

Agricultural Marketing Service Federal Grain Inspection Service

Biotechnology Proficiency Program October 2017 Bi-Annual Report



United States Department of Agriculture

USDA/AMS/FGIS Proficiency Program
Testing for the Presence of Biotechnology-derived Events in Corn and Soybeans
October 2017 Sample Distribution Results

Purpose of USDA/AMS/FGIS Proficiency Program

Through the USDA/AMS/FGIS Corn and Soy Proficiency Program, USDA seeks to improve the overall performance of testing for biotechnology-derived grains and oil seeds. The USDA/AMS/FGIS Proficiency Program helps organizations identify areas of concern and take corrective actions to improve testing precision, capability and reliability.

Program Description and Assessment of Results

The USDA/AMS/FGIS proficiency program report contains inter-laboratory comparisons for the purpose of proficiency testing (i.e. to determine the performance of individual laboratories' ability to detect and/or quantify biotechnology-derived traits in corn or soy as well as to monitor laboratories' continuing performance). The program does not assess the effectiveness of different detection methods for biotechnology-derived traits, nor does it determine the characteristics of fortified samples to a particular degree of accuracy.

In this round of the USDA/AMS/FGIS 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 biotechnology-derived traits, and participants had the choice of providing qualitative and/or quantitative results. Qualitative results were scored by computing the "percentage of correctly reported biotechnology-derived traits" in the samples (Tables 1 to 45 and Figure 1 for DNA-based analysis, and Tables 44 to 53 for protein-based analysis). 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. It should be noted that trait-specific, DNA-based testing can discern between different traits that express the same protein, (e.g. Roundup Ready™ (RUR) and Roundup Ready™ II (RUR II)), whereas in most instances, construct-specific DNA-based testing or protein-based testing cannot.

Consensus mean values were calculated on the sets of quantitative data shown in Tables 54 to 74, with outliers excluded. Data sets were treated equally with this model, assuming no laboratory effect on outcomes, and are most likely idealistic. To assess accuracy of individual participant's submitted quantitative results for a specified biotechnology-derived event, z-scores (based on: (reported value – consensus mean value) / standard deviation) were computed for each reported quantification result (Tables 54 to 74). 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 identify more outliers than should be declared. Some judgment will be necessary when interpreting data at these low levels. Absolute values for z-scores that are > 2 should be scrutinized by the participating lab. Those that are > 3, or classified as outliers, 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 75) was prepared to show the accuracy and precision of compiled quantification results at each fortification level for the various biotechnology-derived events.

Sample Preparation and Composition

USDA/AMS/FGIS receives 100% Biotechnology-derived event trait material from life science companies through materials transfer agreements. Specific GE trait materials are characterized at USDA/AMS/FGIS and tested for the presence of all other available traits (also used in the program) by event-specific polymerase chain reaction (PCR) testing. Occasionally, stack-traits are identified. Seed purity and zygosity characteristics are not assessed by USDA/AMS/FGIS. Commercially available and internationally recognized reference material are purchased through the Institute for Reference Materials and Measurements (IRMM) or the American Oil Chemists Society (AOCS) as finely ground flour, containing a certified percentage weight/weight (%w/w), level. USDA/AMS/FGIS uses commercially available reference standards to characterize the composition of proficiency samples prior to disseminating to participants

Biotechnology-derived event-free base material used for fortified sample preparation included both Pioneer Negative Corn (PNC), provided by Pioneer Hi-Bred International, Inc., and Popcorn provided by Amish Country Popcorn. The maize is ground to the consistency of fine flour using a high speed rotor mill, "Pulverisette 14." A 50 gram aliquot of 100% event material (corn or soy) is ground in liquid nitrogen, in a highly controlled environment using a SPEX Certi Prep 6800 Freezer Mill. The 100% event sample is stored at -20 °C until further use. The 100% event material is blended gravimetrically with well characterized non-event maize to a specified %w/w concentration. The sample sets are then analyzed by real-time PCR using USDA/AMS/FGIS in-house validated methods

The corn samples contained various combinations and concentrations of the following biotechnology-derived traits: MON810, GA21, NK603, Herculex[®] (TC1507), MON863, Herculex[®] RW (DAS-59122-7), MIR604, Event 3272, MON 88017, MON 89034, and MIR 162. The soybean samples contained various combinations and concentrations of the following biotechnology-derived traits: the biotechnology-derived glyphosate-tolerant soybeans (Roundup Ready[™]), the glufosinate ammonium tolerant soybeans (A2704-12), the biotechnology-derived glyphosate-tolerant soybeans (Roundup Ready[™] II), and high oleic acid soybeans (DP305423). The various biotechnology-derived event concentration levels were produced on a %w/w basis. A calculated amount of ground biotechnology-derived corn or soybeans was blended to homogeneity with a calculated amount of ground non-biotechnology-derived corn or soybeans to produce concentrations ranging from 0.0 to 2.0% of a specified event. Each participant received four corn and two soybean samples. Individual samples contained approximately 5 grams of ground material.

Samples prepared at a particular %w/w fortification should in theory be concordant with consensus values as cited in the report. In many instances, however, the %w/w fortification value did not agree with analytical data generated by PCR when compared to commercially available reference standards using in-house validated methods. The trend of generating lower reported concentrations compared with gravimetric fortified values can have several possible explanations, including that of differences in trait zygosity between material used in the corn and soybean samples compared with the commercially

available reference materials. For example, USDA/AMS/FGIS in-house validated methods yield composite averages for MON810 to be about half the %w/w fortified levels; conversely, Herculex® RW composite averages were observed to be higher than the %w/w fortifications. USDA/AMS/FGIS data are consistent with historical data generated by USDA/AMS/FGIS proficiency program participants. For this reason, consensus means are used for statistical evaluation in lieu of gravimetric fortification values.

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. One hundred and five (105) organizations received samples in the October 2017 round of proficiency testing, and hundred (100) organizations submitted results to USDA/AMS/FGIS.

- Forty-eight (48) participants submitted **qualitative** results only (of these 48, four (4) participants performed a combination of DNA and protein based testing),
- Six (6) submitted **quantitative** results only (of these 6, two (2) participants performed a combination of DNA and protein based testing),
- Forty-seven (47) participants submitted a combination of **qualitative** and **quantitative** results (of these 47, two (2) participants performed a combination of DNA and protein based testing), and
- Eight (8) participants submitted **protein** based results, using Lateral Flow Strip (LFS) and/or Enzyme-linked Immunosorbent Assay (ELISA) qualitative analyses (of these 8, one (1) participant performed Enzyme-linked Immunosorbent Assay (ELISA) quantitative analysis and one (1) participant performed Lateral Flow Strip (LFS) quantitative analysis.

In this report, participating organizations are identified by a confidential “Participant Identification Number.” Appendix I identifies those organizations who gave USDA/AMS/FGIS permission to list them as participants in the USDA/AMS/FGIS Proficiency Program; several 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 either positive (presence) or negative (absence) for 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:

- Table 1: Qualitative results of corn fortified with 35S for all participants (DNA-based assays).
- Table 2: Percentages of correct results, false negatives, and false positives in qualitative reports of 35S for all participants.
- Table 3: Qualitative results of corn fortified with NOS for all participants (DNA-based assays).
- Table 4: Percentages of correct results, false negatives, and false positives in qualitative reports of NOS for all participants.
- Table 5: Qualitative results of corn fortified with FMV for all participants (DNA-based assays).
- Table 6: Percentages of correct results, false negatives, and false positives in qualitative reports of FMV for all participants.
- Table 7: Qualitative results of corn fortified with T25 for all participants (DNA-based assays).
- Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports of T25 for all participants.
- Table 9: Qualitative results of corn fortified MON810 with for all participants (DNA-based assays).
- Table 10: Percentages of correct results, false negatives, and false positives in qualitative reports of MON810 for all participants.
- Table 11: Qualitative results of corn fortified GA21 with for all participants (DNA-based assays).
- Table 12: Percentages of correct results, false negatives, and false positives in qualitative reports of GA21 for all participants.
- Table 13: Qualitative results of corn fortified NK603 with for all participants (DNA-based assays).
- Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports of NK603 for all participants.
- Table 15: Qualitative results of corn fortified with Herculex[®] for all participants (DNA-based assays).
- Table 16: Percentages of correct results, false negatives, and false positives in qualitative reports of Herculex[®] for all participants.
- Table 17: Qualitative results of corn fortified with MON863 for all participants (DNA-based assays).
- Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports of MON863 for all participants.
- Table 19: Qualitative results of corn fortified with Herculex[®] RW for all participants (DNA-based assays).
- Table 20: Percentages of correct results, false negatives, and false positives in qualitative reports of Herculex[®] RW for all participants.
- Table 21: Qualitative results of corn fortified with MIR604 for all participants (DNA-based assays).
- Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR604 for all participants.

- Table 23: Qualitative results of corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports of Event 3272 for all participants.
- Table 25: Qualitative results of corn fortified with MON 88017 for all participants (DNA-based assays).
- Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports of MON 88017 for all participants.
- Table 27: Qualitative results of corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports of MON 89034 for all participants.
- Table 29: Qualitative results of corn fortified with MIR162 for all participants (DNA-based assays)
- Table 30: Percentages of correct results, false negatives and false positives in qualitative reports of MIR162 for all participants.
- Table 31: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™) for all participants (DNA-based assays).
- Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS for all participants.
- Table 33: Qualitative results of soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays).
- Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports of A2704-12 for all participants.
- Table 35: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™ II) for all participants (DNA-based assays).
- Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™ II) for all participants.
- Table 37: Qualitative results of soybeans fortified with DP305423 for all participants (DNA-based assays).
- Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports of DP305423 for all participants.
- Table 39: Qualitative results for soybeans fortified with 35S for all participants (DNA-based assays).
- Table 40: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy 35S for all participants.
- Table 41: Qualitative results for soybeans fortified with NOS for all participants (DNA-based assays).
- Table 42: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy NOS for all participants.
- Table 43: Qualitative results of soybeans fortified with FMV for all participants (DNA-based assays).
- Table 44: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy FMV for all participants.

- Table 45: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each biotechnology-derived 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 Data Summaries: This section summarizes protein based sample analysis data:

- Table 46: Lateral Flow Strip (LFS) testing results for the detection of biotechnology-derived events in corn.
- Table 47: Percentage of correct results, false negatives, and false positives in qualitative reports for biotechnology-derived events in corn using Lateral Flow Strip (LFS) testing.
- Table 48: Results for soybeans fortified with CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 49: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for participants using Lateral Flow Strip (LFS) testing.
- Table 50: Results for the detection of biotechnology-derived events in corn using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 51: Percentage of correct results in the detection of biotechnology-derived events in corn using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 52: Results for soybeans fortified with CP4EPSPS and A2704-12 using Enzyme-Linked Immunosorbent Assay (ELISA).
- Table 53: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 using Enzyme-Linked Immunosorbent Assay (ELISA).

Quantitative Data Summaries: This section summarizes DNA based quantitative sample analysis data: z-scores were purposefully left blank on non-fortified (0.0%) samples since a z-score assumes a normal distribution and its interpretation would be distorted.

- Table 54: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays).
- Table 55: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays).
- Table 56: Quantitative results and z-scores for corn fortified with GA21 for all participants (DNA-based assays).
- Table 57: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays).
- Table 58: Quantitative results and z-scores for corn fortified with Herculex® for all participants (DNA-based assays).
- Table 59: Quantitative results and z-scores for corn fortified with MON863 for all participants (DNA-based assays).
- Table 60: Quantitative results and z-scores for corn fortified with Herculex® RW for all participants (DNA-based assays).

- Table 61: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays).
- Table 62: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays).
- Table 63: Quantitative results and z-scores for corn fortified with MON 88017 for all participants (DNA-based assays).
- Table 64: Quantitative results and z-scores for corn fortified with MON 89034 for all participants (DNA-based assays).
- Table 65: Quantitative results and z-scores for corn fortified with MIR162 for all participants (DNA-based assays).
- Table 66: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS in Roundup Ready™ for all participants (DNA-based assays).
- Table 67: Quantitative results and z-scores for soybeans fortified with A2704-12 for all participants (DNA-based assays).
- Table 68: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS in Roundup Ready™ II for all participants (DNA-based assays).
- Table 69: Quantitative results and z-scores for soybeans fortified with DP305423 for all participants (DNA-based assays).
- Table 70: Quantitative results for 35S, NOS, and FMV in corn (DNA-based assays).
- Table 71: Quantitative results for 35S, NOS, and FMV in soybeans (DNA-based assays).
- Table 72: Quantitative results for corn fortified with biotechnology-derived events using Protein Based Lateral Flow Strip (LFS) tests.
- Table 73: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) and A2704-12 (Liberty Link) using Protein Based Lateral Flow Strip (LFS) tests
- Table 74: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)
- Table 75: Descriptive statistics for participants reported quantifications relative to USDA/AMS/FGIS fortification levels using DNA-based assays.
- Appendix I: List of organizations who wished to be identified as a participant in the USDA/AMS/FGIS October 2017 Proficiency Program.

Table 1: Qualitative results of corn fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
1752	P	P	P	N
1754	P	P	P	N
1761	P	P	P	N
1764	P	P	P	N
1770	P	P	P	N
1788	P	P	P	N
1844	P	P	P	N
1847	P	P	P	N
1854	P	N	P	P
1859	P	P	P	N
1862	P	P	P	N
1870	P	P	P	N
1892	P	P	P	N
1895	P	P	P	N
1897	P	P	P	N
2005	P	P	P	N
2031	P	P	P	N
2034	P	P	P	N
2057	P	P	P	N
2076	P	P	P	N
2112	P	P	P	N
2113	P	P	P	P
2126	P	P	P	N
2131	P	P	P	N
2560	P	P	P	N
2691	P	P	P	N
2716	P	P	P	N
2717	P	P	P	N
2723	P	P	P	N
2727	P	P	P	N
2815	P	N	N	N
3885	P	P	P	N
3888	P	P	P	N
3928	P	P	P	N
3945	P	P	P	N
3946	P	P	P	N
3949	P	P	P	N
4504	P	P	P	N
4932	P	P	P	N
4933	P	P	P	N

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
4935	P	P	P	N
4937	P	P	P	N
4939	P	P	P	N
4942	P	P	P	N
4945	P	P	P	N
4950	P	P	P	N
4952	P	P	P	N
4956	P	P	P	N
4957	P	P	P	N
4960	P	P	P	N
4966	P	P	P	N
4976	P	P	P	N
4977	P	P	P	N
4978	P	P	P	N
4981	P	P	P	N
4982	P	P	P	P
4987	P	P	P	N
7003	P	P	P	N
7006	P	P	P	N
7008	P	P	P	N
7016	P	P	P	N
7017	P	P	P	N
7019	P	P	P	N
7024	P	P	P	P
7025	P	P	P	N
7026	P	P	P	N
7028	P	P	P	N
7030	P	P	P	N
7032	P	P	P	N
7033	P	N	P	P
7035	P	P	P	N
7036	P	P	P	NR
7037	P	P	P	N
7038	P	P	P	N
7039	P	P	P	N
7040	P	P	P	N
7041	P	P	N	P

Data	Sample 1	Sample 2	Sample 3	Sample 4
N, Results	77	77	77	76
# Negative	0	3	2	70
# Positive	77	74	75	6
% Correct	100.0%	96.1%	97.4%	92.1%
% Incorrect	0.0%	3.9%	2.6%	7.9%

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

Total # Reported Results	307
# Incorrect	11
% Correct	96.4%
# Provided Positives	231
# False Negative	5
% False Negative	2.2%
# Provided Negatives	76
# False Positive	6
% False Positive	7.9%

Table 3: Qualitative results of corn fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
1752	P	P	P	N
1754	P	P	P	N
1761	P	P	P	N
1764	P	P	P	N
1770	P	P	P	N
1788	P	P	P	N
1844	P	P	P	N
1847	P	P	P	N
1854	P	P	P	P
1859	P	P	P	N
1862	P	P	P	N
1870	P	P	P	N
1892	P	P	P	N
1895	P	P	P	N
1897	P	P	P	N
2005	P	P	P	N
2031	P	P	P	N
2034	P	P	P	N
2057	P	P	P	N
2076	P	P	P	N
2112	P	P	P	N
2113	P	P	P	P
2126	P	P	P	N
2131	P	P	P	N
2560	P	P	P	N
2691	P	P	P	N

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
2716	P	P	P	N
2717	P	P	P	N
2723	P	P	P	N
2727	P	P	P	N
2815	P	P	P	N
3885	P	P	P	N
3888	P	P	P	N
3928	P	P	P	N
3945	P	P	P	N
3946	P	P	P	N
3949	P	P	P	N
4504	P	P	P	N
4932	P	P	P	N
4933	P	P	P	N
4935	P	P	P	N
4936	P	P	P	N
4937	P	P	P	N
4939	P	P	P	N
4942	P	P	P	N
4945	P	P	P	N
4950	P	P	P	P
4952	P	P	P	N
4956	P	P	P	N
4957	P	P	P	N
4960	P	P	P	N
4966	P	P	P	N
4976	P	P	P	N
4977	P	P	P	N
4978	P	P	P	N
4981	P	P	P	N
4982	P	P	P	N
4987	P	P	P	N
7003	P	P	P	N
7006	P	P	P	N
7008	P	P	P	N
7016	P	P	P	N
7017	P	P	P	N
7019	P	P	P	N
7024	P	P	P	P
7025	P	P	P	N
7026	P	P	P	N
7028	P	P	P	N
7030	P	P	P	N
7032	P	P	P	N

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
7033	P	N	P	P
7035	P	P	P	N
7036	P	P	P	NR
7037	P	P	P	N
7038	P	P	P	N
7039	P	P	P	N
7040	P	P	P	N
7041	P	P	N	P

Data	Sample 1	Sample 2	Sample 3	Sample 4
N, Results	78	78	78	77
# Negative	0	1	1	71
# Positive	78	77	77	6
% Correct	100.0%	98.7%	98.7%	92.2%
% Incorrect	0.0%	1.3%	1.3%	7.8%

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

Total # Reported Results	311
# Incorrect	8
% Correct	97.4%
# Provided Positives	234
# False Negative	2
% False Negative	0.9%
# Provided Negatives	77
# False Positive	6
% False Positive	7.8%

Table 5: Qualitative results of corn fortified with FMV for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
1754	P	P	N	N
1764	P	N	N	N
1785	P	N	N	N
1859	P	N	N	N
1870	P	N	N	N
1892	P	N	N	N
1895	P	N	N	N
2005	P	N	N	N
2031	P	N	N	N
2057	P	N	N	N
2112	P	N	N	N
2113	P	N	N	N
2131	P	N	N	N
2691	P	N	N	N
2716	P	N	N	N
2717	P	N	N	N
2723	P	N	N	N
3888	P	N	N	N
3928	P	N	N	N
3945	P	N	N	N
3949	N	N	N	N
4504	P	N	N	N
4932	P	N	N	N
4935	P	N	N	N
4950	P	N	N	N
4952	P	N	P	N
4957	P	N	N	N
4960	P	N	N	N
4964	P	N	N	N
4966	P	N	N	N
4974	P	N	N	N
4976	P	N	N	N
4978	P	N	N	N
4987	P	N	N	N
7017	P	N	N	N
7019	P	N	N	N
7025	P	N	N	N
7026	P	N	N	N
7030	P	P	N	N
7032	P	N	N	N

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4
7033	P	N	N	N
7036	P	N	N	NR
7037	P	N	N	N
7038	P	P	P	N
7039	P	N	N	N
7040	N	N	N	N
7041	N	N	N	N

Data	Sample 1	Sample 2	Sample 3	Sample 4
N, Results	47	47	47	46
# Negative	3	44	45	46
# Positive	44	3	2	0
% Correct	93.6%	93.6%	95.7%	100.0%
% Incorrect	6.4%	6.4%	4.3%	0.0%

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

Total # Reported Results	187
# Incorrect	8
% Correct	95.7%
# Provided Positives	47
# False Negative	3
% False Negative	6.4%
# Provided Negatives	140
# False Positive	5
% False Positive	3.6%

Table 7: Qualitative results of corn fortified with T25 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.8%	Sample 4 0.0%
1752	N	N	P	N
1764	N	N	P	N
1785	N	N	P	N
1844	N	N	P	N
1854	P	P	P	P
1859	N	N	P	N
1862	N	N	P	N
1892	P	P	P	N
1895	N	N	P	N
1897	N	N	P	N
2005	P	P	P	N
2034	N	N	P	N
2060	P	P	P	N
2089	N	N	P	N
2112	N	N	P	N
2113	N	N	N	N
2126	N	N	P	N
2131	N	N	P	N
2560	N	N	P	N
2569	N	N	P	N
2691	P	P	N	N
2694	N	N	P	N
2732	N	N	P	N
3928	N	N	P	N
3929	N	N	P	N
4504	P	P	P	N
4936	N	N	P	N
4937	N	N	P	N
4942	N	N	P	N
4945	N	N	P	N
4950	P	P	P	N
4957	N	N	P	N
4964	P	P	P	N
4966	N	N	P	N
4976	N	N	P	N
7025	N	N	P	N
7027	N	N	P	N

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.8%	Sample 4 0.0%
7032	N	N	P	N
7036	N	N	P	N
7037	N	N	P	N
7039	N	N	P	N

Data	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.8%	Sample 4 0.0%
N, Results	41	41	41	41
# Negative	33	33	2	40
# Positive	8	8	39	1
% Correct	80.5%	80.5%	95.1%	97.6%
% Incorrect	19.5%	19.5%	4.9%	2.4%

Table 8: Percentages of correct results, false negatives, and false positives in qualitative reports of T25 for all participants

Total # Reported Results	164
# Incorrect	19
% Correct	88.4%
# Provided Positives	41
# False Negative	2
% False Negative	4.9%
# Provided Negatives	123
# False Positive	17
% False Positive	13.8%

Table 9: Qualitative results of corn fortified with MON810 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.5%	Sample 2 2.0%	Sample 3 0.0%	Sample 4 0.0%
1761	P	P	N	N
1785	P	P	N	N
1788	P	P	N	N
1844	P	P	N	N
1854	P	P	N	N
1859	P	P	N	N
1862	P	P	N	N
1892	P	P	N	N

Participant Number	Sample 1 0.5%	Sample 2 2.0%	Sample 3 0.0%	Sample 4 0.0%
1895	P	P	N	N
1897	P	P	N	N
2034	P	P	N	N
2060	P	P	N	N
2089	P	P	N	N
2113	P	P	N	N
2126	P	P	N	N
2131	P	P	N	N
2560	P	P	N	N
2569	P	P	N	N
2691	N	N	P	N
4937	P	P	N	N
4945	P	P	N	N
4950	N	P	N	N
4964	P	P	N	N
4966	P	P	N	N
4978	P	P	N	N
4987	P	P	N	N
7025	P	P	N	N
7027	P	P	N	N
7032	P	P	N	N
7036	P	P	N	N
7037	P	P	N	N
7039	P	P	N	N

Data	Sample 1 0.5%	Sample 2 2.0%	Sample 3 0.0%	Sample 4 0.0%
N, Results	32	32	32	32
# Negative	2	1	31	32
# Positive	30	31	1	0
% Correct	93.8%	96.9%	96.9%	100.0%
% Incorrect	6.3%	3.1%	3.1%	0.0%

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

Total # Reported Results	128
# Incorrect	4
% Correct	96.9%
# Provided Positives	64
# False Negative	3
% False Negative	4.7%
# Provided Negatives	64
# False Positive	1
% False Positive	1.6%

Table 11: Qualitative results of corn fortified with GA21 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.2%	Sample 3 0.5%	Sample 4 0.0%
1785	N	P	P	N
1788	N	P	P	N
1844	N	P	P	N
1854	P	P	P	P
1859	N	P	P	N
1862	N	N	P	N
1892	N	P	P	N
1895	N	P	P	N
1897	N	P	P	N
2034	N	P	P	N
2060	N	P	P	N
2089	N	P	P	N
2112	N	P	P	N
2113	N	P	P	N
2126	N	P	P	N
2131	N	P	P	N
2560	N	P	P	N
2569	N	P	P	N
2691	N	P	P	N
2717	N	P	P	N
3929	N	P	P	N
4937	N	P	P	N
4942	N	P	P	N
4945	N	P	P	N

Participant Number	Sample 1 0.0%	Sample 2 0.2%	Sample 3 0.5%	Sample 4 0.0%
4950	N	P	P	N
4960	N	P	P	N
4964	N	P	P	N
4966	N	P	P	N
4978	N	P	P	N
7025	N	P	P	N
7027	N	P	P	N
7032	P	P	N	N
7036	N	P	P	N
7037	N	P	P	N
7039	N	P	P	N

Data	Sample 1 0.0%	Sample 2 0.2%	Sample 3 0.5%	Sample 4 0.0%
N, Results	35	35	35	35
# Negative	33	1	1	34
# Positive	2	34	34	1
% Correct	94.3%	97.1%	97.1%	97.1%
% Incorrect	5.7%	2.9%	2.9%	2.9%

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

Total # Reported Results	140
# Incorrect	5
% Correct	96.4%
# Provided Positives	70
# False Negative	2
% False Negative	2.9%
# Provided Negatives	70
# False Positive	3
% False Positive	4.3%

Table 13: Qualitative results of corn fortified with NK603 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 1.5%	Sample 4 0.0%
1752	N	N	P	N
1761	N	N	P	N

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 1.5%	Sample 4 0.0%
1785	N	N	P	N
1788	N	N	P	N
1844	N	N	P	N
1854	P	P	P	P
1859	N	N	P	N
1862	N	N	P	N
1892	N	N	P	N
1895	N	N	P	N
1897	N	N	P	N
2034	N	N	P	N
2060	N	N	P	N
2089	N	N	P	N
2113	N	N	P	N
2126	N	N	P	N
2131	N	N	P	N
2560	N	N	P	N
2569	N	N	P	N
2691	N	N	P	N
2720	N	N	P	N
2824	N	N	P	N
3928	N	N	P	N
3929	N	N	P	N
4937	N	N	P	N
4942	N	N	P	N
4945	N	N	P	N
4950	N	N	P	N
4956	N	N	P	N
4960	N	N	P	N
4964	N	N	P	N
4966	N	N	P	N
4974	N	N	P	N
4978	N	N	P	N
4987	N	N	P	N
7025	N	N	P	N
7027	N	N	P	N
7032	N	N	P	N
7036	N	N	P	N
7037	N	N	P	N
7039	N	N	P	N

Data	Sample 1 0.0%	Sample 2 0.0%	Sample 3 1.5%	Sample 4 0.0%
N, Results	41	41	41	41
# Negative	40	40	0	40
# Positive	1	1	41	1
% Correct	97.6%	97.6%	100.0%	97.6%
% Incorrect	2.4%	2.4%	0.0%	2.4%

Table 14: Percentages of correct results, false negatives, and false positives in qualitative reports of NK603 for all participants

Total # Reported Results	164
# Incorrect	3
% Correct	98.2%
# Provided Positives	41
# False Negative	0
% False Negative	0.0%
# Provided Negatives	123
# False Positive	2
% False Positive	1.6%

Table 15: Qualitative results of corn fortified with Herculex® for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.2%	Sample 4 0.0%
1752	N	P	P	N
1761	N	P	P	N
1785	N	P	P	N
1844	N	P	P	N
1844	N	P	P	N
1854	N	P	P	P
1859	N	P	P	N
1862	N	P	P	N
1892	N	P	P	N
1895	N	P	P	N
1897	N	P	P	N
2034	N	P	P	N
2060	N	P	P	N
2089	N	P	P	N
2112	N	P	P	N
2113	N	P	P	N

Participant Number	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.2%	Sample 4 0.0%
2126	N	P	P	N
2131	N	P	N	N
2560	N	P	P	N
2569	N	P	P	N
2691	N	P	P	N
2824	N	P	P	N
3929	N	P	P	N
4937	N	P	P	N
4942	N	P	P	N
4950	N	P	P	N
4960	N	P	P	N
4964	N	P	P	N
4966	N	P	P	N
4978	N	P	P	N
7025	N	P	P	N
7027	N	P	P	N
7032	N	P	P	N
7037	N	P	P	N
7039	N	P	P	N

Data	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.2%	Sample 4 0.0%
N, Results	35	35	35	35
# Negative	35	0	1	34
# Positive	0	35	34	1
% Correct	100.0%	100.0%	97.1%	97.1%
% Incorrect	0.0%	-2.9%	2.9%	2.9%

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

Total # Reported Results	140
# Incorrect	1
% Correct	99.3%
# Provided Positives	70
# False Negative	0
% False Negative	0.0%
# Provided Negatives	70
# False Positive	1
% False Positive	1.4%

Table 17: Qualitative results of corn fortified with MON863 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 1.0%	Sample 2 0.0%	Sample 3 0.2%	Sample 4 0.0%
1785	P	N	P	N
1788	P	N	P	N
1844	P	N	P	N
1854	P	P	P	P
1859	P	N	P	N
1862	P	N	P	N
1892	P	N	P	N
1895	P	N	N	N
1897	P	N	P	N
2034	P	N	P	N
2060	P	N	P	N
2089	P	N	P	N
2112	P	N	P	N
2113	P	P	P	P
2126	P	N	P	N
2131	P	N	P	N
2560	P	N	P	N
2569	P	N	P	N
2691	P	N	P	N
3929	P	N	P	N
4937	P	N	P	N
4942	P	N	P	N
4945	P	N	P	N
4950	P	N	P	N
4956	P	N	P	N
4964	P	N	P	N
4966	P	N	P	N
4974	P	N	P	N
7025	P	N	P	N
7027	P	N	P	N
7032	P	NR	P	N
7036	P	P	P	NR
7037	P	N	P	N
7039	P	N	P	N

Data	Sample 1 1.0%	Sample 2 0.0%	Sample 3 0.2%	Sample 4 0.0%
N, Results	34	33	34	33
# Negative	0	30	1	31
# Positive	34	3	33	2
% Correct	100.0%	90.9%	100.0%	93.9%
% Incorrect	0.0%	9.1%	0.0%	6.1%

Table 18: Percentages of correct results, false negatives, and false positives in qualitative reports of MON863 for all participants

Total # Reported Results	134
# Incorrect	5
% Correct	96.3%
# Provided Positives	68
# False Negative	1
% False Negative	1.5%
# Provided Negatives	66
# False Positive	5
% False Positive	7.6%

Table 19: Qualitative results of corn fortified with Herculex® RW for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in bold face)

Participant Number	Sample 1 0.5%	Sample 2 0.0%	Sample 3 1.0%	Sample 4 0.0%
1752	P	N	P	N
1761	P	N	P	N
1785	P	N	P	N
1844	P	N	P	N
1859	P	N	P	N
1862	P	N	P	N
1892	P	N	P	N
1895	P	N	P	N
2005	P	N	P	N
2034	P	N	P	N
2060	P	N	P	N
2089	P	N	P	N
2113	P	N	P	N
2126	P	N	P	N
2131	P	N	P	N
2560	P	N	P	N

Participant Number	Sample 1 0.5%	Sample 2 0.0%	Sample 3 1.0%	Sample 4 0.0%
2569	P	N	P	N
2691	P	N	P	N
3929	P	N	P	N
4504	P	N	P	N
4937	P	N	P	N
4942	P	N	P	N
4945	P	N	P	N
4950	N	N	P	N
4952	P	N	P	N
4960	P	N	P	N
4964	P	N	P	N
4966	P	N	P	N
4974	P	N	P	N
4978	P	N	P	N
7025	P	N	P	N
7027	P	N	P	N
7037	P	N	P	N

Data	Sample 1 0.5%	Sample 2 0.0%	Sample 3 1.0%	Sample 4 0.0%
N, Results	33	33	33	33
# Negative	1	33	0	33
# Positive	32	0	33	0
% Correct	97.0%	100.0%	100.0%	100.0%
% Incorrect	3.0%	0.0%	0.0%	0.0%

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

Total # Reported Results	132
# Incorrect	1
% Correct	99.2%
# Provided Positives	66
# False Negative	1
% False Negative	1.5%
# Provided Negatives	66
# False Positive	0
% False Positive	0.0%

Table 21: Qualitative results of corn fortified with MIR604 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.5%	Sample 4 0.0%
1785	N	N	P	N
1844	N	N	P	N
1854	P	P	P	P
1859	N	N	P	N
1862	N	N	P	N
1895	N	N	P	N
1897	N	N	P	N
2034	N	N	P	N
2060	N	N	P	N
2089	N	N	P	N
2113	N	N	P	N
2126	N	N	P	N
2131	N	N	P	N
2560	N	N	P	N
2569	N	N	P	N
2691	N	N	P	N
2717	N	N	P	N
2720	N	N	P	N
2824	N	N	P	N
3928	N	N	P	N
3929	N	N	P	N
4937	N	N	P	N
4942	N	N	P	N
4945	N	N	P	N
4950	N	N	P	P

Participant Number	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.5%	Sample 4 0.0%
4956	N	N	P	N
4960	N	N	P	N
4964	N	N	P	N
4966	N	N	P	N
4978	N	N	P	N
7025	N	N	P	N
7027	N	N	P	N
7032	N	N	P	N
7036	N	N	P	N
7037	N	N	P	N
7039	N	N	P	N

Data	Sample 1 0.0%	Sample 2 0.0%	Sample 3 0.5%	Sample 4 0.0%
N, Results	36	36	36	36
# Negative	35	35	0	34
# Positive	1	1	36	2
% Correct	97.2%	97.2%	100.0%	94.4%
% Incorrect	2.8%	2.8%	0.0%	5.6%

Table 22: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR604 for all participants

Total # Reported Results	144
# Incorrect	4
% Correct	97.2%
# Provided Positives	36
# False Negative	0
% False Negative	0.0%
# Provided Negatives	108
# False Positive	4
% False Positive	3.7%

Table 23: Qualitative results of corn fortified with Event 3272 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 1.0%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%
1761	P	N	N	N
1785	P	N	N	N
1844	P	N	N	N
1859	P	N	N	N
1895	P	N	N	N
2005	P	N	N	N
2034	P	N	N	N
2113	P	N	N	N
2126	P	N	N	N
2131	P	N	N	N
2691	P	N	N	N
3928	P	N	N	N
4504	P	N	N	N
4937	P	N	N	N
4942	P	N	N	N
4945	P	N	N	N
4950	P	N	N	N
4957	P	N	N	N
4960	P	N	N	N
4964	P	N	N	N
4966	P	N	N	N
4974	P	N	N	N
4978	P	N	N	N
4987	P	N	N	N
7025	P	N	N	N
7027	P	N	N	N
7036	P	N	N	N
7037	P	N	N	N

Data	Sample 1 1.0%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%
N, Results	28	28	28	28
# Negative	0	28	28	28
# Positive	28	0	0	0
% Correct	100.0%	100.0%	100.0%	100.0%
% Incorrect	0.0%	0.0%	0.0%	0.0%

Table 24: Percentages of correct results, false negatives, and false positives in qualitative reports of Event 3272 for all participants

Total # Reported Results	112
# Incorrect	0
% Correct	100.0%
# Provided Positives	28
# False Negative	0
% False Negative	0.0%
# Provided Negatives	84
# False Positive	0
% False Positive	0.0%

Table 25: Qualitative results of Corn fortified with MON88017 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.2%	Sample 2 0.5%	Sample 3 0.0%	Sample 4 0.0%
1761	P	P	N	N
1785	P	P	N	N
1844	P	P	N	N
1854	P	P	P	P
1859	P	P	N	N
1862	P	P	N	N
1895	P	P	N	N
1897	P	P	N	N
2031	P	P	N	N
2034	P	P	N	N
2060	P	P	N	N
2089	P	P	N	N
2113	P	P	N	N
2126	P	P	N	N
2131	N	N	N	N
2560	P	P	N	N
2569	P	P	N	N
2691	P	P	N	N
2824	P	P	N	N
3929	P	P	N	N
4504	P	P	N	N
4937	P	P	N	N
4942	P	P	N	N
4945	P	P	N	N

Participant Number	Sample 1 0.2%	Sample 2 0.5%	Sample 3 0.0%	Sample 4 0.0%
4950	N	P	N	N
4960	P	P	N	N
4964	P	P	N	N
4966	P	P	N	N
4974	P	P	N	N
4978	P	P	N	N
4987	P	P	N	N
7025	P	P	N	N
7027	P	P	N	N
7032	P	P	N	N
7036	P	P	N	N
7037	P	P	N	N
7039	P	P	N	N

Data	Sample 1 0.2%	Sample 2 0.5%	Sample 3 0.0%	Sample 4 0.0%
N, Results	37	37	37	37
# Negative	2	1	36	36
# Positive	35	36	1	1
% Correct	94.6%	100.0%	97.3%	97.3%
% Incorrect	5.4%	0.0%	2.7%	2.7%

Table 26: Percentages of correct results, false negatives, and false positives in qualitative reports of MON88017 for all participants

Total # Reported Results	148
# Incorrect	5
% Correct	96.6%
# Provided Positives	74
# False Negative	3
% False Negative	4.1%
# Provided Negatives	74
# False Positive	2
% False Positive	2.7%

Table 27: Qualitative results of corn fortified with MON89034 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in bold face)

Participant Number	Sample 1 0.5%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%
1761	P	N	N	N
1785	P	N	N	N
1844	P	N	N	N
1854	P	P	P	P
1859	P	N	N	N
1862	P	N	N	N
1895	P	N	N	N
1897	P	N	N	N
2031	P	N	N	N
2034	P	N	N	N
2060	P	N	N	N
2089	P	N	N	N
2113	P	N	N	N
2126	P	N	N	N
2131	P	N	N	N
2560	P	N	N	N
2569	P	N	N	N
2691	P	N	N	N
2824	P	N	N	N
3929	P	N	N	N
4504	P	N	N	N
4937	P	N	N	N
4942	P	N	N	N
4945	P	N	N	N
4950	P	N	N	N
4957	P	N	N	N
4960	P	N	N	N
4964	P	N	N	N
4966	P	N	N	N
4976	P	N	N	N
4978	P	N	N	N
7025	P	N	N	N
7027	P	N	N	N
7032	P	N	N	N
7036	P	N	N	N
7037	P	N	N	N
7039	P	N	N	N

Participant Number	Sample 1 0.5%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%
7040	P	P	P	N
7041	P	P	N	P

Data	Sample 1 0.5%	Sample 2 0.0%	Sample 3 0.0%	Sample 4 0.0%
N, Results	39	39	39	39
# Negative	0	36	37	37
# Positive	39	3	2	2
% Correct	102.6%	92.3%	94.9%	94.9%
% Incorrect	-2.6%	7.7%	5.1%	5.1%

Table 28: Percentages of correct results, false negatives, and false positives in qualitative reports of MON89034 for all participants

Total # Reported Results	156
# Incorrect	7
% Correct	95.5%
# Provided Positives	39
# False Negative	0
% False Negative	0.0%
# Provided Negatives	117
# False Positive	7
% False Positive	6.0%

Table 29: Qualitative results of corn fortified with MIR162 for all participants (DNA-based assays) (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.0%	Sample 4 0.0%
1785	N	P	N	N
1844	N	P	N	N
1854	P	P	P	P
1859	N	P	N	N
1862	N	P	N	N
1895	N	P	N	N
1897	N	P	N	N
2034	N	P	N	N
2060	N	P	N	N
2089	N	P	N	N
2113	N	P	N	N

Participant Number	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.0%	Sample 4 0.0%
2126	N	P	N	N
2131	N	P	N	N
MIR 162	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.0%	Sample 4 0.0%
Participant Number	0.0%	1.0%	0.0%	0.0%
2560	N	P	N	N
2569	N	P	N	N
2824	N	P	N	N
3928	N	P	N	N
3929	N	P	N	N
4504	N	P	N	N
4937	N	P	N	N
4942	N	P	N	N
4950	N	P	P	N
4960	N	P	N	N
4964	N	P	N	N
4966	N	P	N	N
4987	N	P	N	N
7025	N	P	N	N
7027	N	P	N	N
7032	N	P	N	N
7036	N	P	N	N
7037	N	P	N	N
7039	N	P	N	N

Data	Sample 1 0.0%	Sample 2 1.0%	Sample 3 0.0%	Sample 4 0.0%
N, Results	32	32	32	32
# Negative	31	0	30	31
# Positive	1	32	2	1
% Correct	96.9%	100.0%	93.8%	96.9%
% Incorrect	3.1%	0.0%	6.3%	3.1%

Table 30: Percentages of correct results, false negatives, and false positives in qualitative reports of MIR162 for all participants

Total # Reported Results	128
# Incorrect	4
% Correct	96.9%
# Provided Positives	32
# False Negative	0
% False Negative	0.0%
# Provided Negatives	96
# False Positive	4
% False Positive	4.2%

Table 31: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.5%
1752	N	P
1844	N	P
1847	N	P
1854	P	P
1859	N	P
1862	N	P
1892	N	P
1897	N	P
2034	N	P
2089	N	P
2131	N	P
2560	N	P
2569	N	P
2717	N	P
3928	N	P
4937	N	P
4945	N	P
4950	N	P
4956	N	P
4964	N	P
4966	N	P
4974	N	P
4987	N	P
7027	N	P
7032	N	P

Participant Number	Sample 1 0.0%	Sample 2 0.5%
7036	N	P
7037	N	P
7039	N	P

Data	Sample 1 0.0%	Sample 2 0.5%
N, Results	28	28
# Negative	27	0
# Positive	1	28
% Correct	96.4%	100.0%
% Incorrect	3.6%	0.0%

Table 32: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™) for all participants

Total # Reported Results	56
# Incorrect	1
% Correct	98.2%
# Provided Positives	28
# False Negative	0
% False Negative	0.0%
# Provided Negatives	28
# False Positive	1
% False Positive	3.6%

Table 33: Qualitative results of soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface)

Participant Number	Sample 1 0.0%	Sample 2 0.5%
1752	N	P
1785	N	P
1844	N	P
1847	N	P
1859	N	P
1862	N	P
1892	N	P
1897	N	P
2034	N	P
2060	N	P

Participant Number	Sample 1 0.0%	Sample 2 0.5%
2089	N	P
2131	N	P
2560	N	P
2691	N	P
2692	N	P
3928	N	P
4936	N	P
4937	N	P
4942	N	P
4945	N	P
4950	N	P
4957	P	N
4964	N	P
4966	N	P
7027	N	P
7032	N	P
7034	N	P
7036	N	P
7037	N	P

Data	Sample 1 0.0%	Sample 2 0.5%
N, Results	29	29
# Negative	28	1
# Positive	1	28
% Correct	96.6%	96.6%
% Incorrect	3.4%	3.4%

Table 34: Percentages of correct results, false negatives, and false positives in qualitative reports of A2704-12 (Liberty Link®) for all participants

Total # Reported Results	58
# Incorrect	2
% Correct	96.6%
# Provided Positives	29
# False Negative	1
% False Negative	3.4%
# Provided Negatives	29
# False Positive	1
% False Positive	3.4%

Table 35: Qualitative results of soybeans fortified with CP4 EPSPS (Roundup Ready™ II) for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in boldface).

Participant Number	Sample 1 0.0%	Sample 2 0.0%
1752	N	N
1764	N	N
1785	N	N
1844	N	N
1847	N	N
1859	N	N
1862	N	N
1870	N	N
1892	N	N
1897	N	N
2005	N	N
2034	N	N
2060	N	N
2089	N	N
2112	N	N
2131	N	N
2560	N	N
2569	N	N
2691	N	N
2692	N	N
2727	N	N
2824	N	N
4504	N	N
4932	N	N
4935	N	N
4936	N	N
4937	N	N
4942	N	P
4945	N	N
4950	N	N
4957	N	N
4960	N	N
4964	N	N
4966	N	N
4976	N	N
4978	N	N
4987	N	N

Participant Number	Sample 1 0.0%	Sample 2 0.0%
7025	N	N
7027	N	N
7032	N	N
7037	N	N

Data	Sample 1 0.0%	Sample 2 0.0%
N, Results	41	41
# Negative	41	40
# Positive	0	1
% Correct	100.0%	97.6%
% Incorrect	0.0%	2.4%

Table 36: Percentages of correct results, false negatives, and false positives in qualitative reports of CP4 EPSPS (Roundup Ready™ II) for all participants

Total # Reported Results	82
# Incorrect	1
% Correct	98.8%
# Provided Positives	0
# False Negative	0
% False Negative	0.0%
# Provided Negatives	41
# False Positive	1
% False Positive	2.4%

Table 37: Qualitative results of soybeans fortified with DP305423 for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Participant Number	Sample 1 0.0%	Sample 2 0.5%
1752	N	P
1761	N	P
1785	N	P
1844	N	P
1847	N	P
1854	P	P
1859	N	P
1862	N	P
1897	N	P

Participant Number	Sample 1 0.0%	Sample 2 0.5%
2005	N	P
2034	N	P
2060	N	P
2131	N	P
2691	N	P
2692	N	P
2717	N	P
2824	N	P
3929	N	P
4937	N	P
4942	N	P
4945	N	P
4950	P	N
4956	N	P
4957	P	N
4960	N	P
4964	N	P
4966	N	P
4974	N	P
4978	N	P
4987	N	P
7025	N	P
7027	N	P
7034	N	P
7036	N	P
7037	N	P
7038	N	P
7039	N	P
7040	N	P
7041	N	P

Data	Sample 1 0.0%	Sample 2 0.5%
N, Results	39	39
# Negative	36	2
# Positive	3	37
% Correct	92.3%	94.9%
% Incorrect	7.7%	5.1%

Table 38: Percentages of correct results, false negatives, and false positives in qualitative reports of DP305423 for all participants

Total # Reported Results	78
# Incorrect	5
% Correct	93.6%
# Provided Positives	39
# False Negative	2
% False Negative	5.1%
# Provided Negatives	39
# False Positive	3
% False Positive	7.7%

Table 39: Qualitative results for soybeans fortified with 35S for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Participant Number	Sample 1 N	Sample 2 P
1752	N	P
1754	N	P
1761	N	P
1764	N	P
1770	N	P
1785	N	P
1844	N	P
1854	P	P
1859	N	P
1870	N	P
1892	N	P
1895	N	P
1897	N	P
2005	N	P
2031	N	P
2034	N	P
2057	N	P
2076	N	P
2112	N	P
2131	N	P
2560	N	P
2691	N	P
2692	N	P
2716	N	P
2717	N	P
2723	N	P

Participant Number	Sample 1 N	Sample 2 P
2727	N	P
2815	P	P
3885	P	N
3888	N	P
3928	N	P
3929	N	P
3945	N	P
3946	N	P
3949	P	P
4504	N	P
4932	N	P
4933	N	P
4935	N	P
4937	N	P
4939	N	P
4942	N	P
4945	N	P
4950	P	P
4952	N	P
4956	N	P
4960	N	P
4966	N	P
4974	N	P
4976	N	P
4977	N	P
4978	N	P
4981	N	P
4987	N	P
7003	N	P
7006	N	P
7008	N	P
7016	N	P
7017	N	P
7019	N	P
7024	P	P
7025	N	P
7028	N	P
7030	N	P
7032	N	P
7033	P	N
7035	N	P
7036	N	P
7037	N	P

Participant Number	Sample 1 N	Sample 2 P
7039	N	P

Data	Sample 1 N	Sample 2 P
N, Results	70	70
# Negative	63	2
# Positive	7	68
% Correct	90.0%	97.1%
% Incorrect	10.0%	2.9%

Table 40: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy 35S for all participants

Total # Reported Results	140
# Incorrect	9
% Correct	93.6%
# Provided Positives	70
# False Negative	2
% False Negative	2.9%
# Provided Negatives	70
# False Positive	7
% False Positive	10.0%

Table 41: Qualitative results of soybeans fortified with NOS for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Participant Number	Sample 1 N	Sample 2 P
1752	N	P
1754	N	P
1761	N	P
1764	N	P
1770	N	P
1785	N	P
1788	N	P
1854	N	P
1859	N	P
1862	N	P
1870	N	P
1892	N	P

Participant Number	Sample 1 N	Sample 2 P
1895	N	P
1897	N	P
2005	N	P
2031	N	P
2034	N	P
2057	N	P
2076	N	P
2112	N	P
2131	N	P
2560	N	P
2691	N	P
2692	N	P
2716	N	P
2717	N	P
2723	N	P
2727	N	P
2815	P	P
3885	P	N
3887	N	P
3888	N	P
3928	N	P
3929	N	P
3945	N	P
3946	N	P
3949	N	P
4504	N	P
4932	N	P
4933	N	P
4935	N	P
4936	N	P
4937	N	P
4939	N	P
4942	N	P
4945	N	P
4950	P	P
4952	N	P
4956	N	P
4960	N	P
4966	N	P
4974	N	P
4976	N	P
4977	N	P
4978	N	P

Participant Number	Sample 1 N	Sample 2 P
4981	N	P
4987	N	P
7003	N	P
7006	N	P
7008	N	P
7016	N	P
7017	N	P
7019	N	P
7024	P	P
7025	N	P
7028	N	P
7030	N	P
7032	N	P
7033	P	N
7035	N	P
7036	N	P
7037	N	P
7039	N	P

Data	Sample 1 N	Sample 2 P
N, Results	73	73
# Negative	68	2
# Positive	5	71
% Correct	93.2%	97.3%
% Incorrect	6.8%	2.7%

Note: The NOS trait serves as a terminator in RUR and DP305423 in this list of events.

Table 42: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy NOS for all participants

Total # Reported Results	146
# Incorrect	7
% Correct	95.2%
# Provided Positives	73
# False Negative	2
% False Negative	2.7%
# Provided Negatives	73
# False Positive	5
% False Positive	6.8%

Table 43: Qualitative results of soybeans fortified with FMV for all participants (DNA-based assays) (N = negative; P = positive; Incorrect results are shown in bold face)

Participant Number	Sample 1 N	Sample 2 N
1754	N	N
1764	N	N
1785	N	N
1844	N	N
1859	N	N
1870	N	N
1892	N	N
1895	N	N
2005	N	N
2031	N	N
2034	N	N
2057	N	N
2112	N	N
2131	N	N
2691	N	N
2716	N	N
2717	N	N
3887	N	N
3888	N	N
3929	N	N
3945	N	N
4504	N	N
4932	N	N
4935	N	N
4936	N	N
4945	N	N
4950	N	P
4952	N	N
4960	N	N
4964	N	N
4966	N	N
4974	N	P
4976	N	N
4978	N	N
4987	N	N
7017	N	N
7019	N	N
7025	N	N
7030	N	N

Participant Number	Sample 1 N	Sample 2 N
7032	N	N
7033	N	N
7036	N	N
7037	N	N
7039	N	N

Data	Sample 1 N	Sample 2 N
N, Results	44	44
# Negative	44	42
# Positive	0	2
% Correct	100.0%	95.5%
% Incorrect	0.0%	4.5%

Note: The FMV trait is a promoter in RURII in this list of events.

Table 44: Percentages of correct results, false negatives, and false positives in qualitative reports of Soy FMV for all participants

Total # Reported Results	88
# Incorrect	2
% Correct	97.7%
# Provided Positives	0
# False Negative	0
% False Negative	0.0%
# Provided Negatives	88
# False Positive	2
% False Positive	2.3%

Table 45: Composite percentages of correct results, false negatives, and false positives in qualitative reports for each biotechnology-derived 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	FMV	T25	MON810
N, Results	307	311	187	164	128
Reported Incorrect	11	8	8	19	4
% Correct	96.4%	97.4%	95.7%	88.4%	96.9%
# Provided Positives	231	234	47	41	64
N, False Negatives	5	2	3	2	3
% False Negative	2.2%	0.9%	6.4%	4.9%	4.7%
# Provided Negatives	76	77	140	123	64
N, False Positives	6	6	5	17	1
% False Positives	7.9%	7.8%	3.6%	13.8%	1.6%

Event	GA21	NK603	Herculex®	MON863	Herculex® RW
N, Results	140	164	140	134	132
Reported Incorrect	5	3	1	5	1
% Correct	96.4%	98.2%	99.3%	96.3%	99.2%
# Provided Positives	70	41	70	68	66
N, False Negatives	2	0	0	1	1
% False Negative	2.9%	0.0%	0.0%	1.5%	1.5%
# Provided Negatives	70	123	70	66	66
N, False Positives	3	2	1	5	0
% False Positives	4.3%	1.6%	1.4%	7.6%	0.0%

Event	MIR604	EV3272	MON88017	MON89034	MIR162	RUR
N, Results	144	112	148	156	128	56
Reported Incorrect	4	0	5	7	4	1
% Correct	97.2%	100.0%	96.6%	95.5%	96.9%	98.2%
# Provided Positives	36	28	74	39	32	28
N, False Negatives	0	0	3	0	0	0
% False Negative	0.0%	0.0%	4.1%	0.0%	0.0%	0.0%
# Provided Negatives	108	84	74	117	96	28
N, False Positives	4	0	2	7	4	1
% False Positives	3.7%	0.0%	2.7%	6.0%	4.2%	3.6%

Event	LL	RUR II	DP305423	Soy 35S	Soy NOS	Soy FMV
N, Results	58	82	78	140	146	88
Reported Incorrect	2	1	5	9	7	2
% Correct	96.6%	98.8%	93.6%	93.6%	95.2%	97.7%
# Provided Positives	29	0	39	70	73	0
N, False Negatives	1	0	2	2	2	0
% False Negative	3.4%	0.0%	5.1%	2.9%	2.7%	0.0%
# Provided Negatives	29	41	39	70	73	88
N, False Positives	1	1	3	7	5	2
% False Positives	3.4%	2.4%	7.7%	10.0%	6.8%	2.3%

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 45.

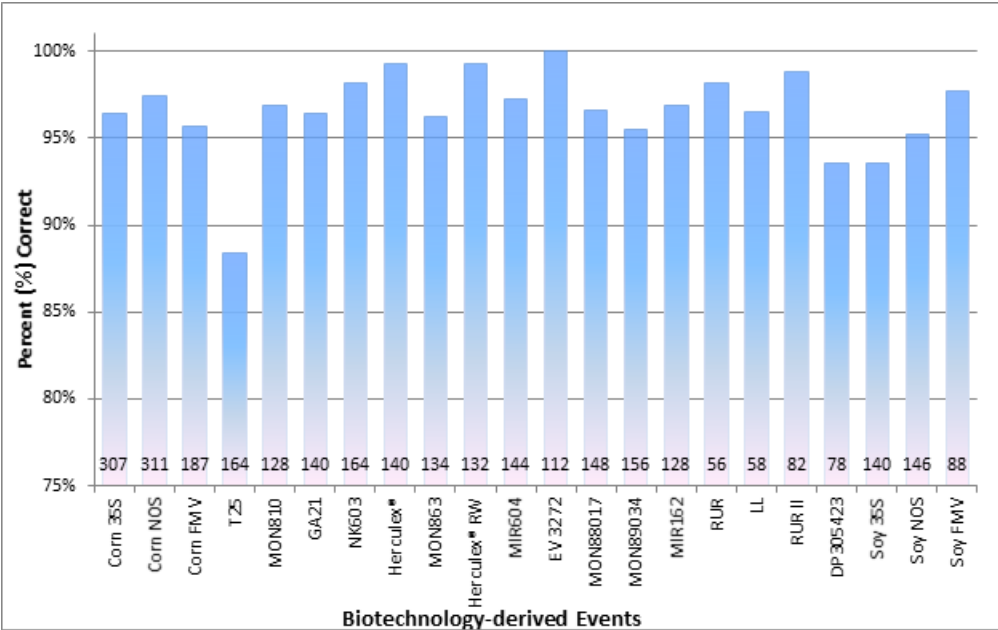


Table 46: Protein Based Lateral Flow Strip (LFS) Testing results for the detection of biotechnology-derived events in corn (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4	
T 25	0.00%	0.00%	0.80%	0.00%	LOD
1843	N	N	P	N	0.5%
1895	N	N	N*	N	0.5%
2815	N	N	P	N	Not Provided
4994	N	N	N	N	Not Provided
EPSPS (NK603/MON88017)	0.2%	0.50%	1.50%	0.00%	
1843	P	P	P	N	0.5%
1895	N*	N*	P	N	0.5%
2815	P	P	P	N	Not Provided
3931	P	P	P	P	0.1%
4902	P	P	P	P	0.1%
4994	N	P	P	N	Not Provided
Cry1Ab (MON810)	0.50%	2.00%	0.00%	0.00%	
1843	N	N	N	N	Not Provided
1895	N*	N	N	N	0.8%
2815	P	P	N	N	Not Provided
3931	P	P	P	P	0.5%
4902	P	P	P	P	0.5%
4994	N	N	N	N	Not Provided
Herculex	0.0%	1.00%	0.20%	0.00%	
1843	N	N*	N*	N	0.5%
1895	N	N*	N*	N	0.5%
2815	N	P	P	N	Not Provided
3931	N	P	P	N	0.9%
4902	N	P	P	N	0.9%
4994	N	N	N	N	Not Provided
Cry3Bb1 (MON863/MON88017)	1.20%	0.50%	0.20%	0.00%	
1843	P	P	P	N	0.5%
1895	P	N*	N*	N	0.5%
2815	P	P	P	N	Not Provided
4994	P	N	N	N	Not Provided
Hclx RW	0.50%	0.00%	1.00%	0.00%	
1843	P	N	P	N	0.5%
1895	P	N	P	N	0.5%
2815	P	N	P	N	Not Provided
4994	P	N	P	N	Not Provided

MIR 604	0.00%	0.00%	0.50%	0.00%	
1843	N	N	P	N	1.0%
1895	N	N	P	N	1.0%
2815	N	N	P	N	Not Provided
4994	N	N	P	N	Not Provided
Cry2A (MON89034)	0.50%	0.00%	0.00%	0.00%	
1843	N*	N	N	N	1.0%
Vip3A (MIR162)	0.00%	1.00%	0.00%	0.00%	
1843	N	P	N	N	0.25%
Event3272	0.00%	1.00%	0.00%	0.00%	
4994	N	N	N	N	Not Provided

* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 47: Percentage of correct results, false negatives, and false positives in reports for biotechnology-derived events in corn using Protein Based Lateral Flow Strip (LFS) Testing

Event	T25	EPSPS	Cry1Ab	Herculex	Cry3Bb1
Total # Reported Results	16	24	24	24	16
# Incorrect	1	3	9	2	2
% Correct	93.8%	87.5%	62.5%	91.7%	87.5%
# Provided Positives	3	16	11	12	12
# False Negatives	1	1	5	2	2
% False Negatives	33.3%	6.3%	45.5%	16.7%	16.7%
# Provided Negatives	12	6	12	12	4
# False Positives	0	2	4	0	0
% False Positive	0.0%	33.3%	33.3%	0.0%	0.0%

Event	Hclx RW	MIR 604	Cry2A	Vip3A	Event3272
Total # Reported Results	16	16	4	4	4
# Incorrect	0	0	0	0	1
% Correct	100.0%	100.0%	100.0%	100.0%	75.0%
# Provided Positives	8	4	0	1	1
# False Negatives	0	0	0	0	1
% False Negatives	0.0%	0.0%	0.0%	0.0%	100.0%
# Provided Negatives	8	12	4	3	3
# False Positives	0	0	0	0	0
% False Positive	0.0%	0.0%	0.0%	0.0%	0.0%

Table 48: Results for soybeans fortified with CP4EPSPS (RUR/RURII) and A2704-12 for all participants using Protein Based Lateral Flow Strip (LFS) Testing (N = negative; P = positive; NR = not reported; Incorrect results are shown in boldface)

CP4 EPSPS (RUR & RURII) Participant Number	Sample 1 0.00%	Sample 2 0.50%	LOD
1782	N	P	0.10%
1843	N	P	0.10%
1895	N	P	0.25%
2126	N	P	0.10%
2815	N	P	Not Provided
3931	N	P	0.10%
4902	N	P	0.10%
4994	N	P	Not Provided

A2704-12 (Liberty Link) Participant Number	Sample 1 0.0%	Sample 2 0.5%	LOD
1782	N	P	0.5%
1843	N	P	0.5%
1895	N	P	0.5%
2815	N	P	Not Provided
4994	N	P	Not Provided

Table 49: Percentage of correct results in qualitative reports for CP4EPSPS and A2704-12 for all participants using Protein Based Lateral Flow Strip (LFS) Testing

Event	CP4 EPSPS (RUR & RURII)	A2704-12 (LL)
Total # Reported results	16	10
# Incorrect	0	0
% Correct	100.0%	100.0%
# Provided Positives	8	5
# False Negative	0	0
% False Negative	0.0%	0.0%
# Provided Negatives	8	5
# False Positive	0	0
% False Positive	0.0%	0.0%

Table 50: Results for the detection of biotechnology-derived events in corn using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Participant	Sample 1	Sample 2	Sample 3	Sample 4	LOD
Cry1Ab (MON810)	0.50%	2.00%	0.00%	0.00%	
1895	P	P	N	N	Not Provided
Herculex	0.0%	1.00%	0.20%	0.00%	
1895	N	P	P	N	Not Provided
Cry3Bb1 (MON863/MON88017)	1.20%	0.50%	0.20%	0.00%	
1895	P	P	N	N	Not Provided

Table 51: Percentage of correct results in the detection of biotechnology-derived events in corn using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event	Cry1Ab	Herculex	Cry3Bb1
Total # Reported results	4	4	4
# Incorrect	0	0	0
% Correct	100.0%	100.0%	100.0%
# Provided Positives	2	2	3
# False Negative	0	0	1
% False Negative	0.0%	0.0%	33.3%
# Provided Negatives	2	2	1
# False Positive	0	0	0
% False Positive	0.0%	0.0%	0.0%

Table 52: Results for soybeans fortified with CP4EPSPS for participants using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

CP4 EPSPS (RUR & RURII) Participant Number	Sample 1 0.00%	Sample 2 0.50%	LOD
2126	N	P	Not Provided

Table 53: Percentage of correct results in qualitative reports for CP4EPSPS for participants using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event	CP4 EPSPS (RUR & RURII)
Total # Reported results	4
# Incorrect	0
% Correct	100.0%
# Provided Positives	3
# False Negative	0
% False Negative	0.0%
# Provided Negatives	1
# False Positive	0
% False Positive	0.0%

Table 54: Quantitative results and z-scores for corn fortified with T25 for all participants (DNA-based assays). Quantifications marked in **red** indicate value is an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	0.0%	0.0%	0.8%	0.0%	
Consensus Mean	0.0%	0.0%	0.53%	0.0%	
Participant Number	Result	Result	Result	z-score	Result
1754	0.00	0.00	0.70	0.58	0.00
1844	0.00	0.00	0.65	0.41	0.00
1870	0.00	0.00	0.85	1.07	0.00
1895	0.00	0.00	0.36	-0.55	0.00
2057	0.00	0.00	0.61	0.28	0.00
2716	0.00	0.00	2.90		0.00
2723	0.00	0.00	0.10	-1.41	0.00
2723*	NR	NR	0.28	-0.81	NR
4932	0.00	0.00	0.69	0.54	0.00
4952	0.00	0.00	0.40	-0.41	0.00
7017	0.00	0.00	0.10	-1.41	0.00
7030	0.00	0.00	1.04	1.70	NR

*-Digital PCR results

NR – Not Reported

Table 55: Quantitative results and z-scores for corn fortified with MON810 for all participants (DNA-based assays). Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.5%		2.0%		0.0%	0.0%
Consensus Mean	0.50%		1.89%		0.0%	0.0%
Participant Number	Result	z-score	Result	z-score	Result	Result
1752	0.25	-1.13	1.48	-0.61	0.00	0.00
1754	0.40	-0.46	1.20	-1.02	0.00	0.00
1764	0.25	-1.13	1.08	-1.20	0.00	0.00
1770	0.39	-0.51	1.32	-0.84	0.00	0.00
1844	0.41	-0.42	1.88	-0.02	0.00	0.00
1870	0.38	-0.55	1.90	0.01	0.00	0.00
1895	0.31	-0.86	1.09	-1.18	0.00	0.00
2005	0.89	1.71	2.87	1.43	0.00	0.00
2031	0.62	0.52	3.00	1.62	0.00	0.00
2057	0.53	0.12	1.90	0.01	0.00	0.00
2112	0.64	0.60	2.62	1.07	0.00	0.00
2716	0.46	-0.20	1.76	-0.20	0.00	0.00
2723	0.05	-2.02	0.70	-1.75	0.00	0.00
2723*	0.68	0.78	2.23	0.49	NR	NR
2727	0.97	2.07	3.46	2.30	0.00	0.00
2732	P		2.34	0.65	0.00	0.00
3928	0.17	-1.48	0.85	-1.53	0.00	0.00
3929	0.54	0.16	1.62	-0.40	0.00	0.00
4504	0.75	1.09	1.20	-1.02	0.00	0.00
4936	0.44	-0.28	1.81	-0.12	0.00	0.00
4942	0.83	1.45	2.71	1.20	0.00	0.00
4952	0.70	0.87	2.50	0.89	0.00	0.00
4957	0.38	-0.55	1.36	-0.79	0.00	0.00
4960	0.31	-0.86	1.75	-0.21	0.00	0.00
4976	0.50	-0.02	2.30	0.60	0.00	0.00
7017	0.38	-0.55	1.80	-0.14	0.00	0.00
7026	0.74	1.05	2.18	0.42	0.00	0.00
7030	0.64	0.60	2.14	0.36	0.00	NR

*-Digital PCR results

NR – Not Reported

Table 56: 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 the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier. Quantifications marked in **red** indicate values are an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	0.0%	0.2%		0.5%		0.0%
Consensus Mean	0.0%	0.21%		0.57%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result
1752	0.00	0.22	0.10	0.67	0.48	0.00
1754	0.00	0.20	-0.24	0.40	-0.85	0.00
1761	0.00	0.47		0.95	1.85	0.00
1764	0.00	0.25	0.62	0.37	-1.00	0.00
1770	0.00	0.14	-1.27	0.46	-0.56	0.00
1844	0.00	0.14	-1.27	0.56	-0.06	0.00
1870	0.00	0.22	0.10	0.48	-0.46	0.00
1895	0.00	0.21	-0.07	0.30	-1.34	0.00
2005	0.00	0.22	0.10	0.55	-0.11	0.00
2057	0.00	0.23	0.28	0.63	0.28	0.00
2716	0.00	0.73		0.90	1.61	0.00
2723	0.00	0.30	1.48	1.00	2.10	0.00
2723*	NR	0.11	-1.78	0.34	-1.15	NR
2727	0.00	0.20	-0.24	0.51	-0.31	0.00
3928	0.00	0.16	-0.93	0.53	-0.21	0.00
4932	0.00	0.22	0.10	0.62	0.23	0.00
4936	0.00	<0.1		0.30	-1.34	0.00
4952	0.00	0.35	2.34	0.50	-0.36	0.00
4957	0.00	0.19	-0.41	0.42	-0.75	0.00
4974	0.00	0.50		0.90	1.61	0.00
4976	0.00	2.00		0.50	-0.36	0.00
7017	0.00	0.21	-0.07	0.57	-0.01	0.00
7030	0.00	0.28	1.14	0.72	0.72	NR

*-Digital PCR results

NR – Not Reported

Table 57: Quantitative results and z-scores for corn fortified with NK603 for all participants (DNA-based assays). Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier. Quantifications marked in **red** indicate values are an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	0.0%	0.0%	1.5%		0.0%
Consensus Mean	0.0%	0.0%	1.45%		0.0%
Participant Number	Result	Result	Result	z-score	Result
1754	0.00	0.00	1.30	-0.43	0.00
1764	0.00	0.00	1.34	-0.31	0.00
1844	0.00	0.00	1.36	-0.26	0.00
1870	0.00	0.00	1.20	-0.72	0.00
1895	0.00	0.00	1.09	-1.03	0.00
2005	0.00	0.00	1.27	-0.52	0.00
2057	0.00	0.00	1.73	0.80	0.00
2112	0.00	0.00	1.60	0.43	0.00
2716	0.00	0.00	2.17	2.07	0.00
2723	0.00	0.00	10.00		0.00
2723*	NR	NR	2.10	1.87	NR
2727	0.00	0.00	1.70	0.72	0.00
2732	0.00	0.00	1.56	0.32	0.00
4504	0.00	0.00	1.50	0.14	0.00
4932	0.00	0.00	1.34	-0.31	0.00
4936	0.00	0.00	0.84	-1.75	0.00
4952	0.00	0.00	2.00	1.58	0.00
4957	0.00	0.00	1.45	0.00	0.00
4976	0.00	0.00	1.10	-1.00	0.00
7017	0.00	0.00	1.04	-1.18	0.00
7026	0.00	0.00	1.54	0.26	0.00
7030	0.00	0.00	1.21	-0.69	NR

*-Digital PCR results

NR – Not Reported

Table 58: 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 either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	0.0%	1.0%		0.2%		0.0%
Consensus Mean	0.0%	0.47%		0.13%		0.0%
Participant Number	Result	Result	z-score	Result	z-score	Result
1754	0.00	0.50	0.18	0.10	-0.80	0.00
1764	0.00	0.62	0.89	0.13	0.15	0.00
1844	0.00	0.56	0.53	0.15	0.79	0.00
1870	0.00	0.46	-0.05	0.15	0.79	0.00
1895	0.00	0.55	0.47	0.16	1.10	0.00
2005	0.00	0.51	0.24	0.15	0.79	0.00
2057	0.00	0.56	0.53	0.19	2.06	0.00
2716	0.00	0.18	-1.70	0.10	-0.80	0.00
2723	0.00	0.13	-1.99	0.00		0.00
2723*	NR	0.00		NR		NR
2727	0.00	0.73	1.53	0.00		0.00
2732	0.00	0.58	0.65	NR		0.00
3928	0.00	0.25	-1.28	0.10	-0.80	0.00
4504	0.00	0.40	-0.40	0.44		0.00
4936	0.00	0.34	-0.76	0.10	-0.80	0.00
4945	0.00	0.75	1.65	0.11	-0.49	0.00
4952	0.00	0.40	-0.40	0.10	-0.80	0.00
4957	0.00	0.50	0.18	0.11	-0.49	0.00
4976	0.00	0.40	-0.40	0.10	-0.80	0.00
7017	0.00	0.41	-0.35	0.10	-0.80	0.00
7026	0.00	0.72	1.47	0.18	1.74	0.00
7030	0.00	0.30	-0.99	0.10	-0.80	NR

*-Digital PCR results

NR – Not Reported

Table 59: 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 $z < -2$. Quantifications marked in **red** indicate values determined to be either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	1.0%		0.0%	0.2%		0.0%
Consensus Mean	1.23%		0.0%	0.17%		0.0%
Participant Number	Result	z-score	Result	Result	z-score	Result
1752	1.15	-0.14	0.00	0.10	-1.33	0.00
1754	1.30	0.13	0.00	0.20	0.57	0.00
1764	1.85	1.10	0.00	0.17	0.00	0.00
1844	1.01	-0.39	0.00	0.13	-0.76	0.00
1870	0.85	-0.67	0.00	0.13	-0.76	0.00
1895	0.83	-0.70	0.00	0.00		0.00
2005	1.63	0.71	0.00	0.13	-0.76	0.00
2057	1.35	0.21	0.00	0.19	0.38	0.00
2694	P		0.00	0.22	0.95	0.00
2716	2.57	2.37	0.00	0.25	1.52	0.00
2723	0.50	-1.29	0.00	0.00		0.00
2723*	1.82	1.04	NR	NR		NR
2727	0.68	-0.97	0.00	0.21	0.76	0.00
2732	1.05	-0.32	0.00	NR		0.00
3928	0.76	-0.83	0.00	0.17	0.00	0.00
4504	0.13	-1.94	0.00	0.89		0.00
4936	0.93	-0.53	0.00	0.12	-0.95	0.00
4952	1.80	1.01	0.00	0.20	0.57	0.00
4957	P		1.41	0.13	-0.76	0.00
4960	1.71	0.85	0.00	0.13	-0.76	0.00
4976	1.00	-0.40	0.00	0.30	2.48	0.00
7017	1.08	-0.26	0.00	0.14	-0.57	0.00
7030	1.80	1.01	0.00	0.14	-0.57	NR

*-Digital PCR results

NR – Not Reported

N - Fortification level/Consensus Mean below Participants’ LOD, assessed as Provided Negative

P - Qualitative data only

Table 60: Quantitative results and z-scores for corn fortified with Herculex® RW for all participants (DNA-based assays). Values highlighted in yellow indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.5%		0.0%	1.0%		0.0%
Consensus Mean	1.12%		0.0%	1.74%		0.0%
Participant Number	Result	z-score	Result	Result	z-score	Result
1754	0.90	-0.47	0.00	2.00	0.41	0.00
1764	1.61	1.06	0.00	1.45	-0.47	0.00
1844	0.74	-0.82	0.00	1.28	-0.74	0.00
1870	0.93	-0.41	0.00	1.18	-0.90	0.00
1895	0.21	-1.97	0.00	0.73	-1.62	0.00
2057	0.98	-0.30	0.00	1.30	-0.71	0.00
2716	2.05	2.02	0.00	3.37	2.60	0.00
2723	1.50	0.83	0.00	2.30	0.89	0.00
2723*	1.72	1.30	NR	2.35	0.97	NR
2727	1.38	0.57	0.00	1.91	0.27	0.00
2732	P		0.00	2.11	0.59	0.00
3928	0.95	-0.37	0.00	2.07	0.52	0.00
4936	0.87	-0.54	0.00	1.52	-0.36	0.00
4957	1.10	-0.04	0.00	1.57	-0.28	0.00
7017	0.75	-0.80	0.00	1.25	-0.79	0.00
7030	1.09	-0.06	0.00	1.51	-0.37	NR

*-Digital PCR results

NR – Not Reported

Table 61: Quantitative results and z-scores for corn fortified with MIR604 for all participants (DNA-based assays). Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.0%	0.0%	0.5%		0.0%
Consensus Mean	0.0%	0.0%	0.37%		0.0%
Participant Number	Result	Result	Result	z-score	Result
1752	0.00	0.00	0.43	0.41	0.00
1754	0.00	0.00	0.20	-1.23	1.00
1761	0.00	0.00	0.56	1.33	0.00
1764	0.00	0.00	0.40	0.19	0.00
1770	0.00	0.00	0.50	0.90	0.00
1844	0.00	0.00	0.56	1.33	0.00
1870	0.00	0.00	0.36	-0.09	0.00
1895	0.00	0.00	0.27	-0.74	0.00
2005	0.00	0.00	0.34	-0.24	0.00
2057	0.00	0.00	0.54	1.19	0.00
2716	0.00	0.00	0.10	-1.95	0.00
2723	0.00	0.00	0.14	-1.66	0.00
2723*	NR	NR	0.40	0.19	NR
2727	0.00	0.00	0.09	-2.02	0.00
4504	0.00	0.00	0.45	0.55	0.00
4936	0.00	0.00	0.40	0.19	0.00
4952	0.00	0.00	0.50	0.90	1.00
4957	0.00	0.00	0.43	0.41	0.00
4974	0.00	0.00	0.30	-0.52	0.00
4976	0.00	0.00	0.40	0.19	0.00
7017	0.00	0.00	0.48	0.76	0.00
7030	0.00	0.00	0.36	-0.09	NR

*-Digital PCR results

NR – Not Reported

Table 62: Quantitative results and z-scores for corn fortified with Event 3272 for all participants (DNA-based assays). Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	1.0%		0.0%	0.0%	0.0%
Consensus Mean	1.23%		0.0%	0.0%	0.0%
Participant Number	Result	z-score	Result	Result	Result
1752	1.27	0.14	0.00	0.00	0.00
1754	1.30	0.24	0.00	0.00	0.00
1764	1.37	0.49	0.00	0.00	0.00
1844	1.22	-0.04	0.00	0.00	0.00
1870	1.12	-0.40	0.00	0.00	0.00
1895	1.23	0.00	0.00	0.00	0.00
2057	1.46	0.81	0.00	0.00	0.00
2716	0.71	-1.85	0.00	0.00	0.00
2723	1.20	-0.11	0.00	0.00	0.00
2723*	1.40	0.60	NR	NR	NR
4932	0.90	-1.18	0.00	0.00	0.00
4936	1.08	-0.54	0.00	0.00	0.00
4952	2.00	2.74	0.00	0.00	0.00
4976	1.20	-0.11	0.00	0.00	0.00
7017	1.04	-0.68	0.00	0.00	0.00
7030	0.98	-0.89	0.00	0.00	NR
7032	1.45	0.78	0.00	0.00	0.00

*-Digital PCR results

NR – Not Reported

Table 63: Quantitative results and z-scores for corn fortified with MON 88017 for all participants (DNA-based assays). Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.2%		0.5%		0.0%	0.0%
Consensus Mean	0.34%		0.74%		0.0%	0.0%
Participant Number	Result	z-score	Result	z-score	Result	Result
1752	0.14	-0.98	0.35	-1.11	0.00	0.00
1754	0.20	-0.69	0.50	-0.68	0.00	0.00
1764	0.32	-0.10	0.85	0.33	0.00	0.00
1844	0.28	-0.30	0.65	-0.25	0.00	0.00
1870	0.20	-0.69	0.64	-0.27	0.00	0.00
1895	0.12	-1.08	0.30	-1.25	0.00	0.00
2005	0.25	-0.44	0.79	0.16	0.00	0.00
2057	0.38	0.20	0.95	0.62	0.00	0.00
2716	0.64	1.48	1.57	2.40	0.00	0.00
2723	0.70	1.77	1.50	2.20	0.00	0.00
2723*	0.43	0.44	0.81	0.22	NR	NR
2732	NR		0.90	0.47	0.00	0.00
4932	0.50	0.79	0.68	-0.16	0.00	0.00
4936	0.20	-0.69	0.39	-0.99	0.00	0.00
4952	0.25	-0.44	0.45	-0.82	0.00	0.00
4957	0.23	-0.54	0.55	-0.53	0.00	0.00
4976	0.20	-0.69	0.60	-0.39	0.00	0.00
7017	0.25	-0.44	0.49	-0.71	0.00	0.00
7030	0.83	2.41	1.00	0.76	0.00	NR

* -Digital PCR results

NR – Not Reported

Table 64: Quantitative results and z-scores for corn fortified with MON 89034 for all participants (DNA-based assays). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set.

%w/w Fortification Level	0.5%		0.0%	0.0%	0.0%
Consensus Mean	0.51%		0.0%	0.0%	0.0%
Participant Number	Result	z-score	Result	Result	Result
1752	0.54	0.10	0.00	0.00	0.00
1754	0.30	-0.87	0.00	0.00	0.00
1764	0.66	0.59	0.00	0.00	0.00
1844	0.28	-0.95	0.00	0.00	0.00
1870	0.90	1.56	0.00	0.00	0.00
1895	0.12	-1.60	0.00	0.00	0.00
2005	0.36	-0.63	0.00	0.00	0.00
2057	0.66	0.59	0.00	0.00	0.00
2716	0.48	-0.14	0.00	0.00	0.00
2723	0.90	1.56	0.00	0.00	0.00
2723*	0.90	1.56	NR	NR	NR
2732	0.69	0.71	0.00	0.00	0.00
3928	0.30	-0.87	0.00	0.00	0.00
4932	0.63	0.47	0.00	0.00	0.00
4936	0.22	-1.19	0.00	0.00	0.00
4952	0.30	-0.87	0.00	0.00	0.00
7017	0.29	-0.91	0.00	0.00	0.00
7026	0.50	-0.06	0.00	0.00	0.00
7030	0.75	0.95	0.00	NR	NR

* -Digital PCR results

NR – Not Reported

Table 65: Quantitative results and z-scores for corn fortified with MIR162 for all participants (DNA-based assays). Values highlighted in **yellow** indicate z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.0%	1.0%		0.0%	0.0%
Consensus Mean	0.0%	1.79%		0.0%	0.0%
Participant Number	Result	Result	z-score	Result	Result
1752	0.00	1.99	0.27	0.00	0.00
1754	0.00	0.80	-1.39	0.00	0.00
1761	0.00	1.83	0.05	0.00	0.00
1764	0.00	2.65	1.20	0.00	0.00
1770	0.00	2.05	0.36	0.00	0.00
1844	0.00	1.74	-0.08	0.00	0.00
1870	0.00	1.00	-1.11	0.00	0.00
1895	0.00	1.04	-1.06	0.00	0.00
2005	0.00	2.35	0.78	0.00	0.00
2057	0.00	2.87	1.51	0.00	0.00
2716	0.00	1.77	-0.03	0.00	0.00
2723	0.00	3.50	2.39	0.00	0.00
2723*	NR	1.67	-0.17	NR	NR
2732	0.00	1.75	-0.06	0.00	0.00
4936	0.00	1.42	-0.52	0.00	0.00
4952	0.00	2.60	1.13	0.00	0.00
4957	0.00	1.35	-0.62	0.00	0.00
4974	0.00	0.70	-1.53	0.00	0.00
4976	0.00	2.00	0.29	0.00	0.00
7017	0.00	1.13	-0.93	0.00	0.00
7030	0.00	1.46	-0.47	0.00	NR

*-Digital PCR results

NR – Not Reported

Table 66: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) for all participants (DNA-based assays). Quantifications marked in **red** indicate values determined to be either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the “Grubb’s Test for Outliers”. Values highlighted in **yellow** indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.0%	0.5%	
Consensus Mean	0.0%	0.43%	
Participant Number	Result	Result	z-score
1754	0.00	0.50	0.63
1761	0.00	0.42	-0.06
1764	0.00	0.22	-1.77
1770	0.00	0.58	1.31
1782	0.00	0.50	0.63
1785	0.00	0.35	-0.66
1788	0.00	0.35	-0.66
1844	0.00	0.54	0.97
1870	0.00	0.50	0.63
2005	0.00	0.46	0.28
2031	0.00	0.30	-1.09
2057	0.00	0.43	0.03
2060	<LOD	0.43	0.03
2067	0.00	0.37	-0.49
2691	0.00	0.35	-0.66
2692	0.00	0.32	-0.91
2716	0.00	0.32	-0.91
2723	0.00	0.70	2.34
2723*	NR	0.60	1.48
2727	0.00	0.31	-1.00
3949	NQ	1.01	
4504	0.00	0.66	2.00
4901	0.00	0.48	0.45
4932	0.00	0.63	1.74
4935	0.00	0.40	-0.23
4936	0.00	0.35	-0.66
4942	0.00	0.36	-0.57
4952	0.00	0.40	-0.23
4957	0.62	0.00	
4960	0.00	0.32	-0.91
4976	0.00	0.40	-0.23
4978	0.00	0.29	-1.17
7017	0.00	0.35	-0.66
7025	0.00	0.89	

%w/w Fortification Level	0.0%	0.5%	
Consensus Mean	0.0%	0.43%	
Participant Number	Result	Result	z-score
7030	NR	0.47	0.37

*-Digital PCR results

NR – Not Reported

Table 67: Quantitative results and z-scores for soybeans fortified with A2704-12 (Liberty Link®) for all participants (DNA-based assays). Quantifications marked in red indicate values determined to be either: (1) a positive value for a non-fortified sample (i.e. a false positive result); or (2) a negative value for a fortified sample (i.e. a false negative result); or (3) an outlier determined by the “Grubb’s Test for Outliers”.

%w/w Fortification Level	0.0%	0.5%	
Consensus Mean	0.0%	0.41%	
Participant Number	Result	Result	z-score
1754	0.00	0.50	0.52
1761	0.00	0.39	-0.08
1764	0.00	0.23	-0.96
1770	0.00	0.41	0.03
1844	0.00	0.32	-0.47
1870	0.00	0.43	0.14
1895	0.00	0.94	2.93
2005	0.00	0.34	-0.36
2031	0.00	0.35	-0.30
2057	0.00	0.31	-0.52
2067	0.00	0.39	-0.08
2716	0.00	1.17	
2723	0.00	0.00	
4932	0.00	0.44	0.19
4952	0.00	0.20	-1.12
4960	0.00	0.42	0.08
4976	0.00	0.40	-0.03
4978	0.00	0.11	-1.62
7017	0.00	0.30	-0.58
7025	0.00	0.68	1.50
7030	NR	0.54	0.74

*-Digital PCR results

NR – Not Reported

Table 68: Quantitative results and z-scores for soybeans fortified with CP4 EPSPS as Roundup Ready™ II (RUR II) for all participants (DNA-based assays).

%w/w Fortification Level	0.0%	0.0%
Consensus Mean	0.0%	0.0%
Participant Number	Result	Result
1754	0.00	0.00
1761	0.00	0.00
1764	0.00	0.00
1770	0.00	0.00
1782	0.00	0.00
1844	0.00	0.00
1870	0.00	0.00
2031	0.00	0.00
2057	0.00	0.00
2067	0.00	0.00
2716	0.00	0.00
2723	0.00	0.00
4901	0.00	0.00
4932	0.00	0.00
4935	0.00	0.00
4936	0.00	0.00
4952	0.00	0.00
4960	0.00	0.00
4976	0.00	0.00
4978	0.00	0.00
7017	0.00	0.00
7025	0.00	0.00
7034	0.00	0.00

Table 69: Quantitative results and z-scores for soybeans fortified with DP305423 for all participants (DNA-based assays). Values highlighted in yellow indicate a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

%w/w Fortification Level	0.0%	1.0%	
Consensus Mean	0.0%	0.37%	
Participant Number	Result	Result	z-score
1754	0.00	0.40	0.22
1764	0.00	0.31	-0.43
1844	0.00	0.36	-0.07
1870	0.00	0.50	0.94
2031	0.00	0.26	-0.79
2057	0.00	0.29	-0.57
2067	0.00	0.39	0.15
2716	0.00	0.10	-1.95
2723	0.00	0.20	-1.23
2723*	NR	0.31	-0.43
4504	0.00	0.73	2.61
4932	0.00	0.41	0.29
4936	0.00	0.45	0.58
4952	0.00	0.30	-0.50
4976	0.00	0.40	0.22
7017	0.00	0.44	0.51
7030	0.00	0.52	1.09
7032	0.00	0.28	-0.65

* -Digital PCR results

NR – Not Reported

Table 70: Quantitative results and z-scores for 35S, NOS, and FMV in corn for all participants (DNA based assay). Value highlighted in yellow indicates a z-score outside of the expected range, i.e., $z > +2$ or $z < -2$ that is not considered an outlier.

Event: 35S

Consensus Mean	1.8%		1.6%		2.0%		0.0%
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result
1785	2.00	0.20	1.61	-0.03	1.26	-0.77	0.00
1844	2.00	0.20	1.90	0.42	2.37	0.35	0.00
1895	0.56	-1.18	0.63	-1.52	0.41	-1.63	0.00
2720	1.90	0.10	1.93	0.46	3.36	1.35	0.00
3929	1.58	-0.21	1.32	-0.47	1.62	-0.41	0.00
3949	4.29	2.38	2.99	2.07	3.43	1.42	NQ
4936	1.43	-0.35	1.26	-0.56	2.35	0.33	0.00
4964	1.30	-0.47	1.20	-0.65	1.30	-0.73	<0.01
4974	1.10	-0.66	1.80	0.26	2.10	0.08	0.00

Event: NOS

Consensus mean	1.4%		1.8%		2.6%		0.0%
Participant Number	Result	z-score	Result	z-score	Result	z-score	Result
1785	1.84	1.07	2.67	1.54	3.73	1.33	0.00
1844	1.78	0.92	1.83	0.00	3.33	0.86	0.00
1895	0.94	-1.22	1.62	-0.38	1.12	-1.72	0.00
2720	0.92	-1.27	1.27	-1.02	2.27	-0.38	0.00
3929	1.66	0.61	1.52	-0.57	2.41	-0.22	0.00
4964	1.20	-0.56	1.40	-0.79	2.30	-0.34	0.00
4974	1.60	0.46	2.50	1.23	3.00	0.47	0.00

Event: FMV

Consensus mean	0.3%		0.0%	0.0%	0.0%
Participant Number	Result	z-score	Result	Result	Result
1895	0.21	-0.71	0.00	0.00	0.00
4936	0.30	0.71	0.00	0.00	0.00

Note: Levels cited as Consensus Mean are averages of reported quantitative results of events containing these promoters and terminators. Assigning a more accurate quantification value is beyond the scope of this program at this time.

Table 71: Quantitative results and z-scores for 35S, NOS, and FMV in soybean for all participants (DNA based assay). Z-scores outside of the expected range, i.e., $z > +2$ or $z < -2$ were not observed in this data set. The sample size for event FMV soybean are too small to be statistically significant.

35S Soy

Consensus mean	0.0%	1.1%	
Participant Number	Result	Result	z-score
1844	0.00	1.23	0.22
1862	0.00	0.69	-1.11
1895	0.00	1.77	1.56
2720	0.00	0.59	-1.36
3887	0.00	1.40	0.64
4936	0.00	1.10	-0.10
4964	0.00	1.20	0.15

NOS Soy

Consensus mean	0.0%	0.6%	
Participant Number	Result	Result	z-score
1895	0.00	0.71	0.71
4964	0.00	0.4	-0.71

FMV Soy

Participant Number	Sample 1	Sample 2
1844	0.00	0.0
1895	0.00	0.0
2723	0.00	0.0

Note: Levels cited as Consensus Mean are averages of reported quantitative results of events containing these promoters and terminators. Assigning a more accurate quantification value is beyond the scope of this program at this time.

Table 72: Quantitative results for corn fortified with biotechnology-derived events using Protein Based Lateral Flow Strip (LFS) tests. Quantifications marked in red indicate values determined to be a negative value for a fortified sample (i.e. a false negative result).

Participant Number	Sample 1	Sample 2	Sample 3	Sample 4	
T 25	0.00%	0.00%	0.80%	0.00%	LOD
1895	0.00	0.00	0.46	0.00	0.5%
EPSPS (NK603/MON88017)	0.2%	0.50%	1.50%	0.00%	
1895	0.00*	0.00*	1.5	0.00	0.5%
Cry1Ab (MON810)	0.50%	2.00%	0.00%	0.00%	
1895	0.00*	0.00	0.00	0.00	0.8%
Herculex	0.0%	1.00%	0.20%	0.00%	
1895	0.00	0.00*	0.00*	0.00	0.5%
Cry3Bb1 (MON863/MON88017)	1.20%	0.50%	0.20%	0.00%	
1895	0.88	0.00*	0.00*	0.00	0.5%
Hclx RW	0.50%	0.00%	1.00%	0.00%	
1895	0.85	0.00	0.95	0.00	0.5%
MIR 604	0.00%	0.00%	0.50%	0.00%	
1895	0.00	0.00	0.7	0.00	1.0%

* - Fortification level/Consensus Mean below Participants' LOD, assessed as Provided Negative

Table 73: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) and A2704-12 (Liberty Link) using Protein Based Lateral Flow Strip (LFS) tests

CP4 EPSPS (RUR & RURII)	Sample 1	Sample 2	
Participant Number	0.00%	0.50%	LOD
1895	0.0	>3	0.25%

A2704-12 (Liberty Link)	Sample 1	Sample 2	LOD
Participant Number	0.0%	0.5%	
1895	0.0	1.5	0.5%

Table 74: Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA)

Event: RUR/RUR II			
%w/w Fortification Level	0.0%	0.5%	
Participant Number	Result	Result	LOD
1782	0.00	0.40	0.3%

Table 75: Descriptive statistics for participants reported quantifications relative to USDA/AMS/FGIS fortification levels using DNA-based assays. % Relative standard deviation (%RSD_R) = [standard deviation/mean value x 100]. Outliers were determined by the Grubb's Test for Outliers and **excluded** from calculations involving reported mean, standard deviation, and % relative deviation but were **included** in the range of results.

Biotechnology-derived Event	Reported Results (N)	Gravimetric Fortification (%w/w)	Consensus Mean	Standard Deviation	% Relative Standard Deviation	Range of Results (%)
T25	12	0.8	0.53	0.30	56.6	0.10 - 2.9
MON810	27	0.5	0.50	0.23	46.0	0.05 - 0.97
MON810	28	2.0	1.89	0.68	36.0	0.70 - 3.46
GA21	22	0.2	0.21	0.06	28.6	0.11 - 2.0
GA21	23	0.5	0.57	0.20	35.1	0.3 - 1.00
NK603	22	1.5	1.45	0.35	24.1	0.84 - 10.00
Herculex	20	0.2	0.13	0.03	23.1	0.0 - 0.44
Herculex	22	1.0	0.47	0.17	36.2	0.0 - 0.75
MON863	22	0.2	0.17	0.05	29.4	0.0 - 0.89
MON863	23	1.0	1.23	0.57	46.3	0.13 - 2.57
HerculexRW	16	0.5	1.12	0.46	41.1	0.21 - 2.05
HerculexRW	16	1.0	1.74	0.63	36.2	0.73 - 3.37
MIR604	22	0.5	0.37	0.14	37.8	0.09 - 0.56
EV3272	17	1.0	1.23	0.28	22.8	0.71 - 2.00
MON88017	18	0.2	0.34	0.20	58.8	0.12 - 0.83
MON88017	19	0.5	0.74	0.35	47.3	0.3 - 1.57
MON89034	19	0.5	0.51	0.25	49.0	0.12 - 0.9
MIR 162	21	1.0	1.79	0.71	39.7	0.70 - 3.5
RUR	35	0.5	0.43	0.12	27.9	0.00 - 1.01

Biotechnology-derived Event	Reported Results (N)	Gravimetric Fortification (%w/w)	Consensus Mean	Standard Deviation	% Relative Standard Deviation	Range of Results (%)
LL	21	0.5	0.41	0.18	43.9	0.00 - 1.17
DP305424	18	1.0	0.37	0.14	37.8	0.10 - 0.73

Summary of Findings

It is recognized that some organizations participate in this program to retain their ISO accreditation. Participation also serves to provide a verification of current laboratory practices and/or aids in identifying areas for improvement. These factors should be taken into consideration when reviewing the following analyses.

USDA/AMS/FGIS does not dictate detection methods for biotechnology-derived traits. An individual laboratory may provide a Limit of Detection (LOD) for its particular detection method. When the consensus mean in an event-fortified sample falls below the provided LOD, a negative result is considered a correct answer, and is assessed as a provided negative.

• Qualitative Sample Analysis

DNA-based Testing. The typical method of DNA-based testing for qualitative determination of events is by conventional PCR which generally has a sensitivity of 0.01% w/w biotechnology-derived 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 gravimetric fortification level in this round of proficiency testing was 0.2% w/w; therefore, if the event was present it should be detectable by a laboratory that employs conventional PCR. As evidenced by the summary of performance scores (**Table 45** and **Figure 1**), all of the sixteen (16) biotechnology-derived events were correctly detected with greater than 90% except T25, and fourteen (14) of the sixteen (16) biotechnology-derived events were correctly detected with greater than or equal to 95% reliability, and one (1) of the sixteen (16) biotechnology-derived events were correctly detected with 100% reliability.

Eleven (11) participants reported using an End-point PCR test method. Five (5) participants reported using Digital PCR.

Protein-based Testing. The methods of protein-based testing were lateral flow strip (LFS) and enzyme-linked immunosorbent assay (ELISA). The LFS test has a sensitivity ranging between 0.1- 2.0% w/w for corn events and 0.1- 0.50% w/w for soybean events according to some kit manufacturers. Generally, ELISA has a sensitivity of 0.1- 1.0% w/w for corn and soy events (Ahmed, 2004). The test results for MON863 and MON88017 are combined because both events express the *C3Bb1* protein, and protein-based testing cannot distinguish between the two events. The event Herculex® contains the *pat* (phosphinothricin N-transferase) gene, but combining the results is problematic.

• Quantitative Sample Analysis

DNA-based Testing. The typical method of DNA-based testing for quantitative determination of biotechnology-derived events is by real-time quantitative PCR

(qPCR). 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 75**). Because test samples were fortified ranging from 0.2- 2.0 % 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. Low instances of false positive results were observed when using qPCR to detect the presence of Biotechnology-derived traits in these proficiency samples.

Nine (9) participants submitted quantitative results for 35S event in corn, seven (7) participants' submitted quantitative results for NOS event, and two (2) participants' submitted quantitative results for FMV event (**Table 70**). The target %w/w levels for these traits should be additive for all events containing either 35S or NOS fortified into the sample. Validated methods to quantify with a high degree of accuracy for the presence of 35S and NOS, in samples fortified with multiple traits, is beyond the scope of the program at this time. The number of results for soybean NOS and FMV are too small to hold statistical significance.

Seven (7) laboratories submitted quantitative results for the 35S event in soybean, two (2) laboratories submitted quantitative results for the NOS event, and three (3) laboratory submitted quantitative results for the FMV event (**Tables 71**).

One laboratory submitted Quantitative results for corn fortified with biotechnology-derived events using Lateral Flow Strip (LFS) testing (**Table 72**).

One laboratory submitted Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) and A2704-12 (I9berty Link) using Lateral Flow Strip (LFS) testing (**Table 73**).

One laboratory submitted Quantitative results for soybeans fortified with CP4 EPSPS as Roundup Ready™ (RUR) using Protein Based Enzyme-Linked Immunosorbent Assay (ELISA) (**Table 74**).

Quantitative data from previous rounds of our proficiency sample distributions can be found at: <http://www.gipsa.usda.gov/fgis/proficiencyprogram.aspx>

Individual Performance Assessment. The performance of each participating laboratory for quantifying biotechnology-derived events in the proficiency samples can be observed by inspecting Tables 54 through 74. 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 target value. Interpretation of z-scores assumes that the data have a normal distribution. Data from samples with lower fortification

levels (e.g., 0.2% w/w) and from tables with low numbers of results are not normally distributed and caution should be used when interpreting their z-scores.

Monitoring and improving the performance of laboratories that use PCR technologies for the detection and/or quantification of biotechnology-derived events in corn and soybeans will improve the reliability of testing methods and the marketing of these commodities. The USDA/AMS/FGIS proficiency testing program should be a complement to other quality assurance measures that laboratories use to improve their analytical capabilities.

Note: The biotechnology-derived seed or grain used to prepare these samples was made available to USDA/AMS/FGIS by the Life Science Organizations. Care was taken to ensure the biotechnology-derived 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 biotechnology-derived traits used in this proficiency program and USDA/AMS/FGIS encourages the use of these reference materials when developing internal validated methods.

To obtain additional information on the USDA/AMS/FGIS Proficiency Program, contact Dr. Brian Beecher at US 816-891-0453, or by e-mail at Brian.S.Beecher@usda.gov or Dr. Ramaswamy Mani at US 816-891-0418, or by e-mail at Ramaswamy.Mani@usda.gov. For questions regarding this report, contact Dr. Ramaswamy Mani at US 816-891-0418, or by e-mail at Ramaswamy.Mani@usda.gov.

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List of organizations who wished to be identified as a participant in the USDA/AMS/FGIS October 2017 Proficiency Program. Participant identification numbers are listed below with permission from the organization.

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