PMO Drug Residue Screening Procedures Manual

Who can screen?

Approved Industry Analyst
Approved Industry Supervisor
Certified NCIMS Laboratory Analyst
Certified NCIMS Industry Supervisor

Who can train those who screen?

The State Lab Evaluation Officer (LEO) trains the Approved Industry Supervisors and Certified Industry Supervisors. The Approved Industry Supervisor or Certified Industry Supervisor trains the Industry Analysts and submits training documentation to the LEO for confirmation and approval.

What methods can be used for screening?

Only those tests 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 I / Cowside II Tablet Beta-Lactam Test
Charm SL Beta-Lactam Test
Charm II Tablet Beta-Lactam Test (Quantitative Assay)
Charm II Tablet Transit Beta-Lactam Test
Charm I / Cowside II Test for Cloxacillin in Milk (Competitive Assay)
Charm II Test for Cloxacillin in Milk (Competitive Assay)
Charm II Tetracycline Drug Test*(Competitive Assay)
Charm II Sulfa Drug Test*(Competitive Assay)
Delvotest P 5 Pack
Delvotest Test P/Delvotest P Mini
Delvotest SP/Delvotest SP Mini
Delvo-X-Press Beta-Lactam Residue Test Kit
Penzyme Milk Test
Penzyme III Test Procedure
Snap Beta-Lactam Test Kit (Reader)
Snap Beta-Lactam Test Kit (Visual)
Parallux Beta-Lactam Assay

*Non-Beta-Lactam Screening Tests
What procedures are used for screening?

A bulk tank truckload sample is collected by a licensed or evaluated sampler and screened, using an appropriate test method listed above. **An initial test is run on the load sample and if it tests positive, additional tests are run on the same sample in duplicate with positive and negative controls. If the controls give the correct responses and one or both of the duplicate samples give a positive result, the load is considered presumptive positive.** Re-sampling or re-testing is not allowed except for legitimate reasons that can be documented and justified. The results of any initial positive are recorded on form DY319 and **must** be reported immediately to the Michigan Department of Agriculture Dairy Section (MDA) - Lansing (FAX 517-373-3792, business hours phone 517-373-1060, or after hours phone 517-373-9743) even if the load is **not** considered presumptive positive. The screening site must run positive and negative controls daily and take corrective action if the appropriate responses are not obtained on the controls. A copy of the form DY319, with the presumptive positive results recorded, will be sent with the presumptive positive load or load sample and provided to the Certified Analyst or Certified Supervisor performing the testing for load confirmation. If the buyer so chooses, the load may be disposed of at this point without any further testing.

Who takes control of the presumptive positive load?

The MDA 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 the MDA by the milk handler or cooperative. These protocols will provide information as to where the presumptive positive loads or load samples and producer samples are to be confirmed and producer tracebacks run, from each screening site that their milk enters. The MDA 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 NCIMS approved laboratory or certified industry supervisor site. 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. MDA policy is that a licensed or evaluated sampler will obtain a new load sample from the presumptive positive load on which to run the confirmation test. Test results will be recorded on form DY319 and reported immediately to MDA-Lansing using the above FAX or phone numbers.

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. Equivalent means that the test method detects at least the same Beta-lactam drugs as the original test method at the safe levels or below. A table for determination of equivalence is found in the attached, current M-I-96-10. The screening test positive (Load Confirmation) results are obtained by testing the presumptive positive load sample in duplicate with a positive and negative control.

What reports are required for producers?

All producer samples represented in a screening test positive load must be tested at a NCIMS Approved Laboratory or Certified Industry Supervisor site using the same or an equivalent drug residue test used to produce the load confirmation results. A confirmed producer test positive 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 with a positive and negative control. The results of the producer trace back testing must be reported on form DY319 to MDA - Lansing. Any positive producer sample results, including those associated with initial test positives and confirmed negative loads, must be reported to MDA - Lansing on a form DY320. A negative follow-up on the producer is also reported on the DY320. (See Forms, attached).

What forms are required at a screening site?

DY332-Industry Supervisor Record of Training/Evaluation of Industry Analysts
Required at all screening sites with Industry Analysts. It must be maintained to document training of current Industry Analysts by the Industry Supervisor. Copy must be received and confirmed by LEO before approval to screen. Any addition or removal of Industry Supervisors or Analysts must be promptly reported to the LEO.

DY333-Training Confirmation and Approval for Industry Analyst
Used to confirm receipt of DY332 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, participate in split samples or an on-site evaluation.

DY318-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. Use 01/2002 version or newer. Industry supervisors have modified this form to include additional information and these modified forms are acceptable if they include the information required on the 01/2002 (8 1/2 x 11) version and are approved by MDA.

DY319-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 phone (517-373-1060) to MDA - Lansing as soon as possible. This applies to weekends and holidays also, using phone number 517-373-9743. Use the 01/2002 version or newer.

DY330-Monthly Residue Screening Report
This form is for the National Milk Drug Residue DataBase and is a summary of milk samples screened each month. Information from this form and from any completed DY319 and DY320 is used by MDA to submit a monthly summary to the national database.

DY331-Inspectors's Review of Drug Screening Procedures
State inspectors are to review screening procedures at each screening site during every routine inspection (every three months). They will complete this form and leave a copy, along with the processing plant/receiving station/transfer station inspection sheet (DY-366). They will check to see that trained Industry Analysts are running the tests; that daily positive / negative controls are run; that the test kits and controls are properly stored; and that the test procedures and record keeping listed on the Appendix N 2400 series test form are being followed.

Appendix N Bulk Milk Tanker Screening Test Form (2400 series, not attached)
This instruction sheet is specific to the screening test being used, provides procedural, facility, equipment, and record keeping requirements necessary for performing the test method. It is also used as a check sheet when evaluating proficiency of a screening site. See remarks in the paragraph on the Inspector's Review Form.

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

What additional forms are required at a confirmation site?

DY320-Drug Residue Positive Producer Report
Use of this form for reporting a producer’s positive and for a producer’s negative follow-up is explained above. Normally, the positive producer’s information will be sent prior to the negative producer’s follow-up.

DY326- 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 the milk in their bulk tank has been confirmed negative.

DY327-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 will be made by MDA inspectors during or after disposals to verify disposal.

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

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

Where can follow up tests be run?

An approved NCIMS Laboratory or Certified Industry Supervisor is required for all official follow up tests.

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

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

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

The MDA-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 MDA-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 onsite evaluation at least every 2 years.

What is a state inspector’s responsibility?

A state inspector is responsible for: reviewing and evaluating procedures at drug screening sites every 3 months and recording the information on form DY131; biennially evaluating the proficiency of the drug residue screening site in cooperation
with the MDA-LEO; **comparing** the results of the 10% screening program with the results from the screening site on those same loads; **spot-checking** disposal sites for confirmation that loads of positive antibiotic milk are disposed of properly (observations can be reported on a DY 327, memo, inspection sheet or special report and be sent to the MDA Resource Specialist); **collecting** samples required for PMO Section 7 and for a portion of PMO Appendix N; **investigating** and reporting circumstances of a positive drug residue on DY321.

**What samples need to be collected?**

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

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

**Appendix N:** Licensed or evaluated samplers are required to obtain a sample from **every** farm pick up bulk tank truck at its first receiving point and the sample is to be screened for Beta-lactam drug residues prior to commingling with other milk. **This is required for all Grade A-IMS milk regardless of whether the receiving point is IMS listed.** In addition, State inspectors will collect samples from 10% of the farm bulk tank trucks received daily, at each screening site location, once every 3 months **unless the screening site is a certified site with all certified analysts.** These “10%” samples (and the producer samples from each load sampled) will be delivered to a State laboratory for Beta-lactam drug residue analysis.

**What drug residue test methods are used for 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 Delvo 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.

**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 with positive and negative controls and if the controls give the correct response, and either one or both of the duplicate samples tests positive, the sample is considered confirmed positive.
Attachments: DY318; DY319; DY320; DY321; DY326; DY327; DY330; DY331; DY332; DY-333; M-a-85; M-a-86; M-I-96-10; and Michigan Department of Agriculture Drug Residue Program Procedures Supplemental to M-a-86.

Each screening site can make copies of these forms to satisfy their needs, or the forms can be requested from the MI Dept. of Agriculture Dairy Division at (517)-373-1060.