NATIONAL MILK DRUG RESIDUE DATABASE FISCAL YEAR 2020 ANNUAL REPORT

October 1, 2019 - September 30, 2020

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NATIONAL MILK DRUG RESIDUE DATABASE FISCAL YEAR 2020 ANNUAL REPORT October 1, 2019 - September 30, 2020

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 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. However, as State and industry participation in the database has increased, reporting of the number of samples and tests has similarly increased. 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 2020 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 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. This revision includes editing the name and test code for the Charm Amphenical test and changing the test to a validated status. The 2020 revision also includes the addition of the following test kits to the list: the Charm BL30SEC, the Charm ROSA Gentamicin, the Charm ROSA Amphenicol, the Charm ROSA Quinolone, the IDEXX SNAP Gentamicin, the Neogen BetaStar S for Sulfonamides, and the Neogen BetaStar S for Quinolones. The name of the previously titled Enrofloxacin drug family was changed to the Quinolone drug family. The Charm SL-Floroquinolone test name was changed to Charm ROSA Enrofloxacin and the Charm tests for Novobiocin and Spectinomycin were made inactive. Finally, the 11-2020 revision includes a number of edits to the test kit names based upon the recommendations that we received from FDA and the test kit manufacturers. The document containing all these edits is available on the contractor's website at: https://nmdrd.com/DrugCodeList-11-2020.pdf.

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.

SUMMARY AND DISCUSSION

This report presents summary data on samples and tests conducted during Fiscal Year 2020 (October 1, 2019 to September 30, 2020). Fifty States and 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 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 that is found positive is rejected for human consumption.

During this period, **3,870,695** samples were analyzed for animal drug residues. Of these samples **536** were positive for a drug residue. A total of **4,049,727** tests were reported on the samples for three (3) 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 2020, a total of **539** tests were reported as positive for a drug residue. Nineteen (19) 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 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 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 PMO and/or applicable State regulations.

Table 1 -- Sample Results

Sample	Total Samples	Source of Number Positive	Percent Positive	Disposition per PMO (Pounds)
Bulk Milk	3,473,887	334	0.010%	15,370,000
Pickup Tanker				
Pasteurized	26,614	0	0.000%	0
Fluid Milk and				
Milk Products				
Producer	314,679	202	0.064%	497,000
Other	55,515	0	0.000%	0
TOTALS	3,870,695	536	*	15,867,000

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	3,247,033	307	28,266	1	3,275,299	308	0.009%	14,441,000
Pasteurized Fluid Milk	1,869	0	24,069	0	25,938	0	0.000%	0
and Milk Products								
Producer	198,121	146	100,545	38	298,666	184	0.062%	433,000
Other	43,869	0	9,676	0	53,545	0	0.000%	0
NON-GRADE "A"								
Bulk Milk Pickup Tanker ¹	184,974	24	13,614	2	198,588	26	0.013%	929,000
Pasteurized Fluid Milk	291	0	385	0	676	0	0.000%	0
and Milk Products								
Producer	15,730	18	283	0	16,013	18	0.112%	64,000
Other	1,509	0	461	0	1,970	0	0.000%	0
TOTALS	3,693,396	495	177,299	41	3,870,695	536	*	15,867,000 ²

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".

Note that this represents 0.007% of the total milk supply of the United States with an annual production of 218 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 (4,049,727) is greater than the number of samples (3,870,695). 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, 2019 to September 30, 2020. 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	3,652,685	337	0.009%
Pasteurized Fluid Milk and Milk Products	26,674	0	0.000%
Producer	314,852	202	0.064%
Other	55,516	0	0.000%
TOTALS	4,049,727	539	*

See Table 1 for explanation

Table 3A -- Validated Tests Conducted

Source	Total	Number of	Percent
of Sample	Tests	Positive	Positive
		Tests	
Bulk Milk	3,652,672	337	0.009%
Pickup Tanker			
Pasteurized	26,674	0	0.000%
Fluid Milk and			
Milk Products			
Producer	314,852	202	0.064%
Other	55,516	0	0.000%
TOTALS	4,049,714	539	*

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	13	0	0.000%
Pasteurized Fluid Milk and Milk Products	0	0	0.000%
Producer	0	0	0.000%
Other	0	0	0.000%
TOTALS	13	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	3,425,831	310	28,266	1	3,454,097	311	0.009%
Pasteurized Fluid Milk and	1,869	0	24,129	0	25,998	0	0.000%
Milk Products							
Producer	198,276	146	100,563	38	298,839	184	0.062%
Other	43,869	0	9,677	0	53,546	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	184,974	24	13,614	2	198,588	26	0.013%
Pasteurized Fluid Milk and	291	0	385	0	676	0	0.000%
Milk Products							
Producer	15,730	18	283	0	16,013	18	0.112%
Other	1,509	0	461	0	1,970	0	0.000%
TOTALS	3,872,349	498	177,378	41	4,049,727	539	*

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	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	3,425,818	310	28,266	1	3,454,084	311	0.009%
Pasteurized Fluid Milk and	1,869	0	24,129	0	25,998	0	0.000%
Milk Products							
Producer	198,276	146	100,563	38	298,839	184	0.062%
Other	43,869	0	9,677	0	53,546	0	0.000%
NON-GRADE "A"							
Bulk Milk Pickup Tanker ¹	184,974	24	13,614	2	198,588	26	0.013%
Pasteurized Fluid Milk and	291	0	385	0	676	0	0.000%
Milk Products							
Producer	15,730	18	283	0	16,013	18	0.112%
Other	1,509	0	461	0	1,970	0	0.000%
TOTALS	3,872,336	498	177,378	41	4,049,714	539	*

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 4B -- Non-Validated Tests Conducted by Industry and Regulatory Agencies

		1				T	
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	13	0	0	0	13	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%
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	13	0	0	0	13	0	*

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
BETA lactams	3,863,002	534
SULFONAMIDES	89,726	5
SULFAMETHAZINE	13	0
TETRACYCLINES	96,986	0
TOTALS	4,049,727	539

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

Family/Drug	Total Tests	Total
		Positive
BETA lactams	3,863,002	534
SULFONAMIDES	89,726	5
TETRACYCLINES	96,986	0
TOTALS	4,049,714	539

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

Family/Drug	Total Tests	Total Positive	
SULFAMETHAZINE	13	0	
TOTALS	13	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 SL Beta lactams, which was used for more than 1.7 million tests, Charm 3 SL-3, was used for more than 1.6 million tests, Delvotest P 5 Pack, used for nearly 3.26 thousand tests, and IDEXX New SNAP Beta lactam, used for nearly 95 thousand tests.

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

Tests Used by Family/Drug	Number of	Number Positive	Percent Positive
BETA lactams	Tests	Positive	Positive
Charm 3 SL-3	1,610,067	173	0.011%
Charm BsDA ⁺⁺	9,170	7	0.076%
Charm II Tablet Competitive	11,944	2	0.017%
Charm II Tablet Sequential Beta lactams	4,438	1	0.023%
Charm SL Beta lactams	1,733,919	141	0.008%
Charm TRIO - Beta lactams	53,055	4	0.008%
Delvotest P 5 Pack ⁺⁺	325,787	172	0.053%
Delvotest P Mini - Beta lactams ⁺⁺	18,251	7	0.038%
IDEXX New SNAP Beta-Lactam	94,847	27	0.028%
Neogen BetaStar Advanced for	1,524	0	0.000%
Beta-lactams			
SULFONAMIDES			
Charm II Tablet Competitive	18	0	0.000%
Charm ROSA Sulfonamides	36,527	2	0.005%
Charm TRIO - Sulfonamides	53,175	3	0.006%
TLC Sulfonamide	6	0	0.000%
SULFAMETHAZINE			
IDEXX SNAP Sulfamethazine**	13	0	0.000%
TETRACYCLINES			
Charm II Tablet Competitive	433	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.)	38,685	0	0.000%
Orange			
Charm TRIO - Tetracyclines	53,075	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	4,793	0	0.000%
TOTALS	4,049,727	539	*

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	18	0	0.000%
Charm ROSA Sulfonamides	36,527	2	0.005%
Charm TRIO - Sulfonamides	53,175	3	0.006%
TLC Sulfonamide	6	0	0.000%
NON-VALIDATED FOR SULFAMETHAZINE			
IDEXX SNAP Sulfamethazine**	13	0	0.000%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	433	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.)	38,685	0	0.000%
Orange			
Charm TRIO - Tetracyclines	53,075	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	4,793	0	0.000%
TOTALS	186,725	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 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
BETA lactams	3,243,594	305	23,927	1	3,267,521	306
SULFONAMIDES	89,577	5	0	0	89,577	5
Sulfamethazine	13	0	0	0	13	0
TETRACYCLINES	92,647	0	4,339	0	96,986	0
TOTALS	3,425,831	310	28,266	1	3,454,097	311

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	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	1,869	0	24,129	0	25,998	0
TOTALS	1,869	0	24,129	0	25,998	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	198,276	146	100,545	38	298,821	184
SULFONAMIDES	0	0	18	0	18	0
TOTALS	198,276	146	100,563	38	298,839	184

<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	43,744	0	9,677	0	53,421	0
SULFONAMIDES	125	0	0	0	125	0
TOTALS	43,869	0	9,677	0	53,546	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	184,974	24	13,614	2	198,588	26
TOTALS	184,974	24	13,614	2	198,588	26

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	291	0	385	0	676	0
TOTALS	291	0	385	0	676	0

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	15,730	18	283	0	16,013	18
TOTALS	15,730	18	283	0	16,013	18

<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	1,509	0	455	0	1,964	0
SULFONAMIDES	0	0	6	0	6	0
TOTALS	1,509	0	461	0	1,970	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.

<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
BETA lactams							
Charm 3 SL-3	1,435,758	150	3,590	0	1,439,348	150	0.010%
Charm BsDA ⁺⁺	3,341	0	0	0	3,341	0	0.000%
Charm II Tablet Competitive	11,944	2	0	0	11,944	2	0.017%
Charm II Tablet Sequential Beta lactams	4,390	1	12	0	4,402	1	0.023%
Charm SL Beta lactams	1,631,916	122	19,681	1	1,651,597	123	0.007%
Charm TRIO - Beta lactams	53,055	4	0	0	53,055	4	0.008%
Delvotest P 5 Pack++	8,796	1	445	0	9,241	1	0.011%
Delvotest P Mini - Beta lactams ⁺⁺	3,377	0	0	0	3,377	0	0.000%
IDEXX New SNAP Beta-Lactam	89,493	25	199	0	89,692	25	0.028%
Neogen BetaStar Advanced for Beta-lactams	1,524	0	0	0	1,524	0	0.000%
Sulfonamides							
Charm ROSA Sulfonamides	36,402	2	0	0	36,402	2	0.005%
Charm TRIO - Sulfonamides	53,175	3	0	0	53,175	3	0.006%
Sulfamethazine							
IDEXX SNAP Sulfamethazine	13	0	0	0	13	0	0.000%
Tetracyclines							
Charm II Tablet Competitive	433	0	0	0	433	0	0.000%
Charm ROSA Tetracycline-SL(Dil. Conf.) Orange	38,685	0	0	0	38,685	0	0.000%
Charm TRIO - Tetracyclines	53,075	0	0	0	53,075	0	0.000%
IDEXX SNAP Tetracycline (Dil. Conf.)	454	0	4,339	0	4,793	0	0.000%
TOTALS	3,425,831	310	28,266	1	3,454,097	311	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/

<u>Table 8-2 -- Number of Tests by Method by Family/Drug Grade "A" Pasteurized Fluid Milk and Milk Products</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	1,320	0	0	0	1,320	0	0.000%
Charm BsDA ⁺⁺	0	0	454	0	454	0	0.000%
Charm SL Beta lactams	0	0	196	0	196	0	0.000%
Delvotest P 5 Pack++	506	0	22,725	0	23,231	0	0.000%
Delvotest P Mini - Beta lactams++	43	0	299	0	342	0	0.000%
IDEXX New SNAP Beta-Lactam	0	0	455	0	455	0	0.000%
TOTALS	1,869	0	24,129	0	25,998	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

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	4,161	3	42	3	4,203	6	0.143%
Charm BsDA ⁺⁺	4,627	7	159	0	4,786	7	0.146%
Charm II Tablet Sequential Beta lactams	1	0	35	0	36	0	0.000%
Charm SL Beta lactams	7,167	8	2,100	3	9,267	11	0.119%
Delvotest P 5 Pack ⁺⁺	169,603	122	96,437	31	266,040	153	0.058%
Delvotest P Mini - Beta lactams++	11,511	6	1,771	1	13,282	7	0.053%
IDEXX New SNAP Beta-Lactam	1,206	0	1	0	1,207	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	0	0	18	0	18	0	0.000%
TOTALS	198,276	146	100,563	38	298,839	184	0.062%

^{**} 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	5,186	0	91	0	5,277	0	0.000%
Charm BsDA ⁺⁺	0	0	15	0	15	0	0.000%
Charm SL Beta lactams	33,740	0	2,071	0	35,811	0	0.000%
Delvotest P 5 Pack**	3,612	0	7,329	0	10,941	0	0.000%
Delvotest P Mini - Beta lactams++	45	0	44	0	89	0	0.000%
IDEXX New SNAP Beta-Lactam	1,161	0	127	0	1,288	0	0.000%
Sulfonamides							
Charm ROSA Sulfonamides	125	0	0	0	125	0	0.000%
TOTALS	43,869	0	9,677	0	53,546	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/

<u>Table 8-5 -- Number of Tests by Method by Family/Drug Non-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
BETA lactams							
Charm 3 SL-3	146,322	15	13,597	2	159,919	17	0.011%
Charm SL Beta lactams	35,977	7	12	0	35,989	7	0.019%
Delvotest P 5 Pack++	33	0	5	0	38	0	0.000%
Delvotest P Mini - Beta lactams++	671	0	0	0	671	0	0.000%
IDEXX New SNAP Beta-Lactam	1,971	2	0	0	1,971	2	0.101%
TOTALS	184,974	24	13,614	2	198,588	26	0.013%

^{**}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**	291	0	385	0	676	0	0.000%
TOTALS	291	0	385	0	676	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 8-7 -- 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 BsDA ⁺⁺	574	0	0	0	574	0	0.000%
Charm SL Beta lactams	41	0	1	0	42	0	0.000%
Delvotest P 5 Pack**	14,437	18	236	0	14,673	18	0.123%
Delvotest P Mini - Beta lactams ⁺⁺	444	0	46	0	490	0	0.000%
IDEXX New SNAP Beta-Lactam	234	0	0	0	234	0	0.000%
TOTALS	15,730	18	283	0	16,013	18	0.112%

^{**} 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 SL Beta lactams	742	0	275	0	1,017	0	0.000%
Delvotest P 5 Pack ⁺⁺	767	0	180	0	947	0	0.000%
Sulfonamides							
TLC Sulfonamide	0	0	6	0	6	0	0.000%
TOTALS	1,509	0	461	0	1,970	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/