

**USDA/GIPSA Proficiency Program**  
**Testing for the Presence of Biotechnology Events in Corn and Soybeans**  
**November 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 sample distribution, 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 specified transgenic event, z-scores (based on: reported value – fortification value / standard deviation) were computed for each reported quantification result (Tables 35 to 47). Tests for outliers and z-scores assume a normal distribution. At the 0% or 0.1% fortification levels, the distributions are not likely normal. These are probably skewed. Anything above 0 for the 0% spike level would probably be considered an outlier. At the 0.1% level, outlier tests will likely declare more outliers than should be declared. Some judgment will be necessary when interpreting data at these low levels. For levels higher than 0.1%, outliers were not included in the standard deviation used to compute the z-scores. Z-scores that are > 2 should be scrutinized by the participating lab. Those that are > 3 are clearly suspect and action should be taken by the participating laboratory. 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 homogeneity with a calculated amount of non-transgenic corn to produce concentrations from 0.1 to 5.0% of the event. The soybean samples were either non-transgenic soybeans, or fortified soybean samples containing 0.5 to 1.5% of the transgenic glyphosate-tolerant soybeans (RoundUp Ready®). Each participant received six corn and three soybean samples. Each sample contained approximately 15 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. Fifty-three organizations participated in the November 2008 round of proficiency testing.

- Seventeen participants submitted **qualitative** results only,
- Fifteen submitted **quantitative** results only, and
- Twenty-one 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 listed organizations requested that their identity remain anonymous.

## **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: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS for all participants.
- 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 Participants #1843 and #1851.
- 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: (z-scores were purposefully left blank in Tables 35- 47 on non-fortified (0.0%) samples since a z-score assumes a normal distribution and the interpretation may be distorted).

- 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 37: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).
- Table 38: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).
- Table 39: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).
- Table 40: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).
- Table 41: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).
- Table 42: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).
- Table 43: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).
- Table 44: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays).
- Table 45: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).
- 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).
- Table 47: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS for all participants (DNA-based assays).
- Table 48: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.
- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA November 2008 Proficiency Program.

**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	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
1761	N	P	P	P	P	P
1769	N	P	P	P	P	P
1770	N	P	P	P	P	P
1774	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1844	N	P	P	P	P	P
1854	N	P	P	P	P	P
1858	N	P	P	P	P	P
1870	N	P	P	P	P	P
1871	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
1893	N	P	P	P	P	P
1896	N	P	P	P	P	P
2005	N	P	P	P	P	P
2031	N	P	P	P	P	P
2034	N	P	P	P	P	P
2039	N	P	P	P	P	P
2050	N	P	P	P	P	P
2054	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	<b>N</b>	<b>N</b>	P
2095	N	P	P	P	P	P
2100	N	P	P	P	P	P
2112	N	P	P	P	P	P
2132	N	P	P	P	P	P
2692	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	N	P	P	P	P	P
2724	N	P	P	P	P	P
2725	<b>P</b>	P	P	P	P	P

<b>2732</b>	N	P	P	P	P	P
<b>2808</b>	<b>P</b>	P	P	P	P	P
<b>2831</b>	N	P	P	P	P	P
<b>2832</b>	N	P	P	P	P	P
<b>2833</b>	N	P	<b>N</b>	P	P	P
<b>N, Results</b>						
	42	42	42	42	42	42
<b># Negative</b>	40	0	1	1	1	0
<b># Positive</b>	2	42	41	41	41	42
<b>% Correct</b>	95.2%	100.0%	97.6%	97.6%	97.6%	100.0%
<b>% Incorrect</b>	4.8%	0.0%	2.4%	2.4%	2.4%	0.0%

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

<b>Total # Reported results</b>	252
<b># Incorrect</b>	5
<b>% Correct</b>	98.0%
<b># Provided Positives (P)</b>	210
<b># False Negative</b>	3
<b>% False Negative</b>	1.4%
<b># Provided Negatives (N)</b>	42
<b># False Positive</b>	2
<b>% False Positive</b>	4.8%

**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
1761	N	P	P	P	P	P
1770	N	P	P	P	P	P
1774	N	P	P	P	P	P
1781	N	P	P	P	P	P
1785	N	P	P	P	P	P
1844	N	P	P	P	P	P
1854	N	P	P	P	P	P
1858	N	P	P	P	P	P
1870	N	P	P	P	P	P
1875	N	P	P	P	P	P
1892	N	P	P	P	P	P
1893	N	P	P	P	P	P
1896	N	P	P	P	P	P
2005	N	P	P	P	P	P
2031	N	P	P	P	P	P
2034	N	P	P	P	P	P
2039	N	P	P	P	P	P
2050	N	P	P	P	P	P
2054	N	P	P	P	P	P
2057	N	P	P	P	P	P
2076	N	P	P	<b>N</b>	<b>N</b>	P
2095	N	P	P	P	P	P
2112	N	P	P	P	P	P
2132	N	P	P	P	P	P
2692	N	P	P	P	P	P
2716	N	P	P	P	P	P
2719	N	P	P	P	P	P
2724	N	P	P	P	P	P
2732	N	P	P	P	P	P
2808	<b>P</b>	<b>N</b>	P	<b>N</b>	P	P
2831	N	P	P	P	P	P
2832	N	P	P	P	P	P
2833	N	P	<b>N</b>	P	P	P



<b>N, Results</b>	36	36	36	36	36	36
<b># Negative</b>	35	1	1	2	1	0
<b># Positive</b>	1	35	35	34	35	36
<b>% Correct</b>	97.2%	97.2%	97.2%	94.4%	97.2%	100.0%
<b>% Incorrect</b>	2.8%	2.8%	2.8%	5.6%	2.8%	0.0%

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

<b>Total # Reported results</b>	216
<b># Incorrect</b>	6
<b>% Correct</b>	97.2%
<b># Provided Positives (P)</b>	180
<b># False Negative</b>	5
<b>% False Negative</b>	2.8%
<b># Provided Negatives (N)</b>	36
<b># False Positive</b>	1
<b>% False Positive</b>	2.8%

**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%	0.5%	0.1%	0.0%	0.8%	1.5%
1752	N	P	P	N	P	P
1773	N	P	P	N	P	P
1774	N	P	P	<b>P</b>	P	P
1781	N	P	P	N	P	P
1785	N	P	P	N	P	P
1788	N	P	P	<b>P</b>	P	P
1844	N	P	P	N	P	P
1854	N	<b>N</b>	P	<b>P</b>	P	P
1859	N	P	P	N	P	P
1892	N	P	P	<b>P</b>	P	P
1893	N	P	P	N	P	P
1896	N	P	P	N	P	P
2005	N	P	P	N	P	P
2034	N	<b>N</b>	P	<b>P</b>	P	P
2039	N	P	P	<b>P</b>	P	P
2060	N	P	P	<b>P</b>	P	P
2089	N	P	P	N	P	P
2112	N	P	P	N	P	P
2132	N	P	P	<b>P</b>	P	P
2692	N	P	P	N	P	P
2732	N	P	P	N	P	P
2831	N	P	P	N	P	P
2832	N	P	P	N	P	P
<b>N, Results</b>						
	23	23	23	23	23	23
<b># Negative</b>						
	23	2	0	15	23	23
<b># Positive</b>						
	0	21	23	8	0	0
<b>% Correct</b>						
	100.0%	91.3%	100.0%	65.2%	100.0%	100.0%
<b>% Incorrect</b>						
	0.00%	8.7%	0.0%	34.8%	0.0%	0.0%

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

<b>Total # Reported results</b>	138
<b># Incorrect</b>	10
<b>% Correct</b>	92.8%
<b># Provided Positives</b>	92
<b># False Negative</b>	2
<b>% False Negative</b>	2.2%
<b># Provided Negatives</b>	46
<b># False Positive</b>	8
<b>% False Positive</b>	17.4%

**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 2	Sample 3	Sample 4	Sample 6
Participant Number	0.0%	0.1%	0.0%	0.0%	0.5%
1752	N	P	N	N	P
1770	N	P	N	N	P
1773	N	P	N	<b>P</b>	P
1774	N	P	N	<b>P</b>	P
1781	N	P	N	N	P
1785	N	P	N	N	P
1844	N	P	N	N	P
1854	N	P	N	<b>P</b>	P
1859	N	P	N	N	P
1892	N	P	N	N	P
1893	N	P	N	N	P
1896	N	P	N	N	P
2005	N	P	N	N	P
2034	N	<b>N</b>	N	N	P
2039	N	P	N	N	P
2054	N	P	N	<b>P</b>	P
2095	N	P	N	N	P
2692	N	P	N	N	P
2732	N	P	N	N	P
2831	N	P	N	N	P
<b>N, Results</b>	20	20	20	20	20
<b># Negative</b>	20	1	20	16	0
<b># Positive</b>	0	19	0	4	20
<b>% Correct</b>	100.0%	95.0%	100.0%	80.0%	100.0%
<b>% Incorrect</b>	0.0%	5.0%	0.0%	20.0%	0.0%

*\*Data for sample number 5 was deleted from the table due to inconsistencies in report results.*

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

<b>Total # Reported results</b>	100
<b># Incorrect</b>	5
<b>% Correct</b>	95.0%
<b># Provided Positives</b>	40
<b># False Negative</b>	1
<b>% False Negative</b>	2.5%
<b># Provided Negatives</b>	60
<b># False Positive</b>	4
<b>% False Positive</b>	6.7%

**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%	0.8%	0.0%	0.1%	0.1%
1752	N	N	P	N	P	P
1769	N	N	P	N	P	P
1773	N	N	P	N	P	P
1774	N	N	P	N	P	P
1785	N	N	P	N	P	P
1788	N	N	P	N	P	P
1844	N	N	P	N	P	P
1854	N	<b>P</b>	P	<b>P</b>	<b>N</b>	P
1859	N	N	P	N	P	P
1892	N	N	P	N	P	P
1893	N	N	P	N	P	P
2034	N	N	P	N	<b>N</b>	<b>N</b>
2060	N	N	P	N	P	P
2089	N	N	P	N	P	P
2095	N	N	P	N	NR	P
2132	N	N	P	N	P	P
2692	N	N	P	N	P	P
2724	N	N	P	N	P	P
2808	N/R	N	N/R	N	N/R	N/R
2831	N	N	P	N	P	P
<b>N, Results</b>	19	20	19	20	18	19
<b># Negative</b>	19	19	0	19	2	1
<b># Positive</b>	0	1	19	1	16	18
<b>% Correct</b>	100.0%	95.0%	100.0%	95.0%	88.9%	94.7%
<b>% Incorrect</b>	0.0%	5.0%	0.0%	5.0%	11.1%	5.3%

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

Total # Reported results	115
# Incorrect	5
% Correct	95.7%
# Provided Positives	56
# False Negative	3
% False Negative	5.4%
# Provided Negatives	59
# False Positive	2
% False Positive	3.4%

**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%	3.0%	0.4%	0.8%	0.3%	0.0%
1752	N	P	P	P	P	N
1773	N	P	P	P	P	<b>P</b>
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
1854	N	P	P	P	P	<b>P</b>
1859	N	P	P	P	P	N
1892	N	P	P	P	P	N
1893	N	P	P	P	P	N
2005	N	P	P	P	P	N
2034	N	P	<b>N</b>	P	<b>N</b>	N
2039	N	P	P	P	P	N
2060	N	P	P	P	P	N
2089	N	P	P	P	P	N
2112	N	P	P	P	P	<b>P</b>
2692	N	P	P	P	P	N
2831	N	P	P	P	P	N
2832	N	P	P	P	P	N
<b>N, Results</b>	19	19	19	19	19	19
<b># Negative</b>	19	0	1	0	1	16
<b># Positive</b>	0	19	18	19	18	3
<b>% Correct</b>	100.0%	100.0%	94.7%	100.0%	94.7%	84.2%
<b>% Incorrect</b>	0.0%	0.0%	5.3%	0.0%	5.3%	15.8%

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

<b>Total # Reported results</b>	114
<b># Incorrect</b>	5
<b>% Correct</b>	95.6%
<b># Provided Positives</b>	76
<b># False Negative</b>	2
<b>% False Negative</b>	2.6%
<b># Provided Negatives</b>	38
<b># False Positive</b>	3
<b>% False Positive</b>	7.9%



**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%	1.5%	0.0%	0.8%	0.1%	3.0%
1752	N	P	N	P	P	P
1773	N	P	<b>P</b>	P	P	P
1774	N	P	N	P	P	P
1785	N	P	N	P	P	P
1788	N	P	N	P	P	P
1844	N	P	N	P	<b>N</b>	P
1854	N	P	N	P	P	P
1858	N	P	N	P	P	P
1859	N	P	N	P	P	P
1892	N	P	N	P	<b>N</b>	P
1893	N	P	N	P	P	P
2005	N	P	N	P	P	P
2034	N	P	N	P	<b>N</b>	P
2039	N	P	N	P	P	P
2060	N	P	N	P	P	P
2089	N	P	N	P	P	P
2095	N	P	N	P	P	P
2112	N	P	N	P	P	P
2132	N	P	<b>P</b>	P	P	P
2724	N	P	N	P	P	P
2808	N/R	P	N/R	P	N/R	N/R
2831	N	P	N	P	P	P
<b>N, Results</b>	21	22	21	22	21	21
<b># Negative</b>	21	0	19	0	3	0
<b># Positive</b>	0	22	2	22	18	21
<b>% Correct</b>	100.0%	100.0%	90.5%	100.0%	85.7%	100.0%
<b>% Incorrect</b>	0.0%	0.0%	9.5%	0.0%	14.3%	0.0%

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

<b>Total # Reported results</b>	128
<b># Incorrect</b>	5
<b>% Correct</b>	96.1%
<b># Provided Positives</b>	86
<b># False Negative</b>	3
<b>% False Negative</b>	3.5%
<b># Provided Negatives</b>	42
<b># False Positive</b>	2
<b>% False Positive</b>	4.8%

**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).**

<b>Bt11</b>	<b>Sample 1</b>	<b>Sample 2</b>	<b>Sample 3</b>	<b>Sample 4</b>	<b>Sample 5</b>	<b>Sample 6</b>
<b>Participant Number</b>	<b>0.0%</b>	<b>3.0%</b>	<b>0.5%</b>	<b>0.4%</b>	<b>0.0%</b>	<b>1.5%</b>
1752	N	P	P	P	N	P
1773	N	P	P	P	N	P
1774	N	P	P	P	N	P
1785	N	P	P	P	N	P
1788	N	P	P	P	N	P
1844	N	P	P	P	N	P
1854	N	P	P	P	<b>P</b>	P
1858	N	P	P	P	N	P
1859	N	P	P	P	N	P
1892	N	P	P	P	N	P
1893	N	P	P	P	N	P
2005	N	P	P	P	N	P
2034	N	P	P	P	N	P
2039	N	P	P	P	N	P
2060	N	P	P	P	N	P
2089	N	P	P	P	N	P
2095	N	P	P	P	N	P
2112	N	P	P	P	N	P
2132	N	P	P	P	N	P
2724	N	P	P	P	N	P
2808	N	N/R	P	N/R	<b>P</b>	P
2831	N	P	P	P	N	P
<b>N, Results</b>						
	22	21	22	21	22	22
<b># Negative</b>	22	0	0	0	20	0
<b># Positive</b>	0	21	22	21	2	22
<b>% Correct</b>	100.0%	100.0%	100.0%	100.0%	90.9%	100.0%
<b>% Incorrect</b>	0.0%	0.0%	0.0%	0.0%	9.1%	0.0%

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

<b>Total # Reported results</b>	130
<b># Incorrect</b>	2
<b>% Correct</b>	98.5%
<b># Provided Positives</b>	86
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	44
<b># False Positive</b>	2
<b>% False Positive</b>	4.6%

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

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	1.5%	0.1%	0.4%	0.0%	0.5%
1752	N	P	P	P	N	P
1773	N	P	P	P	N	P
1774	N	P	P	P	N	P
1785	N	P	P	P	N	P
1788	N	P	P	P	N	<b>N</b>
1844	N	P	P	P	N	P
1854	N	P	<b>N</b>	P	N	<b>N</b>
1859	N	P	P	P	N	P
1893	N	P	P	P	N	P
2005	N	P	P	P	N	P
2034	N	P	P	P	N	P
2039	N	P	P	P	N	P
2054	N	P	P	P	N	P
2060	N	P	P	P	N	P
2089	N	P	P	P	N	P
2095	N	P	P	P	N	P
2692	N	P	P	P	N	P
2831	N	P	P	P	N	P
<b>N, Results</b>						
	18	18	18	18	18	18
<b># Negative</b>	18	0	1	0	18	2
<b># Positive</b>	0	18	17	18	0	16
<b>% Correct</b>	100.0%	100.0%	94.4%	100.0%	100.0%	88.9%
<b>% Incorrect</b>	0.0%	0.0%	5.6%	0.0%	0.0%	11.1%

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

<b>Total # Reported results</b>	108
<b># Incorrect</b>	3
<b>% Correct</b>	97.2%
<b># Provided Positives</b>	72
<b># False Negative</b>	3
<b>% False Negative</b>	4.2%
<b># Provided Negatives</b>	36
<b># False Positive</b>	0
<b>% False Positive</b>	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%	0.5%	0.0%	0.8%	0.0%
1752	N	N	P	N	P	N
1773	N	N	P	N	P	N
1774	N	N	P	N	P	N
1785	N	N	P	N	P	N
1844	N	N	P	N	P	N
1854	N	N	P	N	P	N
1859	N	N	P	N	P	N
1893	N	N	P	N	P	N
2005	N	N	P	N	P	N
2034	N	N	P	N	P	N
2039	N	N	P	N	P	N
2054	N	N	P	N	P	N
2060	N	N	P	N	P	N
2089	N	N	P	N	P	N
2112	N	N	P	N	P	N
2692	N	N	P	N	P	N
2831	N	N	P	N	P	N
2832	N	N	P	<b>P</b>	P	N
<b>N, Results</b>	18	18	18	18	18	18
<b># Negative</b>	18	18	0	17	0	18
<b># Positive</b>	0	0	18	1	18	0
<b>% Correct</b>	100.0%	100.0%	100.0%	94.4%	100.0%	100.0%
<b>% Incorrect</b>	0.0%	0.0%	0.0%	5.6%	0.0%	0.0%

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

<b>Total # Reported results</b>	108
<b># Incorrect</b>	1
<b>% Correct</b>	99.1%
<b># Provided Positives</b>	36
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	72
<b># False Positive</b>	1
<b>% False Positive</b>	1.4%

**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	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.0%	0.0%	0.5%	1.5%	0.4%	0.0%
1752	N	N	P	P	P	N
1773	N	N	P	P	P	N
1774	N	N	P	P	P	N
1785	N	N	P	P	P	N
1788	N	N	P	P	P	N
1844	N	N	P	P	P	N
1854	N	N	P	P	P	N
1859	N	N	P	P	P	N
1893	N	N	P	P	P	N
2005	N	N	P	P	P	N
2034	N	N	P	P	P	N
2039	N	N	P	P	P	N
2060	N	N	P	P	P	N
2089	N	N	P	P	P	N
2831	N	N	P	P	P	N
2832	N	<b>P</b>	P	P	P	<b>P</b>
<b>N, Results</b>	16	16	16	16	16	16
<b># Negative</b>	16	15	0	0	0	15
<b># Positive</b>	0	1	16	16	16	1
<b>% Correct</b>	100.0%	93.7%	100.0%	100.0%	100.0%	93.7%
<b>% Incorrect</b>	0.0%	6.3%	0.0%	0.0%	0.0%	6.3%

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

<b>Total # Reported results</b>	96
<b># Incorrect</b>	2
<b>% Correct</b>	97.9%
<b># Provided Positives</b>	48
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	48
<b># False Positive</b>	2
<b>% False Positive</b>	4.2%

**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%	0.0%	0.5%	0.8%	0.1%	0.0%
1752	N	N	P	P	P	N
1773	N	N	P	P	P	N
1774	N	N	P	P	P	N
1785	N	N	P	P	P	N
1844	N	N	P	P	P	N
1859	N	N	P	P	P	N
1893	N	N	P	P	P	N
2034	N	N	P	P	P	N
2039	N	N	P	P	P	N
2060	N	N	P	P	P	N
2089	N	N	P	P	P	N
2112	N	N	P	P	P	N
2831	N	N	P	P	P	N
<b>N, Results</b>	13	13	13	13	13	13
<b># Negative</b>	13	13	0	0	0	13
<b># Positive</b>	0	0	13	13	13	0
<b>% Correct</b>	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
<b>% Incorrect</b>	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.**

<b>Total # Reported results</b>	78
<b># Incorrect</b>	0
<b>% Correct</b>	100.0%
<b># Provided Positives</b>	39
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	39
<b># False Positive</b>	0
<b>% False Positive</b>	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
<b>Participant Number</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.1%</b>	<b>0.5%</b>	<b>1.5%</b>	<b>0.0%</b>
1752	N	N	P	P	P	N
1773	N	N	P	P	P	N
1774	N	N	P	P	P	N
1785	N	N	P	P	P	N
1844	N	N	P	P	P	N
1859	N	N	P	P	P	N
1893	N	N	P	P	P	N
2034	N	N	P	P	P	N
2039	N	N	P	P	P	N
2060	N	N	P	P	P	N
2089	N	N	P	P	P	N
2831	N	N	P	P	P	N
<b>N, Results</b>	12	12	12	12	12	12
<b># Negative</b>	12	12	0	0	0	12
<b># Positive</b>	0	0	12	12	12	0
<b>% Correct</b>	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
<b>% Incorrect</b>	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.**

<b># Reported results</b>	72
<b># Incorrect</b>	0
<b>% Correct</b>	100.0%
<b># Provided Positives</b>	36
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	36
<b># False Positive</b>	0
<b>% False Positive</b>	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%	0.5%	1.5%
1752	N	P	P
1774	N	P	P
1785	N	P	P
1788	N	P	P
1844	N	P	P
1854	N	P	P
1858	N	P	P
1859	N	P	P
1892	N	P	P
2034	N	P	P
2054	N	P	P
2076	N	P	P
2100	N	P	P
2692	N	P	P
2717	N	P	P
2724	N	P	P
2831	N	P	P
2832	N	P	P
2833 (NOS test)	<b>P</b>	<b>N</b>	P
2833 (35S test)	<b>P</b>	P	P
<b>N, Results</b>	20	20	20
<b># Negative</b>	18	1	0
<b># Positive</b>	2	19	20
<b>% Correct</b>	90.0%	95.0%	100.0%
<b>% Incorrect</b>	10.0%	5.0%	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	60
# Incorrect	3
% Correct	95.0%
# Provided Positives	40
# False Negative	1
% False Negative	2.5%
# Provided Negatives	20
# False Positive	2
% False Positive	10.0%

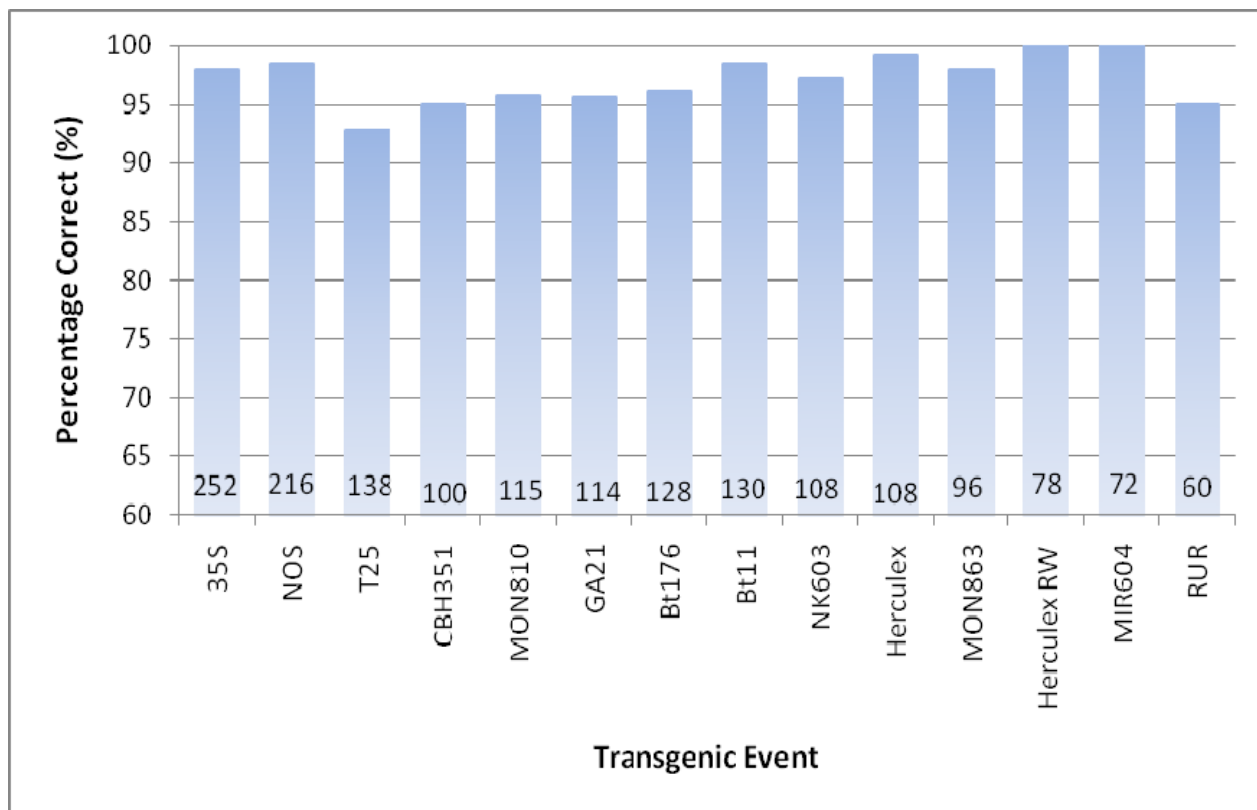
**Table 29: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each transgenic event for all participants (DNA-based assays).**

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	252	216	138	100	115	114	128
Reported Incorrect	5	6	10	5	5	5	5
% Correct	98.0%	97.2%	92.8%	95.0%	95.7%	95.6%	96.1%
N, Provided Positives	210	180	92	40	56	76	86
N, False Negatives	3	5	2	1	3	2	3
% False Negative	1.4%	2.8%	2.2%	2.5%	5.4%	2.6%	3.5%
N, Provided Negatives	42	36	46	60	59	38	42
N, False Positives	2	1	8	4	2	3	2
% False Positives	4.8%	2.8%	17.4%	6.7%	3.4%	7.9%	4.8%

Event	Bt11	NK603	Herculex	MON863	HerculexRW	MIR604	RUR
N, Results	130	108	108	96	78	72	60
Reported Incorrect	2	3	1	2	0	0	3
% Correct	98.5%	97.2%	99.1%	97.9%	100.0%	100.0%	95.0%
N, Provided Positives	86	72	36	48	39	36	40
N, False Negatives	0	3	0	0	0	0	1
% False Negative	0.0%	4.2%	0.0%	0.0%	0.0%	0.0%	2.5%
N, Provided Negatives	44	36	72	48	39	36	20
N, False Positives	2	0	1	2	0	0	2
% False Positives	4.6%	0.0%	1.4%	4.2%	0.0%	0.0%	10.0%



**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 and #1851 (only these two participants submitted such results).**

Participant Number 1843							Participant Number 1851			
Sample Number	Transgenic Event						Sample Number	Transgenic Event		
	T25	NK603	Cry 1 Ab	Herculex	Mon863	Herculex RW		NK 603	Mon863	Herculex RW
1	<1	<0.5	<2	<0.5	<0.5	<0.5	1	<0.5	<0.1	<0.1
2	<1	≥0.5	≥2	<0.5	<0.5	<0.5	2	≥0.5	<0.1	<0.1
3	<1	<0.5	≥2	≥0.5	≥0.5	≥0.5	3	*NR	≥0.1	≥0.1
4	<1	≥0.5	<2	<0.5	≥0.5	≥0.5	4	≥0.5	≥0.1	≥0.1
5	<1	<0.5	<2	≥0.5	≥0.5	<0.5	5	<0.5	≥0.1	≥0.1
6	<1	≥0.5	≥2	<0.5	<0.5	<0.5	6	≥0.5	<0.1	<0.1
<b>Total # Reported results</b>	6	6	6	6	6	6	<b>Total # Reported results</b>	5	6	6
<b># Incorrect</b>	1	0	0	0	0	0	<b># Incorrect</b>	0	0	0
<b>% Correct</b>	83.3%	100.0%	100.0%	100.0%	100.0%	100.0%	<b>% Correct</b>	100.0%	100.0%	100.0%
<b># Provided Positives<sup>a</sup></b>	1	3	3	2	3	2	<b># Provided Positives</b>	3	3	3
<b># False Negative</b>	1	0	0	0	0	0	<b># False Negative</b>	0	0	0
<b>% False Negative</b>	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	<b>% False Negative</b>	0.0%	0.0%	0.0%
<b># Provided Negatives<sup>b</sup></b>	5	3	3	4	3	4	<b># Provided Negatives</b>	2	3	3
<b># False Positive</b>	0	0	0	0	0	0	<b># False Positive</b>	0	0	0
<b>% False Positive</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	<b>% False Positive</b>	0.0%	0.0%	0.0%
<b>LODs (%w/w)</b>	1	0.5	2	0.5	0.5	0.5	<b>LODs (%w/w)</b>	0.5	0.1	0.1

<sup>a</sup>Only samples fortified **at or above** the participants LOD are considered in this table as provided positives.

<sup>b</sup>Only samples fortified **below** the participants LOD are considered in this table as provided negatives.

**Participant 1843**

**T25** sample 6 (1.5% w/w) was fortified to a level above the participants reported LOD and thus datum was scored as incorrect in results table.

**Participant 1851**

\*NR (Not Reported)

**Mon863** sample 5 (0.4% w/w) was fortified to a level above the participants reported LOD and thus datum was scored as incorrect in results table.

**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%	0.5%	1.5%
1843	N	P	P
1851	N	P	P
<b>N, Results</b>			
	2	2	2
<b># Negative</b>	2	0	0
<b># Positive</b>	0	2	2
<b>% Correct</b>	100.0%	100.0%	100.0%
<b>% Incorrect</b>	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.**

<b>Total # Reported results</b>	6
<b># Incorrect</b>	0
<b>% Correct</b>	100.0%
<b># Provided Positives</b>	4
<b># False Negative</b>	0
<b>% False Negative</b>	0.0%
<b># Provided Negatives</b>	2
<b># False Positive</b>	0
<b>% False Positive</b>	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%	0.50%	1.50%
1754	N	P	P
1843	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%

**Table 35: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).** Values highlighted in yellow indicate z-scores outside of the expected range, i.e.,  $z > 2$  and quantifications marked in red indicate values determined to be outliers by the Grubb's Test for Outliers or a positive value for a non-fortified sample (i.e. a false positive result).

Event: T25												
%w/w Fortification Level	0.0%		0.5%		0.1%		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		0.40	-0.60	0.1	0.00	0.00		0.60	-0.73	0.80	-2.57
1755	0.0		0.20	-1.81	0.0	-2.86	0.00		0.30	-1.83	1.10	-1.47
1761	0.0		0.50	0.00	1.0	25.77	0.60		1.20	1.47	0.70	-2.93
1769	0.0		0.34	-0.96	0.06	-1.15	0.00		0.60	-0.73	1.01	-1.80
1770	0.0		0.50	0.00	0.1	0.00	0.00		0.80	0.00	1.30	-0.73
1780	0.0		0.53	0.18	0.09	-0.29	0.00		0.73	-0.26	1.51	0.04
1870	0.0		0.60	0.60	0.10	0.00	0.00		0.80	0.00	1.90	1.47
1875	0.0		0.21	-1.75	0.05	-1.43	0.00		0.35	-1.65	0.69	-2.97
2050	0.0		0.70	1.20	0.96	24.63	0.96		2.80	7.33	2.30	2.93
2057	0.0		0.60	0.60	0.10	0.00	0.00		1.00	0.73	1.40	-0.37
2716	0.0		0.30	-1.20	0.10	0.00	0.00		0.80	0.00	4.90	12.46

**Table 36: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).** Z-scores outside of the expected range of  $z > 2$  were not observed in this data set.

Event: CBH351										
%w/w Fortification Level	0.0%		0.1%		0.0%		0.0%		0.5%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.10	0.00	0.00		0.00		0.30	-1.32
1755	0.00		0.10	0.00	0.00		0.00		0.40	-0.66
1870	0.00		0.10	0.00	0.00		0.00		0.60	0.66
1875	0.00		0.13	1.94	0.00		0.00		0.46	-0.26
2050	0.00		0.13	1.94	0.00		0.00		0.73	1.52
2057	0.00		0.10	0.00	0.00		0.00		0.50	0.00



**Table 37: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).** Values in yellow indicate z-scores outside of expected range i.e.,  $z > 2$ . No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: MON810												
%w/w Fortification Level	0.0%		0.0%		0.8%		0.0%		0.1%		0.1%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.50	-2.30	0.00		0.10	0.00	0.10	0.00
1755	0.00		0.00		0.40	-3.06	0.00		0.05	-1.22	0.10	0.00
1761	0.00		0.00		0.50	-2.30	0.00		0.20	2.43	0.10	0.00
1770	0.00		0.00		0.60	-1.53	0.00		0.10	0.00	0.10	0.00
1773	0.00		0.00		0.40	-3.06	0.00		0.10	0.00	0.10	0.00
1780	0.00		0.00		0.59	-1.61	0.00		0.09	-0.24	0.10	0.00
1781	0.00		0.00		0.40	-3.06	0.00		0.10	0.00	0.10	0.00
1788	0.00		0.00		0.43	-2.83	0.00		0.10	0.00	0.10	0.00
1870	0.00		0.00		0.40	-3.06	0.00		0.08	-0.49	0.05	-1.20
1871	0.00		0.00		0.40	-3.06	0.00		0.10	0.00	0.10	0.00
1875	0.00		0.00		0.29	-3.91	0.00		0.03	-1.70	0.05	-1.20
1896	0.00		0.00		0.42	-2.91	0.00		0.04	-1.46	0.00	-2.40
2005	0.00		0.00		0.38	-3.22	0.00		0.10	0.00	0.10	0.00
2112	0.00		NR		0.41	-2.99	0.00		0.05	-1.22	0.05	-1.20
2031	0.00		0.00		0.25	-4.21	0.00		0.10	0.00	0.00	-2.40
2039	0.00		0.00		0.60	-1.53	0.00		0.10	0.00	0.10	0.00
2050	0.00		0.00		0.54	-1.99	0.00		0.10	0.00	0.10	0.00
2057	0.00		0.00		0.70	-0.77	0.00		0.10	0.00	0.10	0.00
2716	0.00		0.00		0.53	-2.07	0.00		0.10	0.00	0.11	0.24
2719	0.00		0.00		0.50	-2.30	0.00		0.10	0.00	0.10	0.00
2832	0.00		0.00		0.80	0.00	0.00		0.20	2.43	0.20	2.40

**Table 38: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).** Values highlighted in yellow indicate z-scores outside of expected range, i.e.,  $z > 2$  and quantifications marked in red indicate values determined to be outliers by the Grubb's Test for Outliers or a positive value for a non-fortified sample (i.e. a false positive result).

Event: GA21												
%w/w Fortification Level	0.0%		3.0%		0.4%		0.8%		0.3%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		5.50	2.03	0.60	2.15	1.20	1.53	0.40	0.69	0.10	
1755	0.00		1.30	-1.38	0.50	1.08	0.40	-1.53	0.30	0.00	0.00	
1761	0.00		0.30	-2.19	0.40	0.00	0.70	-0.38	0.60	2.07	0.00	
1769	0.00		1.82	-0.96	0.27	-1.40	0.47	-1.27	0.20	-0.69	P	
1770	0.00		2.10	-0.73	0.40	0.00	0.70	-0.38	0.30	0.00	0.00	
1780	0.00		2.21	-0.64	0.41	0.11	0.55	-0.96	0.46	1.10	0.00	
1781	0.00		1.50	-1.22	0.50	1.08	0.50	-1.15	0.30	0.00	0.00	
1870	0.00		1.90	-0.89	0.30	-1.08	0.50	-1.15	0.20	-0.69	0.00	
1871	NR		2.00	-0.81	0.30	-1.08	0.50	-1.15	0.20	-0.69	0.10	
1875	0.00		2.17	-0.67	0.30	-1.08	0.58	-0.84	0.19	-0.76	0.01	
1896	0.00		2.50	-0.41	0.42	0.22	0.84	0.15	0.37	0.48	0.00	
2050	0.00		2.80	-0.16	0.40	0.00	0.73	-0.27	0.67	2.55	0.00	
2057	0.00		2.40	-0.49	0.40	0.00	1.30	1.92	0.40	0.69	0.00	
2716	0.00		3.08	0.06	0.40	0.00	0.78	-0.08	0.39	0.62	0.00	
2720	0.00		0.19	-2.28	0.28	-1.29	0.57	-0.88	0.25	-0.34	0.00	

**Table 39: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).** Values highlighted in **yellow** indicate z-scores outside of expected range, i.e.,  $z > 2$  and quantifications marked in **red** indicate values determined to be outliers by the Grubb's Test for Outliers or a positive value for a non-fortified sample.

Event: Bt176												
%w/w Fortification Level	0.0%		1.5%		0.0%		0.8%		0.1%		3.0%	
Participant Number	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score
1754	0.00		0.10	-2.85	0.00		0.10	-3.75	0.10	0.00	1.50	-1.24
1755	0.00		0.50	-2.03	0.00		0.30	-2.68	0.04	-1.41	1.10	-1.57
1761	0.00		4.00	5.08	0.00		0.50	-1.61	0.20	2.35	5.00	1.65
1769	0.00		1.01	-1.00	0.00		0.52	-1.50	0.07	-0.70	1.97	-0.85
1770	0.00		1.00	-1.02	0.00		0.50	-1.61	0.10	0.00	2.10	-0.74
1780	0.00		1.49	-0.02	0.00		0.71	-0.48	0.13	0.70	3.14	0.12
1781	0.00		1.10	-0.81	0.00		0.60	-1.07	0.10	0.00	2.00	-0.82
1788	0.00		1.10	-0.81	0.00		0.69	-0.59	0.10	0.00	1.70	-1.07
1870	0.00		1.60	0.20	0.00		0.70	-0.54	0.10	0.00	2.60	-0.33
1871	0.00		1.80	0.61	0.00		0.70	-0.54	0.12	0.47	2.50	-0.41
1875	0.00		1.01	-1.00	0.00		0.44	-1.93	0.08	-0.47	1.89	-0.92
1896	0.00		1.01	-1.00	0.00		0.43	-1.98	0.06	-0.94	0.00	-2.47
2050	0.00		1.12	-0.77	0.00		0.65	-0.80	0.15	1.17	2.70	-0.25
2057	0.00		1.30	-0.41	0.00		0.80	0.00	0.10	0.00	2.40	-0.49
2692	0.00		1.08	-0.85	0.00		0.65	-0.80	P		1.69	-1.08
2716	0.00		1.43	-0.14	0.00		0.80	0.00	0.12	0.47	5.00	1.65
2719	0.00		0.85	-1.32	0.80		0.40	-2.14	0.10	0.00	1.65	-1.11
2832	0.00		2.30	1.63	0.00		1.70	4.83	0.20	2.35	3.00	0.00

**Table 40: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).** Values highlighted in **yellow** indicate z-scores outside of expected range, i.e.,  $z > 2$  and quantifications marked in **red** indicate values determined to be outliers by the Grubb's Test for Outliers or a positive value for a non-fortified sample (i.e. a false positive result).

Event: Bt11												
%w/w Fortification Level	0.0%		3.0%		0.5%		0.4%		0.0%		1.5%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		2.40	-0.48	0.40	-0.30	0.20	-0.57	0.00		1.30	-0.25
1755	0.00		2.00	-0.79	0.20	-0.90	0.10	-0.86	0.00		0.80	-0.86
1761	0.00		5.00	1.59	0.50	0.00	0.40	0.00	0.00		4.10	3.19
1769	0.00		2.30	-0.56	0.37	-0.39	0.33	-0.20	0.00		1.18	-0.39
1770	0.00		3.80	0.63	0.80	0.90	0.50	0.29	0.00		1.80	0.37
1780	0.00		2.52	-0.38	0.49	-0.03	0.30	-0.29	0.00		1.51	0.01
1781	0.00		1.10	-1.51	0.10	-1.19	0.10	-0.86	0.00		0.70	-0.98
1788	0.00		2.50	-0.40	0.34	-0.48	0.38	-0.06	0.00		0.73	-0.95
1870	0.00		2.60	-0.32	0.60	0.30	0.50	0.29	0.00		1.80	0.37
1875	0.00		2.13	-0.69	0.48	-0.06	0.47	0.20	0.00		1.11	-0.48
1896	0.00		4.87	1.48	0.98	1.43	0.70	0.86	0.00		2.20	0.86
2050	0.00		2.48	-0.41	0.47	-0.09	0.31	-0.26	0.00		1.75	0.31
2057	0.00		2.10	-0.71	0.40	-0.30	0.40	0.00	0.00		1.20	-0.37
2692	0.00		5.77	2.20	0.65	0.45	0.67	0.77	0.00		2.07	0.70
2716	0.00		3.10	0.08	1.50	2.98	1.60	3.43	0.80		1.50	0.00
2719	*NR		2.70	-0.24	0.80	0.90	0.30	-0.29	0.00		1.20	-0.37
2832	0.00		37.40	27.30	2.30	5.37	5.40	14.30	0.00		30.70	35.84

\*NR = Not Reported

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

Event: NK603												
%w/w Fortification Level	0.0%		1.5%		0.1%		0.4%		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	0.00		0.30	-3.72	0.10	0.00	0.10	-2.69	0.00		0.10	-2.37
1755	0.00		1.00	-1.55	0.10	0.00	0.20	-1.79	0.00		0.40	-0.59
1761	0.00		0.40	-3.41	0.00	-2.62	0.10	-2.69	0.00		0.20	-1.78
1769	0.00		0.52	-3.04	0.00	-2.62	0.17	-2.06	0.00		0.17	-1.96
1770	0.00		0.80	-2.17	0.10	0.00	0.20	-1.79	0.00		0.40	-0.59
1780	0.00		1.38	-0.37	0.08	-0.52	0.31	-0.81	0.00		0.73	1.37
1781	0.00		0.80	-2.17	0.10	0.00	0.30	-0.90	0.00		0.40	-0.59
1870	0.00		1.00	-1.55	0.10	0.00	0.30	-0.90	0.00		0.40	-0.59
1875	0.00		1.00	-1.55	0.07	-0.79	0.24	-1.43	0.00		0.56	0.36
1896	0.00		1.31	-0.59	0.07	-0.79	0.23	-1.52	0.00		0.32	-1.07
2112	0.00		1.23	-0.84	0.11	0.26	0.34	-0.54	0.00		0.43	-0.42
2050	0.00		1.00	-1.55	0.10	0.00	0.40	0.00	0.00		0.52	0.12
2057	0.00		1.30	-0.62	0.10	0.00	0.50	0.90	0.00		0.50	0.00
2095	0.00		0.80	-2.17	0.10	0.00	0.10	-2.69	0.00		0.20	-1.78
2716	0.00		0.97	-1.64	0.10	0.00	0.30	-0.90	0.00		1.50	5.94
2719	0.00		1.20	-0.93	0.15	1.31	0.31	-0.81	0.00		0.50	0.00
2832	0.00		5.80	13.32	0.30	5.25	1.80	12.55	0.00		1.90	8.31

**Table 42: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).** Values in **yellow** indicate z-scores outside of expected range i.e.,  $z > 2$ . No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: Herculex												
%w/w Fortification Level	0.0%		0.0%		0.5%		0.0%		0.8%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.10	-2.34	0.00		0.20	-1.79	0.00	
1755	0.00		0.00		0.30	-1.17	0.00		0.40	-1.19	0.00	
1761	0.00		0.00		0.20	-1.76	0.00		0.50	-0.90	0.00	
1769	0.00		0.00		0.17	-1.93	0.00		0.24	-1.67	0.00	
1770	0.00		0.00		0.20	-1.76	0.00		0.30	-1.49	0.00	
1780	0.00		0.00		0.34	-0.94	0.00		0.51	-0.87	0.00	
1781	0.00		0.00		0.40	-0.59	0.00		0.70	-0.30	0.00	
1870	0.00		0.00		0.20	-1.76	0.00		0.40	-1.19	0.00	
1871	0.00		0.00		0.20	-1.76	0.00		0.40	-1.19	0.00	
1875	0.00		0.00		0.16	-1.99	0.00		0.24	-1.67	0.00	
1896	0.00		0.00		0.30	-1.17	0.00		0.47	-0.98	0.00	
2050	0.00		0.00		0.57	0.41	0.00		1.40	1.79	0.00	
2057	0.00		0.00		0.60	0.59	0.00		1.00	0.60	0.00	
2716	0.00		0.00		0.58	0.47	0.00		0.80	0.00	0.00	
2719	0.00		0.00		0.10	-2.34	0.00		0.20	-1.79	0.00	

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

Event: MON863												
%w/w Fortification Level	0.0%		0.0%		0.5%		1.5%		0.4%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		2.40	7.56	1.50	0.00	0.70	1.47	0.00	
1755	0.00		0.00		1.00	1.99	2.00	1.52	0.60	0.98	0.00	
1761	0.00		0.00		0.70	0.80	0.80	-2.13	0.80	1.96	0.00	
1769	0.00		0.00		0.35	-0.60	0.81	-2.10	0.27	-0.64	0.00	
1770	0.00		0.00		0.90	1.59	1.70	0.61	0.50	0.49	0.00	
1773	0.00		0.00		0.60	0.40	1.70	0.61	0.40	0.00	0.00	
1780	0.00		0.00		0.66	0.64	1.75	0.76	0.59	0.93	0.00	
1781	0.00		0.00		0.60	0.40	1.40	-0.30	0.40	0.00	0.00	
1870	0.00		0.00		0.60	0.40	1.90	1.22	0.60	0.98	0.00	
1871	0.00		0.00		0.60	0.40	1.60	0.30	0.50	0.49	0.00	
1875	0.00		0.00		0.54	0.16	1.71	0.64	0.61	1.03	0.00	
1896	0.00		0.00		1.31	3.22	3.04	4.68	1.06	3.24	0.00	
2112	0.00		0.00		0.56	0.24	1.78	0.85	0.39	-0.05	0.00	
2050	0.00		0.00		1.20	2.79	1.60	0.30	0.90	2.45	0.00	
2057	0.00		0.00		0.60	0.40	1.60	0.30	0.40	0.00	0.00	
2692	0.00		0.00		0.62	0.48	1.42	-0.24	0.35	-0.25	0.00	
2716	0.00		0.00		0.55	0.20	1.50	0.00	0.50	0.49	0.00	
2719	0.00		0.00		0.60	0.40	1.25	-0.76	0.45	0.25	0.00	

**Table 44: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays).** Values in yellow indicate z-scores outside of expected range i.e.,  $z > 2$ . No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: Herculex RW												
%w/w Fortification Level	0.0%		0.0%		0.5%		0.8%		0.1%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		1.00	1.97	1.00	0.45	0.20	1.47	0.00	
1755	0.00		0.00		0.40	-0.39	1.20	0.90	0.10	0.00	0.00	
1761	0.00		0.00		0.60	0.39	0.10	-1.57	0.10	0.00	0.00	
1780	0.00		0.00		0.79	1.14	1.23	0.96	0.14	0.59	0.00	
1781	0.00		0.00		0.90	1.57	1.10	0.67	0.20	1.47	0.00	
1870	0.00		0.00		1.00	1.97	1.40	1.35	0.30	2.93	0.00	
1871	0.00		0.00		0.70	0.79	0.80	0.00	0.20	1.47	0.00	
1875	0.00		0.00		0.81	1.22	1.21	0.92	0.12	0.29	0.00	
1896	0.00		0.00		1.25	2.95	1.92	2.51	0.26	2.35	0.00	
2057	0.00		0.00		0.80	1.18	1.10	0.67	0.20	1.47	0.00	
2716	0.00		0.00		0.42	-0.31	0.80	0.00	0.10	0.00	0.00	

**Table 45: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).** Values in yellow indicate z-scores outside of expected range i.e.,  $z > 2$ . No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: MIR604												
%w/w Fortification Level	0.0%		0.0%		0.1%		0.5%		1.5%		0.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.00		0.20	1.52	0.40	-0.67	1.90	0.84	0.00	
1755	0.00		0.00		0.20	1.52	0.50	0.00	1.40	-0.21	0.00	
1761	0.00		0.00		0.00	-1.52	0.10	-2.70	0.30	-2.52	0.00	
1769	0.00		0.00		0.06	-0.61	0.38	-0.81	1.21	-0.61	0.00	
1780	0.00		0.00		0.13	0.45	0.45	-0.34	1.51	0.02	0.00	
1781	0.00		0.00		0.10	0.00	0.20	-2.02	0.90	-1.26	0.00	
1870	0.00		0.00		0.08	-0.30	0.30	-1.35	1.10	-0.84	0.00	
1871	0.00		0.00		0.10	0.00	0.16	-2.29	0.60	-1.89	0.00	
1875	0.00		0.00		0.04	-0.91	0.23	-1.82	0.59	-1.91	0.00	
1896	0.00		0.00		0.06	-0.61	0.25	-1.69	0.90	-1.26	0.00	
2057	0.00		0.00		0.20	1.52	0.60	0.67	1.70	0.42	0.00	
2716	0.00		0.00		0.12	0.30	0.38	-0.81	1.04	-0.96	0.00	

**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%	0.5%	1.50%
Participant Number	Result	Result	Result
1754	0	0.2	0.9

**Table 47: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays).** Values highlighted in yellow indicate z-scores outside of expected range, i.e.,  $z > 2$  and quantifications marked in red indicate values determined to be outliers by the Grubb's Test for Outliers or a positive value for a non-fortified sample (i.e. a false positive result).

Event: RUR						
%w/w Fortification Level	0.0%		0.5%		1.5%	
Participant Number	Result	z-score	Result	z-score	Result	z-score
1754	0.00		0.40	-0.69	1.20	-0.96
1755	0.00		0.60	0.69	1.00	-1.60
1761	0.00		0.80	2.06	1.50	0.00
1769	0.00		0.55	0.34	1.64	0.45
1770	0.00		0.50	0.00	0.90	-1.92
1773	0.00		0.60	0.69	1.50	0.00
1780	0.00		0.55	0.34	1.33	-0.54
1781	0.00		0.80	2.06	1.80	0.96
1785	0.00		0.56	0.41	1.40	-0.32
1788	0.00		0.75	1.72	1.60	0.32
1858	0.00		0.57	0.48	0.82	-2.18
1862	0.00		0.54	0.28	1.39	-0.35
1870	0.00		0.60	0.69	1.30	-0.64
1875	0.00		0.50	0.00	1.14	-1.15
1892	0.00		0.90	2.75	1.60	0.32
1893	0.10		0.50	0.00	1.40	-0.32
1896	0.00		0.62	0.83	1.35	-0.48
2005	0.00		0.47	-0.21	1.05	-1.44
2031	0.00		0.50	0.00	1.80	0.96
2034	0.00		0.40	-0.69	1.28	-0.70
2039	0.00		0.50	0.00	1.30	-0.64
2050	0.00		0.70	1.38	1.20	-0.96
2057	0.00		0.60	0.69	1.80	0.96
2060	0.00		0.64	0.96	1.91	1.31
2095	0.00		0.50	0.00	1.00	-1.60
2112	0.00		0.55	0.34	1.23	-0.86
2132	0.00		1.45	6.54	2.12	1.98
2692	0.00		0.89	2.68	3.30	5.76
2716	0.00		0.92	2.89	1.47	-0.10
2719	0.00		0.84	2.34	1.58	0.26
2720	0.00		4.00	24.09	1.80	0.96
2725	0.04		0.74	1.65	1.26	-0.77
2808	0.00		0.70	1.38	1.80	0.96

**Table 48: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.** % Relative reproducibility standard deviation (%RSD<sub>R</sub>) = [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 calculations involving reported mean, standard deviation, % relative deviation, and % relative error but were **included** in the range of results.

Transgenic Event	Reported Results (N)	Fortification (% w/w)	Reported Mean	Standard Deviation	% Relative Standard Deviation	% Relative Error	Range of Results
T25	11	0.1	0.08	0.03	37.5%	-20.0%	0.00 - 1.00
T25	11	0.5	0.44	0.17	38.6%	-12.0%	0.20 - 0.70
T25	11	0.8	0.72	0.27	37.5%	-10.0%	0.30 - 2.80
T25	11	1.5	1.27	0.53	41.7%	-15.3%	0.69 - 4.90
CBH351	6	0.1	0.11	0.02	18.2%	10.0%	0.10 - 0.13
CBH351	6	0.5	0.50	0.15	30.0%	0.0%	0.30 - 0.73
MON810	21	0.1	0.10	0.04	40.0%	0.0%	0.03 - 0.20
MON810	21	0.1	0.09	0.04	44.4%	-11.1%	0.00 - 0.2
MON810	21	0.8	0.48	0.13	27.1%	-66.7%	0.25 - 0.80
GA21	15	0.3	0.35	0.15	42.9%	17.0%	0.19 - 0.67
GA21	15	0.4	0.39	0.09	23.1%	-2.5%	0.27 - 0.60
GA21	15	0.8	0.69	0.26	37.7%	-13.8%	0.40 - 1.30
GA21	15	3.0	2.12	1.23	58.0%	-29.3%	0.14 - 5.50
Bt176	18	0.1	0.11	0.04	36.4%	10.0%	0.04 - 0.20
Bt176	18	0.8	0.56	0.19	33.9%	-42.9%	0.10 - 1.70
Bt176	18	1.5	1.16	0.49	42.2%	-22.7%	0.10 - 4.00
Bt176	18	3.0	2.33	1.21	51.9%	-28.8%	0.00 - 5.00
Bt11	17	0.4	0.45	0.35	77.8%	12.5%	0.10 - 5.40
Bt11	17	0.5	0.57	0.34	59.7%	14.0%	0.10 - 2.30
Bt11	17	1.5	1.56	0.81	51.9%	4.0%	0.70 - 30.70
Bt11	17	3.0	2.96	1.26	42.6%	-1.3%	1.10 - 37.40
NK603	17	0.1	0.09	0.04	44.4%	-10.0%	0.10 - 0.30
NK603	17	0.4	0.26	0.11	42.3%	-35.0%	0.10 - 1.80
NK603	17	0.5	0.39	0.17	43.6%	-22.0%	0.10 - 1.90
NK603	17	1.5	0.94	0.32	34.0%	-37.3%	0.30 - 5.80
Herculex	15	0.5	0.29	0.17	58.6%	-42.0%	0.10 - 0.60
Herculex	15	0.8	0.52	0.34	65.4%	-35.0%	0.20 - 1.4
MON863	18	0.4	0.56	0.21	35.7%	40.0%	0.27 - 1.06
MON863	18	0.5	0.71	0.25	35.2%	42.0%	0.35 - 2.40
MON863	18	1.5	1.53	0.33	21.6%	2.0%	0.80 - 3.04
HerculexRW	11	0.1	0.17	0.07	41.0%	70.0%	0.10 - 0.30
HerculexRW	11	0.5	0.79	0.25	32.0%	58.0%	0.40 - 1.25
HerculexRW	11	0.8	1.08	0.45	41.7%	35.0%	0.10 - 1.92
MIR604	12	0.1	0.11	0.07	63.6%	10.0%	0.00 - 0.20
MIR604	12	0.5	0.33	0.15	45.5%	-34.0%	0.10 - 0.60
MIR604	12	1.5	1.10	0.48	43.6%	-26.7%	0.30 - 1.90
RUR	33	0.5	0.62	0.15	24.2%	24.0%	0.40 - 4.00
RUR	33	1.5	1.42	0.31	21.8%	-5.3%	0.82 - 3.30

## Summary of Findings

### Qualitative Sample Analysis

**DNA-based Testing.** The method of DNA-based testing for the qualitative determination of events was by a conventional polymerase chain reaction assay (PCR) which generally 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 detectable by a given laboratory employing conventional PCR. As evidenced by the summary of performance scores (**Table 29** and **Figure 1**), thirteen of the fourteen transgenic events were correctly detected with greater than or equal to 95% reliability. This was a moderate improvement over the performance in the May 2008 round wherein eleven of the fourteen events were detected with greater than or equal to 95% reliability. The only event that tested with less than 95% reliability was T25. The occurrence of T25 in this category was similar to the trend observed in the May 2008 report. The failure of this event to test with greater than 95% reliability was due to a high incidence of false positives (17.8%) and not false negatives (2.2%).

**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 ranging between 0.125 – 1.0% 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 - 1% w/w for corn and soy events (Ahmed, 2004). Laboratories demonstrated good proficiency when using protein-based methods to detect the presence of biotechnology-derived traits in maize that were fortified above their reported LOD (**Table 30**). Laboratories demonstrated good proficiency, without any false positive or false negative results, 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 event was by real-time quantitative PCR. This analytical method has a limit of detection (LOD) of 0.01% w/w and a limit of quantification (LOQ) of approximately 0.1% w/w for a specified 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" of all participants (**Table 48**). Because test samples were fortified ranging from 0.1 – 5.0% w/w of a particular event, it was expected that qPCR technologies would detect the traits in all of the fortified samples but not in non-fortified samples. With regard to the detection specificity and qPCR, a scattered number of detects in non-fortified samples were observed (i.e. false positive results, see **Tables 35, 37, 38, 39, 40, and 47**). Another expectation was that the **inter-laboratory variation** observed in reported quantifications, as measured by the % Relative Standard Deviation, should be higher in samples fortified at lower amounts (e.g. 0.1% w/w) as compared to the variation observed in samples fortified at higher amounts (e.g. 5% w/w). With regard to this inverse relationship between variability (%RSD<sub>R</sub>) in reported quantifications and fortification level, the trend generally held true with the exception of Bt-176



and GA21, and CBH351 (**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.europa.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 value was the %w/w fortification of the samples. In this round of proficiency testing, there were thirty-eight trials of inter-laboratory quantifications (i.e., total number of events at the total number of fortification levels) and in twenty-two of those trials the **inter-laboratory relative error** was observed to be  $\leq 25\%$  (**Table 48**). Thus, these results were approximately 58% concordant with the acceptance criteria for trueness as established by the Joint Research Council/ENGL. Furthermore, there was a tendency for the reported quantifications to be moderately under-estimated (low bias) as evidenced by the observation that approximately 55% of the quantification trials had percentage relative error values that were negative (**Table 48**). This same trend of a low bias in the quantifications in comparison to accepted values was observed in the quantitative data from previous rounds of our proficiency sample distributions which can be found at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=iws-prof-rep>.

**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 this round of inter-laboratory proficiency testing, the  $\%RSD_R$  for several of the transgenic events was greater than 35% for samples that were fortified above 0.1% (**Table 48**). This observation could be due numerous confounders including zygoty, lack of standardization, the presence of inhibitors in the reaction mix, etc. Monitoring and improving the performance of laboratories that use PCR technologies for the detection and/or quantification of transgenic events in corn and soybeans will improve the reliability of testing methods and the marketing of these commodities. The USDA/GIPSA proficiency testing program should be a complement to other quality assurance measures that laboratories use to improve their analytical capabilities.

## References

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Trait check Bt1 corn grain lateral flow test kit user guide. November 2001. Strategic Diagnostics, Inc., Newark, DE, part no. 3099998.

Trait check RUR bulk grain lateral flow test kit user guide. November 2003. Strategic Diagnostics, Inc., Newark, DE, part no. 3099956.

**\*Note:** 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. Reference standards are now commercially available for all transgenic traits used in this proficiency program and GIPSA encourages the use of these reference materials when developing internal validated methods.

To obtain additional information on the USDA/GIPSA Proficiency Program, contact Dr. Tandace Scholdberg, USDA/GIPSA Proficiency Program Manager, at US 816-891-0452, or by e-mail at [Tandace.A.Scholdberg@usda.gov](mailto:Tandace.A.Scholdberg@usda.gov).

**Appendix I:** List of organizations who wished to be identified as a participant in the GIPSA November 2008 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

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