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Michigan Department of Agriculture and Rural Development

PMO Drug Residue Screening Procedures Manual

Food and Dairy Division
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Who can screen?

Approved Industry Analyst (IA)
Approved Industry Supervisor (IS)
Certified NCIMS Laboratory Analyst (CA)
Certified NCIMS Industry Supervisor (CIS)

Who can train those who screen?

The State Milk Laboratory Evaluation Officer (LEO) trains the Approved Industry Supervisors (IS) and Certified Industry Supervisors (CIS). The Approved Industry Supervisor or Certified Industry Supervisor trains the Industry Analysts and submits training documentation (DY 332) to the LEO for confirmation and approval.

What methods can be used for screening?

Only those beta lactam test methods for use under PMO Appendix N approved and listed in the current revision of M-a-85 may be used. They include:

Charm *B.stearothermophilis* tablet Disc Assay
Charm II Tablet Beta-Lactam (Competitive Assay)
Charm II Tablet Beta-Lactam (Sequential Assay)
Charm II Tablet Beta-Lactam Test (Quantitative Assay)
Charm SL Beta-Lactam Test
Charm 3SL3 Beta-Lactam Test
Charm FLUSLBL Flunixin and Beta Lactam Test
Delvotest P 5 Pack (Visual and Reader)
Delvotest Test P/Delvotest P Mini (Visual)
Delvotest SP/Delvotest SP Mini (Visual)
Neogen Beta Star Plus Beta-Lactam Test
New Snap Beta-Lactam Test Kit

What procedures are used for screening?

A bulk milk tanker load sample is collected by a licensed or Appendix N evaluated sampler and screened using an appropriate test method listed above. Testing facilities must check reader calibration with check devices, if applicable, and run a positive and negative control daily on days of testing and take corrective action if the appropriate results are not obtained prior to the load sample being tested. **An initial test is run on the load sample. If the test result is positive, it is recognized as an initial positive load sample. Additional required tests are run on the same initially positive sample in duplicate with additional reader instrument calibration check devices along with positive and negative controls. If the controls give the correct results and one or both of the duplicate samples give a positive result, the load is determined to be presumptive positive**. Re-sampling or re-testing is not allowed except for legitimate reasons that can be documented, justified and approved through the Michigan Department of Agriculture and Rural Development (MDARD), Food/Dairy Division, Dairy Section using the form DY 322. All initial positive and presumptive positive test results are recorded on form DY 319 and **must** be reported immediately to MDARD-Lansing (FAX 517-373-9742 or email: mda-dairyinfo@michigan.gov) even if the load is **not** determined to be presumptive positive. The original, completed DY 319, along with the presumptive positive load sample, temperature control sample and all representative producer samples accompany the presumptive positive load to an

accredited laboratory for load confirmation and producer sample drug residue trace back. If the buyer so chooses, the load may be disposed of at this point without any further testing, but producer trace back **is** still required.

Who takes control of the presumptive positive load?

The MDARD policy is for all presumptive positive loads to remain under control of the milk handler or cooperative and to follow protocols written and submitted in advance as a Memorandum of Understanding (DY 325) to MDARD by the milk handler, processor or cooperative. These protocols will provide information as to where the presumptive positive load samples are to be confirmed and where producer trace back and producer confirmation will be performed from each screening site that their milk enters. MDARD retains the right to take control of any presumptive positive load.

Who can confirm a presumptive positive load sample?

Confirmation of a presumptive positive load sample may be made at either a National Conference on Interstate Milk Shipments (NCIMS) approved laboratory or certified industry supervisor (CIS) site accredited to perform the same or equivalent test method. These locations are listed in the "IMS LIST OF SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS" under Milk Laboratories approved by Federal and state agencies at https://www.accessdata.fda.gov/scripts/ims/mkex/ims/imslb-ce.cfm#MI. Test results will be recorded on form DY 319 and reported immediately to MDARD-Lansing using the above FAX or email address.

What methods can be used for regulatory confirmation of a positive sample?

The same test method as was used for screening or an equivalent test method can be used for confirmation. An equivalent test method will detect at least the same Beta-lactam drugs as the original test method at the target testing levels or below, refer to current M-a-85. A table for determination of equivalence is found in the current M-I-96-10. The **Load Confirmation** results are obtained by testing the presumptive positive load sample in duplicate along with reader calibrator/check devices if applicable, and positive and negative controls. Re-sampling is not allowed except for legitimate reasons that can be documented (DY 322), justified and approved through MDARD. In cases where a presumptive positive test result is obtained using a visual test such as Charm BsDa, Delvotest 5 pack or Delvotest P/SP, which are not Beta-lactam specific test methods, a non-Beta lactam drug residue can cause a positive test result. An equivalent Beta-lactam test method may be used for confirmation but if both duplicate test results are negative (NF) then the sample is required to be re-tested in duplicate for confirmation using the same visual test method originally used to determine the presumptive positive.

What reports are required for producers?

All producer samples represented in a **confirmed load** must be tested at a NCIMS Accredited Laboratory or Certified Industry Supervisor site using the same or an equivalent drug residue test used to produce the load confirmation results. A **confirmed positive producer test** result is obtained in the same manner as a confirmed load. After an initial positive producer result is obtained, the same sample is promptly tested in duplicate with the same test method along with reader calibrator/check devices if applicable, and positive and negative controls. Results of the producer trace back testing must be reported on form DY 319 to MDARD- Lansing. Any positive producer sample results must be reported to MDARD- Lansing on form DY 320. A negative follow-up on the producer is also reported on the DY 320.

What forms are required at an approved screening site?

DY 318-Drug Residue Load Screening Log

Each load of raw milk received must be entered on this form along with the results from the screening test on that load. Industry supervisors may modify this form to include additional information and these modified forms are acceptable if they include the information required on the most recent version and have been approved by the LEO.

DY 319-Positive Load Drug Residue Screening Report

Load and producer information is reported on this form when a load is screened initial positive or presumptive positive. This form is also used to report load confirmation and producer trace back information. The information needs to be reported by FAX (517-373-9742) or email: mda-dairyinfo@michigan.gov to MDARD- Lansing as soon as possible. This also applies to weekends and holidays.

DY 322-Request to Resample

Required at all drug residue screening sites and is used in rare instances when requesting to obtain MDARD approval to resample the incoming load of raw milk.

DY 325-Memorandum of Understanding between the milk owner, buyer or marketing entity and the Michigan Department of Agriculture and Rural Development

Required to document the source of the incoming milk to each processing facility as well as to document where the loads of milk are screened and confirmed including producer trace back, producer confirmation and negative follow up testing.

DY 327-Verification of Disposal for Confirmed Positive Antibiotic Milk

This form is used to identify the location and disposal method for confirmed positive antibiotic milk. Someone who witnessed the disposal verifies the disposal was made at the specific location. Spot checks may be made by MDARD inspectors during or after disposals to verify proper disposal.

DY 330-Monthly Residue Screening Report

The information on this form is used in the National Milk Drug Residue DataBase and is a summary of milk samples screened each month and submitted to the LEO. This data and additional information from any completed DY 319 and DY 320 is used by MDARD to submit a quarterly summary to the national database.

DY 331-Inspectors's Review of Drug Screening Procedures

State inspectors are to review screening procedures at each screening site every three months usually completed during a routine inspection. They will complete this form and leave a copy. They will check to see that trained Industry Analysts/Industry Supervisors are running the tests and that the test procedures, record keeping and the procedures on the Appendix N 2400 series test forms are being followed.

DY 332-Industry Supervisor Record of Training/Evaluation of Industry Analysts

Required at all drug residue screening sites. It must be maintained to document training of current Industry Analysts by the Industry Supervisor. Copy must be received, approved and confirmed by LEO before the Industry Analyst may conduct official screening of loads of milk. Any removal of Industry Supervisors or Industry Analysts must be promptly reported to the LEO using the Laboratory Status Change Form.

DY 333-Training Confirmation and Approval for Industry Analyst

Used to confirm receipt of DY 332 and confirmation of training and approval for each Industry Analyst by the LEO. A copy must be received by the Industry Supervisor from the LEO before an Industry Analyst may officially screen loads of milk or participate in either split samples or an on-site evaluation.

DY 356-Hauler/Sampler and Milk Tank Truck Inspection

Used by the MDARD inspector to document the evaluation of licensed bulk milk hauler/samplers and Appendix N evaluated samplers. Any person obtaining the Appendix N load sample must either be a licensed hauler/sampler or an Appendix N evaluated sampler.

General Requirements Appendix N Bulk Milk Tanker Screening Test Form (2400 series)

This instruction sheet states the general requirements for all laboratories regardless of the test method for which they are approved. General Requirements contains sections such as, Work Area, Storage Space, Thermometers, Refrigerators, Freezers, Sample Requirements and Follow up testing after initial positive test results. It is also used as a check sheet by the LEO when evaluating proficiency of a screening site.

Test Specific Appendix N Bulk Milk Tanker Screening Test Form (2400 series)

This instruction sheet is specific to the screening test being used and provides procedural, facility, equipment and record keeping requirements necessary for performing the test method. It is also used as a check sheet by the LEO when evaluating proficiency of a screening site.

Michigan Department of Agriculture Drug Residue Program Procedures Supplement to M-a-86

This document details Appendix N requirements specifically using the MDARD DY Appendix N reporting forms, gives MDARD contact information and states Michigan's annual proficiency test (split sample) date.

Laboratory Status Change Form

This form is used to keep the LEO informed as to changes at the laboratory such as dropping an analyst, name changes, equipment changes, contact information change etc.

Temperature Check Log

Used to document the daily temperature checks for the laboratory including ambient, refrigerator, freezer and incubator temperatures.

Annual Thermometer Accuracy Check Log

Used to document the annual NIST traceable ice point check, initial and annual accuracy check of all laboratory testing thermometers.

Test Kit Suitability Log

Used to document the suitability testing of each new lot of test kits received prior to the test kit being used for official testing.

Positive and Negative Control Suitability Log

Used to document the suitability testing of each new lot of positive and negative controls prior to the controls being used as daily positive and negative controls.

In addition to the forms above, the following forms are also required at confirmation sites:

DY 320-Drug Residue Positive Producer Report

This form is used to report a producer's positive test result and also to report a producer's negative follow-up test result. Normally, the positive producer's information will be sent prior to the negative producer's follow-up test result.

DY 326- Buyer's Verification of Producer Payment for Contaminated Positive Antibiotic Milk

A person responsible to the milk handler or cooperative completes this form. It verifies that a positive producer has paid for the entire load of contaminated milk that was shipped and confirmed positive, plus any costs of disposal. It is also used to verify that the violative producer's milk was not picked up until milk in their bulk tank confirmed negative.

DY 327-Verification of Disposal for Confirmed Positive Antibiotic Milk

- **Milk for Veal:** Milk contaminated with Beta-lactam drug residues can be sold as feed to veal operations under a Commercial Feed License if the confirmed positive load sample can be diluted 1:100 with known negative raw milk and tests negative. The calves must be held for at least 45 days prior to slaughter. If you have any questions regarding this, please contact the LEO.
- **1:100 Dilution Worksheet:** This worksheet is used to document the 1:100 dilution of the confirmed positive load sample with known negative milk and subsequent testing.

Who collects the producer bulk tank sample for a negative follow up?

An official sampler is required to collect the sample for follow up testing. An official sampler can be a certified industry fieldperson/sampler;a State inspector;a licensed bulk milk hauler/sampler or an evaluated sampler. Normally, the certified industry fieldperson/sampler collects the follow up sample.

Where can follow up tests be run?

An approved NCIMS Accredited Laboratory or Certified Industry Supervisor Site is required to conduct all official follow up tests.

What test kits can be used for the negative follow up?

When a producer's bulk milk tank sample is confirmed positive as a result of PMO Section 6 or Appendix N testing, a follow up bulk tank sample must be run before the producer's permit is reinstated. The same or equivalent test per FDA memorandum M-I-96-10 (latest revision) may be used for this negative follow up or clearing test.

If the producer's sample is confirmed positive with a Delvotest 5-pack, Delvotest P or Delvotest SP, special conditions below dictate when an equivalent test may be used.

1. If the Delvotest result is reported as "*positive for inhibitor*" during Section 6 testing (Beta Lactamase step was **not** used); the Delvotest must be used for the follow-up test.
2. If the Delvotest result is reported as "*positive, other than Beta lactam" during Appendix N testing (Beta Lactamase step **was** used);* the Delvotest must be used for the follow-up test.
3. If the Delvotest result is reported as "*positive, Beta lactam" during Appendix N testing (Beta Lactamase step **was** used),* any equivalent test (per M-I-96-10 latest revision) may be used for the follow up test.

What forms are required for out-of-state screening and confirmation sites?

Out-of-state sites can use the DY forms from the MDARD or they may choose to use the forms that they are more familiar with **as long as the required information is complete** and a contact person is listed.

What is the State Milk Laboratory Evaluation Officer's (LEO) Responsibility?

The State Milk LEO is responsible for providing training for Industry Supervisors/Certified Industry Supervisors and maintaining a current listing of Industry Supervisors/Certified Industry Supervisors and Industry Analysts. The State LEO shall biennially verify each Industry Supervisor's program for drug residue testing and proficiency. The proficiency of an Industry Analyst's performance shall be verified by annual split samples and on-site evaluation at least every two (2) years.

What is a state inspector's responsibility?

A state inspector is responsible for: **reviewing and evaluating** procedures at drug screening sites every three (3) months and recording the information on form DY 331; if available, biennially evaluating the proficiency of the drug residue screening site in cooperation with the State LEO; spot-checking disposal sites for confirmation that loads of positive antibiotic milk are disposed of properly (observations can be reported on a DY 327,inspection sheet or special report and be sent to the MDARD Lansing Office); collecting samples required for PMO Section 7 and if needed, for PMO Appendix N; investigating and reporting circumstances of a positive drug residue on DY 321.

What samples need to be collected?

Industry and regulatory share the responsibility of sample collection for the following three PMO sections that call for antibiotic testing.

Section 6: Official samplers and licensed bulk milk hauler/samplers collect samples from farm bulk tanks. These samples are required to be checked at least 4 out of every 6 months for Beta-lactam drug residues.

Section 7: State inspectors that are certified samplers collect raw milk and pasteurized finished product samples from dairy plants. These samples are required to be checked at least 4 out of every 6 months for Beta-lactam drug residues.

Appendix N: At the first receiving point, (dairy plant, receiving or transfer station), every bulk milk tanker must be sampled by a licensed hauler/sampler or Appendix N evaluated sampler and screened for Beta-lactam drug residues prior to commingling with other milk. Sampling and testing of a defined volume of milk is required in the case of producer-handlers prior to processing. **This is required for all Grade A-IMS milk regardless of whether the receiving point is IMS listed.** MDARD follows this same protocol for non-IMS listed Grade A milk and Manufacturing Grade Milk both in bulk and can shipments.

What drug residue test methods are used for PMO Section 6 and 7 samples?

Both sections of the PMO specify the use of approved tests such as the Charm *B. stearothermophilus* disc assay or the Delvotest 5 Pack. In addition, the State has been given the discretion to allow, **and will allow,** the use of Appendix N screening tests when a faster method is desired. See M-a-85 (latest revision) for the complete list of approved drug residue test methods.

What are the procedures for running monthly Section 6 producer samples?

Producer samples are run similar to Appendix N samples. When a producer sample “screens” positive, duplicate tests are then run along with reader calibrators/check devices (if applicable) and positive and negative controls. If the controls give the correct response and either one or both of the duplicate samples tests positive, the sample is considered confirmed positive.

If the Delvotest result was positive for a producer sample under PMO Section 6 testing, an equivalent Beta-lactam specific test can be used for the producer confirmation test. If neither of the duplicate Beta-lactam specific confirmation test results are positive, the producer’s sample must be re-tested in duplicate using the Delvotest for confirmation.

Copies of the required forms may be obtained from the State Milk Laboratory Evaluation Officer.