3 | -1.4 | 0.4 | -0.4 | 1.9 | -1.2 |
| 1764 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | 0.0 | 0.4 | -0.7 | 0.5 | 0.0 | 4.7 | 1.8 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | 0.0 | 0.4 | -0.7 | 0.4 | -0.4 | 2.4 | -0.6 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.35 | -0.5 | 0.56 | 0.4 | 0.69 | 0.8 | 3.0 | 0.0 |
| 1783 | 0.0 | 0.0 | 0.0 | 0.0 | 0.16 | **-2.4** | 0.15 | **-2.4** | 0.2 | -1.3 | 1.5 | -1.6 |
| 1847 | 0.0 | 0.0 | 0.0 | 0.0 | 0.15 | **-2.5** | 0.3 | -1.4 | 0.32 | -0.8 | 1.9 | -1.2 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -2.0 | 0.4 | -0.7 | 0.3 | -0.9 | 2.4 | -0.6 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -1.0 | 0.5 | 0.0 | 0.5 | 0.0 | 2.6 | -0.4 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | **-3.0** | 0.5 | 0.0 | 0.4 | -0.4 | 2.0 | -1.1 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.26 | -1.4 | 0.4 | -0.7 | 0.36 | -0.6 | 2.3 | -0.7 |
| 2095 | 0.0 | 0.0 | 0.0 | 0.0 | 0.13 | **-2.7** | 0.13 | **-2.6** | 0.14 | -1.6 | 1.5 | -1.6 |
| 2112 | 0.0 | 0.0 | 0.0 | 0.0 | 0.19 | **-2.2** | 0.19 | **-2.2** | 0.2 | -1.3 | 1.09 | **-2.1** |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.13 | **-2.7** | 0.18 | **-2.2** | 0.27 | -1 | 1.71 | -1.4 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.23 | -1.7 | 0.33 | -1.2 | 0.41 | -0.4 | 2.5 | -0.5 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | *4.86 | **46.0** | 0.10 | **-2.8** | 0.1 | -1.8 | 1.52 | -1.6 |
| 2719 | 0.0 | 0.0 | 0.0 | 0.0 | 0.17 | **-2.3** | 0.19 | **-2.2** | 0.12 | -1.7 | 1.1 | **-2.1** |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | *0.83 | **4.4** | *1.1 | **4.2** | 1.0 | **2.2** | 3.8 | 0.8 |

**Table 42: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: Herculex | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.1% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | -0.2 |
| 1847 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.05 | -1.3 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | -0.1 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | **5.2** |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.08 | -0.5 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.04 | -1.5 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 |
| 2719 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | **-2.6** |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | **-2.6** |

**Table 43: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.8% | | 1.5% | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.2 | 1.5 | 2.1 | 1.2 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.7 | -0.4 | 1.5 | 0.0 |
| 1764 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.8 | 0 | 1.2 | -0.6 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.6 | -0.7 | 1.5 | 0.0 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.13 | 1.3 | 1.6 | 0.2 |
| 1783 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.58 | -0.8 | 0.8 | -1.4 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.0 | 0.7 | 1.8 | 0.6 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.9 | 0.4 | 1.5 | 0.0 |
| 2044 | 0.0 | 0.0 | *0.2 | - | 0.0 | 0.0 | *0.1 | - | 0.3 | -1.9 | 0.7 | -1.6 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -1.5 | 1.0 | -0.9 |
| 2095 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.5 | -1.1 | 1.0 | -0.9 |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.68 | -0.4 | 1.56 | 0.1 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.86 | 0.2 | 1.34 | -0.3 |
| 2716 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.51 | -1.1 | 1.49 | 0.0 |
| 2719 | 0.0 | 0.0 | 0.0 | 0.0 | *1.46 | - | 0.0 | 0.0 | 0.74 | -0.2 | 0.0 | **-2.9** |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.54 | -1.0 | 1.6 | 0.2 |

**Table 44: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.8% | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.2 | 1.3 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.2 | 1.3 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.4 | 1.9 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.1 | 0.9 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.1 | 0.9 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.7 | **2.9** |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.0 | 0.6 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.8 | **3.3** |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.9 | 0.3 |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 1.5 | **2.3** |

**Table 45: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: MIR604 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.0% | | 0.5% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score | Result | z-score |
| 1754 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.5 | 0.0 |
| 1755 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.4 |
| 1778 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.4 | -0.4 |
| 1780 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.38 | -0.5 |
| 1870 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.3 |
| 1891 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | -1.3 |
| 2044 | 0.0 | 0.0 | 0.0 | 0.0 | *0.1 | - | 0.0 | 0.0 | 0.0 | 0.0 | 0.8 | 1.3 |
| 2057 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | *1.6 | **5.0** |
| 2128 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 | -0.9 |
| 2694 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.55 | 0.2 |
| 2723 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | **-2.3** |

**Table 46: Quantitative results for soybeans fortified with CP4EPSPS (RUR) using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results).**

| | Event: RUR | | |
|---|---|---|---|
| %w/w Fortification Level | 0.0% | 2.5% | 0.5% |
| Participant Number | Result | Result | Result |
| 1754 | 0.1 | 2.5 | 0.5 |

**Table 47: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays).** Values in **bold** indicate z-scores outside of satisfactory range i.e., z > 2, and, quantifications marked with asterisk (*) indicate values determined to be outliers by the Grubb's Test for Outliers.

| | Event: RUR | | | | | |
|---|---|---|---|---|---|---|
| %w/w Fortification Level | 0.0% | | 0.5% | | 2.5% | |
| Participant Number | Result | z-score | Result | z-score | Result | z-score |
| 1754 | *0.1 | - | 0.5 | 0.0 | 2.5 | 0.0 |
| 1755 | 0.0 | 0.0 | 0.5 | 0.0 | 2.1 | -0.3 |
| 1764 | 0.0 | 0.0 | 0.7 | 0.8 | 2.5 | 0.0 |
| 1773 | 0.0 | 0.0 | 0.6 | 0.4 | 2.2 | -0.2 |
| 1778 | 0.0 | 0.0 | 0.7 | 0.8 | 1.2 | -1.2 |
| 1780 | 0.0 | 0.0 | 0.53 | 0.1 | 2.3 | -0.1 |
| 1783 | 0.0 | 0.0 | 0.4 | -0.4 | 1.58 | -0.8 |
| 1847 | 0.0 | 0.0 | 0.68 | 0.7 | 2.63 | 0.1 |
| 1858 | 0.0 | 0.0 | 0.47 | -0.1 | 2.24 | -0.2 |
| 1858 | 0.0 | 0.0 | 0.47 | -0.1 | 2.24 | -0.2 |
| 1862 | 0.0 | 0.0 | 0.92 | 1.8 | 3.44 | 0.8 |
| 1870 | 0.0 | 0.0 | 0.5 | 0.0 | 2.2 | -0.2 |
| 1891 | 0.0 | 0.0 | 0.7 | 0.8 | 2.5 | 0.0 |
| 2044 | 0.0 | 0.0 | 0.5 | 0.0 | 2.4 | -0.1 |
| 2057 | 0.0 | 0.0 | 0.78 | 1.2 | 3.5 | 0.9 |
| 2060 | 0.0 | 0.0 | 0.49 | 0.0 | 2.24 | -0.2 |
| 2075 | 0.0 | 0.0 | 0.63 | 0.5 | 1.33 | -1.1 |
| 2095 | 0.0 | 0.0 | 0.5 | 0.0 | 1.5 | -0.9 |
| 2128 | 0.0 | 0.0 | 0.16 | -1.4 | 2.07 | -0.4 |
| 2126 | 0.0 | 0.0 | 0.2 | -1.2 | 1.14 | -1.2 |
| 2132 | 0.0 | 0.0 | *5.02 | **19.4** | 1.68 | -0.7 |
| 2691 | 0.0 | 0.0 | 0.64 | 0.6 | 2.6 | 0.1 |
| 2692 | 0.0 | 0.0 | 1.0 | **2.1** | 2.16 | -0.3 |
| 2694 | 0.0 | 0.0 | 0.64 | 0.6 | 1.65 | -0.8 |
| 2716 | 0.0 | 0.0 | 0.44 | -0.2 | 4.88 | **2.2** |
| 2719 | 0.0 | 0.0 | 1.02 | **2.2** | 3.59 | 1.0 |
| 2720 | 0.0 | 0.0 | 0.66 | 0.6 | 1.14 | -1.2 |
| 2723 | 0.0 | 0.0 | 1.2 | **3.0** | 4.8 | **2.1** |
| 2808 | *1.94 | - | 0.8 | 1.2 | 0.4 | -1.9 |

**Table 48: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.** % Relative reproducibility standard deviation (%RSD$_R$ ) = [standard deviation/mean value x 100]; % Relative error = [reported value – fortified value/fortified value x 100]. Outliers were determined by the Grubb's Test for Outliers and excluded from final results.

| Transgenic Event | Reported Results (N) | Fortification (%w/w) | Reported Mean | Standard Deviation | % Relative Standard Deviation | % Relative Error | Range of Results |
|---|---|---|---|---|---|---|---|
| T25 | 12 | 0.1 | 0.11 | 0.03 | 29% | 12% | 0.08 – 0.2 |
| T25 | 12 | 0.4 | 0.44 | 0.13 | 29% | 11% | 0.1 – 0.63 |
| T25 | 12 | 1.5 | 1.09 | 0.46 | 42% | -27% | 0.0 – 1.6 |
| | | | | | | | |
| CBH351 | 7 | 0.5 | 0.33 | 0.20 | 62% | -35% | 0.0 – 0.57 |
| CBH351 | 7 | 3.0 | 2.27 | 1.46 | 64% | -24% | 0.3 – 4.7 |
| | | | | | | | |
| MON810 | 19 | 0.1 | 0.12 | 0.14 | 113% | 22% | 0.0 – 0.48 |
| MON810 | 19 | 0.4 | 0.24 | 0.14 | 57% | -40% | 0.0 – 0.52 |
| MON810 | 19 | 1.5 | 1.06 | 1.10 | 100% | -29% | 0.5 – 5.0 |
| MON810 | 19 | 5.0 | 2.36 | 1.19 | 50% | -53% | 0.0 – 4.6 |
| | | | | | | | |
| GA21 | 16 | 0.5 | 0.41 | 0.23 | 56% | -18% | 0.1 – 0.9 |
| GA21 | 16 | 0.8 | 0.75 | 0.49 | 66% | -6% | 0.12 – 4.53 |
| GA21 | 16 | 1.5 | 1.11 | 0.50 | 45% | -26% | 0.1 – 2.0 |
| | | | | | | | |
| Bt176 | 15 | 0.1 | 0.09 | 0.04 | 52% | -14% | 0.0 – 0.4 |
| Bt176 | 15 | 0.4 | 0.38 | 0.12 | 33% | -4% | 0.2 – 0.64 |
| Bt176 | 15 | 0.5 | 0.43 | 0.17 | 39% | -15% | 0.2 – 0.8 |
| Bt176 | 14 | 0.8 | 0.56 | 0.18 | 31% | -30% | 0.3 – 4.8 |
| Bt176 | 14 | 3.0 | 2.12 | 0.69 | 32% | -29% | 1.3 – 3.4 |
| | | | | | | | |
| Bt11 | 16 | 0.4 | 0.3 | 0.13 | 45% | -25% | 0.1 – 1.0 |
| Bt11 | 32 | 1.5 | 1.13 | 0.45 | 45% | -25% | 0.0 – 3.05 |
| | | | | | | | |
| NK603 | 18 | 0.4 | 0.22 | 0.10 | 42% | -44% | 0.1 – 4.86 |
| NK603 | 36 | 0.5 | 0.34 | 0.19 | 54% | -32% | 0.1 – 1.1 |
| NK603 | 18 | 3.0 | 2.22 | 0.91 | 41% | -26% | 1.11 – 4.7 |
| | | | | | | | |
| Herculex | 14 | 0.1 | 0.09 | 0.07 | 79% | -10 | 0.0 – 0.3 |
| | | | | | | | |
| MON863 | 16 | 0.8 | 0.72 | 0.25 | 36% | -11% | 0.3 – 1.2 |
| MON863 | 16 | 1.5 | 1.29 | 0.5 | 36% | -14% | 0.0 – 2.1 |
| | | | | | | | |
| HerculexRW | 10 | 0.8 | 1.29 | 0.3 | 23% | 61% | 0.9 – 1.8 |
| | | | | | | | |
| MIR604 | 11 | 0.5 | 0.38 | 0.22 | 58% | -25% | 0.0 – 1.6 |
| | | | | | | | |
| RUR | 29 | 0.5 | 0.62 | 0.23 | 37% | 24% | 0.16 – 5.02 |
| RUR | 29 | 2.5 | 2.30 | 1.00 | 44% | -8% | 0.4 – 4.88 |

**Summary of Findings**

**Qualitative Sample Analysis**

**DNA-based Testing.** The method of DNA-based testing for the qualitative determination of events was the conventional polymerase chain reaction assay (PCR) which has a sensitivity of 0.01% w/w transgenic event. The lowest fortification level in this round of proficiency testing was 0.1%w/w; therefore, if the event was present it should be detectible by a given laboratory employing conventional PCR. As evidenced by the summary of performance scores (Table 29 and Figure 1), eleven of the fourteen transgenic events were detected with greater than or equal to 95% accuracy. This was a moderate improvement over the performance in the October 2007 round wherein nine of the fourteen events were detected with greater than or equal to 95% accuracy. Events that tested with less than 95% accuracy were T25, Bt11, and RUR. The occurrence of T25 in this category was similar to the trend observed in the October 2007 report. The failure of these events to test with less than 95% accuracy was due to a combination of false negative (non-detects) and false positives. In the case of T25, 13% of the reported results were false positives and 11% were false negatives; Bt11 was not detected 11.8% of the time in spite of the samples being fortified at 0.4% and 1.5% w/w, respectively. Finally, a false positive result was observed on RUR 12.5% of the time, this trend was not observed in the October 2007 round (www.usda.gov/biotechnology_proficiency_program).

**Protein-based Testing.** The principle methods of protein-based testing were lateral flow strips (LFS) and enzyme-linked immunosorbent assay (ELISA). The LFS test has a sensitivity of ≈0.8% w/w for corn events and ≈0.1% w/w for soybean event RUR (Strategic Diagnostics Inc., 2001 & 2003); ELISA has a sensitivity of ≈0.5% to 1% w/w for corn and soy events (Ahmed, 2004). Some participants stated that their minimum detection limit (MDL) was 0.125% w/w thus; test samples that were fortified at 0.1% w/w were excluded from the statistical analysis in this report. Laboratories demonstrated good proficiency when using protein-based methods to detect the presence of biotechnology-derived traits in maize (Table 30). In the assessment of Cry1Ab, some laboratories stated that their MDL was greater than the fortification level of transgenic events that coded for the Cry1Ab protein; these samples were excluded from statistical analysis. Laboratories demonstrated good proficiency when using protein-based methods to detect the presence of the CP4EPSPS protein in samples fortified with the RoundUp Ready trait (Tables 31 to 34).

**Quantitative Sample Analysis**

**DNA-based Testing.** The method of DNA-based testing for the quantitative determination of transgenic events in was real-time quantitative PCR. This analytical method has a limit of detection (LOD) of 0.01 %w/w event and a limit of quantification (LOQ) of ≈0.1 %w/w event (Ahmed, 2004; Lipp et. al., 2005).

**Composite Performance Assessment.** These data combined the participants reported quantifications and evaluated the group's performance by considering the mean value of "reported results" for all participants (Table 48). Because test samples were fortified at ranges between 0.1% to 5% w/w of the event, it was expected that detection of an event should be

possible in all such samples.  With regard to the detection sensitivity of PCR, a scattered number of non-detects in fortified samples were observed (Tables 36, 39, 42, 43, and 45), and this amounted to only 2.7% of the reported quantitative results; therefore, this expectation was supported by the data. Another expectation was that the *inter-laboratory variation* observed in reported quantifications (as measured by the %$RSD_R$) should be higher in the lower fortified samples (e.g., 0.1%w/w) as compared to the variation observed in higher fortified samples (e.g., 5%w/w) because at lower fortification levels there are fewer genome copies available for PCR amplification thereby challenging the reproducibility of PCR. With regard to this inverse relationship between variability (%$RSD_R$) in reported quantifications and fortification level, in four of the nine events for which multi-level fortifications were provided, this expectation proved valid (Table 48).  This inverse relationship has been observed in the quantitative data from previous rounds of USDA/GIPSA proficiency sample distributions. Though similar trends in these characteristics of inter-laboratory variation were observed, the amount of this variation was for the most part greater than the acceptance criteria of $\leq$ 35% as established by the Joint Research Council/ENGL (http://gmo-crl.jrc.ec.eu).

As established by the Joint Research Council/ENGL, the acceptance criterion for trueness is that the "percentage relative error " in the result should be $\leq$ 25% in comparison to an accepted reference value—in this case the reference values were the %w/w fortifications of the samples. In this round of proficiency testing, there were twenty-nine trials of inter-laboratory quantifications (i.e., total number of transgenic events and fortification level combinations) and in eighteen of those trials the *inter-laboratory relative error* was observed to be $\leq$ 25% (Table 48).  Thus, approximately 62% of the quantification trials were concordant with the acceptance criterion for trueness.  Furthermore, there was a tendency for the reported quantifications to be moderately under-estimated (low bias) as evidenced by the observation that approximately 83% of the quantification trials (twenty-four of twenty-nine) had "percentage relative error" values that were negatively signed (Table 48).  This same trend of a low bias in the quantifications was observed in the quantitative data from previous rounds of our proficiency sample distributions.

**Individual Performance Assessment.**  The performance of each participating laboratory for quantifying transgenic events in the proficiency samples can be observed by inspecting Tables 35 through 47.  To assess the accuracy of their reported quantifications z-scores were computed. Laboratories with z-scores above +2 or below -2 were noted because their result was greater than two standard deviations from the expected value.  Interpretation of z-scores assumes that the data have a normal distribution.  Data from samples with lower fortification levels (e.g., 0.1%w/w) may not be normally distributed and caution should be used when interpreting their z-scores.

In summary, for the assessment of biological/chemical residue in crops, food, feed, and environmental samples it is recommended that an analytical method have a %$RSD_R$ of less than 35% (Joint Research Council/ENGL).  In this round of inter-laboratory proficiency testing the %$RSD_R$ for several of the transgenic events was greater than 35% (Table 48).  This was due to the wide range of quantifications reported by individual labs and numerous confounders could have contributed to this variability.  Monitoring and improving the performance of laboratories that use PCR for the detection and/or quantification of transgenic events in grains will improve the reliability of testing methods and the marketing of this commodity.  The USDA/GIPSA proficiency testing program should be a complement to other quality assurance measures that laboratories use to improve their analytical capabilities.

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**Note:  It is important to understand that there are no internationally recognized standard reference materials for all transgenic events.  The transgenic seed or grain used to prepare these samples was made available to GIPSA by the Life Science Organizations.  Care was taken to ensure the transgenic material was either essentially 100% positive for the event, or adjusted accordingly.  The fortified samples were prepared using a process that has been verified to produce homogenous mixes, and representative samples were analyzed to ensure proper fortification and homogeneity.**

To obtain additional information on the USDA/GIPSA Proficiency Program, contact Luke Shokere, USDA/GIPSA Proficiency Program Manager, at US 816-891-0452, or by e-mail at Luke.A.Shokere@usda.gov.

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