# NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2012 ANNUAL REPORT October 1, 2011 - September 30, 2012

# **Submitted by:**

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### NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2012 ANNUAL REPORT October 1, 2011 - September 30, 2012

### **INTRODUCTION**

The National Milk Drug Residue Data Base (NMDRD) is a voluntary industry reporting program. Mandatory reporting is required by State Regulatory Agencies under the National Conference on Interstate Milk Shipments (NCIMS). Data are reported on the extent of the national testing activities, the analytical methods used, the kind and extent of the animal drug residues identified, and the amount of contaminated milk that was removed from the human food supply. The system includes all milk, Grade "A" and non-Grade "A", commonly known as manufacturing grade. Grade "A" milk represents approximately 95% of the milk supply in the United States and is regulated through the NCIMS by the State Regulatory Agencies. Manufacturing grade milk is under the direction of the Regulatory Agencies in the States where it is produced and may be subject to the standards recommended by the United States Department of Agriculture (USDA). Data reported to the NMDRD are for educational and analytical purposes and are not intended or suitable for regulatory action or follow-up.

### **BACKGROUND**

The NCIMS is a voluntary organization directed and controlled by member States to promote the availability of a high quality milk supply. The Food and Drug Administration (FDA) and the NCIMS through their collaborative efforts have developed a cooperative, federal-state program (the Grade "A" Interstate Milk Shippers Program) to ensure the sanitary quality of Grade "A" milk and milk products shipped in interstate commerce. During the 1991 meeting of the NCIMS, the Conference authorized a national program to compile the results of milk drug residue testing by industry and State Regulatory Agencies.

Subsequently, FDA awarded a contract to develop a NMDRD. The data base is operated by an independent third party, under contract to the FDA. The data base design was developed in consultation with a project advisory group with members from the FDA and a NCIMS committee representing dairy producers, dairy processors, USDA, State Regulatory Agencies, and academia. The data base was designed to promote maximum participation by the dairy industry to report on a voluntary basis all of their testing results, without compromising any confidential data. Information regarding individual firm's data is not submitted to the data base contractor.

It is important to recognize that the samples and tests reported do not necessarily represent one hundred percent (100%) of the milk supply from every State. However, as State and industry participation in the data base increased, reporting of the number of samples and tests similarly increased.

Continuing efforts are being made to ensure that there is uniform reporting among all the States and the industry and to ensure that the drugs and test methods reported are correct.

During FY 2006, a web-based version of the reporting software was developed, field evaluated, and then made available to all data reporters on September 1, 2006. Instructions for registering and using the software are posted on the contractor's web site at: <a href="www.kandc-sbcc.com/nmdrd/">www.kandc-sbcc.com/nmdrd/</a>. Forty-eight (48) data reporters utilized the web-based software to submit all or part of their data for the FY 2011 Annual Report.

At the request of one of the attendees at a meeting of the NCIMS, the contractor converted all of the tabular information from previous Annual Reports into Microsoft Excel format and posted them on the contractor's web site at: <a href="www.kandc-sbcc.com/nmdrd/">www.kandc-sbcc.com/nmdrd/</a>. All of the Annual Reports are now available in portable document file (pdf), Microsoft Excel and Open Document Spreadsheet (ods) formats.

In April of 2012, a revised Drug Code List was electronically distributed to all State Program Managers and State Data Reporters as well as posted on the contractor's web site at: <a href="www.kandc-sbcc.com/nmdrd/">www.kandc-sbcc.com/nmdrd/</a>.

#### **SUMMARY**

This report presents summary data on samples and tests conducted during Fiscal Year 2012 (October 1, 2011 to September 30, 2012). All 50 States and Puerto Rico submitted data for this report. We appreciate all the data provider's cooperation for this fiscal year's report.

The Grade "A" Pasteurized Milk Ordinance (PMO), the regulations, which govern the State Regulatory Agencies in the implementation and enforcement of their Grade "A" milk safety program, requires that all bulk milk pickup tankers be sampled and analyzed for animal drug residues before the milk is processed. Any bulk milk pickup tanker found positive is rejected for human consumption.

During this period **3,775,440** samples were analyzed for animal drug residues. Of these samples **828** were positive for a drug residue. A total of **3,875,613** tests were reported on the samples for nine different groups of families or individual drugs. Twenty-four (24) testing methods were used to analyze the samples for drug residues. Details are presented in the Tables in this report.

### SAMPLE RESULTS

A <u>SAMPLE</u> is defined as representing a load or lot of milk sampled and analyzed, e.g. a bulk milk pickup tanker, producer, or milk transport tanker, a silo, etc.

Table 1 shows the results of the samples tested by source.

Data are reported by four SOURCES OF SAMPLES:

- 1. Bulk Milk Pickup Tanker bulk raw milk from a dairy farm.
- 2. <u>Pasteurized Fluid Milk and Milk Products</u> after pasteurization; finished product in package form or bulk. This term includes milk products such as milk, reduced fat milk, lowfat milk, nonfat milk, and creams.
- 3. <u>Producer</u> raw milk obtained from the farm bulk tank/silo from a dairy farm. Samples are reported by the permitting State, rather than by the analyzing State.
- 4. Other milk from milk plant tanks/silos, milk transport tankers, etc.

A <u>POSITIVE</u> result, as used in this report, means that the sample was found to be positive for a drug residue by a test acceptable for taking regulatory action in a certified laboratory by a certified analyst or the milk was rejected on the basis of an initial screening test by the milk processor.

The <u>DISPOSITION per PMO</u> column represents the amount of milk contained in the bulk milk pickup tanker, milk transport tanker, farm bulk tank/silo, milk plant tank/silo or lot found to be positive and disposed of in accordance with the PMO and/or applicable State regulations.

| TABLE 1 Sample Results<br>October 1, 2011 to September 30, 2012 |                  |                    |                     |                                    |  |  |  |  |
|---|------------------|--------------------|---------------------|------------------------------------|--|--|--|--|
| Source<br>of Sample   | Total<br>Samples | Number<br>Positive | Percent<br>Positive | Disposition per<br>PMO<br>(Pounds) |  |  |  |  |
| Bulk Milk<br>Pickup Tanker                                      | 3,196,413        | 542                | 0.017%              | 23,207,000                         |  |  |  |  |
| Pasteurized<br>Fluid Milk and<br>Milk Products                  | 40,882           | 0                  | 0.000%              | 0                                  |  |  |  |  |
| Producer  | 483,990          | 277                | 0.057%              | 232,000                            |  |  |  |  |
| Other   | 54,155           | 9                  | 0.017%              | 278,000                            |  |  |  |  |
| TOTALS  | 3,775,440        | 828                | *                   | 23,717,000                         |  |  |  |  |

The asterisk (\*) notes that a summary of the percent positive cannot be provided because there is no uniformity in terms of sampling in the four categories. For example, the PMO sets forth specific sampling requirements for Beta lactams testing as follows:

- 1. <u>Bulk Milk Pickup Tanker Samples</u> -- samples are taken on receipt of every tanker load at a milk receiving facility;
- 2. <u>Pasteurized Fluid Milk and Milk Products</u> -- a minimum of four samples in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, must be tested for each finished milk or milk product from each milk plant during any consecutive six months;
- 3. <u>Producer</u> -- each producer must be tested at least four times in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, during any consecutive six months; and
- 4. Other -- samples are conducted on a random basis.

Table 2 presents these results in greater detail and indicates the number of samples conducted by industry and by State Regulatory Agencies. Industry samples are taken by processing facilities, receiving and transfer stations, and marketing groups or cooperatives. Industry sampling and testing may be conducted to meet the industry requirements of Appendix N of the PMO, which sets forth testing and reporting requirements for animal drug residues or for quality control purposes. Regulatory samples are taken by State and Local Regulatory Agencies.

# TABLE 2 -- Industry and Regulatory Samples October 1, 2011 to September 30, 2012

| Source of<br>Sample                         | Number of<br>Industry<br>Samples | Number of<br>Positive<br>Industry<br>Samples | Number of<br>Regulatory<br>Samples | Number of<br>Positive<br>Regulatory<br>Samples | Total<br>Samples | Total<br>Positive<br>Samples | Total<br>Percent<br>Positive | Disposition<br>Per PMO<br>(Pounds) |
|---|----------------------------------|--|------------------------------------|--|------------------|------------------------------|------------------------------|------------------------------------|
| GRADE A                                     |                                  |  |                                    |  |                  |                              |                              |                                    |
| Bulk Milk Pickup Tanker                     | 3,042,058                        | 510  | 13,712                             | 1  | 3,055,770        | 511                          | 0.017%                       | 22,163,000                         |
| Pasteurized Fluid Milk and<br>Milk Products | 4,007                            | 0  | 35,391                             | 0  | 39,398           | 0                            | 0.000%                       | 0                                  |
| Producer                                    | 359,918                          | 212  | 99,547                             | 44   | 459,465          | 256                          | 0.056%                       | 232,000                            |
| Other                                       | 39,325                           | 9  | 7,742                              | 0  | 47,067           | 9                            | 0.019%                       | 278,000                            |
| NON-GRADE A                                 |                                  |  |                                    |  |                  |                              |                              |                                    |
| Bulk Milk Pickup Tanker <sup>1</sup>        | 140,621                          | 31   | 22                                 | 0  | 140,643          | 31                           | 0.022%                       | 1,044,000                          |
| Pasteurized Fluid Milk and<br>Milk Products | 1,449                            | 0  | 35                                 | 0  | 1,484            | 0                            | 0.000%                       | 0                                  |
| Producer                                    | 24,410                           | 21   | 115                                | 0  | 24,525           | 21                           | 0.086%                       | 0                                  |
| Other                                       | 7,035                            | 0  | 53                                 | 0  | 7,088            | 0                            | 0.000%                       | 0                                  |
| TOTALS                                      | 3,618,823                        | 783  | 156,617                            | 45   | 3,775,440        | 828                          | *                            | 23,717,000²                        |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

<sup>&</sup>lt;sup>2</sup> Note that this represents 0.012 % of the total milk supply of the United States with an annual production of 198.9 billion pounds.

<sup>\*</sup> See Table 1 for explanation

### **TESTS CONDUCTED**

An objective of the NMDRD is to record every test run on each sample analyzed. Since some samples are analyzed for more than one drug residue, the number of tests conducted (3,875,613) is greater than the number of samples (3,775,440). To avoid duplicate reporting of samples, the number of samples analyzed is reported separately from the number of tests run in the data base.

Table 3 presents summary results of the number of tests which were conducted during October 1, 2011 to September 30, 2012. The term, validated test, as used in this report, is a test used for the screening of raw milk for drug residue, which has been evaluated by FDA in accordance with the standards established for the evaluation of these types of tests and found acceptable by the NCIMS in accordance with Appendix N of the PMO. In addition, FDA validated drug residue detection procedures for screening and quantization of drug residues in milk may be used. Table 3A presents summary results using validated tests and Table 3B presents summary results using non-validated tests.

| TABLE 3 Tests Conducted<br>October 1, 2011 to September 30, 2012 |                |                     |        |  |  |  |  |  |
|--|----------------|---------------------|--------|--|--|--|--|--|
| Source<br>of Sample  | Total<br>Tests | Percent<br>Positive |        |  |  |  |  |  |
| Bulk Milk<br>Pickup Tanker                                       | 3,292,858      | 542                 | 0.016% |  |  |  |  |  |
| Pasteurized<br>Fluid Milk and<br>Milk Products                   | 40,958         | 0                   | 0.000% |  |  |  |  |  |
| Producer   | 487,506        | 277                 | 0.057% |  |  |  |  |  |
| Other  | 54,291         | 9                   | 0.017% |  |  |  |  |  |
| TOTALS   | 3,875,613      | 828                 | *      |  |  |  |  |  |

<sup>\*</sup> See Table 1 for explanation

| TABLE 3A Validated Tests Conducted<br>October 1, 2011 to September 30, 2012 |                |                     |        |  |  |  |  |  |
|---|----------------|---------------------|--------|--|--|--|--|--|
| Source<br>of Sample   | Total<br>Tests | Percent<br>Positive |        |  |  |  |  |  |
| Bulk Milk<br>Pickup Tanker  | 3,217,229      | 527                 | 0.016% |  |  |  |  |  |
| Pasteurized Fluid<br>Milk and Milk<br>Products                              | 40,891         | 0                   | 0.000% |  |  |  |  |  |
| Producer  | 486,644        | 277                 | 0.057% |  |  |  |  |  |
| Other   | 53,726         | 9                   | 0.017% |  |  |  |  |  |
| TOTALS  | 3,798,490      | 813                 | *      |  |  |  |  |  |

<sup>\*</sup> See Table 1 for explanation

| TABLE 3B Non-Validated Tests Conducted<br>October 1, 2011 to September 30, 2012 |                |                     |        |  |  |  |  |  |
|---|----------------|---------------------|--------|--|--|--|--|--|
| Source<br>of Sample   | Total<br>Tests | Percent<br>Positive |        |  |  |  |  |  |
| Bulk Milk<br>Pickup Tanker  | 75,629         | 15                  | 0.020% |  |  |  |  |  |
| Pasteurized Fluid<br>Milk and Milk<br>Products                                  | 67             | 0                   | 0.000% |  |  |  |  |  |
| Producer  | 862            | 0                   | 0.000% |  |  |  |  |  |
| Other   | 565            | 0                   | 0.000% |  |  |  |  |  |
| TOTALS  | 77,123         | 15                  | *      |  |  |  |  |  |

<sup>\*</sup> See Table 1 for explanation

Table 4 presents additional details in terms of the tests conducted by industry and by State Regulatory Agencies. Tables 4A and 4B present these data by validated and non-validated tests.

| TABLE 4 Tests Conducted by Industry and Regulatory Agencies October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                    |                            |                           |
|---|--------------------------------|--|----------------------------------|--|--------------------|----------------------------|---------------------------|
| Source<br>of Sample   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | <b>Total Tests</b> | Total<br>Positive<br>Tests | Total Percent<br>Positive |
| GRADE A   |                                |  |                                  |  |                    |                            |                           |
| Bulk Milk Pickup Tanker   | 3,137,917                      | 510  | 13,712                           | 1  | 3,151,629          | 511                        | 0.016%                    |
| Pasteurized Fluid Milk<br>and Milk Products   | 4,007                          | 0  | 35,462                           | 0  | 39,469             | 0                          | 0.000%                    |
| Producer  | 363,073                        | 212  | 99,810                           | 44   | 462,883            | 256                        | 0.055%                    |
| Other   | 39,445                         | 9  | 7,757                            | 0  | 47,202             | 9                          | 0.019%                    |
| NON-GRADE A   |                                |  |                                  |  |                    |                            |                           |
| Bulk Milk Pickup Tanker <sup>1</sup>  | 141,207                        | 31   | 22                               | 0  | 141,229            | 31                         | 0.022%                    |
| Pasteurized Fluid Milk<br>and Milk Products   | 1,454                          | 0  | 35                               | 0  | 1,489              | 0                          | 0.000%                    |
| Producer  | 24,508                         | 21   | 115                              | 0  | 24,623             | 21                         | 0.085%                    |
| Other   | 7,036                          | 0  | 53                               | 0  | 7,089              | 0                          | 0.000%                    |
| TOTALS  | 3,718,647                      | 783  | 156,966                          | 45   | 3,875,613          | 828                        | *                         |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

<sup>\*</sup> See Table 1 for explanation

| TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2011 to September 30, 2012 |                                |  |                                  |  |             |                            |                           |
|--|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------------|
| Source<br>of Sample  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Total Percent<br>Positive |
| GRADE A  |                                |  |                                  |  |             |                            |                           |
| Bulk Milk Pickup Tanker  | 3,062,342                      | 495  | 13,658                           | 1  | 3,076,000   | 496                        | 0.016%                    |
| Pasteurized Fluid Milk<br>and Milk Products  | 4,007                          | 0  | 35,395                           | 0  | 39,402      | 0                          | 0.000%                    |
| Producer   | 362,211                        | 212  | 99,810                           | 44   | 462,021     | 256                        | 0.055%                    |
| Other  | 38,983                         | 9  | 7,654                            | 0  | 46,637      | 9                          | 0.019%                    |
| NON-GRADE A  |                                |  |                                  |  |             |                            |                           |
| Bulk Milk Pickup Tanker <sup>1</sup>   | 141,207                        | 31   | 22                               | 0  | 141,229     | 31                         | 0.022%                    |
| Pasteurized Fluid Milk<br>and Milk Products  | 1,454                          | 0  | 35                               | 0  | 1,489       | 0                          | 0.000%                    |
| Producer   | 24,508                         | 21   | 115                              | 0  | 24,623      | 21                         | 0.085%                    |
| Other  | 7,036                          | 0  | 53                               | 0  | 7,089       | 0                          | 0.000%                    |
| TOTALS   | 3,641,748                      | 768  | 156,742                          | 45   | 3,798,490   | 813                        | *                         |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

<sup>\*</sup> See Table 1 for explanation

| TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |                           |
|---|--------------------------------|--|----------------------------------|--|----------------|----------------------------|---------------------------|
| Source<br>of Sample   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests | Total Percent<br>Positive |
| GRADE A   |                                |  |                                  |  |                |                            |                           |
| Bulk Milk Pickup Tanker   | 75,575                         | 15   | 54                               | 0  | 75,629         | 15                         | 0.020%                    |
| Pasteurized Fluid Milk<br>and Milk Products   | 0                              | 0  | 67                               | 0  | 67             | 0                          | 0.000%                    |
| Producer  | 862                            | 0  | 0                                | 0  | 862            | 0                          | 0.000%                    |
| Other   | 462                            | 0  | 103                              | 0  | 565            | 0                          | 0.000%                    |
| NON-GRADE A   |                                |  |                                  |  |                |                            |                           |
| Bulk Milk Pickup Tanker <sup>1</sup>  | 0                              | 0  | 0                                | 0  | 0              | 0                          | 0.000%                    |
| Pasteurized Fluid Milk<br>and Milk Products   | 0                              | 0  | 0                                | 0  | 0              | 0                          | 0.000%                    |
| Producer  | 0                              | 0  | 0                                | 0  | 0              | 0                          | 0.000%                    |
| Other   | 0                              | 0  | 0                                | 0  | 0              | 0                          | 0.000%                    |
| TOTALS  | 76,899                         | 15   | 224                              | 0  | 77,123         | 15                         | *                         |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

<sup>\*</sup> See Table 1 for explanation

Table 5 shows the number of tests conducted by the family of drugs and by individual drug. Tables 5A and 5B present these data by validated and non-validated tests. At the 2011 meeting of the NCIMS in Baltimore, Maryland, a new category of drug residue testing received Conference acceptance. This test method detects more than one drug family and is listed under the category "Multiple Drug Family." The first test kit accepted under this category was Charm FLUSLBL which detects both Beta lactams and Flunixin. A positive result on this test method indicates that the sample is violative for either Beta lactams or Flunixin. This test method does not differentiate which drug family caused the positive result.

| TABLE 5 Number of Tests Conducted by Family/Drug<br>October 1, 2011 to September 30, 2012 |             |                   |  |  |  |  |
|---|-------------|-------------------|--|--|--|--|
| Family/Drug   | Total Tests | Total<br>Positive |  |  |  |  |
| AMINOGLYCOSIDES   | 36          | 0                 |  |  |  |  |
| BETA lactams  | 3,720,542   | 777               |  |  |  |  |
| CLOXACILLIN   | 101         | 0                 |  |  |  |  |
| ENROFLOXACIN  | 9,431       | 2                 |  |  |  |  |
| MACROLIDES  | 50          | 0                 |  |  |  |  |
| MULTIPLE DRUG FAMILY TEST   | 692         | 0                 |  |  |  |  |
| SULFONAMIDES  | 96,475      | 28                |  |  |  |  |
| TETRACYCLINE  | 4,715       | 0                 |  |  |  |  |
| TETRACYCLINES   | 43,571      | 21                |  |  |  |  |
| TOTALS  | 3,875,613   | 828               |  |  |  |  |

| TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2011 to September 30, 2012 |           |     |  |  |  |  |
|---|-----------|-----|--|--|--|--|
| Family/Drug Total Tests Total Positive  |           |     |  |  |  |  |
| BETA lactams  | 3,720,542 | 777 |  |  |  |  |
| CLOXACILLIN   | 101       | 0   |  |  |  |  |
| MULTIPLE DRUG FAMILY TEST   | 692       | 0   |  |  |  |  |
| SULFONAMIDES  | 56,072    | 19  |  |  |  |  |
| TETRACYCLINES   | 21,083    | 17  |  |  |  |  |
| TOTALS  | 3,798,490 | 813 |  |  |  |  |

# TABLE 5B -- Number of Non-Validated Tests Conducted by Family/Drug October 1, 2011 to September 30, 2012

| Family/Drug     | Total Tests | Total<br>Positive |
|-----------------|-------------|-------------------|
| AMINOGLYCOSIDES | 36          | 0                 |
| ENROFLOXACIN    | 9,431       | 2                 |
| MACROLIDES      | 50          | 0                 |
| SULFONAMIDES    | 40,403      | 9                 |
| TETRACYCLINE    | 4,715       | 0                 |
| TETRACYCLINES   | 22,488      | 4                 |
| TOTALS          | 77,123      | 15                |

Table 6 presents details on the tests used. The data in this table are comparable to Table 5, but the data are arranged by tests within each family/drug. Therefore, the Totals are the same in both tables. The testing methods with the largest use were: Charm SL - Beta lactams, which was used more than 2.3 million times, Delvotest P 5 Pack - Beta lactams which was used more than 486 thousand times, Charm 3 SL-3 which was used more than 228 thousand times and IDEXX New SNAP which was used almost 215 thousand times. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines. At the 2011 meeting of the NCIMS in Baltimore, Maryland, a new category of drug residue testing received Conference acceptance. This test method detects more than one drug family and is listed under the category "Multiple Drug Family." The first test kit accepted under this category was Charm FLUSLBL which detects both Beta lactams and Flunixin. A positive result on this test method indicates that the sample is violative for either Beta lactams or Flunixin. This test method does not differentiate which drug family caused the positive result.

| TABLE 6 Number of Tests by Method by Family/Drug<br>October 1, 2011 to September 30, 2012 |                    |                    |                     |  |  |  |  |  |  |
|---|--------------------|--------------------|---------------------|--|--|--|--|--|--|
| Tests Used by Family/Drug   | Number of<br>Tests | Number<br>Positive | Percent<br>Positive |  |  |  |  |  |  |
| AMINOGLYCOSIDES   |                    |                    |                     |  |  |  |  |  |  |
| Charm II Tablet Competitive<br>Aminoglycosides**  | 36                 | 0                  | 0.000%              |  |  |  |  |  |  |
| BETA lactams  |                    |                    |                     |  |  |  |  |  |  |
| Charm 3 SL-3  | 228,831            | 34                 | 0.015%              |  |  |  |  |  |  |
| Charm BSDA Tablet - Beta lactams  | 32,094             | 22                 | 0.069%              |  |  |  |  |  |  |
| Charm II Tablet Competitive   | 160,450            | 28                 | 0.017%              |  |  |  |  |  |  |
| Charm II Tablet Quantitative  | 38                 | 0                  | 0.000%              |  |  |  |  |  |  |
| Charm II Tablet Sequential  | 87,989             | 18                 | 0.020%              |  |  |  |  |  |  |
| Charm SL Beta lactams   | 2,307,954          | 319                | 0.014%              |  |  |  |  |  |  |
| Charm SL-6  | 157,303            | 43                 | 0.027%              |  |  |  |  |  |  |
| Delvotest P 5 Pack - Beta lactams   | 486,024            | 256                | 0.053%              |  |  |  |  |  |  |
| Delvotest P/Delvotest P Mini  | 44,152             | 1                  | 0.002%              |  |  |  |  |  |  |
| Delvotest SP/Delvotest SP Mini  | 294                | 0                  | 0.000%              |  |  |  |  |  |  |
| IDEXX New SNAP  | 214,931            | 56                 | 0.026%              |  |  |  |  |  |  |
| Neogen BetaStar   | 482                | 0                  | 0.000%              |  |  |  |  |  |  |
| CLOXACILLIN   |                    |                    |                     |  |  |  |  |  |  |
| Charm II Test for Cloxacillin in Milk   | 101                | 0                  | 0.000%              |  |  |  |  |  |  |
| ENROFLOXACIN  |                    |                    |                     |  |  |  |  |  |  |
| Charm SL-Floroquinlone**  | 9,431              | 2                  | 0.021%              |  |  |  |  |  |  |
| MACROLIDES  |                    |                    |                     |  |  |  |  |  |  |
| Charm II Tablet Sequential - Macrolides**   | 50                 | 0                  | 0.000%              |  |  |  |  |  |  |

### TABLE 6 -- Number of Tests by Method by Family/Drug October 1, 2011 to September 30, 2012

| Tests Used by Family/Drug            | Number of<br>Tests | Number<br>Positive | Percent<br>Positive |
|--------------------------------------|--------------------|--------------------|---------------------|
| MULTIPLE DRUG FAMILY TEST            |                    |                    |                     |
| Charm FLUSLBL                        | 692                | 0                  | 0.000%              |
| SULFONAMIDES                         |                    |                    |                     |
| Agri-Screen for Sulfonamides** & *** | 2,415              | 2                  | 0.083%              |
| Charm II Tablet Competitive          | 56,072             | 19                 | 0.034%              |
| Charm II Tablet Sequential**         | 2,649              | 0                  | 0.000%              |
| Charm SL Sulfa Test**                | 35,339             | 7                  | 0.020%              |
| TETRACYCLINE                         |                    |                    |                     |
| SNAP - Tetracycline**                | 4,715              | 0                  | 0.000%              |
| TETRACYCLINES                        |                    |                    |                     |
| Charm II Tablet Competitive          | 21,083             | 17                 | 0.081%              |
| Charm SL - Tetracyclines**           | 22,488             | 4                  | 0.018%              |
| TOTALS                               | 3,875,613          | 828                | *                   |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".  $^{**}$  Non-Validated Test Method

<sup>\*\*\*</sup> FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

### TABLE 6A -- Comparison of Validated and Non-Validated Tests for Sulfonamides and Tetracyclines October 1, 2011 to September 30, 2012

| Tests By Method by Family/Drug       | Number of<br>Tests | Number<br>Positive | Percent Positive |
|--------------------------------------|--------------------|--------------------|------------------|
| VALIDATED FOR SULFONAMIDES           |                    |                    |                  |
| Charm II Tablet Competitive          | 56,072             | 19                 | 0.034%           |
| NON-VALIDATED FOR SULFONAMIDES       |                    |                    |                  |
| Agri-Screen for Sulfonamides** & *** | 2,415              | 2                  | 0.083%           |
| Charm II Tablet Sequential**         | 2,649              | 0                  | 0.000%           |
| Charm SL Sulfa Test**                | 35,339             | 7                  | 0.020%           |
| VALIDATED FOR TETRACYCLINES          |                    |                    |                  |
| Charm II Tablet Competitive          | 21,083             | 17                 | 0.081%           |
| NON-VALIDATED FOR TETRACYCLINES      |                    |                    |                  |
| Charm SL - Tetracyclines**           | 22,488             | 4                  | 0.018%           |
| TOTALS                               | 140,046            | 49                 | *                |

<sup>&</sup>lt;sup>1</sup> It is a common practice in some States, including two large milk production States, that bulk milk pickup tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

\*\* Non-Validated Test Method

 $<sup>^{***}</sup>$  FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

Tables 7-1 to 7-8 present additional details of the testing conducted. These Tables show the testing by the family of drugs and by individual drugs and present results in terms of Grade "A" and Non-Grade "A" testing. Data on individual drugs listed in these Tables, e.g., Cloxacillin, etc., are not included in the Totals for the family of drugs, e.g, Beta lactams, etc. At the 2011 meeting of the NCIMS in Baltimore, Maryland, a new category of drug residue testing received Conference acceptance. This test method detects more than one drug family and is listed under the category "Multiple Drug Family." The first test kit accepted under this category was Charm FLUSLBL which detects both Beta lactams and Flunixin. A positive result on this test method indicates that the sample is violative for either Beta lactams or Flunixin. This test method does not differentiate which drug family caused the positive result.

| TABLE 7-1 – Grade A Bulk Milk Pickup Tanker Testing<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                    |                            |  |  |  |
|--|--------------------------------|--|----------------------------------|--|--------------------|----------------------------|--|--|--|
| Family/Drug  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | <b>Total Tests</b> | Total<br>Positive<br>Tests |  |  |  |
| AMINOGLYCOSIDES  | 36                             | 0  | 0                                | 0  | 36                 | 0                          |  |  |  |
| BETA lactams   | 2,985,272                      | 460  | 13,571                           | 0  | 2,998,843          | 460                        |  |  |  |
| Cloxacillin  | 0                              | 0  | 72                               | 0  | 72                 | 0                          |  |  |  |
| ENROFLOXACIN   | 9,431                          | 2  | 0                                | 0  | 9,431              | 2                          |  |  |  |
| MACROLIDES   | 48                             | 0  | 0                                | 0  | 48                 | 0                          |  |  |  |
| MULTIPLE DRUG<br>FAMILY TEST   | 664                            | 0  | 0                                | 0  | 664                | 0                          |  |  |  |
| SULFONAMIDES   | 95,096                         | 27   | 15                               | 1  | 95,111             | 28                         |  |  |  |
| TETRACYCLINE   | 3,799                          | 0  | 54                               | 0  | 3,853              | 0                          |  |  |  |
| TETRACYCLINES  | 43,571                         | 21   | 0                                | 0  | 43,571             | 21                         |  |  |  |
| TOTALS   | 3,137,917                      | 510  | 13,712                           | 1  | 3,151,629          | 511                        |  |  |  |

| TABLE 7-2 Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |  |
|--|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|--|
| Family/Drug  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |  |
| BETA lactams   | 3,881                          | 0  | 35,395                           | 0  | 39,276         | 0                          |  |  |
| SULFONAMIDES   | 126                            | 0  | 67                               | 0  | 193            | 0                          |  |  |
| TOTALS   | 4,007                          | 0  | 35,462                           | 0  | 39,469         | 0                          |  |  |

| TABLE 7-3 Grade A Producer Testing<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |  |  |
|---|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|--|--|
| Family/Drug   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |  |  |
| BETA lactams  | 361,671                        | 212  | 99,723                           | 44   | 461,394        | 256                        |  |  |  |
| MULTIPLE DRUG<br>FAMILY TEST  | 0                              | 0  | 28                               | 0  | 28             | 0                          |  |  |  |
| SULFONAMIDES  | 540                            | 0  | 59                               | 0  | 599            | 0                          |  |  |  |
| TETRACYCLINE  | 862                            | 0  | 0                                | 0  | 862            | 0                          |  |  |  |
| TOTALS  | 363,073                        | 212  | 99,810                           | 44   | 462,883        | 256                        |  |  |  |

| TABLE 7-4 Grade A Other Testing (Milk from milk plant tanks/silos, milk transport tankers, etc.) October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |  |
|--|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|--|
| Family/Drug  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |  |
| BETA lactams   | 38,974                         | 9  | 7,625                            | 0  | 46,599         | 9                          |  |  |
| Cloxacillin  | 0                              | 0  | 29                               | 0  | 29             | 0                          |  |  |
| MACROLIDES   | 2                              | 0  | 0                                | 0  | 2              | 0                          |  |  |
| SULFONAMIDES   | 469                            | 0  | 103                              | 0  | 572            | 0                          |  |  |
| TOTALS   | 39,445                         | 9  | 7,757                            | 0  | 47,202         | 9                          |  |  |

| TABLE 7-5 Non-Grade A Bulk Milk Pickup Tanker Testing<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |
|--|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|
| Family/Drug  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |
| BETA lactams   | 141,207                        | 31   | 22                               | 0  | 141,229        | 31                         |  |
| TOTALS   | 141,207                        | 31   | 22                               | 0  | 141,229        | 31                         |  |

| TABLE 7-6 Non-Grade A Pasteurized Fluid Milk and Milk Products Testing<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |
|---|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|
| Family/Drug   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |
| BETA lactams  | 1,454                          | 0  | 35                               | 0  | 1,489          | 0                          |  |

0

35

1,489

0

1,454

**TOTALS** 

| TABLE 7-7 Non-Grade A Producer Testing<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |  |
|---|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|--|
| Family/Drug   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |  |
| BETA lactams  | 24,508                         | 21   | 115                              | 0  | 24,623         | 21                         |  |  |
| TOTALS  | 24,508                         | 21   | 115                              | 0  | 24,623         | 21                         |  |  |

| TABLE 7-8 Non-Grade A Other Testing (Milk from milk plant tanks/silos, milk transport tankers, etc.) October 1, 2011 to September 30, 2012 |                                |  |                                  |  |                |                            |  |
|--|--------------------------------|--|----------------------------------|--|----------------|----------------------------|--|
| Family/Drug  | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total<br>Tests | Total<br>Positive<br>Tests |  |
| BETA lactams   | 7,036                          | 0  | 53                               | 0  | 7,089          | 0                          |  |
| TOTALS   | 7,036                          | 0  | 53                               | 0  | 7,089          | 0                          |  |

Tables 8-1 to 8-8 present details on the number of tests conducted by industry and by State Regulatory Agencies. The data are arranged by <u>test</u> within each <u>family/drug</u> and present results in terms of sample type and Grade "A" and Non-Grade "A" testing. At the 2011 meeting of the NCIMS in Baltimore, Maryland, a new category of drug residue testing received Conference acceptance. This test method detects more than one drug family and is listed under the category "Multiple Drug Family." The first test kit accepted under this category was Charm FLUSLBL which detects both Beta lactams and Flunixin. A positive result on this test method indicates that the sample is violative for either Beta lactams or Flunixin. This test method does not differentiate which drug family caused the positive result.

| Table 8-1 Number of Tests by Method by Family/Drug<br>Grade A Bulk Milk Pickup Tanker<br>October 1, 2011 to September 30, 2012 |                                |  |                                  |  |             |                            |                     |  |  |  |  |
|--|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|--|--|--|--|
| Tests Used by<br>Family/Drug   | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |  |  |  |  |
| AMINOGLYCOSIDES  |                                |  |                                  |  |             |                            |                     |  |  |  |  |
| Charm II Tablet<br>Competitive<br>Aminoglycosides**  | 36                             | 0  | 0                                | 0  | 36          | 0                          | 0.000%              |  |  |  |  |
| BETA lactams   |                                |  |                                  |  |             |                            |                     |  |  |  |  |
| Charm 3 SL-3   | 217,137                        | 31   | 0                                | 0  | 217,137     | 31                         | 0.014%              |  |  |  |  |
| Charm BSDA<br>Tablet - Beta<br>lactams   | 16,620                         | 9  | 0                                | 0  | 16,620      | 9                          | 0.054%              |  |  |  |  |
| Charm II Tablet<br>Competitive   | 150,782                        | 25   | 7,418                            | 0  | 158,200     | 25                         | 0.016%              |  |  |  |  |
| Charm II Tablet<br>Quantitative  | 0                              | 0  | 38                               | 0  | 38          | 0                          | 0.000%              |  |  |  |  |
| Charm II Tablet<br>Sequential  | 84,173                         | 18   | 87                               | 0  | 84,260      | 18                         | 0.021%              |  |  |  |  |
| Charm SL Beta<br>lactams   | 2,148,778                      | 282  | 529                              | 0  | 2,149,307   | 282                        | 0.013%              |  |  |  |  |
| Charm SL-6   | 146,371                        | 40   | 297                              | 0  | 146,668     | 40                         | 0.027%              |  |  |  |  |
| Delvotest P 5 Pack - Beta lactams  | 13,865                         | 3  | 4,994                            | 0  | 18,859      | 3                          | 0.016%              |  |  |  |  |
| Delvotest<br>P/Delvotest P Mini  | 3,546                          | 0  | 186                              | 0  | 3,732       | 0                          | 0.000%              |  |  |  |  |
| Delvotest<br>SP/Delvotest SP<br>Mini   | 90                             | 0  | 0                                | 0  | 90          | 0                          | 0.000%              |  |  |  |  |
| IDEXX New<br>SNAP  | 203,428                        | 52   | 22                               | 0  | 203,450     | 52                         | 0.026%              |  |  |  |  |
| Neogen BetaStar  | 482                            | 0  | 0                                | 0  | 482         | 0                          | 0.000%              |  |  |  |  |

## Table 8-1 -- Number of Tests by Method by Family/Drug Grade A Bulk Milk Pickup Tanker October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug                    | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | <b>Total Tests</b> | Total<br>Positive<br>Tests | Percent<br>Positive |
|---|--------------------------------|--|----------------------------------|--|--------------------|----------------------------|---------------------|
| Cloxacillin                                     |                                |  |                                  |  |                    |                            |                     |
| Charm II Test for<br>Cloxacillin in Milk        | 0                              | 0  | 72                               | 0  | 72                 | 0                          | 0.000%              |
| Enrofloxacin                                    |                                |  |                                  |  |                    |                            |                     |
| Charm SL-<br>Floroquinlone**                    | 9,431                          | 2  | 0                                | 0  | 9,431              | 2                          | 0.021%              |
| Macrolides                                      |                                |  |                                  |  |                    |                            |                     |
| Charm II Tablet<br>Sequential -<br>Macrolides** | 48                             | 0  | 0                                | 0  | 48                 | 0                          | 0.000%              |
| Multiple Drug Family<br>Test                    |                                |  |                                  |  |                    |                            |                     |
| Charm FLUSLBL                                   | 664                            | 0  | 0                                | 0  | 664                | 0                          | 0.000%              |
| Sulfonamides                                    |                                |  |                                  |  |                    |                            |                     |
| Agri-Screen for Sulfonamides** & ***            | 2,245                          | 2  | 0                                | 0  | 2,245              | 2                          | 0.089%              |
| Charm II Tablet<br>Competitive                  | 55,323                         | 18   | 15                               | 1  | 55,338             | 19                         | 0.034%              |
| Charm II Tablet<br>Sequential**                 | 2,649                          | 0  | 0                                | 0  | 2,649              | 0                          | 0.000%              |
| Charm SL Sulfa<br>Test**                        | 34,879                         | 7  | 0                                | 0  | 34,879             | 7                          | 0.020%              |
| Tetracycline                                    |                                |  |                                  |  |                    |                            |                     |
| SNAP -<br>Tetracycline**                        | 3,799                          | 0  | 54                               | 0  | 3,853              | 0                          | 0.000%              |
| Tetracyclines                                   |                                |  |                                  |  |                    |                            |                     |
| Charm II Tablet<br>Competitive                  | 21,083                         | 17   | 0                                | 0  | 21,083             | 17                         | 0.081%              |
| Charm SL -<br>Tetracyclines**                   | 22,488                         | 4  | 0                                | 0  | 22,488             | 4                          | 0.018%              |
| TOTALS  | 3,137,917                      | 510  | 13,712                           | 1  | 3,151,629          | 511                        | 0.016%              |

<sup>\*\*</sup> Non-Validated Test Method

 $<sup>^{\</sup>ast\ast\ast}$  FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

### Table 8-2 -- Number of Tests by Method by Family/Drug Grade A Pasteurized Fluid Milk and Milk Products October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |             |                            |                     |
| Charm BSDA Tablet - Beta lactams     | 243                            | 0  | 1,297                            | 0  | 1,540       | 0                          | 0.000%              |
| Charm II Tablet<br>Sequential        | 0                              | 0  | 490                              | 0  | 490         | 0                          | 0.000%              |
| Charm SL Beta<br>lactams             | 50                             | 0  | 805                              | 0  | 855         | 0                          | 0.000%              |
| Charm SL-6                           | 1,597                          | 0  | 1,023                            | 0  | 2,620       | 0                          | 0.000%              |
| Delvotest P 5 Pack -<br>Beta lactams | 1,594                          | 0  | 26,808                           | 0  | 28,402      | 0                          | 0.000%              |
| Delvotest P/Delvotest<br>P Mini      | 355                            | 0  | 4,059                            | 0  | 4,414       | 0                          | 0.000%              |
| Delvotest<br>SP/Delvotest SP Mini    | 0                              | 0  | 40                               | 0  | 40          | 0                          | 0.000%              |
| IDEXX New SNAP                       | 42                             | 0  | 873                              | 0  | 915         | 0                          | 0.000%              |
| Sulfonamides                         |                                |  |                                  |  |             |                            |                     |
| Agri-Screen for Sulfonamides** & *** | 0                              | 0  | 67                               | 0  | 67          | 0                          | 0.000%              |
| Charm II Tablet<br>Competitive       | 126                            | 0  | 0                                | 0  | 126         | 0                          | 0.000%              |
| TOTALS                               | 4,007                          | 0  | 35,462                           | 0  | 39,469      | 0                          | 0.000%              |

<sup>\*\*</sup> Non-Validated Test Method

 $<sup>^{\</sup>ast\ast\ast}$  FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

# Table 8-3 -- Number of Tests by Method by Family/Drug Grade A Producer October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |             |                            |                     |
| Charm 3 SL-3                         | 2,653                          | 1  | 0                                | 0  | 2,653       | 1                          | 0.038%              |
| Charm BSDA Tablet - Beta lactams     | 9,527                          | 12   | 1,852                            | 0  | 11,379      | 12                         | 0.105%              |
| Charm II Tablet<br>Competitive       | 957                            | 0  | 47                               | 0  | 1,004       | 0                          | 0.000%              |
| Charm II Tablet<br>Sequential        | 0                              | 0  | 1,911                            | 0  | 1,911       | 0                          | 0.000%              |
| Charm SL Beta<br>lactams             | 5,453                          | 4  | 1,030                            | 1  | 6,483       | 5                          | 0.077%              |
| Charm SL-6                           | 4,649                          | 3  | 1,229                            | 0  | 5,878       | 3                          | 0.051%              |
| Delvotest P 5 Pack -<br>Beta lactams | 318,871                        | 191  | 75,086                           | 42   | 393,957     | 233                        | 0.059%              |
| Delvotest P/Delvotest<br>P Mini      | 15,438                         | 0  | 18,488                           | 1  | 33,926      | 1                          | 0.003%              |
| Delvotest<br>SP/Delvotest SP Mini    | 116                            | 0  | 0                                | 0  | 116         | 0                          | 0.000%              |
| IDEXX New SNAP                       | 4,007                          | 1  | 80                               | 0  | 4,087       | 1                          | 0.024%              |
| Multiple Drug Family<br>Test         |                                |  |                                  |  |             |                            |                     |
| Charm FLUSLBL                        | 0                              | 0  | 28                               | 0  | 28          | 0                          | 0.000%              |
| Sulfonamides                         |                                |  |                                  |  |             |                            |                     |
| Charm II Tablet<br>Competitive       | 540                            | 0  | 59                               | 0  | 599         | 0                          | 0.000%              |
| Tetracycline                         |                                |  |                                  |  |             |                            |                     |
| SNAP -<br>Tetracycline**             | 862                            | 0  | 0                                | 0  | 862         | 0                          | 0.000%              |
| TOTALS                               | 363,073                        | 212  | 99,810                           | 44   | 462,883     | 256                        | 0.055%              |

<sup>\*\*</sup> Non-Validated Test Method

### Table 8-4 -- Number of Tests by Method by Family/Drug Grade A Other (Milk from milk plant tanks/silos, milk transport tankers, etc.) October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug                    | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|---|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                                    |                                |  |                                  |  |             |                            |                     |
| Charm 3 SL-3                                    | 1,901                          | 0  | 0                                | 0  | 1,901       | 0                          | 0.000%              |
| Charm BSDA Tablet<br>- Beta lactams             | 1,238                          | 0  | 334                              | 0  | 1,572       | 0                          | 0.000%              |
| Charm II Tablet<br>Competitive                  | 1,246                          | 3  | 0                                | 0  | 1,246       | 3                          | 0.241%              |
| Charm II Tablet<br>Sequential                   | 1,299                          | 0  | 29                               | 0  | 1,328       | 0                          | 0.000%              |
| Charm SL Beta<br>lactams                        | 27,905                         | 6  | 1,144                            | 0  | 29,049      | 6                          | 0.021%              |
| Charm SL-6                                      | 1,965                          | 0  | 171                              | 0  | 2,136       | 0                          | 0.000%              |
| Delvotest P 5 Pack -<br>Beta lactams            | 2,265                          | 0  | 4,530                            | 0  | 6,795       | 0                          | 0.000%              |
| Delvotest P/Delvotest<br>P Mini                 | 351                            | 0  | 1,209                            | 0  | 1,560       | 0                          | 0.000%              |
| Delvotest<br>SP/Delvotest SP Mini               | 0                              | 0  | 48                               | 0  | 48          | 0                          | 0.000%              |
| IDEXX New SNAP                                  | 804                            | 0  | 160                              | 0  | 964         | 0                          | 0.000%              |
| Cloxacillin                                     |                                |  |                                  |  |             |                            |                     |
| Charm II Test for<br>Cloxacillin in Milk        | 0                              | 0  | 29                               | 0  | 29          | 0                          | 0.000%              |
| Macrolides                                      |                                |  |                                  |  |             |                            |                     |
| Charm II Tablet<br>Sequential -<br>Macrolides** | 2                              | 0  | 0                                | 0  | 2           | 0                          | 0.000%              |
| Sulfonamides                                    |                                |  |                                  |  |             |                            |                     |
| Agri-Screen for Sulfonamides** & ***            | 0                              | 0  | 103                              | 0  | 103         | 0                          | 0.000%              |
| Charm II Tablet<br>Competitive                  | 9                              | 0  | 0                                | 0  | 9           | 0                          | 0.000%              |
| Charm SL Sulfa<br>Test**                        | 460                            | 0  | 0                                | 0  | 460         | 0                          | 0.000%              |
| TOTALS  | 39,445                         | 9  | 7,757                            | 0  | 47,202      | 9                          | 0.019%              |

<sup>\*\*</sup> Non-Validated Test Method

 $<sup>^{\</sup>ast\ast\ast}$  FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

# Table 8-5 -- Number of Tests by Method by Family/Drug Non-Grade A Bulk Milk Pickup Tanker October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |             |                            |                     |
| Charm 3 SL-3                         | 7,140                          | 2  | 0                                | 0  | 7,140       | 2                          | 0.028%              |
| Charm BSDA Tablet - Beta lactams     | 80                             | 0  | 0                                | 0  | 80          | 0                          | 0.000%              |
| Charm SL Beta<br>lactams             | 118,445                        | 26   | 12                               | 0  | 118,457     | 26                         | 0.022%              |
| Delvotest P 5 Pack -<br>Beta lactams | 10,838                         | 0  | 10                               | 0  | 10,848      | 0                          | 0.000%              |
| Delvotest P/Delvotest<br>P Mini      | 25                             | 0  | 0                                | 0  | 25          | 0                          | 0.000%              |
| IDEXX New SNAP                       | 4,679                          | 3  | 0                                | 0  | 4,679       | 3                          | 0.064%              |
| TOTALS                               | 141,207                        | 31   | 22                               | 0  | 141,229     | 31                         | 0.022%              |

| Table 8-6 Number of Tests by Method by Family/Drug   |
|--|
| Non-Grade A Pasteurized Fluid Milk and Milk Products |
| October 1, 2011 to September 30, 2012                |

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |             |                            |                     |
| Delvotest P 5 Pack -<br>Beta lactams | 1,278                          | 0  | 35                               | 0  | 1,313       | 0                          | 0.000%              |
| Delvotest P/Delvotest<br>P Mini      | 176                            | 0  | 0                                | 0  | 176         | 0                          | 0.000%              |
| TOTALS                               | 1,454                          | 0  | 35                               | 0  | 1,489       | 0                          | 0.000%              |

### Table 8-7 -- Number of Tests by Method by Family/Drug Non-Grade A Producer October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | Total Tests | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|-------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |             |                            |                     |
| Charm BSDA Tablet - Beta lactams     | 902                            | 1  | 1                                | 0  | 903         | 1                          | 0.111%              |
| Charm SL Beta<br>lactams             | 33                             | 0  | 2                                | 0  | 35          | 0                          | 0.000%              |
| Delvotest P 5 Pack -<br>Beta lactams | 23,407                         | 20   | 70                               | 0  | 23,477      | 20                         | 0.085%              |
| Delvotest P/Delvotest<br>P Mini      | 166                            | 0  | 42                               | 0  | 208         | 0                          | 0.000%              |
| TOTALS                               | 24,508                         | 21   | 115                              | 0  | 24,623      | 21                         | 0.085%              |

### Table 8-8 -- Number of Tests by Method by Family/Drug Non-Grade A Other (Milk from milk plant tanks/silos, milk transport tankers, etc.) October 1, 2011 to September 30, 2012

| Tests Used by<br>Family/Drug         | Number of<br>Industry<br>Tests | Number of<br>Positive<br>Industry<br>Tests | Number of<br>Regulatory<br>Tests | Number of<br>Positive<br>Regulatory<br>Tests | <b>Total Tests</b> | Total<br>Positive<br>Tests | Percent<br>Positive |
|--------------------------------------|--------------------------------|--|----------------------------------|--|--------------------|----------------------------|---------------------|
| BETA lactams                         |                                |  |                                  |  |                    |                            |                     |
| Charm SL Beta<br>lactams             | 3,762                          | 0  | 6                                | 0  | 3,768              | 0                          | 0.000%              |
| Charm SL-6                           | 1                              | 0  | 0                                | 0  | 1                  | 0                          | 0.000%              |
| Delvotest P 5 Pack -<br>Beta lactams | 2,333                          | 0  | 40                               | 0  | 2,373              | 0                          | 0.000%              |
| Delvotest P/Delvotest<br>P Mini      | 104                            | 0  | 7                                | 0  | 111                | 0                          | 0.000%              |
| IDEXX New SNAP                       | 836                            | 0  | 0                                | 0  | 836                | 0                          | 0.000%              |
| TOTALS                               | 7,036                          | 0  | 53                               | 0  | 7,089              | 0                          | 0.000%              |