### NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2013 ANNUAL REPORT October 1, 2012 - September 30, 2013

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### **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: <u>www.kandc-sbcc.com/nmdrd/</u>. Forty-nine (49) data reporters utilized the web-based software to submit all or part of their data for the FY 2013 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: <u>www.kandc-sbcc.com/nmdrd/</u>. 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: <u>www.kandc-sbcc.com/nmdrd/</u>.

On April 21, 2013, contractor staff made a presentation to thirty-four (34) attendees of the NCIMS meeting in Indianapolis, Indiana, addressing the Annual Reports for FY 2011 and 2012, and the webbased reporting application. This included a demonstration of the software and a "real-time" opportunity for participants to use the application. In addition, contractor staff spoke to the first General Session of the Conference to explain the brief shut down of the web-based reporting application after the previous contract expired and before a new contract was awarded. All websites associated with the third party drug residue data base have been operational since April 1, 2013.

It should be noted that the Charm BSDA Tablet-Beta Lactam, Delvotest P 5 Pack - Beta lactams, Delvotest P/Delvotest P Mini and Delvotest SP/Delvotest SP Mini are non-specific detectors of inhibitors. The NCIMS evaluated these kits for the detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The manner in which these tests are reported does not make it possible to separate the use/nonuse of beta lactamase. These tests could best be described as "Microbial Inhibitor Tests, since a finding of "Not Found (NF)" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. Further information can be obtained from the technical bulletin posted on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

### **SUMMARY**

This report presents summary data on samples and tests conducted during Fiscal Year 2013 (October 1, 2012 to September 30, 2013). All fifty (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 tankers be sampled and analyzed for animal drug residues before the milk is processed. Any bulk milk tanker found positive is rejected for human consumption.

During this period **3,761,500** samples were analyzed for animal drug residues. Of these samples **731** were positive for a drug residue. A total of **4,115,774** tests were reported on the samples for ten (10) different groups of families or individual drugs. Twenty-six (26) 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. <u>Bulk Milk Pickup Tanker</u> 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. <u>Other</u> 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 ResultsOctober 1, 2012 to September 30, 2013								
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)				
Bulk Milk Pickup Tanker	3,198,228	445	0.014%	19,553,000				
Pasteurized Fluid Milk and Milk Products	40,435	0	0.000%	0				
Producer	467,429	281	0.060%	339,000				
Other	55,408	5	0.009%	240,000				
TOTALS	3,761,500	731	*	20,132,000				

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 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. <u>Other</u> -- 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 SamplesOctober 1, 2012 to September 30, 2013									
Source of Sample	Number of Industry Samples	Number of Positive Industry Samples	Number of Regulatory Samples	Number of Positive Regulatory Samples	Total Samples	Total Positive Samples	Total Percent Positive	Disposition Per PMO (Pounds)	
GRADE A									
Bulk Milk Pickup Tanker	3,079,003	421	7,951	3	3,086,954	424	0.014%	18,664,000	
Pasteurized Fluid Milk and Milk Products	2,052	0	36,738	0	38,790	0	0.000%	0	
Producer	337,249	208	106,228	51	443,477	259	0.058%	339,000	
Other	37,148	5	9,909	0	47,057	5	0.011%	240,000	
NON-GRADE A									
Bulk Milk Pickup Tanker <sup>1</sup>	111,198	21	76	0	111,274	21	0.019%	889,000	
Pasteurized Fluid Milk and Milk Products	1,582	0	63	0	1,645	0	0.000%	0	
Producer	23,792	22	160	0	23,952	22	0.092%	0	
Other	8,293	0	58	0	8,351	0	0.000%	0	
TOTALS	3,600,317	677	161,183	54	3,761,500	731	*	20,132,000 <sup>2</sup>	

<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>2</sup> Note that this represents 0.01% of the total milk supply of the United States with an annual production of 201 billion pounds.

### **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 (4,115,774) is greater than the number of samples (3,761,500). 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, 2012 to September 30, 2013. 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 ConductedOctober 1, 2012 to September 30, 2013							
Source of Sample	TotalNumber ofTestsTestsPositive		Percent Positive				
Bulk Milk Pickup Tanker	3,551,724	446	0.013%				
Pasteurized Fluid Milk and Milk Products	40,678	0	0.000%				
Producer	467,919	281	0.060%				
Other	55,453	5	0.009%				
TOTALS	4,115,774	732	*				

TABLE 3A Validated Tests ConductedOctober 1, 2012 to September 30, 2013							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pickup Tanker	3,431,395	435	0.013%				
Pasteurized Fluid Milk and Milk Products	40,678	0	0.000%				
Producer	467,918	281	0.060%				
Other	52,488	5	0.010%				
TOTALS	3,992,479	721	*				

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\* See Table 1 for explanation

TABLE 3B Non-Validated Tests ConductedOctober 1, 2012 to September 30, 2013							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pickup Tanker	120,329	11	0.009%				
Pasteurized Fluid Milk and Milk Products	0	0	0.000%				
Producer	1	0	0.000%				
Other	2,965	0	0.000%				
TOTALS	123,295	11	*				

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 AgenciesOctober 1, 2012 to September 30, 2013							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pickup Tanker	3,432,432	422	7,972	3	3,440,404	425	0.012%
Pasteurized Fluid Milk and Milk Products	2,192	0	36,841	0	39,033	0	0.000%
Producer	337,459	208	106,458	51	443,917	259	0.058%
Other	37,185	5	9,917	0	47,102	5	0.011%
NON-GRADE A							
Bulk Milk Pickup Tanker <sup>1</sup>	111,244	21	76	0	111,320	21	0.019%
Pasteurized Fluid Milk and Milk Products	1,582	0	63	0	1,645	0	0.000%
Producer	23,842	22	160	0	24,002	22	0.092%
Other	8,293	0	58	0	8,351	0	0.000%
TOTALS	3,954,229	678	161,545	54	4,115,774	732	*

<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".

TABLE 4A Validated Tests Conducted by Industry and Regulatory AgenciesOctober 1, 2012 to September 30, 2013							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pickup Tanker	3,313,176	411	7,940	3	3,321,116	414	0.012%
Pasteurized Fluid Milk and Milk Products	2,192	0	36,841	0	39,033	0	0.000%
Producer	337,459	208	106,457	51	443,916	259	0.058%
Other	34,543	5	9,594	0	44,137	5	0.011%
NON-GRADE A							
Bulk Milk Pickup Tanker <sup>1</sup>	110,203	21	76	0	110,279	21	0.019%
Pasteurized Fluid Milk and Milk Products	1,582	0	63	0	1,645	0	0.000%
Producer	23,842	22	160	0	24,002	22	0.092%
Other	8,293	0	58	0	8,351	0	0.000%
TOTALS	3,831,290	667	161,189	54	3,992,479	721	*

<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 comminging of the two grades of milk, all data related to these loads are reported under non-Grade "A".

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory AgenciesOctober 1, 2012 to September 30, 2013							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pickup Tanker	119,256	11	32	0	119,288	11	0.009%
Pasteurized Fluid Milk and Milk Products	0	0	0	0	0	0	0.000%
Producer	0	0	1	0	1	0	0.000%
Other	2,642	0	323	0	2,965	0	0.000%
NON-GRADE A							
Bulk Milk Pickup Tanker <sup>1</sup>	1,041	0	0	0	1,041	0	0.000%
Pasteurized Fluid Milk 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	122,939	11	356	0	123,295	11	*

<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". \* See Table 1 for explanation

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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.

TABLE 5 Number of Tests Conducted by Family/Drug         October 1, 2012 to September 30, 2013						
Family/Drug	Total Tests	Total Positive				
AMINOGLYCOSIDES	36	0				
BETA lactams	3,706,466	708				
CLOXACILLIN	91	0				
ENROFLOXACIN	12,435	2				
MACROLIDES	49	0				
MULTIPLE DRUG FAMILY TEST	350	0				
SULFONAMIDES	214,604	9				
SULFAMETHAZINE	332	0				
TETRACYCLINE	5,787	1				
TETRACYCLINES	175,624	12				
TOTALS	4,115,774	732				

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2012 to September 30, 2013							
Family/DrugTotal TestsTotal Positive							
BETA lactams	3,706,466	708					
CLOXACILLIN	91	0					
MULTIPLE DRUG FAMILY TEST	350	0					
SULFONAMIDES	151,032	5					
TETRACYCLINES	134,540	8					
TOTALS	3,992,479	721					

TABLE 5B Number of Non-Validated Tests Conducted by Family/Drug October 1, 2012 to September 30, 2013						
Family/Drug Total Tests Total Positive						
AMINOGLYCOSIDES	36	0				
ENROFLOXACIN	12,435	2				
MACROLIDES	49	0				
SULFONAMIDES	63,572	4				
SULFAMETHAZINE	332	0				
TETRACYCLINE	5,787	1				
TETRACYCLINES	41,084	4				
TOTALS	123,295	11				

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 approximately 2.3 million times, Delvotest P 5 Pack - Beta lactams which was used more than 481 thousand times, Charm 3 SL-3 which was used approximately 286 thousand times, Charm SL-6 which was used approximately 208 thousand times and IDEXX New Snap which was used more than 203 thousand times. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive	
AMINOGLYCOSIDES				
Charm II Tablet Competitive Aminoglycosides <sup>**</sup>	36	0	0.000%	
BETA lactams				
Charm 3 SL-3	285,776	36	0.013%	
Charm BSDA Tablet - Beta lactams <sup>++</sup>	29,941	21	0.070%	
Charm II Tablet Competitive	101,567	20	0.020%	
Charm II Tablet Quantitative	18	0	0.000%	
Charm II Tablet Sequential	74,242	10	0.013%	
Charm SL Beta lactams	2,299,297	290	0.013%	
Charm SL-6	207,923	23	0.011%	
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	481,365	261	0.054%	
Delvotest P/Delvotest P Mini <sup>++</sup>	22,663	1	0.004%	
Delvotest SP/Delvotest SP Mini <sup>++</sup>	118	0	0.000%	
IDEXX New SNAP	203,205	46	0.023%	
Neogen BetaStar	351	0	0.000%	
CLOXACILLIN				
Charm II Test for Cloxacillin in Milk	91	0	0.000%	
ENROFLOXACIN				
Charm SL-Floroquinlone**	12,435	2	0.016%	
MACROLIDES				
Charm II Tablet Sequential - Macrolides**	49	0	0.000%	
MULTIPLE DRUG FAMILY TEST				
Charm FLUSLBL	350	0	0.000%	

### TABLE 6 -- Number of Tests by Method by Family/Drug

October 1, 2012 to September 50, 2015						
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive			
SULFONAMIDES						
Agri-Screen for Sulfonamides** & ***	6,020	2	0.033%			
Charm II Tablet Competitive	151,022	5	0.003%			
Charm II Tablet Sequential**	2,660	0	0.000%			
Charm SL Sulfa Test <sup>**</sup>	54,892	2	0.004%			
TLC Sulfonamide	10	0	0.000%			
SULFAMETHAZINE						
IDEXX SNAP SULFA(SMZ)**	332	0	0.000%			
TETRACYCLINE						
SNAP - Tetracycline**	5,787	1	0.017%			
TETRACYCLINES						
Charm II Tablet Competitive	134,540	8	0.006%			
Charm SL - Tetracyclines**	41,084	4	0.010%			
TOTALS	4,115,774	732	*			

### TABLE 6 -- Number of Tests by Method by Family/DrugOctober 1, 2012 to September 30, 2013

\*\* Non-Validated Test Method

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

FDA evaluated these tests and they do not perform as inbeied-see M-1-99-4 <sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kande-sbcc.com/nmdrd/.

Tests for Sulfonamides and Tetracyclines October 1, 2012 to September 30, 2013						
Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive			
VALIDATED FOR SULFONAMIDES						
Charm II Tablet Competitive	151,022	5	0.003%			
TLC Sulfonamide	10	0	0.000%			
NON-VALIDATED FOR SULFONAMIDES						
Agri-Screen for Sulfonamides <sup>** &amp; ***</sup>	6,020	2	0.033%			
Charm II Tablet Sequential**	2,660	0	0.000%			
Charm SL Sulfa Test <sup>**</sup>	54,892	2	0.004%			
NON-VALIDATED FOR SULFAMETHAZINE						
IDEXX SNAP SULFA(SMZ)**	332	0	0.000%			
VALIDATED FOR TETRACYCLINES						
Charm II Tablet Competitive	134,540	8	0.006%			
NON-VALIDATED FOR TETRACYCLINES						
Charm SL - Tetracyclines**	41,084	4	0.010%			
TOTALS	390,560	21	*			

## TABLE 6A -- Comparison of Validated and Non-Validated

\*\* Non-Validated Test Method
\*\*\* 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, Sulfamethazine, etc., are not included in the Totals for the family of drugs, e.g., Beta lactams, Sulfonamides, etc.

TABLE 7-1 – Grade A Bulk Milk Pickup Tanker TestingOctober 1, 2012 to September 30, 2013							
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	
AMINOGLYCOSIDES	36	0	0	0	36	0	
BETA lactams	3,028,331	398	7,874	3	3,036,205	401	
Cloxacillin	0	0	63	0	63	0	
ENROFLOXACIN	11,394	2	0	0	11,394	2	
MACROLIDES	48	0	0	0	48	0	
MULTIPLE DRUG FAMILY TEST	350	0	0	0	350	0	
SULFONAMIDES	211,973	9	3	0	211,976	9	
Sulfamethazine	38	0	0	0	38	0	
TETRACYCLINE	4,644	1	32	0	4,676	1	
TETRACYCLINES	175,618	12	0	0	175,618	12	
TOTALS	3,432,432	422	7,972	3	3,440,404	425	

## TABLE 7-2 – Grade A Pasteurized Fluid Milk and Milk Products Testing<br/>October 1, 2012 to September 30, 2013

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	1,978	0	36,834	0	38,812	0
SULFONAMIDES	214	0	7	0	221	0
TOTALS	2,192	0	36,841	0	39,033	0

TABLE 7-3 – Grade A Producer Testing October 1, 2012 to September 30, 2013							
Family/DrugNumber of IndustryNumber of PositiveNumber of RegulatoryNumber of PositiveTotal TestsTotal PositiveTestsIndustry TestsIndustry TestsTestsRegulatory TestsTestsTests						Positive	
BETA lactams	336,669	208	106,421	51	443,090	259	
MACROLIDES	0	0	1	0	1	0	
SULFONAMIDES	790	0	36	0	826	0	
TOTALS	337,459	208	106,458	51	443,917	259	

TABLE 7-4 – Grade A Other Testing (Milk from milk plant tanks/silos, milk transport					
tankers, etc.)					
October 1, 2012 to September 30, 2013					

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	34,531	5	9,563	0	44,094	5
Cloxacillin	0	0	28	0	28	0
SULFONAMIDES	1,572	0	3	0	1,575	0
Sulfamethazine	294	0	0	0	294	0
TETRACYCLINE	788	0	323	0	1,111	0
TOTALS	37,185	5	9,917	0	47,102	5

TABLE 7-5 – Non-Grade A Bulk Milk Pickup Tanker Testing
October 1, 2012 to September 30, 2013

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	110,191	21	76	0	110,267	21
ENROFLOXACIN	1,041	0	0	0	1,041	0
SULFONAMIDES	6	0	0	0	6	0
TETRACYCLINES	6	0	0	0	6	0
TOTALS	111,244	21	76	0	111,320	21

TABLE 7-6 – Non-Grade A Pasteurized Fluid Milk and Milk Products Testing         October 1, 2012 to September 30, 2013						
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	1,582	0	63	0	1,645	0
TOTALS	1,582	0	63	0	1,645	0

TABLE 7-7 – Non-Grade A Producer Testing         October 1, 2012 to September 30, 2013										
Family/Drug	Number of Industry Tests	Industry Positive Regulatory Positive Tests Positive								
BETA lactams	23,842	22	160	0	24,002	22				
TOTALS	23,842	22	160	0	24,002	22				

TABLE 7-8 – Non-Grade A Other Testing (Milk from milk plant tanks/silos, milk transport tankers, etc.) October 1, 2012 to September 30, 2013										
Family/Drug	Number of Industry Tests	Industry Positive Regulatory Positive								
BETA lactams	8,293	0	58	0	8,351	0				
TOTALS	8,293	0	58	0	8,351	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.

Та	Table 8-1 Number of Tests by Method by Family/DrugGrade A Bulk Milk Pickup TankerOctober 1, 2012 to September 30, 2013										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
AMINOGLYCOSIDES											
Charm II Tablet Competitive Aminoglycosides <sup>**</sup>	36	0	0	0	36	0	0.0009				
BETA lactams											
Charm 3 SL-3	272,332	33	0	0	272,332	33	0.0129				
Charm BSDA Tablet - Beta lactams <sup>++</sup>	15,931	5	0	0	15,931	5	0.0319				
Charm II Tablet Competitive	99,500	20	66	0	99,566	20	0.0209				
Charm II Tablet Quantitative	0	0	18	0	18	0	0.0009				
Charm II Tablet Sequential	71,510	10	130	0	71,640	10	0.0149				
Charm SL Beta lactams	2,169,635	262	1,726	2	2,171,361	264	0.0129				
Charm SL-6	197,634	21	140	0	197,774	21	0.0119				
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	10,013	5	5,677	1	15,690	6	0.0389				
Delvotest P/Delvotest P Mini <sup>++</sup>	1,585	0	1	0	1,586	0	0.0009				
IDEXX New SNAP	189,840	42	116	0	189,956	42	0.0229				
Neogen BetaStar	351	0	0	0	351	0	0.000				
Cloxacillin											
Charm II Test for Cloxacillin in Milk	0	0	63	0	63	0	0.000				
Enrofloxacin											
Charm SL- Floroquinlone <sup>**</sup>	11,394	2	0	0	11,394	2	0.0189				

Table 8-1 Number of Tests by Method by Family/DrugGrade A Bulk Milk Pickup TankerOctober 1, 2012 to September 30, 2013										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive			
Macrolides										
Charm II Tablet Sequential - Macrolides <sup>**</sup>	48	0	0	0	48	0	0.000%			
Multiple Drug Family Test										
Charm FLUSLBL	350	0	0	0	350	0	0.000%			
Sulfonamides										
Agri-Screen for Sulfonamides <sup>** &amp; ***</sup>	6,020	2	0	0	6,020	2	0.033%			
Charm II Tablet Competitive	149,961	5	3	0	149,964	5	0.003%			
Charm II Tablet Sequential <sup>**</sup>	2,660	0	0	0	2,660	0	0.000%			
Charm SL Sulfa Test <sup>**</sup>	53,332	2	0	0	53,332	2	0.004%			
SULFAMETHAZINE										
IDEXX SNAP SULFA(SMZ)**	38	0	0	0	38	0	0.000%			
Tetracycline										
SNAP - Tetracycline <sup>**</sup>	4,644	1	32	0	4,676	1	0.021%			
Tetracyclines										
Charm II Tablet Competitive	134,534	8	0	0	134,534	8	0.006%			
Charm SL - Tetracyclines**	41,084	4	0	0	41,084	4	0.010%			
TOTALS	3,432,432	422	7,972	3	3,440,404	425	0.012%			

\*\* Non-Validated Test Method \*\*\* FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

<sup>++</sup> NCIMS evaluated these tests and use you in the perform as naceto-see with <sup>+2</sup> <sup>+2</sup> <sup>+4</sup> these sets and use you have the set of the performance of the performan

# Table 8-2 -- Number of Tests by Method by Family/DrugGrade A Pasteurized Fluid Milk and Milk ProductsOctober 1, 2012 to September 30, 2013

	-		F	-	F		
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive
BETA lactams							
Charm BSDA Tablet - Beta lactams <sup>++</sup>	0	0	2,450	0	2,450	0	0.000%
Charm II Tablet Sequential	0	0	520	0	520	0	0.000%
Charm SL Beta lactams	111	0	766	0	877	0	0.000%
Charm SL-6	1,167	0	1,473	0	2,640	0	0.000%
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	507	0	28,329	0	28,836	0	0.000%
Delvotest P/Delvotest P Mini <sup>++</sup>	49	0	2,581	0	2,630	0	0.000%
IDEXX New SNAP	144	0	715	0	859	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	214	0	0	0	214	0	0.000%
TLC Sulfonamide	0	0	7	0	7	0	0.000%
TOTALS	2,192	0	36,841	0	39,033	0	0.000%

<sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

Tal	Table 8-3 Number of Tests by Method by Family/Drug Grade A Producer October 1, 2012 to September 30, 2013										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
BETA lactams											
Charm 3 SL-3	2,793	1	10	0	2,803	1	0.036%				
Charm BSDA Tablet - Beta lactams <sup>++</sup>	6,099	13	1,468	0	7,567	13	0.172%				
Charm II Tablet Competitive	1,171	0	0	0	1,171	0	0.000%				
Charm II Tablet Sequential	0	0	1,769	0	1,769	0	0.000%				
Charm SL Beta lactams	2,452	4	2,501	1	4,953	5	0.101%				
Charm SL-6	3,357	2	1,295	0	4,652	2	0.043%				
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	313,144	186	85,060	50	398,204	236	0.059%				
Delvotest P/Delvotest P Mini <sup>++</sup>	2,767	1	13,965	0	16,732	1	0.006%				
Delvotest SP/Delvotest SP Mini <sup>++</sup>	14	0	0	0	14	0	0.000%				
IDEXX New SNAP	4,872	1	353	0	5,225	1	0.019%				
Macrolides											
Charm II Tablet Sequential - Macrolides <sup>**</sup>	0	0	1	0	1	0	0.000%				
Sulfonamides											
Charm II Tablet Competitive	790	0	36	0	826	0	0.000%				
TOTALS	337,459	208	106,458	51	443,917	259	0.058%				

\*\* Non-Validated Test Method

<sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

### 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, 2012 to September 30, 2013

Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive
BETA lactams							
Charm 3 SL-3	3,373	0	0	0	3,373	0	0.000%
Charm BSDA Tablet - Beta lactams <sup>++</sup>	1,427	0	168	0	1,595	0	0.000%
Charm II Tablet Competitive	129	0	0	0	129	0	0.000%
Charm II Tablet Sequential	0	0	28	0	28	0	0.000%
Charm SL Beta lactams	25,106	5	1,284	0	26,390	5	0.019%
Charm SL-6	2,473	0	167	0	2,640	0	0.000%
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	980	0	6,136	0	7,116	0	0.000%
Delvotest P/Delvotest P Mini <sup>++</sup>	147	0	1,302	0	1,449	0	0.000%
IDEXX New SNAP	896	0	478	0	1,374	0	0.000%
Cloxacillin							
Charm II Test for Cloxacillin in Milk	0	0	28	0	28	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	12	0	0	0	12	0	0.000%
Charm SL Sulfa Test <sup>**</sup>	1,560	0	0	0	1,560	0	0.000%
TLC Sulfonamide	0	0	3	0	3	0	0.000%
SULFAMETHAZINE							
IDEXX SNAP SULFA(SMZ)**	294	0	0	0	294	0	0.000%
Tetracycline							
SNAP - Tetracycline <sup>**</sup>	788	0	323	0	1,111	0	0.000%
TOTALS	37,185	5	9,917	0	47,102	5	0.011%

\*\* Non-Validated Test Method

<sup>1+</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

Table 8-5 Number of Tests by Method by Family/Drug Non-Grade A Bulk Milk Pickup Tanker October 1, 2012 to September 30, 2013											
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
BETA lactams											
Charm 3 SL-3	7,247	2	0	0	7,247	2	0.028%				
Charm II Tablet Competitive	701	0	0	0	701	0	0.000%				
Charm II Tablet Sequential	285	0	0	0	285	0	0.000%				
Charm SL Beta lactams	91,196	16	12	0	91,208	16	0.018%				
Charm SL-6	217	0	0	0	217	0	0.000%				
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	5,786	0	64	0	5,850	0	0.000%				
Delvotest P/Delvotest P Mini <sup>++</sup>	87	0	0	0	87	0	0.000%				
IDEXX New SNAP	4,672	3	0	0	4,672	3	0.064%				
Enrofloxacin											
Charm SL- Floroquinlone**	1,041	0	0	0	1,041	0	0.000%				
Sulfonamides											
Charm II Tablet Competitive	6	0	0	0	6	0	0.000%				
Tetracyclines											
Charm II Tablet Competitive	6	0	0	0	6	0	0.000%				
TOTALS	111,244	21	76	0	111,320	21	0.019%				

#### \*\* Non-Validated Test Method

<sup>11</sup> NCIMS evaluated treatments for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kande-sbcc.com/nmdrd/.

Table 8-6 Number of Tests by Method by Family/Drug Non-Grade A Pasteurized Fluid Milk and Milk Products October 1, 2012 to September 30, 2013											
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
BETA lactams											
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	1,519	0	63	0	1,582	0	0.000%				
Delvotest P/Delvotest P Mini <sup>++</sup>	63	0	0	0	63	0	0.000%				
TOTALS	1,582	0	63	0	1,645	0	0.000%				

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<sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

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Table 8-7 Number of Tests by Method by Family/Drug Non-Grade A Producer October 1, 2012 to September 30, 2013											
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
BETA lactams											
Charm BSDA Tablet - Beta lactams <sup>++</sup>	2,398	3	0	0	2,398	3	0.125%				
Charm SL Beta lactams	96	0	0	0	96	0	0.000%				
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	21,242	19	129	0	21,371	19	0.089%				
Delvotest P/Delvotest P Mini <sup>++</sup>	11	0	22	0	33	0	0.000%				
Delvotest SP/Delvotest SP Mini <sup>++</sup>	95	0	9	0	104	0	0.000%				
TOTALS	23,842	22	160	0	24,002	22	0.092%				

<sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.

### 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, 2012 to September 30, 2013

					F		
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive
BETA lactams							
Charm 3 SL-3	21	0	0	0	21	0	0.000%
Charm SL Beta lactams	4,411	0	1	0	4,412	0	0.000%
Delvotest P 5 Pack - Beta lactams <sup>++</sup>	2,659	0	57	0	2,716	0	0.000%
Delvotest P/Delvotest P Mini <sup>++</sup>	83	0	0	0	83	0	0.000%
IDEXX New SNAP	1,119	0	0	0	1,119	0	0.000%
TOTALS	8,293	0	58	0	8,351	0	0.000%

<sup>++</sup> NCIMS evaluated these kits for detection of beta lactams; however, unless the kits are used with beta lactamase, they do not specifically identify the presence of beta lactams. The reporting of these tests does not make it possible to separate the use/nonuse of beta lactamase. A finding of "Not Found" would indicate the test did not detect any inhibitor for which it is sensitive, including, but not limited to, antibiotics or non-specific inhibitors such as sanitizers. See the technical bulletin on the contractor's website at: www.kandc-sbcc.com/nmdrd/.