NATIONAL MILK DRUG RESIDUE DATABASE FISCAL YEAR 2021 ANNUAL REPORT

October 1, 2020 - September 30, 2021

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5630 Fishers Lane, Room 2129
Rockville, MD 20857

Submitted by:

GLH, Incorporated

501 V.E.S. Road, Suite W225 Lynchburg, VA 24503 434-386-3702

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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" as well as non-Grade "A", which is commonly known as manufacturing grade milk. 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 safe, 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 database is operated by GLH, Incorporated, an independent third party, under contract to the FDA. The database 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 database was designed to promote maximum voluntary participation by the dairy industry in reporting all of their testing results, without compromising any confidential data. The information submitted to the database is not specific to individual firms, but instead consists of numbers of milk drug residue tests organized by categories including test kit method, drug family, and sample type. 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.

FY 2021 ACTIVITIES

Fifty-three (53) data reporters utilized the web-based software implemented on September 1, 2006 to submit all or part of their data for the FY 2021 Annual Report.

Continuing efforts are being made to ensure that there is uniform reporting among all the States and the industry and that the drugs and test methods reported are correct. Through collaboration with test kit manufacturers and the FDA, the contractor is regularly updating the drug code list utilized with the reporting application so that outdated codes are removed and new test codes can be created for new test kits. The most recent revision of the NMDRD Drug Test Kit List was placed on the NMDRD website and in the web-based application on November 4th, 2020. The link for the 11-2020 revision containing all these edits is https://nmdrd.com/DrugCodeList-11-2020.pdf.

During FY 2021, the contractor completed the special task of planning, preparing, and hosting an informational webinar regarding the NMDRD. The webinar project was an outcome of deliberations by the NCIMS Appendix N Modification Committee, which had concluded that an informational webinar would help the states do a better job of uniformly reporting regulatory and industry testing. The contractor developed the webinar content around three key aspects of the database including inputting of drug residue testing data by State reporters and Third-Party Certifiers to the database, processing of this information by GLH, Incorporated staff, and finally, the output of the work in the form of the NMDRD Annual Report. Information was included regarding the background of Appendix N and the NMDRD, common questions received from reporters, and common reporting errors. A question/answer session was included following the formal presentation. The questions and responses were reviewed by the FDA and Appendix N Modification Committee panelists. There were 76 registrations and 54 unique viewers representing 24 states. A link to the YouTube recording of the webinar along with pdf files containing the slides and questions/answers has been posted to https://www.nmdrd.com.

The contractor would like to thank Ms. Laurie Bucher Kurtz (FDA), Dr. Thomas Graham (FDA), Mr. Roger Hooi (Appendix N Modification Committee Chair), and Mr. Frank Barcellos (Webinar Moderator and Appendix N Modification Committee member), for their assistance and support in completing the webinar project.

This annual report and all previous annual reports are available on the contractor's website at: https://www.nmdrd.com. The reports are available in portable document file (pdf) format and the tables only are provided in Microsoft Excel and Open Document Spreadsheet (ods) formats.

SAMPLES AND TESTS REPORTED

This report presents summary data on samples and tests conducted during Fiscal Year 2021 (October 1, 2020 to September 30, 2021). Fifty States, Puerto Rico and two (2) Third Party Certifiers (TPC) authorized under the International Certification Program (ICP) submitted 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 programs, 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 that is found positive is rejected for human consumption.

During this period, **3,894,704** samples were analyzed for animal drug residues. Of these samples **451** were positive for a drug residue. A total of **4,043,513** tests were reported on the samples for four (4) different groups or families of drugs. Since some samples are analyzed for more than one (1) drug residue, the number of tests conducted is greater than the number of samples. During FY 2021, a total of **455** tests were reported as positive for a drug residue. Twenty-three (23) testing methods were used to analyze the samples for drug residues. Key residue findings, by test method and sample source, can be found in Tables 8-1 to 8-8 of this report.

SAMPLE RESULTS

A <u>SAMPLE</u> is defined as representing a load or lot of milk sampled and analyzed. Samples may include, for example, milk collected from a bulk milk pickup tanker, a raw milk supply that has not been transported in a bulk milk pickup tanker, a producer's bulk milk tank, a milk transport tanker, a plant silo, or a pasteurized finished product. 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 Bulk Milk Pickup Tanker</u> bulk raw milk from dairy farm(s).
- 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 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 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</u> per <u>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 <u>PMO</u> and/or applicable State regulations.

Table 1 -- Sample Results

Sample	Total Samples	Source of Number Positive	Percent Positive	Disposition per PMO (Pounds)
Bulk Milk Pickup Tanker	3,494,330	290	0.008%	13,068,000
Pasteurized Fluid Milk and Milk Products	31,009	1	0.003%	1,000
Producer	326,206	160	0.049%	168,000
Other	43,159	0	0.000%	0
TOTALS	3,894,704	451	*	13,237,000

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 -- Industry and Regulatory Samples

Source of	Number	Number of	Number of	Number of	Total	Total	Total	Disposition
Sample	of	Positive	Regulatory	Positive	Samples	Positive	Percent	Per PMO
	Industry	Industry	Samples	Regulatory		Samples	Positive	(Pounds)
	Samples	Samples		Samples				
GRADE "A"								
Bulk Milk Pickup Tanker	3,294,756	268	2,058	2	3,296,814	270	0.008%	12,091,000
Pasteurized Fluid Milk	1,882	0	27,977	0	29,859	0	0.000%	0
and Milk Products								
Producer	199,885	115	111,960	25	311,845	140	0.045%	168,000
Other	30,959	0	9,694	0	40,653	0	0.000%	0
NON-GRADE "A"								
Bulk Milk Pickup Tanker ¹	196,216	19	1,300	1	197,516	20	0.010%	977,000
Pasteurized Fluid Milk	980	0	170	1	1,150	1	0.087%	1,000
and Milk Products								
Producer	13,862	20	499	0	14,361	20	0.139%	0
Other	1,567	0	939	0	2,506	0	0.000%	0
TOTALS	3,740,107	422	154,597	29	3,894,704	451	*	13,237,000 ²

¹ It is a common practice in some states, including two large milk producing states, that bulk milk pickup tankers collect 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".

² Note that this represents 0.006% of the total milk supply of the United States with an annual production of 223 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 (4,043,513) is greater than the number of samples (3,894,704). 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, 2020 to September 30, 2021. 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.

Table 3 -- Tests Conducted by Sample Sources

Source of Sample	Total Tests	Number of Positive Tests	Percent Positive
Bulk Milk Pickup Tanker	3,642,984	290	0.008%
Pasteurized Fluid Milk and Milk Products	31,020	1	0.003%
Producer	326,348	164	0.050%
Other	43,161	0	0.000%
TOTALS	4,043,513	455	*

See Table 1 for explanation

Table 3A -- Validated Tests Conducted

Source of Sample	Total Tests	Number of Positive	Percent Positive
		Tests	
Bulk Milk	3,642,865	290	0.008%
Pickup Tanker			
Pasteurized	31,020	1	0.003%
Fluid Milk and			
Milk Products			
Producer	326,340	164	0.050%
Other	43,148	0	0.000%
TOTALS	4,043,373	455	*

^{*} See Table 1 for explanation

Table 3B -- Non-Validated Tests Conducted

Source of Sample	Total Tests	Number of Positive Tests	Percent Positive
Bulk Milk Pickup Tanker	119	0	0.000%
Pasteurized Fluid Milk and Milk Products	0	0	0.000%
Producer	8	0	0.000%
Other	13	0	0.000%
TOTALS	140	0	*

^{*} 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.

Table 4 -- Tests Conducted by Industry and Regulatory Agencies

Source	Number of	Number of	Number of	Number of	Total	Total	Total Percent
of Sample	Industry	Positive	Regulatory	Positive	Tests	Positive	Positive
-	Tests	Industry	Tests	Regulatory		Tests	
		Tests		Tests			
GRADE "A"							
Bulk Milk Pickup Tanker	3,443,299	268	2,169	2	3,445,468	270	0.008%
Pasteurized Fluid Milk and	1,882	0	27,988	0	29,870	0	0.000%
Milk Products							
Producer	199,909	119	111,990	25	311,899	144	0.046%
Other	30,959	0	9,695	0	40,654	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	196,216	19	1,300	1	197,516	20	0.010%
Pasteurized Fluid Milk and	980	0	170	1	1,150	1	0.087%
Milk Products							
Producer	13,950	20	499	0	14,449	20	0.138%
Other	1,568	0	939	0	2,507	0	0.000%
TOTALS	3,888,763	426	154,750	29	4,043,513	455	*

¹ It is a common practice in some states, including two large milk producing states, that bulk milk pickup tankers collect 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 -- Validated Tests Conducted by Industry and Regulatory Agencies

Source of Sample	Number of Industry	Number of Positive	Number of Regulatory	Number of Positive	Total Tests	Total Positive	Total Percent Positive
	Tests	Industry Tests	Tests	Regulatory Tests		Tests	
GRADE "A"							
Bulk Milk Pickup Tanker	3,443,183	268	2,166	2	3,445,349	270	0.008%
Pasteurized Fluid Milk and Milk Products	1,882	0	27,988	0	29,870	0	0.000%
Producer	199,901	119	111,990	25	311,891	144	0.046%
Other	30,946	0	9,695	0	40,641	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	196,216	19	1,300	1	197,516	20	0.010%
Pasteurized Fluid Milk and Milk Products	980	0	170	1	1,150	1	0.087%
Producer	13,950	20	499	0	14,449	20	0.138%
Other	1,568	0	939	0	2,507	0	0.000%
TOTALS	3,888,626	426	154,747	29	4,043,373	455	*

¹ It is a common practice in some states, including two large milk producing states, that bulk milk pickup tankers collect 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

<u>Table 4B -- Non-Validated Tests Conducted by Industry and Regulatory Agencies</u>

Source	Number of	Number of	Number of	Number of	Total	Total	Total Percent
of Sample	Industry	Positive	Regulatory	Positive	Tests	Positive	Positive
	Tests	Industry	Tests	Regulatory		Tests	
		Tests		Tests			
GRADE "A"							
Bulk Milk Pickup Tanker	116	0	3	0	119	0	0.000%
Pasteurized Fluid Milk and	0	0	0	0	0	0	0.000%
Milk Products							
Producer	8	0	0	0	8	0	0.000%
Other	13	0	0	0	13	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	0	0	0	0	0	0	0.000%
Pasteurized Fluid Milk and	0	0	0	0	0	0	0.000%
Milk Products							
Producer	0	0	0	0	0	0	0.000%
Other	0	0	0	0	0	0	0.000%
TOTALS	137	0	3	0	140	0	*

¹ It is a common practice in some states, including two large milk producing states, that bulk milk pickup tankers collect 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. Tables 5A and 5B present these data by validated and non-validated tests.

Table 5 -- Number of Tests Conducted by Family/Drug

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	3	0
BETA lactams	3,889,444	451
SULFONAMIDES	74,970	4
SULFAMETHAZINE	124	0
TETRACYCLINES	78,972	0
TOTALS	4,043,513	455

Table 5A -- Number of Validated Tests Conducted by Family/Drug

Family/Drug	Total Tests	Total Positive
BETA lactams	3,889,444	451
SULFONAMIDES	74,957	4
TETRACYCLINES	78,972	0
TOTALS	4,043,373	455

Table 5B -- Number of Non-Validated Tests Conducted by Family/Drug

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	3	0
SULFONAMIDES	13	0
SULFAMETHAZINE	124	0
TOTALS	140	0

Table 6 presents details on the tests used, and the total test numbers are the same in both tables. The test numbers for each drug test method are arranged by test method within each drug family. Test methods with the largest use to detect drug residues were: Charm 3 SL-3, used for 1,751,398 tests; Charm SL Beta lactams, used for 1,566,295 tests; Delvotest P 5 Pack, used for 336,393 tests, and IDEXX New SNAP Beta Lactam, used for 98,436 tests.

Table 6 -- Number of Tests by Method by Family/Drug

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
AMINOGLYCOSIDES			
Charm ROSA Gentamicin**	3	0	0.000%
BETA lactams			
Charm 3 SL-3	1,751,398	154	0.009%
Charm BL30SEC	43,246	1	0.002%
Charm BsDA++	7,977	6	0.075%
Charm II Tablet Competitive	12,216	4	0.033%
Charm II Tablet Quantitative	82	0	0.000%
Charm II Tablet Sequential Beta lactams	4,139	0	0.000%
Charm SL Beta lactams	1,566,295	115	0.007%
Charm TRIO - Beta lactams	58,118	0	0.000%
Delvotest P 5 Pack++	336,393	150	0.045%
Delvotest P Mini - Beta lactams++	9,563	0	0.000%
IDEXX New SNAP Beta-Lactam	98,436	21	0.021%
Neogen BetaStar Advanced for	1,581	0	0.000%
Beta-lactams			
SULFONAMIDES			
Charm II Tablet Competitive	23	2	8.696%
Charm II Tablet Sequential**	13	0	0.000%
Charm ROSA Sulfonamides	16,705	1	0.006%
Charm TRIO - Sulfonamides	58,229	1	0.002%
SULFAMETHAZINE			
IDEXX SNAP Sulfamethazine**	124	0	0.000%
TETRACYCLINES			
Charm II Tablet Competitive	211	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.)	14,113	0	0.000%
Orange			
Charm TRIO - Tetracyclines	58,221	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	6,417	0	0.000%
Neogen BetaStar Advanced for Tetracycline	10	0	0.000%
TOTALS	4,043,513	455	*

^{*} 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 shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

<u>Table 6A -- Comparison of Validated and Non-Validated Tests for Sulfonamides and Tetracyclines</u>

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	23	2	8.696%
Charm ROSA Sulfonamides	16,705	1	0.006%
Charm TRIO - Sulfonamides	58,229	1	0.002%
NON-VALIDATED FOR SULFONAMIDES			
Charm II Tablet Sequential**	13	0	0.000%
NON-VALIDATED FOR SULFAMETHAZINE			
IDEXX SNAP Sulfamethazine**	124	0	0.000%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	211	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.)	14,113	0	0.000%
Orange			
Charm TRIO - Tetracyclines	58,221	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	6,417	0	0.000%
Neogen BetaStar Advanced for Tetracycline	10	0	0.000%
TOTALS	154,066	4	*

^{*} 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 present results in terms of Grade "A" and Non-Grade "A" testing.

Table 7-1 -- Grade "A" Bulk Milk Pickup Tanker Testing

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	0	0	3	0	3	0
BETA lactams	3,289,415	266	2,164	2	3,291,579	268
SULFONAMIDES	74,933	2	1	0	74,934	2
Sulfamethazine	116	0	0	0	116	0
TETRACYCLINES	78,835	0	1	0	78,836	0
TOTALS	3,443,299	268	2,169	2	3,445,468	270

Table 7-2 -- Grade "A" Pasteurized Fluid Milk and Milk Products Testing

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests Regulatory Tests		Total Tests	Total Positive Tests
BETA lactams	1,882	0	27,988	0	29,870	0
TOTALS	1,882	0	27,988	0	29,870	0

Table 7-3 -- Grade "A" Producer Testing

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	199,775	119	111,967	23	311,742	142
SULFONAMIDES	0	0	23	2	23	2
Sulfamethazine	8	0	0	0	8	0
TETRACYCLINES	126	0	0	0	126	0
TOTALS	199,909	119	111,990	25	311,899	144

<u>Table 7-4 -- Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.)</u>

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	30,946	0	9,695	0	40,641	0
SULFONAMIDES	13	0	0	0	13	0
TOTALS	30,959	0	9,695	0	40,654	0

Table 7-5 -- Non-Grade "A" Bulk Milk Pickup Tanker Testing

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	196,206	19	1,300	1	197,506	20
TETRACYCLINES	10	0	0	0	10	0
TOTALS	196,216	19	1,300	1	197,516	20

Table 7-6 -- Non-Grade "A" Pasteurized Fluid Milk and Milk Products Testing

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	980	0	170	1	1,150	1
TOTALS	980	0	170	1	1,150	1

Table 7-7 -- Non-Grade "A" Producer Testing

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	13,950	20	499	0	14,449	20
TOTALS	13,950	20	499	0	14,449	20

<u>Table 7-8 -- Non-Grade "A" Other Testing (Milk from Milk plant tanks/silos, milk transport tankers, etc.)</u>

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	1,568	0	939	0	2,507	0
TOTALS	1,568	0	939	0	2,507	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 test within each family/drug_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 for tests that are approved/validated or acceptable for testing milk and milk products for regulatory purposes.

<u>Table 8-1 -- Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pickup</u> Tanker

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 ROSA Gentamicin**	0	0	3	0	3	0	0.000%
BETA lactams							
Charm 3 SL-3	1,605,851	138	498	0	1,606,349	138	0.009%
Charm BL30SEC	30,869	1	0	0	30,869	1	0.003%
Charm BsDA++	2,270	1	0	0	2,270	1	0.044%
Charm II Tablet Competitive	12,216	4	0	0	12,216	4	0.033%
Charm II Tablet Quantitative	82	0	0	0	82	0	0.000%
Charm II Tablet Sequential Beta lactams	4,096	0	0	0	4,096	0	0.000%
Charm SL Beta lactams	1,478,370	104	864	0	1,479,234	104	0.007%
Charm TRIO - Beta lactams	58,118	0	0	0	58,118	0	0.000%
Delvotest P 5 Pack++	2,684	0	780	2	3,464	2	0.058%
Delvotest P Mini - Beta lactams++	3,050	0	3	0	3,053	0	0.000%
IDEXX New SNAP Beta-Lactam	90,312	18	19	0	90,331	18	0.020%
Neogen BetaStar Advanced for Beta-lactams	1,497	0	0	0	1,497	0	0.000%
Sulfonamides							
Charm ROSA Sulfonamides	16,704	1	1	0	16,705	1	0.006%
Charm TRIO - Sulfonamides	58,229	1	0	0	58,229	1	0.002%
Sulfamethazine							
IDEXX SNAP Sulfamethazine**	116	0	0	0	116	0	0.000%
Tetracyclines							
Charm II Tablet Competitive	211	0	0	0	211	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	14,107	0	1	0	14,108	0	0.000%
Charm TRIO - Tetracyclines	58,221	0	0	0	58,221	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	6,296	0	0	0	6,296	0	0.000%
TOTALS	3,443,299	268	2,169	2	3,445,468	270	0.008%

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/

<u>Table 8-2 -- Number of Tests by Method by Family/Drug Grade "A" Pasteurized Fluid Milk</u> and Milk Products

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	1,316	0	4	0	1,320	0	0.000%
Charm BsDA++	0	0	618	0	618	0	0.000%
Charm SL Beta lactams	0	0	145	0	145	0	0.000%
Delvotest P 5 Pack++	542	0	26,698	0	27,240	0	0.000%
Delvotest P Mini - Beta lactams++	0	0	43	0	43	0	0.000%
IDEXX New SNAP Beta-Lactam	24	0	480	0	504	0	0.000%
TOTALS	1,882	0	27,988	0	29,870	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/

Table 8-3 -- Number of Tests by Method by Family/Drug Grade "A" Producer Testing

	1												
Tests Used by Family/Drug	Number	Number	Number of	Number of	Total	Total	Percent						
	of	of	Regulatory	Positive	Tests	Positive	Positive						
	Industry	Positive	Tests	Regulatory		Tests							
	Tests	Industry		Tests									
		Tests											
BETA lactams													
Charm 3 SL-3	5,158	0	243	3	5,401	3	0.056%						
Charm BL30SEC	216	0	0	0	216	0	0.000%						
Charm BsDA++	4,443	5	0	0	4,443	5	0.113%						
Charm II Tablet	0	0	42	0	42	0	0.000%						
Sequential Beta lactams													
Charm SL Beta lactams	8,992	4	4,072	2	13,064	6	0.046%						
Delvotest P 5 Pack++	174,766	109	106,243	18	281,009	127	0.045%						
Delvotest P Mini - Beta	4,000	0	1,362	0	5,362	0	0.000%						
lactams++													
IDEXX New SNAP	2,200	1	5	0	2,205	1	0.045%						
Beta-Lactam													
Sulfonamides													
Charm II Tablet	0	0	23	2	23	2	8.696%						
Competitive													
Sulfamethazine													
IDEXX SNAP	8	0	0	0	8	0	0.000%						
Sulfamethazine**													
Tetracyclines													
Charm ROSA	5	0	0	0	5	0	0.000%						
Tetracycline-SL(Dil.													
Conf.) Orange													
IDEXX SNAP	121	0	0	0	121	0	0.000%						
Tetracycline (Dil. Conf.)													
TOTALS	199,909	119	111,990	25	311,899	144	0.046%						

^{**} 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/

<u>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.)</u>

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	4,184	0	208	0	4,392	0	0.000%
Charm BsDA++	0	0	13	0	13	0	0.000%
Charm II Tablet	0	0	1	0	1	0	0.000%
Sequential Beta lactams							
Charm SL Beta lactams	23,756	0	2,097	0	25,853	0	0.000%
Delvotest P 5 Pack++	1,279	0	7,230	0	8,509	0	0.000%
Delvotest P Mini - Beta lactams++	31	0	7	0	38	0	0.000%
IDEXX New SNAP Beta-Lactam	1,696	0	139	0	1,835	0	0.000%
Sulfonamides							
Charm II Tablet Sequential ^{**}	13	0	0	0	13	0	0.000%
TOTALS	30,959	0	9,695	0	40,654	0	0.000%

^{**} Non-Validated Test Method

<u>Table 8-5 -- Number of Tests by Method by Family/Drug Non-Grade "A" Bulk Milk Pickup Tanker</u>

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	132,636	12	1,291	1	133,927	13	0.010%
Charm BL30SEC	12,161	0	0	0	12,161	0	0.000%
Charm SL Beta lactams	47,098	5	0	0	47,098	5	0.011%
Delvotest P 5 Pack++	133	0	9	0	142	0	0.000%
Delvotest P Mini - Beta lactams++	875	0	0	0	875	0	0.000%
IDEXX New SNAP Beta-Lactam	3,219	2	0	0	3,219	2	0.062%
Neogen BetaStar Advanced for Beta-lactams	84	0	0	0	84	0	0.000%
Tetracyclines							
Neogen BetaStar Advanced for Tetracycline	10	0	0	0	10	0	0.000%
TOTALS	196,216	19	1,300	1	197,516	20	0.010%

^{**} 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/

<u>Table 8-6 -- Number of Tests by Method by Family/Drug Non-Grade "A" Pasteurized Fluid</u> Milk and Milk Products

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++	980	0	170	1	1,150	1	0.087%
TOTALS	980	0	170	1	1,150	1	0.087%

^{**} 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 -- Number of Tests by Method by Family/Drug Non-Grade "A" Producer Testing

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	0	2	0	3	0	0.000%
Charm BsDA++	633	0	0	0	633	0	0.000%
Charm SL Beta lactams	32	0	0	0	32	0	0.000%
Delvotest P 5 Pack++	12,792	20	455	0	13,247	20	0.151%
Delvotest P Mini - Beta lactams++	150	0	42	0	192	0	0.000%
IDEXX New SNAP Beta-Lactam	342	0	0	0	342	0	0.000%
TOTALS	13,950	20	499	0	14,449	20	0.138%

^{**} 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/

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

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	6	0	0	0	6	0	0.000%
Charm SL Beta lactams	641	0	228	0	869	0	0.000%
Delvotest P 5 Pack++	921	0	711	0	1,632	0	0.000%
TOTALS	1,568	0	939	0	2,507	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/