

USDA/GIPSA Proficiency Program
Testing for the Presence of Biotechnology Events in Corn and Soybeans
October 2010 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 35 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 – mean reported value / standard deviation) were computed for each reported quantification result (Tables 44 to 60). Tests for outliers and z-scores assume a normal distribution. At the 0.0 or 0.1% fortification levels, and on tables with a limited number of results, the distributions are not likely normal and are probably skewed. A false positive on a 0.0% spike level is considered an outlier. At the 0.1% fortification 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 61) 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: T-25, CBH351, MON810, GA21, Bt-176, Bt-11, NK603, Herculex, MON863, Herculex RW, MIR 604 (Agrisure RWTM), Event 3272; 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 ranging from 0.1 to 2.0% of a specified event. The soybean samples were non-transgenic soybeans, or fortified soybean samples containing 0.1 to 1.5% of the transgenic glyphosate-tolerant soybeans (RoundUp Ready®), the glufosinate ammonium tolerant soybeans (A2704-12), and/or the transgenic glyphosate-tolerant soybeans (RoundUp ReadyII®). Each participant received six corn and four 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. No analytical methodologies were specified, and organizations used both DNA- and protein-based testing technologies. Sixty-two organizations received samples in the October 2010 round of proficiency testing, and fifty-seven organizations submitted results.

- Twenty-three participants submitted **qualitative** results only, (1 participant included protein),
- Six submitted **quantitative** results only,
- Twenty-four participants submitted a combination of **qualitative** and **quantitative** results (one participant performed DNA and protein based), and
- Four participants submitted **protein** based results, using Lateral Flow Strip (LFS) qualitative and/or Enzyme-linked Immunosorbent Assay (ELISA) quantitative analyses.

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 is 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 (%w/w) 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:

DNA Based Testing

- 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 T-25 for all participants (DNA-based assays).

- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T-25 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 Bt-11 for all participants (DNA-based assays).
- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports for Bt-11 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 corn 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 corn 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 corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports for Event 3272 for all participants.
- Table 29: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays).
- Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS for all participants.
- Table 31: Qualitative results for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays).
- Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports for A2704-12 for all participants.
- Table 33: Qualitative results for soybeans fortified with Roundup Ready II for all participants (DNA-based assays).
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- Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports for RoundUp Ready II for all participants.
- Table 35: Composite 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).

Protein Based Testing

- Table 36: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing).
- Table 37: Percentage of correct results, false negatives, and false positives in qualitative reports for transgenic events in corn using Lateral Flow Strip (LFS) Testing.
- Table 38: Qualitative results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) Testing.
- Table 39: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) Testing.
- Table 40: Qualitative results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 41: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 42: Qualitative results for soybeans fortified with CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).
- Table 43: 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 40- 53 on non-fortified (0.0%) samples since a z-score assumes a normal distribution and the interpretation may be distorted).

DNA Based Testing

- Table 44: Quantitative results and z-scores for corn fortified with T-25 for all participants (DNA-based assays).
- Table 45: Quantitative results and z-scores for corn fortified with CBH351 for all participants (DNA-based assays).
- Table 46: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).
- Table 47: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).
- Table 48: Quantitative results and z-scores for corn fortified with Bt176 for all participants (DNA-based assays).
- Table 49: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays).

- Table 50: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).
- Table 51: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays).
- Table 52: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).
- Table 53: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays).
- Table 54: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).
- Table 55: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 56: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RoundUp Ready) for all participants (DNA-based assays).
- Table 57: Quantitative results and z-scores for soybeans fortified with A2704-12 for all participants (DNA-based assays).
- Table 58: Quantitative results and z-scores for soybeans fortified with RoundUp Ready II for all participants (DNA-based assays).
- Table 59: Quantitative results for 35S and NOS in Maize (DNA based assay)
- Table 60: Results for 35S and NOS in soybeans (DNA based assay)
- Table 61: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays.
- Table 62: Quantitative results for corn fortified with CBH 351 using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results).
- Table 63: Quantitative results for soybeans fortified with CP4EPSPS (RUR) using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)
- Appendix I: List of organizations who wished to be identified as a participant in the GIPSA May 2009 Proficiency Program.

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

35S	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	P	P	P	P	N	P
1752	P	P	P	P	N	P
1754	P	P	P	P	N	P
1761	P	P	P	P	N	P
1773	P	P	P	P	N	P
1774	P	P	P	P	N	P
1844	P	P	P	P	N	P
1847	P	P	P	P	N	P
1854	P	P	P	P	N	P
1855	P	P	P	P	N	P
1858	P	P	P	P	N	P
1859	P	P	P	P	N	P
1862	P	P	P	P	N	P
1870	P	P	P	P	N	P
1875	P	P	P	P	N	P
1892	P	P	P	P	N	P
1893	P	P	P	P	N	P
1897	P	P	P	P	N	P
2031	P	P	P	N	N	P
2039	P	P	P	P	N	P
2057	P	P	P	P	N	P
2076	P	P	P	P	N	P
2100	P	P	P	P	N	P
2112	P	P	P	P	N	P
2113	P	P	P	P	N	P
2123	P	P	P	P	N	P
2126	P	P	P	P	N	P
2131	P	P	P	P	N	P
2132	P	P	P	P	N	P
2694	P	P	P	P	N	P
2708	P	P	P	P	N	P
2716	P	P	P	P	N	P
2719	P	P	P	P	N	P
2720	P	P	P	P	N	P
2727	P	P	P	P	N	P
2732	P	P	P	P	N	P
2822	P	P	P	P	N	P
2829	P	P	P	P	N	P
3095	P	P	P	P	N	P
3929	P	P	P	P	N	P
4500	P	P	P	P	N	P
4502	P	P	P	P	N	P
4936	P	P	P	P	N	P
N, Results	42	42	42	42	42	42
# Negative	0	0	0	1	42	0
# Positive	42	42	42	41	0	42
% Correct	100%	100%	100%	97.6%	100%	100%
% Incorrect	0.0%	0.0%	0.0%	2.4%	0.0%	0.0%

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

Total # Reported results	252
# Incorrect	1
% Correct	99.6%
# Provided Positives (P)	209
# False Negative	1
% False Negative	0.5%
# Provided Negatives (N)	42
# False Positive	0
% False Positive	0.0%

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

NOS	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	P	P	P	P	N	P
1752	P	P	P	P	N	P
1754	P	P	P	P	N	P
1761	P	P	P	P	N	P
1773	P	P	P	P	N	P
1774	P	P	P	P	N	P
1844	P	P	P	P	N	P
1847	P	P	P	P	N	P
1854	P	P	P	P	N	P
1855	P	P	P	P	N	P
1858	P	P	P	P	N	P
1859	P	P	P	P	N	P
1862	P	P	P	P	N	P
1870	P	P	P	P	N	P
1875	P	P	P	P	N	P
1892	P	P	P	P	N	P
1893	P	P	P	P	N	P
1897	P	P	P	P	N	P
2031	P	P	P	P	N	P
2039	P	P	P	P	N	P
2057	P	P	P	P	N	P
2076	P	P	P	P	N	P
2112	P	P	P	P	N	P
2113	P	P	P	P	N	P
2123	P	N	N	P	N	P
2126	P	P	P	P	N	P
2131	P	P	P	P	N	P
2132	P	P	P	P	N	P
2694	P	P	P	P	N	P
2708	P	N	P	P	N	P
2716	P	P	P	P	N	P
2719	P	P	P	P	N	P
2727	P	P	P	P	N	P
2732	P	P	P	P	N	P
2822	P	P	P	P	N	P
2829	P	P	P	P	N	P
3095	P	P	P	P	N	P
3929	P	P	P	P	N	P
4500	P	P	P	P	N	P
4502	P	P	P	P	N	P
4936	P	P	P	P	N	P
N, Results	40	40	40	40	40	40
# Negative	0	2	1	0	40	0
# Positive	40	38	39	40	0	40
% Correct	100%	94.9%	97.4%	100%	100%	100%
% Incorrect	0.0%	5.0%	2.5%	0.0%	0.0%	0.0%

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

Total # Reported results	240
# Incorrect	3
% Correct	98.8%
# Provided Positives (P)	197
# False Negative	3
% False Negative	1.5%
# Provided Negatives (N)	40
# False Positive	0
% False Positive	0%

Table 5: Qualitative results for corn fortified with T-25 for all participants (DNA-based assays) (N = negative; P = positive).

T25	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	1.0%	0.0%	2.0%	*0%	0.0%	0.5%
1752	P	N	P	N	N	P
1773	P	N	P	P	N	P
1774	P	N	P	P	N	P
1788	P	N	P	P	N	P
1844	P	N	P	N	N	P
1854	P	N	P	P	N	P
1859	P	N	P	N	N	P
1862	P	N	P	N	N	P
1892	P	N	P	P	N	P
1893	P	N	P	N	N	P
1897	P	N	P	P	N	P
2060	P	N	P	P	N	P
2089	P	N	P	N	N	P
2113	P	N	P	N	N	N
2126	P	N	P	N	N	P
2131	P	N	P	N	N	P
2132	P	N	P	P	N	P
2560	P	N	P	N	N	P
2694	P	N	P	P	N	P
2708	P	N	P	N	N	P
2732	P	N	P	N	N	P
2822	P	N	P	N	N	P
3929	P	N	P	N	N	P
4500	P	N	P	N	N	P
4502	P	N	P	N	N	P
4936	N	N	P	N	N	P
N, Results	26	26	26	26	26	26
# Negative	1	26	0	17	26	1
# Positive	25	0	26	9	0	25
% Correct	96.2%	100%	100%	65.4%	100%	96.2%
% Incorrect	3.8%	0%	0%	34.6%	0%	3.8%

Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports for T-25 for all participants.

Total # Reported results	156
# Incorrect	11
% Correct	93.0%
# Provided Positives	78
# False Negative	2
% False Negative	2.6%
# Provided Negatives	78
# False Positive	9
% False Positive	11.5%

*- historic unusually high rate of false positive results

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 5	Sample 6
Participant Number	1.0%	0.0%	0.1%	0.0%	0.0%	0.0%
1752	P	N	P	N	N	N
1773	P	N	P	P	N	N
1774	P	N	P	N	N	N
1788	P	N	P	N	N	N
1844	P	N	P	P	N	N
1854	P	P	≤0.5%*	P	N	N
1859	P	N	P	N	N	N
1875	P	N	P	N	N	N
1892	P	N	P	N	N	N
1893	P	N	P	N	N	N
1897	P	N	P	N	N	N
2039	P	N	P	N	N	N
2113	P	N	P	N	N	N
2131	P	N	P	N	N	N
2732	P	N	P	P	N	N
3095	P	N	P	N	N	N
N, Results	16	16	16	16	16	16
# Negative	0	15	0	12	16	16
# Positive	16	1	15	4	0	0
% Correct	100%	93.8%	100%	75.0%	100%	100%
% Incorrect	0%	6.3%	0.0%	25.0%	0%	0%

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

Total # Reported results	96
# Incorrect	5
% Correct	94.8%
# Provided Positives	31
# False Negative	0
% False Negative	0.0%
# Provided Negatives	65
# False Positive	5
% False Positive	7.7%

* - Fortification level below participant's LOD, counted as Provided Negative

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	1.0%	0.5%	2.0%	0.0%	0.0%	0.1%
1752	P	P	P	N	N	P
1774	P	P	P	N	N	P
1788	P	P	P	N	N	P
1844	P	P	P	N	N	P
1854	P	P	P	N	N	≤0.5% *
1858	P	P	P	N	N	P
1859	P	P	P	N	N	P
1862	P	P	P	N	N	P
1892	P	P	P	N	N	P
1893	P	P	P	N	N	P
1897	P	P	P	N	N	P
2060	P	P	P	N	N	P
2089	P	P	P	N	N	P
2113	P	P	P	N	N	P
2126	P	P	P	N	N	P
2131	P	P	P	N	N	P
2132	P	P	P	N	N	P
2560	P	P	P	N	N	P
2569	P	P	P	N	N	P
2708	P	P	P	N	N	P
2719	P	P	P	N	N	N
2822	P	P	P	N	N	P
2824	P	P	P	N	N	≤0.2% *
2829	P	P	P	P	N	N
3095	P	P	P	N	N	P
3929	P	P	P	N	N	P
4500	P	P	P	N	N	P
4502	P	P	P	N	N	P
N, Results	28	28	28	28	28	28
# Negative	0	0	0	27	28	2
# Positive	28	28	28	1	0	24
% Correct	100%	100%	100%	96.4%	100%	89.3%
% Incorrect	0%	0%	0%	3.6%	0%	7.1%

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

Total # Reported results	168
# Incorrect	3
% Correct	98.2%
# Provided Positives	112
# False Negative	2
% False Negative	1.8%
# Provided Negatives	58
# False Positive	1
% False Positive	98.3%

* - Fortification level below participant's LOD, counted as Provided Negative

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	0.1%	0.2%	0.0%	0.8%	0.0%	0.6%
1752	P	P	N	P	N	P
1774	P	P	N	P	N	P
1788	P	P	N	P	N	P
1844	P	P	N	P	N	P
1854	P	P	P	P	N	P
1858	P	P	N	P	N	P
1859	P	P	N	P	N	P
1862	P	P	N	P	N	P
1892	P	P	N	P	N	P
1893	P	P	N	P	N	P
1897	P	P	N	P	N	P
2039	P	P	N	P	N	P
2060	P	P	N	P	N	P
2089	P	P	N	P	N	P
2113	P	P	N	P	N	P
2126	P	P	N	P	N	P
2131	P	P	N	P	N	P
2560	P	P	N	P	N	P
2569	P	P	N	P	N	P
2708	P	P	N	P	N	P
2719	P	P	N	P	N	P
2720	P	P	N	P	N	P
2727	P	P	N	P	N	P
2822	P	P	N	P	N	P
2824	P	P	P	P	P	N
3095	P	P	N	P	N	P
3929	P	P	N	P	N	P
4500	P	P	N	P	N	P
4502	P	P	N	P	N	P
4936	P	P	N	P	N	P
N, Results	30	30	30	30	30	30
# Negative	0	0	28	0	29	1
# Positive	30	30	2	30	1	29
% Correct	100%	100%	93.3%	100%	96.7%	96.7%
% Incorrect	0%	0%	6.7%	0%	3.3%	3.3%

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

Total # Reported results	180
# Incorrect	4
% Correct	97.8%
# Provided Positives	120
# False Negative	1
% False Negative	0.8%
# Provided Negatives	60
# False Positive	3
% False Positive	5.0%

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	0.1%	0.5%	1.5%	0.8%	0.0%	0.1%
1752	P	P	P	P	N	P
1773	P	P	P	P	N	P
1774	P	P	P	P	N	P
1788	P	P	P	P	N	P
1844	P	P	P	P	N	P
1854	P	P	N	P	N	≤0.5% *
1858	P	P	P	P	N	P
1859	P	P	P	P	N	P
1862	P	P	P	P	N	P
1892	P	P	P	P	N	P
1893	P	P	P	P	N	P
1897	P	P	P	P	N	P
2039	P	P	P	P	N	P
2060	P	P	P	P	N	P
2113	P	P	P	P	N	P
2126	P	P	P	P	N	P
2131	P	P	P	P	N	P
2569	P	P	P	P	N	P
2708	P	P	P	P	N	P
2822	N	P	P	P	N	N
3095	P	P	P	P	N	P
3929	P	P	P	P	N	P
4500	P	P	P	P	N	P
4502	P	P	P	P	N	P
N, Results						
	24	24	24	24	24	24
# Negative	1	0	1	0	24	1
# Positive	23	24	23	24	0	22
% Correct	95.8%	100%	95.8%	100%	100%	95.8%
% Incorrect	4.2%	0%	4.2%	0%	0%	4.2%

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

Total # Reported results	144
# Incorrect	4
% Correct	97.2%
# Provided Positives	119
# False Negative	3
% False Negative	2.5%
# Provided Negatives	25
# False Positive	0
% False Positive	0%

* - Fortification Level below participant's LOD,
counted as Provided Negative

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%	0.8%	0.1%	0.4%	0.0%	1.5%
1752	N	P	P	P	N	P
1773	N	P	P	P	N	P
1774	N	P	P	P	N	P
1788	N	P	P	P	N	P
1844	N	P	P	P	N	P
1854	N	P	P	≤0.5%*	N	P
1858	N	P	P	P	N	P
1859	N	P	P	P	N	P
1862	N	P	P	P	N	P
1892	N	P	P	P	N	P
1893	N	P	P	P	N	P
1897	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
2113	N	P	N	P	N	P
2126	N	P	P	P	N	P
2131	N	P	P	P	N	P
2560	N	P	P	P	N	P
2569	N	P	P	P	N	P
2694	N	P	P	P	N	P
2727	N	P	N	P	N	P
2822	N	P	P	P	N	P
2824	P	P	P	P	P	N
2829	N	P	P	P	N	P
3095	N	P	P	P	N	P
3929	N	P	P	P	N	P
4500	N	P	P	P	N	P
N, Results	28	28	28	28	28	28
# Negative	27	0	2	1	27	1
# Positive	1	28	26	27	1	27
% Correct	96.4%	100%	92.9%	100%	96.4%	96.4%
% Incorrect	3.6%	0%	7.1%	0%	3.6%	3.6%

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

Total # Reported results	168
# Incorrect	5
% Correct	97.0%
# Provided Positives	111
# False Negative	3
% False Negative	2.7%
# Provided Negatives	57
# False Positive	2
% False Positive	3.5%

* - Fortification Level below participant's LOD, counted as Provided Negative

Table 17: Qualitative results for corn fortified with NK603 for all participants. (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	1.3%	0.0%	0.65%	0.4%	0.0%	0.0%
1752	P	N	P	P	N	N
1761	P	N	P	P	N	P
1773	P	N	P	P	N	N
1774	P	N	P	P	N	N
1788	P	N	P	P	N	N
1844	P	N	P	P	N	N
1854	P	N	P	P	N	N
1858	P	N	P	P	N	N
1859	P	N	P	P	N	N
1862	P	N	P	P	N	N
1893	P	N	P	P	N	N
1897	P	N	P	P	N	N
2060	P	N	P	P	N	N
2089	P	N	P	P	N	N
2113	P	N	P	P	N	N
2126	P	N	P	P	N	N
2131	P	N	P	P	N	N
2132	P	N	P	P	N	N
2560	P	N	P	P	N	N
2569	P	N	P	P	N	N
2708	P	N	P	P	N	N
2719	P	N	P	P	N	N
2822	P	N	P	P	N	N
2824	P	N	P	P	N	N
3929	P	N	P	P	N	N
4500	P	N	P	P	N	N
4502	P	N	P	P	N	N
4936	P	N	P	P	N	P
N, Results	28	28	28	28	28	28
# Negative	0	28	0	0	28	26
# Positive	28	0	28	28	0	2
% Correct	100.0%	100%	100%	100%	100%	92.9%
% Incorrect	0.0%	0%	0%	0%	0%	7.1%

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

Total # Reported results	168
# Incorrect	2
% Correct	98.8%
# Provided Positives	84
# False Negative	0
% False Negative	0.0%
# Provided Negatives	84
# False Positive	2
% False Positive	2.4%

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	0.1%	0.0%	0.0%	0.0%	0.0%	0.75%
1752	P	N	N	N	N	P
1761	P	N	N	N	N	P
1773	P	N	N	N	N	P
1774	P	N	N	N	N	P
1844	P	N	N	N	N	P
1854	P	P	N	N	N	P
1859	P	N	N	N	N	P
1862	P	N	N	N	N	P
1893	P	N	N	N	N	P
2039	P	N	N	N	N	P
2060	P	N	N	N	N	P
2089	P	N	N	N	N	P
2113	P	N	N	N	N	P
2126	P	N	N	N	N	P
2131	P	N	N	N	N	P
2560	P	N	N	N	N	P
2569	N	N	N	N	N	P
2708	P	N	N	N	N	P
2822	P	N	N	N	N	P
3929	P	N	N	N	N	P
4500	P	N	N	N	N	P
4502	P	N	N	N	N	P
N, Results	22	22	22	22	22	22
# Negative	1	21	22	22	22	0
# Positive	21	1	0	0	0	22
% Correct	95.5%	95.5%	100%	100%	100%	100%
% Incorrect	4.5%	4.5%	0%	0%	0%	0%

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

Total # Reported results	132
# Incorrect	2
% Correct	98.5%
# Provided Positives	44
# False Negative	1
% False Negative	2.3%
# Provided Negatives	88
# False Positive	1
% False Positive	1.1%

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%	0.0%	1.5%	0.0%	0.8%
1761	N	N	N	P	N	P
1773	N	N	N	P	N	P
1774	N	N	N	P	N	P
1788	N	N	N	P	N	P
1844	N	N	N	P	N	P
1854	N	N	N	P	N	P
1859	N	N	N	P	N	P
1893	N	N	N	P	N	P
1897	N	N	N	P	N	P
2039	N	N	N	P	N	P
2060	N	N	N	P	N	P
2089	N	N	N	P	N	P
2113	N	N	N	P	N	P
2126	N	N	N	P	N	P
2131	N	N	N	P	N	P
2560	N	N	N	P	N	P
2569	N	N	N	P	N	P
2708	N	N	N	P	N	P
2719	N	N	N	P	N	P
2822	N	N	N	P	N	P
2824	N	N	N	P	N	N
3929	N	N	N	P	N	P
4500	N	N	N	P	N	P
N, Results	23	23	23	23	23	23
# Negative	23	23	23	0	23	1
# Positive	0	0	0	23	0	22
% Correct	100%	100%	100%	100%	100%	95.7%
% Incorrect	0%	0%	0%	0%	0%	4.3%

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

Total # Reported results	138
# Incorrect	1
% Correct	99.3%
# Provided Positives	46
# False Negative	1
% False Negative	2.2%
# Provided Negatives	92
# False Positive	0
% False Positive	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	2.0%	0.0%	0.0%	0.8%	0.0%	0.1%
1752	P	N	N	P	N	P
1761	P	N	N	P	N	P
1773	P	N	N	P	N	P
1774	P	N	N	P	N	P
1844	P	N	N	P	N	P
1859	P	N	N	P	N	P
1893	P	N	N	P	N	P
2039	P	N	N	P	N	P
2060	P	N	N	P	N	P
2089	P	N	N	P	N	P
2113	P	N	N	P	N	P
2126	P	N	N	P	N	P
2131	P	N	N	P	N	P
2560	P	N	N	P	N	P
2569	P	N	N	P	N	P
2708	P	N	N	P	N	P
2822	P	N	N	P	N	P
3929	P	N	N	P	N	P
4500	P	N	N	P	N	P
N, Results	19	19	19	19	19	19
# Negative	0	19	19	0	19	0
# Positive	19	0	0	19	0	19
% Correct	100%	100%	100%	100%	100%	100%
% Incorrect	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	114
# Incorrect	0
% Correct	100%
# Provided Positives	57
# False Negative	0
% False Negative	0%
# Provided Negatives	57
# False Positive	0
% False Positive	0%

Table 25: Qualitative results for corn fortified with MIR604 for all participants (DNA-based assays). (N = negative; P = positive; Incorrect results are shown in boldface).

MIR604	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.5%	0.8%	0.0%	0.5%	0.0%	0.0%
1752	P	P	N	P	N	N
1761	P	P	N	P	N	N
1773	P	P	N	P	N	N
1774	P	P	N	P	N	N
1844	P	P	N	P	N	N
1854	P	P	N	P	N	N
1859	P	P	N	P	N	N
1893	P	P	N	P	N	N
2060	P	P	N	P	N	N
2089	P	P	N	P	N	N
2112	P	P	N	P	N	N
2113	P	P	N	P	N	N
2126	P	P	N	P	N	N
2131	P	P	N	P	N	N
2560	P	P	N	P	N	N
2708	P	P	N	P	N	N
2822	P	P	N	P	N	N
2824	N	P	N	P	P	N
3929	P	P	N	P	N	N
4500	P	P	N	P	N	N
4502	P	P	N	P	N	N
N, Results	21	21	21	21	21	21
# Negative	1	0	21	0	20	21
# Positive	20	21	0	21	1	0
% Correct	95.2%	100%	100%	100%	95.2%	100%
% Incorrect	4.8%	0%	0%	0%	4.8%	0%

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

# Reported results	126
# Incorrect	2
% Correct	98.4%
# Provided Positives	63
# False Negative	1
% False Negative	1.6%
# Provided Negatives	63
# False Positive	1
% False Positive	1.6%

Table 27: Qualitative results for corn fortified with Event 3272 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

Event 3272	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Participant Number	0.1%	0.2%	0.5%	0.0%	0.0%	1.0%
1773	P	P	P	N	N	P
1774	P	P	P	N	N	P
1844	P	P	P	N	N	P
1854	P	N	P	N	N	P
1859	P	P	P	N	N	P
1893	P	P	P	N	N	P
2060	N	N	P	N	N	P
2113	P	P	P	N	N	P
2131	P	P	P	N	N	P
2822	P	P	P	N	N	P
4500	P	P	P	N	N	P
N, Results	11	11	11	11	11	11
# Negative	1	2	0	11	11	0
# Positive	10	9	11	0	0	11
% Correct	90.9%	81.8%	100%	100%	100%	100%
% Incorrect	9.1%	18.2%	0.0%	0.0%	0.0%	0.0%

Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports for Event 3272 for all participants.

# Reported results	66
# Incorrect	3
% Correct	95.5%
# Provided Positives	44
# False Negative	3
% False Negative	6.8%
# Provided Negatives	22
# False Positive	0
% False Positive	0%

Table 29: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready) for all participants (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

CP4 EPSPS	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.2%	0.8%	0.0%
1752	N	P	P	N
1761	N	P	P	N
1774	N	P	P	N
1788	P	P	P	N
1844	N	P	P	N
1854	N	P	P	N
1858	N	P	P	N
1859	N	P	P	N
1892	N	P	P	N
1897	N	P	P	N
2076	N	P	P	N
2100	N	P	P	N
2112	N	P	P	N
2113	N	P	P	N
2131	N	P	P	N
2132	N	P	P	N
2560	N	P	P	N
2719	N	P	P	N
2822	N	P	P	N
2824	P	P	P	P
2829	N	P	P	N
3095	N	P	P	N
N, Results	22	22	22	22
# Negative	20	0	0	21
# Positive	2	22	22	1
% Correct	90.9%	100.00%	100.00%	95.5%
% Incorrect	9.1%	0.0%	0.0%	4.6%

Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS (Roundup Ready) for all participants.

Total # Reported results	88
# Incorrect	3
% Correct	96.6%
# Provided Positives	44
# False Negative	0
% False Negative	0%
# Provided Negatives	44
# False Positive	3
% False Positive	6.8%

Table 31: Qualitative results for soybeans fortified with A2704-12 (Liberty Link Soy) for all participants (DNA-based assays) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

A2704-12	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.1%	0.2%	0.0%	0.0%
1761	P	P	N	N
1774	P	P	N	N
1844	P	P	N	N
1854	P	P	P	N
1859	P	P	N	N
1893	P	P	N	N
2031	P	P	N	N
2060	P	P	N	N
2076	P	N	N	N
2112	P	P	N	N
2113	P	P	N	N
2031	N	P	P	N
2131	P	P	N	N
2132	P	P	N	N
2560	P	P	N	N
2716	P	P	N	N
2719	N	P	N	N
3095	P	P	N	N
4500	P	P	N	N
4502	N	N	N	N
N, Results	20	20	20	20
# Negative	3	2	18	20
# Positive	17	18	2	0
% Correct	85.0%	90.0%	90.0%	100.0%
% Incorrect	15.0%	10.0%	10.0%	0.0%

Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports for A2704-12 (Liberty Link Soy) for all participants.

Total # Reported results	80
# Incorrect	7
% Correct	91.3%
# Provided Positives	40
# False Negative	5
% False Negative	12.5%
# Provided Negatives	40
# False Positive	2
% False Positive	5.0%

Table 33: Qualitative results for soybeans fortified with CP4 EPSPS (Roundup Ready II) for all participants (DNA-based assays) (N = negative; P = positive)

RUR II	Sample 1	Sample 2	Sample 3	Sample 4
Participant Number	0.0%	0.0%	0.5%	0.0%
1774	N	N	P	N
1844	N	N	P	N
1859	N	N	P	N
1870	N	N	P	N
1875	N	N	P	N
1893	N	N	P	N
2031	N	N	P	N
2060	N	N	P	N
2131	N	N	P	N
2560	N	N	P	N
2716	N	N	P	N
4502	N	N	P	N
N, Results	12	12	12	12
# Negative	12	12	0	12
# Positive	0	0	12	0
% Correct	100%	100%	100%	100%
% Incorrect	0.0%	0.0%	0.0%	0.0%

Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports for CP4 EPSPS (Roundup Ready II) for all participants.

Total # Reported results	48
# Incorrect	0
% Correct	100%
# Provided Positives	12
# False Negative	0
% False Negative	0.0%
# Provided Negatives	36
# False Positive	0
% False Positive	0.0%

Table 35: 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	Bt11	NK603
N, Results	252	240	156	96	168	180	144	168	168
Reported Incorrect	1	3	11	6	3	4	4	5	2
% Correct	99.6%	98.8%	92.9%	93.8%	98.2%	97.8%	97.2%	97.0%	98.8%
N, Provided Positives	209	197	78	31	112	120	119	111	84
N, False Negatives	1	3	2	0	2	1	3	3	0
% False Negative	0.5%	1.5%	2.6%	0.0%	1.8%	0.8%	2.5%	2.7%	0%
N, Provided Negatives	42	40	78	65	58	60	25	57	84
N, False Positives	0	0	9	5	1	3	0	2	2
% False Positives	0%	0%	11.5%	7.7%	98.3%	5.0%	0%	3.5%	2.4%

Event	Herculex	MON863	Herculex RW	MIR604	EV3272	RUR	A2704-12	RUR II
N, Results	132	138	114	126	66	84	76	48
Reported Incorrect	2	1	0	2	3	3	7	0
% Correct	98.5%	99.3%	100%	98.4%	95.5%	96.4%	90.8%	100%
N, Provided Positives	44	46	57	63	44	42	38	12
N, False Negatives	1	1	0	1	3	0	5	0
% False Negative	2.3%	2%	0%	1.6%	6.8%	0%	13.2%	0%
N, Provided Negatives	88	92	57	63	22	42	38	36
N, False Positives	1	0	0	1	0	3	2	0
% False Positives	1.1%	0%	0%	1.6%	0%	7.1%	5.3%	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 33.

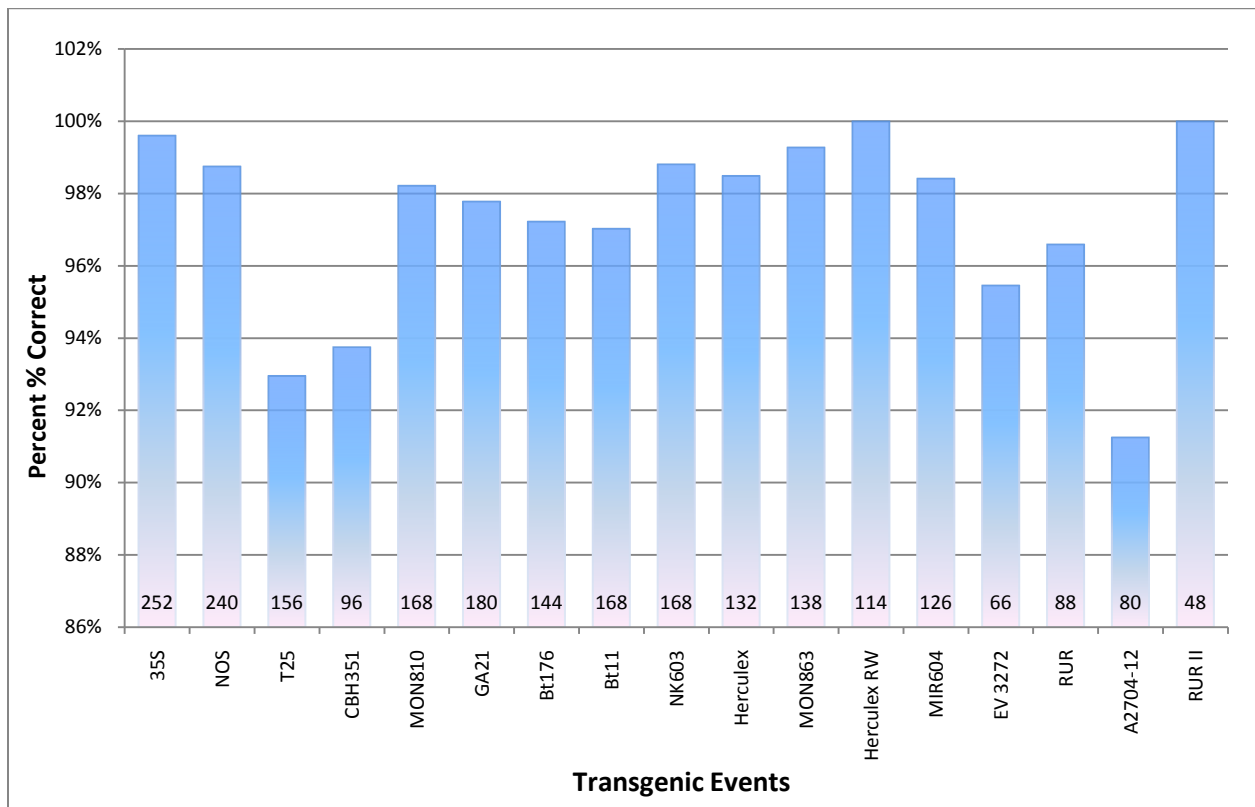


Table 36: Qualitative results for the detection of transgenic events in corn using Lateral Flow Strip (LFS) Testing (Protein-based testing) (N = negative; P = positive; NR = no result submitted; Incorrect results are shown in boldface).

NK603	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	LOD
Participant	1.3%	0.0%	0.65%	0.4%	0.0%	0.0%	
1843	>0.5%	≤0.5%	>0.5%	>0.5%	≤0.5%	≤0.5%	0.5%
3931	>0.1%	≤0.1%	>0.1%	>0.1%	≤0.1%	≤0.1%	0.1%
Cry1Ab	1.1%	1.8%	3.6%	1.2%	0.0%	1.7%	
1843	≤2.0%	≤2.0%	≤2.0%	≤2.0%	≤2.0%	>2.0%	2.0%
3931	>0.1%	>0.1%	>0.1%	>0.1%	≤0.1%	>0.1%	0.1%
Herculex	0.1%	0.0%	0.0%	0.0%	0.0%	0.75%	
1843	≤0.5%	≤0.5%	≤0.5%	≤0.5%	≤0.5%	>0.5%	0.5%
MON863	0.0%	0.0%	0.0%	1.5%	0.0%	0.8%	
1843	≤0.5%	≤0.5%	≤0.5%	>0.5%	≤0.5%	>0.5%	0.5%
Hclx RW	2.0%	0.0%	0.0%	0.8%	0.0%	0.1%	
1843	>0.5%	>0.5%	≤0.5%	>0.5%	≤0.5%	≤0.5%	0.5%
MIR 604	0.5%	0.8%	0.0%	0.5%	0.0%	0.0%	
1843	>0.13%	>0.13%	≤0.13%	>0.13%	≤0.13%	≤0.13%	0.13%

*Note: Only samples fortified **at or above** the participants LOD are considered in this table as provided positives. In some instances, the actual fortified amount is below the participants reported LOD (i.e. Cry1Ab, Herculex). If the participant correctly identified the presence of the trait, even though the sample was fortified below their reported LOD, it was assessed as a correct result. Only samples fortified **below** the participants LOD where a negative result was reported are considered in this table as provided negatives.

Table 37: Percentage of correct results, false negatives, and false positives in qualitative reports for transgenic events in corn using Lateral Flow Strip (LFS) Testing.

Event	NK 603	Cry1Ab	Hclx	Mon863	Hclx RW	MIR 604
Total # Reported Results	12	12	6	6	6	6
# Incorrect	0	1	0	0	0	0
% Correct	100%	91.7%	100%	100%	100%	100%
# Provided Positives	6	10	2	2	2	3
# False Negatives	0	1	0	0	0	0
% False Negatives	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
# Provided Negatives	6	2	4	4	4	3
# False Positives	0	0	0	0	0	0
% False Positive	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Table 38: Qualitative results for soybeans fortified with CP4EPSPS (RUR) and A2704-12 (LL) for all participants using Lateral Flow Strip (LFS) Testing (N = negative; P = positive; (Incorrect results are shown in boldface).

CP4 EPSPS (RUR)	Sample 1	Sample 2	Sample 3	Sample 4	
Participant Number	0.0%	0.2%	0.8%	0.0%	LOD
1782	N	P	P	N	Not Provided
1843	≤0.5%	>0.5%	>0.5%	>0.5%	0.50%
2126	N	P	P	P	Not Provided
3931	≤0.1%	>0.1%	>0.1%	≤0.1%	0.10%

N, Results	4	4	4	4
# Negative	4	0	0	2
# Positive	0	4	4	2
% Correct	100.0%	100.0%	100.0%	50.0%
% Incorrect	0.0%	0.0%	0.0%	50.0%

A2704-12 (Liberty Link)	0.10%	0.20%	0.00%	0.00%	LOD
1782	N	N	N	N	Not Provided
1843	>0.5%	>0.5%	≤0.5%	≤0.5%	0.50%

Note: On Sample 1 in Liberty Link, participant 1843 correctly identified the presence of the trait, even though the sample was fortified below their reported LOD, and was assessed as a correct result.

Table 39: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for all participants using Lateral Flow Strip (LFS) Testing.

Event	RUR	LL
Total # Reported results	16	8
# Incorrect	2	2
% Correct	87.5%	75.0%
# Provided Positives	8	4
# False Negative	0	2
% False Negative	0.0%	50.0%
# Provided Negatives	8	4
# False Positive	2	0
% False Positive	25.0%	0.0%

Table 40: Qualitative results for the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Participant	1	2	3	4	5	6	LOD
NK 603	1.3%	0.0%	0.65%	0.4%	0.0%	0.0%	
3931	>0.1%	≤0.1%	>0.1%	>0.1%	≤0.1%	≤0.1%	0.10%
Cry1 Ab	1.1%	1.8%	3.6%	1.2%	0.0%	1.7%	
3931	>0.1%	>0.1%	>0.1%	>0.1%	≤0.1%	>0.1%	0.10%
Herculex	0.1%	0.0%	0.0%	0.00%	0.0%	0.75%	
3931	≤0.1%	≤0.1%	≤0.1%	≤0.1%	≤0.1%	>0.1%	0.10%

Note: Sample 1 contained Herculex trait that was fortified at the LOD level for LFS testing used by the participant (0.1%). A non-detect result is reported. The reported LOD is assessed as a correct result.

Table 41: Percentage of correct results in the detection of transgenic events in corn using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

	NK 603	Cry1 Ab	Herculex
Total # Reported results	6	6	6
# Incorrect	0	0	0
% Correct	100%	100%	100.0%
# Provided Positives	3	5	2
# False Negative	0	0	0
% False Negative	0.0%	0.0%	0.0%
# Provided Negatives	3	1	4
# False Positive	0	0	0
% False Positive	0.0%	0.0%	0.0%

Table 42: 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	Sample 4	
Participant Number	0.0%	0.20%	1.50%	0.0%	LOD
2817	≤0.3%	≤0.3%	>0.3%	≤0.3%	0.3%
3931	≤0.1%	>0.1%	>0.1%	≤0.1%	0.10%

Table 43: Percentage of correct results in qualitative reports for CP4EPSPS for all participants using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing).

Total # Reported results	8
# Incorrect	0
% Correct	100.0%
# Provided Positives	4
# False Negative	0
% False Negative	0.0%
# Provided Negatives	4
# False Positive	0
% False Positive	0.0%

Table 44: Quantitative results and z-scores for corn fortified with T-25 for all participants (DNA-based assays). Quantification marked in red indicates value determined to be a positive value for a non-fortified sample (i.e. a false positive result). No values were determined to be outliers by the Grubb's Test for Outliers in this data set. Z-scores outside of the expected range of $z > 2$ were not observed in this data set.

Event: T-25									
%w/w Fortification Level	1.0%		0.0%	2.0%		0.0%	0.0%	0.5%	
Participant Number	Result	z-score	Result	Result	z-score	Result	Result	Result	z-score
1754	0.40	1.69	0.00	1.30	0.64	0.00	0.00	0.20	1.47
1761	0.88	0.03	0.00	0.75	1.46	0.28	0.00	0.32	0.54
1780	1.23	1.17	0.00	2.34	0.89	0.00	0.00	0.35	0.31
1870	0.90	0.03	0.00	1.70	0.05	0.00	0.00	0.40	0.08
1875	0.52	1.28	0.00	0.89	1.25	0.00	0.00	0.28	0.85
2057	1.00	0.38	0.00	2.30	0.83	0.00	0.00	0.45	0.47
2128	1.10	0.72	0.00	2.24	0.75	0.00	0.00	0.57	1.40
2716	1.09	0.69	0.00	2.36	0.92	0.00	0.00	0.55	1.24

Table 45: 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. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: CBH351								
%w/w Fortification Level	1.0%		0.0%	0.1%		0.0%	0.0%	0.0%
Participant Number	Result	z-score	Result	Result	z-score	Result	Result	Result
1754	0.50	0.93	0.00	0.10	0.00	0.00	0.00	0.00
1870	0.70	0.13	0.00	0.10	0.00	0.00	0.00	0.00
2057	1.00	1.06	0.00	0.10	0.00	0.00	0.00	0.00

Table 46: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate values determined to be a negative value for a fortified sample (i.e. a false negative result).

Event: MON810										
%w/w Fortification Level	1.0%		0.5%		2.0%		0.0%	0.0%	0.1%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	Result	Result	z-score
1754	0.50	0.17	0.40	1.50	1.40	0.95	0.00	0.00	0.20	2.47
1761	0.25	0.85	0.07	1.26	0.38	1.29	0.00	0.00	0.00	
1773	0.30	0.65	0.10	1.01	0.90	0.15	0.00	0.00	0.10	0.48
1780	0.88	1.73	0.34	1.00	1.76	1.75	0.00	0.00	0.07	0.11
1788	0.24	0.89	0.10	1.01	0.39	1.27	0.00	0.00	0.10	0.48
1847	0.39	0.28	0.19	0.26	0.92	0.10	0.00	0.00	0.02	1.11
1870	0.60	0.58	0.20	0.17	1.00	0.07	0.00	0.00	0.10	1.11
1875	0.56	0.42	0.25	0.25	0.87	0.21	0.00	0.00	0.00	
2031	0.40	0.24	0.28	0.50	0.95	0.04	0.00	0.00	0.04	1.50
2039	0.50	0.17	0.20	0.17	0.90	0.15	0.00	0.00	0.10	0.71
2057	1.00	2.22	0.45	1.92	1.80	1.83	0.00	0.00	0.10	0.48
2128	0.35	0.44	0.17	0.42	0.86	0.24	0.00	0.00	0.02	0.48
2694	0.35	0.44	0.22	0.00	0.89	0.17	0.00	0.00	0.02	1.11
2716	0.99	2.18	0.48	2.17	1.73	1.68	0.00	0.00	0.11	1.11
2719	0.10	1.47	0.10	1.01	0.18	1.73	0.00	0.00	0.00	
2727	0.37	0.36	0.19	0.26	0.79	0.39	0.00	0.00	0.05	1.50
3927	0.36	0.40	0.16	0.51	0.62	0.76	0.00	0.00	0.03	0.51
3929	0.30	0.65	0.15	0.59	0.83	0.30	0.00	0.00	P *	
4500	0.30	0.65	0.14	0.67	0.70	0.59	0.00	0.00	P *	
4936	0.42	0.16	0.00		1.47	0.59	0.00	0.00	0.00	

*- Qualitative data only, see Qualitative Table

Table 47: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays). Z-scores outside of the expected range of $z > 2$ were not observed in this data set. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: GA21										
%w/w Fortification Level	0.1%		0.2%		0.0%	0.8%		0.0%	0.6%	
Participant Number	Result	z-score	Result	z-score	Result	Result	z-score	Result	Result	z-score
1754	0.20	0.01	0.20	0.28	0.00	0.50	0.45	0.00	0.60	0.37
1761	0.27	1.05	0.21	0.39	0.00	0.72	0.71	0.00	0.65	0.73
1773	0.20	0.01	0.20	0.28	0.00	0.70	0.60	0.00	0.70	1.08
1780	0.26	0.90	0.16	0.19	0.00	0.64	0.29	0.00	0.54	0.07
1870	0.20	0.01	0.10	0.89	0.00	0.60	0.08	0.00	0.50	0.35
1875	0.21	0.16	0.11	0.77	0.00	0.57	0.08	0.00	0.54	0.07
2057	0.30	1.49	0.20	0.28	0.00	0.90	1.66	0.00	0.80	1.80
2128	0.10	1.46	0.07	1.24	0.00	0.23	1.87	0.00	0.29	1.86
2694	0.23	0.46	0.18	0.04	0 *	0.69	0.55	0.00	0.52	0.21
2716	0.12	1.17	0.39	2.49	0.00	0.59	0.02	0.00	0.50	0.35
4500	0.10	1.46	0.12	0.66	0.00	0.30	1.51	0.00	0.40	1.07

*- listed as P(<<<), counted as not present

Table 48: 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 the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate values determined to be either: (1) outliers by the “Grubb’s Test for Outliers”; or (2) a negative value for a fortified sample (i.e. a false negative result).

Event: Bt176											
%w/w Fortification Level	0.1%		0.5%		1.5%		0.8%		0.0%	0.1%	
Participant Number	Result	Z-score	Result	Z-score	Result	Z-score	Result	Z-score	Result	Result	Z-score
1754	0.20	0.88	0.20	1.05	1.10	0.31	0.40	0.98	0.00	0.10	0.31
1761	0.30	2.29	0.93	2.15	3.11	2.89	1.39	2.35	0.00	0.11	0.25
1780	0.13	0.11	0.43	0.04	1.47	0.28	0.78	0.30	0.00	0.08	0.41
1788	0.10	0.53	0.26	0.79	0.87	0.68	0.44	0.85	0.00	0.10	0.31
1870	0.00		0.30	0.61	1.30	0.01	0.50	0.64	0.00	0.00	
1875	0.09	0.67	0.34	0.44	0.99	0.49	0.47	0.75	0.00	0.00	
2057	0.10	0.53	0.50	0.26	1.50	0.33	0.80	0.36	0.00	0.10	0.31
2128	0.14	0.03	0.37	0.31	1.42	0.20	0.86	0.57	0.00	0.11	0.25
2694	0.08	0.82	0.32	0.53	1.13	0.26	0.55	0.48	0.00	0.06	0.52
2716	0.10	0.53	0.48	0.18	1.03	0.42	0.56	0.44	0.00	0.10	0.31
2727	0.64	7.09	0.85	1.80	0.63	1.06	1.05	1.21	0.00	0.65	2.66
4500	P *		0.30	0.61	1.00	0.47	0.50	0.64	0.00	P *	

*- Qualitative data only see Qualitative Table

Table 49: Quantitative results and z-scores for corn fortified with Bt11 for all participants (DNA-based assays). Z-scores outside of the expected range of $z > 2$ were not observed in this data set. The quantification marked in red indicates a value determined to be a negative value for a fortified sample (i.e. a false negative result). No values were determined to be outliers by the Grubb’s Test for Outliers in this data set.

Event: Bt11											
%w/w Fortification Level	0.0%	0.8%		0.1%		0.4%		0.0%	1.5%		
Participant Number	Result	Result	z-score	Result	z-score	Result	z-score	Result	Result	z-score	
1754	0.00	0.40	1.25	0.20	2.33	0.40	0.65	0.00	1.10	0.67	
1761	0.00	0.39	1.29	0.05	1.38	0.12	1.81	0.00	0.43	2.08	
1780	0.00	0.83	0.68	0.13	0.60	0.40	0.65	0.00	1.71	0.62	
1788	0.00	0.48	0.89	0.10	0.14	0.14	1.64	0.00	0.89	1.11	
1870	0.00	0.80	0.54	0.10	0.14	0.40	0.65	0.00	1.40	0.03	
1875	0.00	0.64	0.17	0.12	0.35	0.41	0.74	0.00	1.23	0.39	
2057	0.00	0.90	0.99	0.10	0.14	0.40	0.65	0.00	2.20	1.66	
2128	0.00	1.02	1.53	0.14	0.85	0.40	0.65	0.00	1.74	0.68	
2694	0.00	0.62	0.26	0.05	1.38	P *		0.00	1.92	1.06	
2716	0.00	0.77	0.41	0.10	0.14	0.44	1.01	0.00	1.04	0.79	
4500	0.00	0.90	0.99	0.08	0.64	0.30	0.23	0.00	1.70	0.60	
4502	0.00	0.75	0.32	0.10	0.14	0.30	0.23	0.00	1.50	0.18	
4936	0.00	0.32	1.60	0.00		0.20	1.11	0.00	1.55	0.28	

*- Qualitative data only, see Qualitative Table

Table 50: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays). Z-scores outside of the expected range of $z > 2$ were not observed in this data set. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: NK603									
%w/w Fortification Level	1.3%		0.0%	0.65%		0.4%		0.0%	0.0%
Participant Number	Result	z-score	Result	Result	z-score	Result	z-score	Result	Result
1754	1.20	0.17	0.00	0.70	0.53	0.10	1.00	0.00	0.00
1780	1.43	0.68	0.00	0.78	0.82	0.42	1.29	0.00	0.00
1870	1.00	0.26	0.00	0.50	0.20	0.30	0.44	0.00	0.00
1847	0.63	1.08	0.00	0.33	0.81	0.18	0.42	0.00	0.00
1875	1.00	0.26	0.00	0.60	0.17	0.29	0.36	0.00	0.00
2039	1.30	0.39	0.00	0.80	0.89	0.20	0.28	0.00	0.00
2057	2.00	1.93	0.00	1.00	1.62	0.40	1.15	0.00	0.00
2128	0.80	0.70	0.00	0.32	0.85	0.17	0.50	0.00	0.00
2694	0.46	1.45	0.00	0.08	1.72	0.01	1.64	0.00	0.00
2716	1.43	0.68	0.00	0.83	1.00	0.48	1.72	0.00	0.00
2719	1.30	0.39	0.00	0.80	0.89	P *		0.00	0.00
2727	1.04	0.18	0.00	0.32	0.85	0.10	1.00	0.00	0.00
3095	0.40	1.58	0.00	0.20	1.29	0.30	0.44	0.00	0.00
4500	1.70	1.27	0.00	0.50	0.20	0.16	0.57	0.00	0.00

*- Qualitative data only, see Qualitative Table

Table 51: Quantitative results and z-scores for corn fortified with Herculex for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate values determined to be a negative value for a fortified sample (i.e. a false negative result).

Event: Herculex								
%w/w Fortification Level	0.1%		0.0%	0.0%	0.0%	0.0%	0.75%	
Participant Number	Result	z-score	Result	Result	Result	Result	Result	z-score
1754	0.10	0.11	0.00	0.00	0.00	0.00	0.20	1.02
1780	0.08	0.09	0.00	0.00	0.00	0.00	0.64	0.22
1847	0.05	0.39	0.00	0.00	0.00	0.00	0.46	0.29
1870	0.06	0.29	0.00	0.00	0.00	0.00	0.60	0.11
1875	0.00		0.00	0.00	0.00	0.00	0.50	0.17
2057	0.10	0.11	0.00	0.00	0.00	0.00	1.50	2.66
2128	0.04	0.50	0.00	0.00	0.00	0.00	0.42	0.40
2694	0.02	0.70	0.00	0.00	0.00	0.00	0.29	0.77
2716	0.36	2.74	0.00	0.00	0.00	0.00	0.98	1.19
2727	0.04	0.50	0.00	0.00	0.00	0.00	0.67	0.31
3927	0.04	0.50	0.00	0.00	0.00	0.00	0.27	0.82
4500	P *		0.00	0.00	0.00	0.00	0.50	0.17
4936	0.00		0.00	0.00	0.00	0.00	0.26	0.85

*- Qualitative data only see Qualitative Table

Table 52: 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 the expected range, i.e., $z > +2$ or $z < -2$. The quantification marked in red indicate values determined an outlier by the “Grubb’s Test for Outliers”.

Event: MON863								
%w/w Fortification Level	0.0%	0.0%	0.0%	1.5%		0.0%	0.8%	
Participant Number	Result	Result	Result	Result	z-score	Result	Result	z-score
1754	0.00	0.00	0.00	0.80	1.41	0.00	0.30	2.03
1780	0.00	0.00	0.00	1.72	0.11	0.00	0.53	0.65
1870	0.00	0.00	0.00	1.30	0.70	0.00	0.60	0.23
1875	0.00	0.00	0.00	1.74	0.08	0.00	0.61	0.17
2057	0.00	0.00	0.00	1.50	0.42	0.00	0.70	0.38
2128	0.00	0.00	0.00	3.40	2.26	0.00	0.69	0.32
2694	0.00	0.00	0.00	1.26	0.76	0.00	0.61	0.17
2716	0.00	0.00	0.00	1.46	0.48	0.00	0.69	0.32
2719	0.00	0.00	0.00	2.40	0.85	0.00	0.80	0.98
2727	0.00	0.00	0.00	2.79	1.40	0.00	1.09	2.73
4500	0.00	0.00	0.00	1.30	0.70	0.00	0.50	0.83
4502	0.00	0.00	0.00	1.60	0.28	0.00	0.53	0.65
4936	0.00	0.00	0.00	2.09	0.41	0.00	2.37	10.44

Table 53: Quantitative results and z-scores for corn fortified with Herculex RW for all participants (DNA-based assays). Values highlighted in yellow indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$. The quantifications marked in red indicate values determined to be either: (1) an outlier by the “Grubb’s Test for Outliers”, (2) a negative value for a fortified sample (i.e. a false negative result), or (3) a positive value for a non-fortified sample (i.e. a false positive).

Event: Herculex RW									
%w/w Fortification Level	2.0%		0.0%	0.0%	0.8%		0.0%	0.1%	
Participant Number	Result	z-score	Result	Result	Result	z-score	Result	Result	z-score
1754	3.00	0.52	0.00	0.00	1.40	1.03	0.00	0.40	2.62
1780	2.19	0.63	0.00	0.00	0.99	0.14	0.00	0.11	0.26
1847	1.64	1.41	0.00	0.00	0.60	1.26	0.00	0.03	1.05
1870	3.40	1.09	0.00	0.00	1.10	0.17	0.00	0.10	0.36
1875	3.69	1.51	0.00	0.00	1.50	1.32	0.00	0.26	1.23
2057	1.90	1.04	0.00	0.00	0.80	0.69	0.00	0.10	0.36
2112	3.07	0.62	0.00	0.00	1.36	0.92	0.00	0.10	0.36
2128	2.78	0.21	0.00	0.00	1.40	1.03	0.00	0.14	0.04
2694	3.29	0.94	0.00	0.00	1.13	0.26	0.00	0.12	0.16
2716	1.52	1.59	0.00	0.00	0.78	0.74	0.00	0.10	0.36
2727	2.98	0.50	0.00	0.00	0.30	2.12	0.00	0.04	0.95
2732	2.71	0.11	0.00	0.00	1.14	0.29	0.00	0.13	0.06
4500	2.05	0.83	0.00	0.00	1.02	0.06	0.00	P *	
4936	10.00	10.50	0.00	2.72	0.00		0.00	1.09	9.47

*- Qualitative data only, see Qualitative Table

Table 54: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Z-scores outside of the expected range of $z > 2$ were not observed in this data set. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: MIR604									
%w/w Fortification Level	0.5%		0.8%		0.0%	0.5%		0.0%	0.0%
Participant Number	Result	z-score	Result	z-score	Result	Result	z-score	Result	Result
1754	0.40	0.03	0.50	0.62	0.00	0.30	0.29	0.00	0.00
1780	0.41	0.05	0.69	0.82	0.00	0.40	0.51	0.00	0.00
1870	0.30	0.83	0.50	0.62	0.00	0.30	0.29	0.00	0.00
1875	0.60	1.57	0.51	0.55	0.00	0.50	1.31	0.00	0.00
2039	0.40	0.03	0.60	0.14	0.00	0.30	0.29	0.00	0.00
2057	0.50	0.77	0.80	1.66	0.00	0.50	1.31	0.00	0.00
2128	0.44	0.29	0.54	0.32	0.00	0.32	0.13	0.00	0.00
2694	0.42	0.13	0.63	0.37	0.00	0.38	0.35	0.00	0.00
2716	0.53	1.01	0.77	1.43	0.00	0.42	0.67	0.00	0.00
2727	0.14	2.11	0.36	1.68	0.00	0.08	2.06	0.00	0.00
4500	0.30	0.83	0.50	0.62	0.00	0.20	1.10	0.00	0.00

Table 55: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Z-scores outside of the expected range of $z > 2$ were not observed in this data set. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: Event 3272										
%w/w Fortification Level	0.1%		0.2%		0.5%		0.0%	0.0%	1.0%	
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result	Result	Result	z-score
1754	0.10	0.24	0.10	0.82	0.40	1.64	0.00	0.00	0.50	1.64
1780	0.09	0.98	0.16	0.07	0.49	0.30	0.00	0.00	0.92	0.56
1870	0.10	0.24	0.20	0.67	0.60	1.34	0.00	0.00	0.90	0.45
2057	0.10	0.24	0.20	0.67	0.50	0.15	0.00	0.00	1.00	0.98
2128	0.10	0.24	0.05	1.57	0.52	0.15	0.00	0.00	0.66	0.80
4500	0.13	1.95	0.22	0.97	0.55	0.60	0.00	0.00	0.90	0.45

Table 56: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS (RUR) for all participants (DNA-based assays). The value highlighted in yellow indicates a z-score outside of expected range, i.e., $z > +2$ or $z < -2$. Quantifications marked in red indicate values determined to be either: (1) outliers by the “Grubb’s Test for Outliers”; or (2) a quantitative value for a non-fortified sample (i.e. a false positive result).

Event: RUR						
%w/w Fortification Level	0.0%	0.2%		0.8%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result
1754	0.00	0.20	0.19	0.60	0.23	0.00
1773	0.00	0.30	1.57	0.80	1.28	0.00
1780	0.00	0.17	0.22	0.39	0.86	0.00
1788	0.00	0.11	1.05	0.43	0.66	0.00
1847	0.00	0.09	1.33	0.23	1.70	0.00
1855	0.00	0.17	0.22	0.73	0.91	0.00
1868	0.00	0.20	0.19	0.50	0.29	0.00
1870	0.00	0.20	0.19	0.60	0.23	0.00
1875	0.11	0.18	0.09	0.39	0.86	0.00
1893	0.00	0.20	0.19	0.50	0.29	0.00
2031	0.00	0.15	0.50	0.55	0.03	0.00
2057	0.00	0.40	2.95	0.90	1.80	0.00
2060	0.00	0.16	0.36	0.57	0.08	0.00
2128	0.00	0.17	0.22	0.61	0.29	0.00
2692	0.00	0.28	1.30	0.65	0.50	0.00
2716	0.00	0.11	1.05	0.52	0.18	0.00
2719	0.00	0.20	0.19	0.80	1.28	0.00
2720	0.00	0.53	4.75	0.36	1.02	0.00
2727	0.00	0.08	1.47	0.15	2.12	0.00
3927	0.00	0.20	0.19	0.68	0.65	0.00
4500	0.00	0.15	0.50	0.40	0.81	0.00
4502	0.00	0.19	0.05	0.55	0.03	0.00
4936	0.00	0.71	7.23	0.86	1.59	1.29

Table 57: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link) for all participants (DNA-based assays). The quantifications marked in **red** indicate values determined to be either: (1) a negative value for a fortified sample (i.e. a false negative result), or (2) a quantitative value for a non-fortified sample (i.e. a false positive result). No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: A2704-12						
%w/w Fortification Level	0.1%		0.2%		0.0%	0.0%
Participant Number	Result	z-score	Result	z-score	Result	Result
1754	0.10	0.52	0.10	1.59	0.00	0.00
1773	0.10	0.52	0.20	0.01	0.00	0.00
1780	0.14	0.12	0.24	0.66	0.00	0.00
1847	0.14	0.12	0.22	0.33	0.00	0.00
1855	0.10	0.52	0.17	0.47	0.00	0.00
1868	0.30	2.68	0.30	1.62	0.00	0.00
1870	0.20	1.08	0.30	1.62	0.00	0.00
1875	0.10	0.52	0.16	0.63	0.00	0.00
2057	0.10	0.52	0.20	0.01	0.00	0.00
2128	0.08	0.85	0.19	0.15	0.00	0.00
3095	0.10	0.52	0.20	0.01	0.00	0.00
4500	p *		0.11	1.43	0.00	0.00
4936	0.10	0.52	0.00		1.02	1.02

*- Qualitative data only see Qualitative Table

Table 58: Quantitative results and z-scores for soybeans fortified with Roundup Ready II (CP4 EPSPS) for all participants (DNA-based assays). The value highlighted in **yellow** indicates a z-score outside of expected range, i.e., $z > +2$ or $z < -2$. No values were determined to be outliers by the Grubb's Test for Outliers in this data set.

Event: RUR II					
%w/w Fortification Level	0.0%	0.0%	0.5%		0.0%
Participant Number	Result	Result	Result	z-score	Result
1754	0.00	0.00	0.30	0.54	0.00
1773	0.00	0.00	0.20	0.56	0.00
1780	0.00	0.00	0.44	2.08	0.00
1855	0.00	0.00	0.27	0.21	0.00
1868	0.00	0.00	0.20	0.56	0.00
2057	0.00	0.00	0.25	0.01	0.00
2128	0.00	0.00	0.21	0.45	0.00
4500	0.00	0.00	0.14	1.23	0.00

Table 59: Quantitative results for 35S and NOS in Maize (DNA based assay)

Event: 35S						
Sample #	1	2	3	4	5	6
%w/w Fortification Level	7.2%	3.0%	6.9%	5.2%	0.0%	5.5%
Participant Number	Result	Result	Result	Result	Result	Result
1847	5.17	1.30	3.97	2.90	0.00	2.46
2694	11.90	2.78	8.98	5.88	0.00	5.40

Event: NOS						
Sample #	1	2	3	4	5	6
%w/w Fortification Level	7.2%	3.0%	6.9%	5.2%	0.0%	5.5%
Participant Number	Result	Result	Result	Result	Result	Result
1847	1.88	0.82	0.67	1.78	0.00	2.40
2694	6.68	5.34	3.66	13.76	0.00	9.30

Note: Levels cited as %w/w fortification level are total genetic event fortification, less GA 21. A more thorough quantification is not yet in the scope of this program.

Table 60: Results for 35S and NOS in soybeans (DNA based assay)

Event: 35S Soy				
Sample #	1	2	3	4
%w/w Fortification Level	0.1%	0.4%	0.5%	0.0%
Participant Number	Result	Result	Result	Result
1862	0.14%	0.26%	0.39%	0.00%
1870	P	P	P	N
1773	P	P	P	P
2123	P	P	P	N

Event: NOS Soy				
Sample #	1	2	3	4
%w/w Fortification Level	0.1%	0.4%	0.5%	0.0%
Participant Number	Result	Result	Result	Result
1870	N	P	P	N

*Note: As 35S accompanies both RUR and LL genetic modification events, its presence is equivalent to the sum of these events in the sample

Table 61: Descriptive statistics for participants reported quantifications relative to GIPSA fortification levels using DNA-based assays. % Relative 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 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	8	0.5	0.39	0.13	33.1	-22.0	0.20- 0.57
T25	8	1.0	0.89	0.29	32.6	-11.0	0.40- 1.23
T25	8	2.0	1.74	0.68	39.0	-13.3	0.75- 2.36
CBH351	3	0.1	0.10	0.00	0.0	0.0	0.10- 0.10
CBH351	3	1.0	0.73	0.25	34.3	-26.7	0.50 - 1.00
MON810	18	0.1	0.08	0.05	66.5	-24.3	0.00- 0.20
MON810	20	0.5	0.22	0.12	54.2	-55.9	0.00- 0.48
MON810	20	1.0	0.46	0.24	53.3	-54.2	0.10- 1.00
MON810	20	2.0	0.97	0.45	47.0	-51.7	0.18- 1.80
GA21	11	0.1	0.20	0.07	34.0	99.1	0.10- 0.30
GA21	11	0.2	0.18	0.09	48.6	-11.8	0.07- 0.39
GA21	11	0.6	0.55	0.14	25.3	-8.5	0.29- 0.80
GA21	11	0.8	0.59	0.19	32.4	-26.8	0.23- 0.90
Bt176	11	0.1	0.14	0.07	51.4	37.8	0.00- 0.64
Bt176	11	0.1	0.16	0.19	118.5	56.7	0.00- 0.65
Bt176	12	0.5	0.44	0.23	51.8	-12.0	0.20- 0.93
Bt176	12	0.8	0.69	0.30	43.0	-13.5	0.40- 1.39
Bt176	12	1.5	1.30	0.63	48.4	-13.6	0.63- 3.11
Bt11	13	0.1	0.11	0.04	38.1	5.8	0.00- 0.20
Bt11	12	0.4	0.33	0.11	34.8	-18.5	0.12- 0.44
Bt11	13	0.8	0.68	0.22	32.9	-15.2	0.32- 1.02
Bt11	13	1.5	1.42	0.47	33.4	-5.6	0.43 - 2.20
NK603	13	0.4	0.24	0.14	58.4	-40.2	0.01- 0.48
NK603	14	0.65	0.55	0.28	49.7	-14.7	0.08- 1.00
NK603	13	1.3	1.12	0.46	49.7	-14.7	0.40 - 2.00
Herculex	12	0.1	0.09	0.10	111.2	-11.0	0.0- 0.36
Herculex	13	0.75	0.56	0.35	62.9	-25.2	0.20- 1.50
MON863	13	0.8	0.64	0.17	26.0	-20.3	0.30- 2.37
MON863	13	1.5	1.80	0.71	39.5	19.8	0.80- 340

Transgenic Event	Reported Results (N)	Fortification (%w/w)	Reported Mean	Standard Deviation	% Relative Standard Deviation	% Relative Error	Range of Results (%)
HerculexRW	13	0.1	0.14	0.10	74.2	35.8	0.03- 1.09
HerculexRW	14	0.8	1.04	0.35	33.6	30.0	0.00- 1.50
HerculexRW	14	2.0	2.63	0.70	26.7	31.6	1.52-10.00
MIR604	11	0.5	0.40	0.13	31.0	-19.3	0.14- 0.60
MIR604	11	0.5	0.34	0.12	37.0	-32.7	0.08- 0.50
MIR604	11	0.8	0.58	0.13	22.6	-27.3	0.36- 0.80
EV3272	6	0.1	0.10	0.01	13.2	3.3	0.9- 0.13
EV3272	6	0.2	0.16	0.07	43.1	-22.5	0.05- 0.22
EV3272	6	0.5	0.51	0.07	13.1	2.0	0.40- 0.60
EV3272	6	1.0	0.81	0.19	23.5	-18.7	0.50- 1.00
RUR	23	0.2	0.19	0.07	38.9	-6.9	0.08- 0.71
RUR	23	0.8	0.56	0.19	34.4	-30.6	0.15- 0.90
A2704-12	13	0.1	0.13	0.06	47.0	32.7	0.08- 0.30
A2704-12	14	0.2	0.20	0.06	31.3	-0.4	0.00- 0.30
RUR II	8	0.5	0.25	0.09	36.1	-49.8	0.14- 0.44

Table 62: Quantitative results for corn fortified with CBH 531 using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing) for Participant # 1754 (only this participant submitted results).

Event: CBH351						
Sample #	1	2	3	4	5	6
%w/w Fortification Level	1.0%	0.0%	0.1%	0.0%	0.0%	0.0%
Participant Number	Result	Result	Result	Result	Result	Result
1754	1.0	0.0	0.1	0.0	0.0	0.0

Table 63: Quantitative results for soybeans fortified with CP4EPSPS (RUR) using Enzyme-Linked Immunosorbent Assay (ELISA) (Protein-based testing)

Event: RUR				
Sample #	1	2	3	4
%w/w Fortification Level	0.0%	0.2%	0.8%	0.0%
Participant Number	Result	Result	Result	Result
1782	0.00	0.50	0.10	0.00
1754	0.00	0.20	0.50	0.00

Summary of Findings

It is recognized that some participants in this program partake for ISO certification purposes. Long-time, certified participants tend to show consistent and reliable results. For others, participation serves to provide a verification of current laboratory practices and points to areas for improvement. These factors should be considered when reviewing the following analyses.

- **Qualitative Sample Analysis**

DNA-based Testing. The typical method of DNA-based testing for the qualitative determination of events is by a conventional polymerase chain reaction assay (PCR) which generally has a sensitivity of 0.01% w/w transgenic event. This level is consistent with what has been reported by Lipp et.al and represents the lowest concentration of genetic material that can be reliably detected by qualitative PCR.

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 that employs conventional PCR. As evidenced by the summary of performance scores (**Table 35** and **Figure 1**), all of the seventeen transgenic events were correctly detected with greater than or equal to 90% reliability, and fourteen of the seventeen transgenic events were correctly detected with greater than or equal to 95% reliability. Events that tested with less than 95% reliability were T25, CBH 351 and A2704-12. The T25 reliability is affected by the use of a corn sample that has historically shown a high level of false positives, reflecting the possibility of low levels of contamination. That sample is now removed from use. The CBH351 and A2704-12 events historically show less than 95% reliability.

In laboratories using qualitative DNA methods to detect RUR soy, three of forty-two (7.1%) test results generated a false positive result; two of forty-six test results (4.3%) generated false positives using quantitative DNA detection methods on the RUR trait. The possibility of low level contamination of RUR in the event-free samples, below 0.01%, should be considered as plausible.

The RoundUp ReadyII® transgenic event in soybeans is new in this sampling. The twelve participants testing for this trait identified the presence correctly.

Three participants submitted results for the 35S genome in soy, one participant submitted results for the NOS genome in soy. There was one false positive in this grouping.

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 according to Strategic Diagnostics Inc. (2001 & 2003). Generally, ELISA has a sensitivity of 0.1 - 1% w/w for corn and soy events (Ahmed, 2004) and laboratories demonstrated good proficiency when using protein-based methods to detect the presence of biotechnology-derived traits in maize and soybean that were fortified above their reported LOD's (see **Tables 36 through 43**). The LFS's generated a higher than expected percentage

of false positive results (25%) for the RUR trait. However, because of the small sample set (n=4), it is difficult to draw any conclusions from these data sets (see **Tables 38 and 39**). The two participants using ELISA detection methods were 100% correct in all results submitted (see **Tables 40 –43**).

- **Quantitative Sample Analysis**

DNA-based Testing. The typical method of DNA-based testing for the quantitative determination of transgenic event is 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 61**). Because test samples were fortified ranging from 0.1 – 2.0% w/w of a particular event, it was expected that quantitative PCR (qPCR) technologies would detect the traits in all of the fortified samples but not in non-fortified samples. Low instances of false positive results when using qPCR to detect the presence of GE traits in these proficiency samples are typical.

More false negative results (10/13 = 77%) were observed for samples fortified at the 0.1% level for all events combined, suggesting lesser confidence in analytical measurements at a 0.1% fortification level when using qPCR.

Two participants submitted quantitative results for 35S and NOS in corn, and one laboratory submitted quantitative results using qPCR (DNA-based testing) for the 35S genome in Soy. The %w/w fortification levels assumed for these traits is the sum of all traits fortified in the sample (except GA21).

Historical results show lower reported concentrations compared with gravimetric fortification of prepared proficiency samples. The trend of generating lower than expected reported values is possibly due to zygosity in the corn and soy samples. GIPSA in-house validated methods reflect similar observations compared with historical results of participants.

Notably, The composite averages for MON810 were about half the %w/w fortified levels; conversely, Herculex RW composite averages were higher than the %w/w fortifications.

The RoundUp ReadyII® transgenic event in soybeans is new in this sampling. All eight participants measuring this trait identified it correctly. The composite average is 0.25% w/w vs. the fortification level of 0.5% w/w. This composite average agrees with measurements observed by GIPSA when performing quality control characterization of this trait.

In this round of proficiency testing, there were forty-four trials of inter-laboratory quantifications (i.e., total number of events at the total number of fortification levels) and in twenty-six of those trials the **inter-laboratory relative error** was observed to be $\leq 25\%$

(**Table 61**). This is similar to the precision observed in the April 2010 distribution whereby twenty-one of forty-five trials were observed to be $\leq 25\%$. Results with a relative error $\leq 25\%$ meet the acceptance criteria for trueness as established by the Joint Research Council/ENGL. Furthermore, reported quantifications were under-estimated (low bias) in approximately 73% of the trials (**Table 61**). Historically, low bias results were 54% in April 2010 and 67% in November 2009. Quantitative data from previous rounds of our proficiency sample distributions 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 44 through 60. To assess the accuracy of their reported quantifications z-scores were computed. Laboratories with z-scores above +2 or below -2 were noted and highlighted in yellow 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) and from tables with low numbers of results 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 61**). This observation could be due to 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.

Protein-based Testing. Two laboratories submitted quantitative results using a protein-based method (i.e. ELISA). The traits CBH351 and CP4EPSPS were quantified and values similar to what was observed with DNA based methods were reported (**see Tables 62 and 63**). A greater number of reported results are needed before any conclusions can be drawn from these observations and further studies should be considered. Absolute difference values are shown in the tables since z-scores could not be calculated from these results.

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 816-891-0459, or by e-mail at Tandace.A.Scholdberg@usda.gov.

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Appendix I: List of organizations who wished to be identified as a participant in the GIPSA April 2010 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

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