NATIONAL MILK DRUG RESIDUE DATA BASE

FISCAL YEAR 2018 ANNUAL REPORT REVISED

October 1, 2017 - September 30, 2018

Submitted by:

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NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2018 ANNUAL REPORT October 1, 2017 - September 30, 2018

INTRODUCTION

The National Milk Drug Residue Data Base (NMDRD) is a voluntary industry reporting program. Mandatory reporting is required by 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 99% of the milk supply in the United States and is regulated through the NCIMS by the 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. Through collaboration with test kit manufacturers and FDA, the contractor is attempting to update the drug code list utilized with the reporting application at least every six months to assure that outdated codes are removed and new test codes have been created for new test kits. The most

recent drug code list can be found on the data base contractor's web site at: https://www.nmdrd.com/.

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: https://www.nmdrd.com/. Fifty-three (53) data reporters utilized the web-based software to submit all or part of their data for the FY 2018 Annual Report.

On July 1, 2017, a pilot project began to test a percentage of bulk milk tankers for tetracyclines. The testing portion of the pilot project is scheduled to be completed on December 31,2018. This Annual Report includes the results of the testing for tetracyclines conducted during FY 2018. Further details regarding the pilot can be found at:

http://ncims.org/programs/appendix-n-pilot-program/. Eighty-one (81) percent of data reporters indicated testing for tetracyclines was performed in their jurisdiction.

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: https://www.nmdrd.com/. All of the Annual Reports are now available in portable document file (pdf), Microsoft Excel and Open Document Spreadsheet (ods) formats.

SUMMARY

This report presents summary data on samples and tests conducted during Fiscal Year 2018 (October 1, 2017 to September 30, 2018). Fifty (50) States and Puerto Rico and two (2) Third Party Certifiers (TPCs) authorized under the International Certification Program (ICP) submitted data for this report. Puerto Rico submitted only partial data for this report. The contractor appreciates the cooperation of all the data reporters for this fiscal year's report.

The Grade "A" Pasteurized Milk Ordinance (PMO), the regulations which govern Regulatory Agencies in the implementation and enforcement of their Grade "A" milk safety program, requires that all bulk milk tankers and/or all raw milk supplies that have not been transported in bulk milk tankers regardless of final use be sampled and analyzed for animal drug residues before the milk is processed. Any bulk milk tanker and/or all raw milk supply that has not been transported in a bulk milk pickup tanker, found positive is rejected for human consumption.

During this period **4,042,567** samples were analyzed for animal drug residues. Of these samples **584** were positive for a drug residue. A total of **4,201,236** tests were reported on the samples for five (5) different groups of families or individual drugs. Twenty-two (22) 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, for example, a bulk milk pickup tanker, or raw milk supply that has not been transported in a bulk milk pickup tanker, producer, milk transport tankers, a silo, etc.

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

Data are reported by four (4) SOURCES OF SAMPLES:

- 1. <u>Bulk Milk Pickup Tanker and/or Raw Milk Supply That Has Not Been Transported in a</u> 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 and cream.
- 3. <u>Producer</u> raw milk obtained from the 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 tank/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 an accredited laboratory by a certified analyst or the milk was rejected on the basis of an initial screening presumptive positive test by the milk processor.

The <u>DISPOSITION per PMO</u> column represents the amount of milk contained in the tanker, raw milk supply that has not been transported in a bulk milk pickup tanker, tank/silo or lot found to be positive and disposed of in accordance with the PMO and/or applicable State regulations.

Table 1

TABLE 1 Sample Results October 1, 2017 to September 30, 2018								
Source of Sample	Total Samples			Disposition per PMO (Pounds)				
Bulk Milk Pickup Tanker	3,598,385	364	0.010%	15,467,000				
Pasteurized Fluid Milk and Milk Products	32,847	4	0.012%	45,000				
Producer	355,732	210	0.059%	384,000				
Other	55,603	6	0.011%	163,000				
TOTALS	4,042,567	584	*	16,059,000				

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 (4) categories. For example, the PMO sets forth specific sampling requirements for Beta lactams testing as follows:

- 1. <u>Bulk Milk Pickup Tanker Samples and/or Raw Milk Supplies That Have Not Been</u>
 <u>Transported In A Bulk Milk Pickup Tanker</u> -- samples are taken on receipt of every tanker load and/or raw milk supply that has not been transported in a bulk milk pickup tanker at a milk receiving facility;
- 2. Pasteurized Fluid Milk and Milk Products -- a minimum of four (4) samples in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, shall be tested for each finished milk or milk product from each milk plant during any consecutive six (6) months;
- 3. <u>Producer</u> -- each producer shall be tested at least four (4) times in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, during any consecutive six (6) 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 Regulatory Agencies. Industry samples are taken by milk plants, 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 Regulatory Agencies.

Table 2

TABLE 2 Industry and Regulatory Samples October 1, 2017 to September 30, 2018								
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	3,377,358	334	45,458	5	3,422,816	339	0.010%	14,479,000
Pasteurized Fluid Milk and Milk Products	1,984	1	30,173	3	32,157	4	0.012%	45,000
Producer	225,331	152	108,509	31	333,840	183	0.055%	332,000
Other	42,538	2	10,258	4	52,796	6	0.011%	163,000
NON-GRADE "A"								
Bulk Milk Pickup Tanker ¹	161,339	24	14,230	1	175,569	25	0.014%	988,000
Pasteurized Fluid Milk and Milk Products	565	0	125	0	690	0	0.000%	0
Producer	18,664	24	3,228	3	21,892	27	0.123%	52,000
Other	2,439	0	368	0	2,807	0	0.000%	0
TOTALS	3,830,218	537	212,349	47	4,042,567	584	*	16,059,000 ²

¹ 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".

Note that this represents 0.01% of the total milk supply of the United States with an annual production of 217 billion pounds.

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 (1) drug residue, the number of tests conducted (4,201,236) is greater than the number of samples (4,042,567). 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, 2017 to September 30, 2018. 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 quantification 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. Several test procedures for tetracyclines became validated at various times during FY 2018. For ease of reporting, all samples conducted using a validated procedure, regardless of the effective date of validation, are reported as validated tests.

Table 3

TABLE 3 Tests Conducted October 1, 2017 to September 30, 2018								
Source of Sample	Total Tests	Number of Positive Tests	Percent Positive					
Bulk Milk Pickup Tanker	3,755,543	364	0.010%					
Pasteurized Fluid Milk and Milk Products	32,890	4	0.012%					
Producer	356,537	210	0.059%					
Other	56,266	6	0.011%					
TOTALS	4,201,236	584	*					

See Table 1 for explanation

Table 3A

TABLE 3A Validated Tests Conducted October 1, 2017 to September 30, 2018								
Source of Sample	Total Tests	Number of Positive Tests	Percent Positive					
Bulk Milk Pickup Tanker	3,550,953	359	0.010%					
Pasteurized Fluid Milk and Milk Products	32,864	4	0.012%					
Producer	356,155	210	0.059%					
Other	51,515	6	0.012%					
TOTALS	3,991,487	579	*					

^{*}See Table 1 for explanation

Table 3B

TABLE 3B Non-Validated Tests Conducted October 1, 2017 to September 30, 2018								
Source of Sample	Total Tests	Number of Positive Tests	Percent Positive					
Bulk Milk Pickup Tanker	204,590	5	0.002%					
Pasteurized Fluid Milk and Milk Products	26	0	0.000%					
Producer	382	0	0.000%					
Other	4,751	0	0.000%					
TOTALS	209,749	5	*					

See Table 1 for explanation

Table 4 presents additional details in terms of the tests conducted by industry and by Regulatory Agencies. Tables 4A and 4B present these data by validated and non-validated tests. Several test procedures for tetracyclines became validated at various times during FY 2018. For ease of reporting, all samples conducted using a validated procedure, regardless of the effective date of validation, are reported as validated tests.

Table 4

TABLE 4 Tests Conducted by Industry and Regulatory Agencies October 1, 2017 to September 30, 2018							
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	3,532,843	334	46,887	5	3,579,730	339	0.009%
Pasteurized Fluid Milk and Milk Products	1,984	1	30,211	3	32,195	4	0.012%
Producer	225,594	152	109,051	31	334,645	183	0.055%
Other	42,787	2	10,456	4	53,243	6	0.011%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	161,523	24	14,290	1	175,813	25	0.014%
Pasteurized Fluid Milk and Milk Products	570	0	125	0	695	0	0.000%
Producer	18,664	24	3,228	3	21,892	27	0.123%
Other	2,655	0	368	0	3,023	0	0.000%
TOTALS	3,986,620	537	214,616	47	4,201,236	584	*

¹ 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

Table 4A

TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2017 to September 30, 2018							
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	3,331,092	329	44,235	5	3,375,327	334	0.010%
Pasteurized Fluid Milk and Milk Products	1,959	1	30,210	3	32,169	4	0.012%
Producer	225,380	152	108,883	31	334,263	183	0.055%
Other	39,240	2	10,403	4	49,643	6	0.012%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	161,336	24	14,290	1	175,626	25	0.014%
Pasteurized Fluid Milk and Milk Products	570	0	125	0	695	0	0.000%
Producer	18,664	24	3,228	3	21,892	27	0.123%
Other	1,504	0	368	0	1,872	0	0.000%
TOTALS	3,779,745	532	211,742	47	3,991,487	579	*

¹ 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

Table 4B

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2017 to September 30, 2018							
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	201,751	5	2,652	0	204,403	5	0.002%
Pasteurized Fluid Milk and Milk Products	25	0	1	0	26	0	0.000%
Producer	214	0	168	0	382	0	0.000%
Other	3,547	0	53	0	3,600	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	187	0	0	0	187	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	1,151	0	0	0	1,151	0	0.000%
TOTALS	206,875	5	2,874	0	209,749	5	*

¹ 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

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. Several test procedures for tetracyclines became validated at various times during FY 2018. For ease of reporting, all samples conducted using a validated procedure, regardless of the effective date of validation, are reported as validated tests.

Table 5

TABLE 5 Number of Tests Conducted by Family/Drug October 1, 2017 to September 30, 2018						
Family/Drug Total Total Tests Positive						
BETA lactams	3,837,729	579				
CLOXACILLIN	24	0				
SULFONAMIDES	56,816	0				
SULFAMETHAZINE	2,379	0				
TETRACYCLINES	304,288	5				
TOTALS	4,201,236	584				

Table 5A

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2017 to September 30, 2018						
Family/Drug Total Tests Total Positive						
BETA lactams	3,837,729	579				
CLOXACILLIN	24	0				
SULFONAMIDES	52,938	0				
TETRACYCLINES	100,796	0				
TOTALS	3,991,487	579				

Table 5B

TABLE 5B Number of Non-Validated Tests Conducted by Family/Drug October 1, 2017 to September 30, 2018						
Family/Drug Total Tests Total Positive						
SULFONAMIDES	3,878	0				
SULFAMETHAZINE	2,379	0				
TETRACYCLINES	203,492	5				
TOTALS	209,749	5				

Table 6 presents details on the tests used. The data in this table are comparable to Table 5, but the data are arranged by <u>tests</u> within each <u>family/drug</u>. Therefore, the Totals are the same in both tables. The Beta lactams testing methods with the largest use were: Charm SL - Beta lactams, which was used more than <u>1.9 million</u> times, Charm 3 SL-3, which was used almost <u>1.3 million</u> times, Delvotest P 5 Pack - Beta lactams, which was used more than <u>371 thousand</u> times, and IDEXX New SNAP, which was used for more than <u>113 thousand</u> tests.

The tetracycline testing methods with the largest use were: Charm SL-Tetracyclines (green strip) and Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip. Although the Charm ROSA Tetracycline-SL (Dillution Confirmation) orange strip was available and validated with a report code of 95, for the entire Pilot Study timeframe, it was found that some plants and States continued to submit incorrectly Code 89 to the NMDRD when the correct code should have been 95. Therefore, the number of tests conducted on the Charm SL-Tetracyclines (green strip) and the Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip may not be accurate, but the combined total of the two (2) tests and positives submitted to the NMDRD are accurate.

In January 2018, the NCIMS conference approved the Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip. It could be estimated that nine (9) months out of the twelve (12) months or three fourths of the tetracycline tests conducted during the timeframe of this report were the Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip for fiscal year 2018. Regardless of whether the Charm Tetra SL- green strip or the Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip were used, for all intended purposes the two tests are equivalent. FDA has confirmed that all the tetracycline positives reported with tests codes 89 (Charm Tetra SL- green strip) and 95 (Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip were confirmed positive on 95 (Charm ROSA Tetracycline-SL (Dilution Confirmation) orange strip. Therefore, all of the tetracycline reported positives were confirmed at the safe tolerance level of 300 ppb (parts per billion).

Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

Table 6

TABLE 6 Number of Tests by Method by Family/Drug October 1, 2017 to September 30, 2018							
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive				
BETA lactams							
Charm 3 SL-3	1,298,405	135	0.010%				
Charm BSDA Tablet - Beta lactams ⁺⁺	29,484	16	0.054%				
Charm II Tablet Competitive	19,196	0	0.000%				
Charm II Tablet Quantitative	162	0	0.000%				
Charm II Tablet Sequential	11,382	2	0.018%				
Charm SL Beta lactams	1,978,629	207	0.010%				
Charm Trio Test-Beta lactams	766	0	0.000%				
Delvotest P 5 Pack - Beta lactams ⁺⁺	371,633	187	0.050%				

TABLE 6 -- Number of Tests by Method by Family/Drug October 1, 2017 to September 30, 2018

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
Delvotest P/Delvotest P Mini ⁺⁺	14,675	4	0.027%
IDEXX New SNAP	113,397	28	0.025%
CLOXACILLIN			
Charm II Test for Cloxacillin	24	0	0.000%
SULFONAMIDES			
Charm II Tablet Competitive	1,130	0	0.000%
Charm II Tablet Sequential **	3,878	0	0.000%
Charm Rosa Sulf-Sulfonamides	51,042	0	0.000%
Charm Trio Test-Sulf	766	0	0.000%
SULFAMETHAZINE			
IDEXX SNAP Sulfa(SMZ)**	2,379	0	0.000%
TETRACYCLINES			
Charm II Tablet Competitive	1,221	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	98,790	0	0.000%
Charm SL - Tetracyclines	196,858	5	0.003%
Charm Trio Test-Tetra	766	0	0.000%
IDEXX SNAP - Tetracycline	6,634	0	0.000%
Neogen BetaStar Advanced For Tetracycline	19	0	0.000%
TOTALS	4,201,236	584	*

See Table 1 for explanation

Non-Validated Test Method

⁺⁺ 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

TABLE 6A -- Comparison of Validated and Non-Validated Tests for Sulfonamides and Tetracyclines October 1, 2017 to September 30, 2018

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	1,130	0	0.000%
Charm Rosa Sulf-Sulfonamides	51,042	0	0.000%
Charm Trio Test-Sulf	766	0	0.000%
NON-VALIDATED FOR SULFONAMIDES			
Charm II Tablet Sequential	3,878	0	0.000%
NON-VALIDATED FOR SULFAMETHAZINE			
IDEXX SNAP Sulfa(SMZ)**	2,379	0	0.000%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	1,221	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	98,790	0	0.000%
Charm Trio Test-Tetra	766	0	0.000%
Neogen BetaStar Advanced For Tetracycline	19	0	0.000%
NON-VALIDATED FOR TETRACYCLINES			
Charm SL - Tetracyclines	196,858	5	0.003%
IDEXX SNAP - Tetracycline -	6,634	0	0.000%
TOTALS	363,483	5	*

See Table 1 for explanation

Non-Validated Test Method

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

TABLE 7-1 Grade "A" Bulk Milk Pickup Tanker Testing October 1, 2017 to September 30, 2018							
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	3,180,116	329	42,827	5	3,222,943	334	
Cloxacillin	0	0	17	0	17	0	
SULFONAMIDES	56,800	0	0	0	56,800	0	
Sulfamethazine	2,236	0	0	0	2,236	0	
TETRACYCLINES	293,691	5	4,043	0	297,734	5	
TOTALS	3,532,843	334	46,887	5	3,579,730	339	

Table 7-2

TABLE 7-2 Grade "A" Pasteurized Fluid Milk and Milk Products Testing October 1, 2017 to September 30, 2018						
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	1,959	1	30,210	3	32,169	4
TETRACYCLINES	25	0	1	0	26	0
TOTALS	1,984	1	30,211	3	32,195	4

Table 7-3

TABLE 7-3 Grade "A" Producer Testing October 1, 2017 to September 30, 2018							
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	225,108	152	108,867	31	333,975	183	
SULFONAMIDES	0	0	16	0	16	0	
Sulfamethazine	43	0	16	0	59	0	
TETRACYCLINES	443	0	152	0	595	0	
TOTALS	225,594	152	109,051	31	334,645	183	

Table 7-4

TABLE 7-4 -- Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.)
October 1, 2017 to September 30, 2018

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	38,240	2	10,394	4	48,634	6
Cloxacillin	0	0	7	0	7	0
SULFONAMIDES						
Sulfamethazine	84	0	0	0	84	0
TETRACYCLINES	4,463	0	55	0	4,518	0
TOTALS	42,787	2	10,456	4	53,243	6

Table 7-5

TABLE 7-5 Non-Grade "A" Bulk Milk Pickup Tanker Testing
October 1, 2017 to September 30, 2018

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	161,259	24	14,290	1	175,549	25
TETRACYCLINES	264	0	0	0	264	0
TOTALS	161,523	24	14,290	1	175,813	25

TABLE 7-6 -- Non-Grade "A" Pasteurized Fluid Milk and Milk Products Testing October 1, 2017 to September 30, 2018

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	570	0	125	0	695	0
TOTALS	570	0	125	0	695	0

Table 7-7

TABLE 7-7 Non-Grade "A" Producer Testing October 1, 2017 to September 30, 2018						
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	18,664	24	3,228	3	21,892	27
TOTALS	18,664	24	3,228	3	21,892	27

Table 7-8

TABLE 7-8 -- Non-Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.) October 1, 2017 to September 30, 2018

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	1,504	0	368	0	1,872	0
TETRACYCLINES	1,151	0	0	0	1,151	0
TOTALS	2,655	0	368	0	3,023	0

Tables 8-1 to 8-8 present details on the number of tests conducted by industry and by 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. Please reference the latest revision of M-a-85 and or test kit approval memoranda (M-I) for tests that are approved/validated or acceptable for testing milk and milk products for regulatory purposes.

Table 8-1

Table 8	Table 8-1 Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pickup Tanker October 1, 2017 to September 30, 2018											
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	1,181,767	116	20,409	3	1,202,176	119	0.010%					
Charm BSDA Tablet - Beta lactams ⁺⁺	22,234	5	2	0	22,236	5	0.022%					
Charm II Tablet Competitive	19,133	0	0	0	19,133	0	0.000%					
Charm II Tablet Quantitative	0	0	1	0	1	0	0.000%					
Charm II Tablet Sequential	11,353	2	22	0	11,375	2	0.018%					
Charm SL Beta lactams	1,825,803	180	18,312	1	1,844,115	181	0.010%					
Charm Trio Test-Beta lactams	766	0	0	0	766	0	0.000%					
Delvotest P 5 Pack - Beta lactams ⁺⁺	10,147	0	3,452	0	13,599	0	0.000%					
Delvotest P/Delvotest P Mini ⁺⁺	2,030	1	180	0	2,210	1	0.045%					
IDEXX New SNAP	106,883	25	449	1	107,332	26	0.024%					
Cloxacillin												
Charm II Test for Cloxacillin	0	0	17	0	17	0	0.000%					
Sulfonamides												
Charm II Tablet Competitive	1,114	0	0	0	1,114	0	0.000%					
Charm II Tablet Sequential	3,878	0	0	0	3,878	0	0.000%					
Charm Rosa Sulf-Sulfonamides	51,042	0	0	0	51,042	0	0.000%					
Charm Trio Test-Sulf	766	0	0	0	766	0	0.000%					
Sulfamethazine												
IDEXX SNAP	2,236	0	0	0	2,236	0	0.000%					

Table 8-1 -- Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pickup Tanker October 1, 2017 to September 30, 2018

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
Sulfa(SMZ)**							
Tetracyclines							
Charm II Tablet Competitive	1,144	0	0	0	1,144	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	96,143	0	1,391	0	97,534	0	0.000%
Charm SL - Tetracyclines	191,310	5	2,041	0	193,351	5	0.003%
Charm Trio Test-Tetra	766	0	0	0	766	0	0.000%
IDEXX SNAP - Tetracycline	4,327	0	611	0	4,938	0	0.000%
Neogen BetaStar Advanced For Tetracycline	1	0	0	0	1	0	0.000%
TOTALS	3,532,843	334	46,887	5	3,579,730	339	0.009%

^{**} Non-Validated Test Method

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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-2

Table 8-2 -- Number of Tests by Method by Family/Drug Grade "A" Pasteurized Fluid Milk and Milk Products October 1, 2017 to September 30, 2018

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	591	1	287	0	878	1	0.114%
Charm BSDA Tablet - Beta lactams ⁺⁺	624	0	626	0	1,250	0	0.000%
Charm SL Beta lactams	14	0	383	0	397	0	0.000%
Delvotest P 5 Pack - Beta lactams ⁺⁺	663	0	28,093	3	28,756	3	0.010%
Delvotest P/Delvotest P Mini ⁺⁺	67	0	258	0	325	0	0.000%
IDEXX New SNAP	0	0	563	0	563	0	0.000%
Tetracyclines							
Charm SL Tetracyclines	25	0	1	0	26	0	0.000%
TOTALS	1,984	1	30,211	3	32,195	4	0.012%

Non-Validated Test Method

Table 8-3

Table 8-3 -- Number of Tests by Method by Family/Drug Grade "A" Producer Testing October 1, 2017 to September 30, 2018

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	7,277	3	1,629	1	8,906	4	0.045%
Charm BSDA Tablet - Beta lactams ⁺⁺	5,067	10	167	1	5,234	11	0.210%
Charm II Tablet Quantitative	0	0	161	0	161	0	0.000%
Charm SL Beta lactams	7,285	9	3,420	1	10,705	10	0.093%
Delvotest P 5 Pack - Beta lactams ⁺⁺	199,726	128	96,945	27	296,671	155	0.052%

⁺⁺ 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-3 -- Number of Tests by Method by Family/Drug Grade "A" Producer Testing October 1, 2017 to September 30, 2018

					<u> </u>		i e
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
Delvotest P/Delvotest P Mini ⁺⁺	4,262	2	6,519	1	10,781	3	0.028%
IDEXX New SNAP	1,491	0	26	0	1,517	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	0	0	16	0	16	0	0.000%
Sulfamethazine							
IDEXX SNAP Sulfa(SMZ)	43	0	16	0	59	0	0.000%
Tetracyclines							
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	261	0	0	0	261	0	0.000%
Charm SL - Tetracyclines	168	0	33	0	201	0	0.000%
IDEXX SNAP - Tetracycline	3	0	119	0	122	0	0.000%
Neogen BetaStar Advanced For Tetracycline	11	0	0	0	11	0	0.000%
TOTALS	225,594	152	109,051	31	334,645	183	0.055%

Non-Validated Test Method

^{++*} 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-4 -- Number of Tests by Method by Family/Drug Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.)

October 1, 2017 to September 30, 2018

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	5,647	0	145	0	5,792	0	0.000%
Charm BSDA Tablet - Beta lactams ⁺⁺	0	0	2	0	2	0	0.000%
Charm II Tablet Competitive	61	0	2	0	63	0	0.000%
Charm II Tablet Sequential	0	0	7	0	7	0	0.000%
Charm SL Beta lactams	30,629	2	2,058	0	32,687	2	0.006%
Delvotest P 5 Pack - Beta lactams ⁺⁺	272	0	8,018	2	8,290	2	0.024%
Delvotest P/Delvotest P Mini ⁺⁺	84	0	25	0	109	0	0.000%
IDEXX New SNAP	1,547	0	137	2	1,684	2	0.119%
Cloxacillin							
Charm II Test for Cloxacillin	0	0	7	0	7	0	0.000%
Sulfamethazine							
IDEXX SNAP Sulfa(SMZ)	84	0	0	0	84	0	0.000%
Tetracyclines							
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	993	0	2	0	995	0	0.000%
Charm SL Tetracyclines	3,040	0	53	0	3,093	0	0.000%
IDEXX SNAP - Tetracycline	423	0	0	0	423	0	0.000%
Neogen BetaStar Advanced For Tetracycline	7	0	0	0	7	0	0.000%
TOTALS	42,787	2	10,456	4	53,243	6	0.011%

^{**} Non-Validated Test Method

⁺⁺ 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-5

Table 8-5 -- Number of Tests by Method by Family/Drug Non-Grade "A" Bulk Milk Pickup Tanker October 1, 2017 to September 30, 2018

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	66,294	10	14,286	1	80,580	11	0.014%
Charm SL Beta lactams	89,800	14	0	0	89,800	14	0.016%
Delvotest P 5 Pack - Beta lactams ⁺⁺	1,736	0	4	0	1,740	0	0.000%
Delvotest P/Delvotest P Mini ⁺⁺	1,128	0	0	0	1,128	0	0.000%
IDEXX New SNAP	2,301	0	0	0	2,301	0	0.000%
Tetracyclines							
Charm II Tablet Competitive	77	0	0	0	77	0	0.000%
Charm SL Tetracyclines	187	0	0	0	187	0	0.000%
TOTALS	161,523	24	14,290	1	175,813	25	0.014%

Non-Validated Test Method

Table 8-6

Table 8-6 -- Number of Tests by Method by Family/Drug Non-Grade "A" Pasteurized Fluid Milk and Milk Products October 1, 2017 to September 30, 2018

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	0	0	52	0	52	0	0.000%
Delvotest P 5 Pack - Beta lactams ⁺⁺	570	0	73	0	643	0	0.000%
Delvotest P/Delvotest P Mini**	0	0	0	0	0	0	0.000%
TOTALS	570	0	125	0	695	0	0.000%

⁺⁺ 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

^{++*}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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-7

Table 8-7 -- Number of Tests by Method by Family/Drug Non-Grade "A" Producer Testing October 1, 2017 to September 30, 2018

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 ⁺⁺	762	0	0	0	762	0	0.000%
Charm SL Beta lactams	72	0	259	0	331	0	0.000%
Delvotest P 5 Pack - Beta lactams ⁺⁺	17,764	24	2,914	3	20,678	27	0.131%
Delvotest P/Delvotest P Mini**	66	0	55	0	121	0	0.000%
TOTALS	18,664	24	3,228	3	21,892	27	0.123%

^{++*} 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/

Table 8-8 -- Number of Tests by Method by Family/Drug Non-Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.)

October 1, 2017 to September 30, 2018

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	10	0	11	0	21	0	0.000%
Charm SL Beta lactams	278	0	316	0	594	0	0.000%
Delvotest P 5 Pack - Beta lactams ⁺⁺	1,215	0	41	0	1,256	0	0.000%
Delvotest P/Delvotest P Mini ⁺⁺	1	0	0	0	1	0	0.000%
Tetracyclines							
IDEXX SNAP - Tetracycline	1,151	0	0	0	1,151	0	0.000%
TOTALS	2,655	0	368	0	3,023	0	0.000%

Non-Validated Test Method

⁺⁺⁺ 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 technical bulletin on the contractor's website at: https://www.nmdrd.com/