

### Drug Residue Testing – 2400 Series Forms – General Requirements

Kate Angeles, Mary Wegner, Laura Traas, and Natasha Lepak – Laboratory Evaluation Officers – Division of Food and Recreational Safety

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION (DATCP)

Fall 2025 Workshop

1

---

---

---

---

---



---

---

---

### WORK AREA AND STORAGE

- Ample work and storage space
  - Areas neat, clean, and orderly
- Well ventilated and temperature controlled
  - Temperature is specified by test kit manufacturer
  - Humidity is a concern
- Adequate lighting (>50 FC, 100 FC suggested)
  - Placement is important
  - Analysts must not work in their own shadow



2

---

---

---

---

---

---



---

---

### THERMOMETERS OR TEMPERATURE MEASURING DEVICES

National Institute of Standards and Technology (NIST) traceable thermometer ("reference" thermometer)

- Must come with certificate (showing calibration at 3 temperature points or more)
- Must be checked at ice point annually
- Must cover appropriate range of temperatures measured
- Must be graduated in 1.0°C increments
  - Certified labs graduated in 0.5°C increments



3

---

---

---

---

---

---

---

---



THERMOMETERS OR TEMPERATURE MEASURING DEVICES

Working thermometers ("in use" thermometers)

- Sample, incubator, refrigerator, and freezer

Must be checked against NIST thermometer

- Annually (within 12-month period)
- At temperature of use
- Accurate to  $\pm 1.0^{\circ}\text{C}$
- All results documented (date, thermometer IDs, certified thermometer reading, working thermometer reading, correction factor, analyst ID)
- Tagged with ID, date of check, temperature checked at, and correction factor
- No dial thermometers

4

---

---

---

---

---

---


---

---

THERMOMETERS OR TEMPERATURE MEASURING DEVICES

May be calibrated at another location

- Testing done annually
- Documentation of the calibration check must be kept at your lab.
- Thermometers tagged with ID, date of check, temperature checked at, and correction factor
- Lab doing calibration should send documentation of their NIST thermometer



5

---

---

---

---

---

---



---

---

TEMPERATURE MONITORING SYSTEMS

Continuous temperature monitoring: electronic monitoring or chart recorder (App N - refrigeration)

- System must record temperature at same or greater frequency as required for MIG/AIG thermometers:
  - An alert can be set to register when out of acceptable temperature range
  - If temperature is out of range more than two hours, document corrective action taken
  - Backup power source for system in case of power failure
  - Records available and accessible for auditing
  - Weekly comparisons against accurate thermometer (chart recorder)
  - Annual accuracy check required (all systems)

6

---

---

---

---

---

---

---

---

REFRIGERATION

Size appropriate for workload

- Too small impedes proper air flow

Maintains samples at 0.0 to 4.5°C

Controls, media and reagents stored



- No food or drink stored

Temperature recorded once a day

- Certified labs twice per day – A.M. and P.M.
- Corrective action noted if temp unacceptable

Thermometers on top and bottom shelves of use

Thermometer bulb/sensor immersed in liquid



7

---

---

---

---

---



---

---

---

FREEZER

- Size appropriate for workload
- Maintains temperature of -15.0°C or colder
- Controls, media and reagents stored
  - No food or drink stored
- Temperature recorded once a day
  - Certified labs twice per day – A.M. and P.M.
  - Corrective action noted if temperature unacceptable
- Thermometer bulb submerged in anti-freeze liquid



8

---

---

---

---

---



---

---

---

PIPETTORS

- Fixed volume
- Etched or imprinted with identification #
- Proper tips used with pipettor
  - Tips do not need to be sterile (single use)
  - Big enough to allow air space



9

---

---

---

---

---

---

---

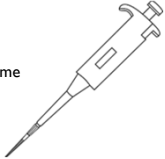

---

PIPETTORS

Accuracy checked every six months

- On-site or at another location (maintain records)
- Tag pipettor with date accuracy check done
  - 10 weighings; average must be within  $\pm 5\%$  of specified volume
- Use deionized water at room temperature.

Recommend a "spare" (certified labs)

10

---

---

---

---

---



---

---

---

BALANCE/SCALE

- Only needed if checking the accuracy of a fixed volume pipettor in-house
- Sensitivity appropriate to use (0.001g sensitivity appropriate in most instances)
- Checked monthly with ASTM 1,2,3, or Class S or SI weights (weights need certificate)
  - Within 30 days prior to pipettor accuracy checks
- Checked annually by a qualified service representative
- Records maintained

11

---

---

---

---

---


---

---

---

TANKER SAMPLE REQUIREMENTS

- Take and record the temperature of tanker.
- Collect a representative sample for antibiotic testing.
  - Record time of sample collection.
  - Temperature control (TC) is required if not tested "without delay".
- Transport samples to lab.
  - Protect samples from contamination.
  - Protect samples from temp abuse.
- Test samples promptly.
  - Record date/time at start of testing.
  - Check and record temperature of TC.
    - Or use temperature of tanker if tested "without delay." (FDA=3min.)
  - Ensure sample temperature is documented in  $^{\circ}\text{C}$  on all lab records.



12

---

---

---

---


---

---


---

---

PRODUCER TRACE BACK SAMPLES



- Samples should be accompanied by hauler TC (pilot) sample to determine temperature of samples.
- Samples should not be leaking.
- Sample tops should not be in direct contact with ice.
- Samples should not be submerged or floating in water/ice.
- Samples not meeting these requirements may still be tested.
  - Condition of samples must be documented.



WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

---

---

---

---

---

---



---

---

13

PERFORMANCE TESTING

- Positive and negative controls run on each new lot of test kits before the lot is used (QC or suitability).
  - Recommend testing upon receipt.
- Positive and negative controls run each day that testing is done.
- Reader calibrator strips/check devices run each day testing is performed.
- Rotate analysts who do performance checks.
- Maintain records for all performance testing.

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

---

---

---

---

---

---

---



---

14

INITIAL TESTING OF TANKER SAMPLE

Documentation must show:

- Lab ID
- Test method used
- Sample ID
- Date and time testing started
- Test result
  - Numeric value (Charm/SNAP) or color (Delvo)
  - Interpretation (NF or POS)
- Analyst ID

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

---

---

---

---

---

---

---

---

15


**VERIFICATION OF INITIAL POSITIVE**

Same analyst tests the same sample in duplicate with positive and negative controls using the same test kit.

Positive and negative controls must work properly.

- ▣ If both duplicates of the sample are negative, the milk may be received (reported as NF).
- ▣ If one or both of duplicate samples test positive, the tanker is presumptive positive.
- ▣ All testing to be documented.

Start filling out positive drug residue report form (for presumptive positive load sample).  
End of testing for screening analyst.



WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

16

---

---

---

---

---


---

---

---

**CONFIRMATION OF PRESUMPTIVE POSITIVE**

- Original tanker load and producer samples must be forwarded to a certified lab that uses an equivalent test method as the screening lab.
- If certified lab confirms load as negative, milk may be used.
- If certified lab confirms load as positive, milk must be disposed of, and producer samples must be tested.
- Producer samples must be tested at the certified lab using the same test that was used to confirm the load as positive.
- All load confirmation testing and producer traceback testing is to be documented.



WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

17

---

---

---

---

---

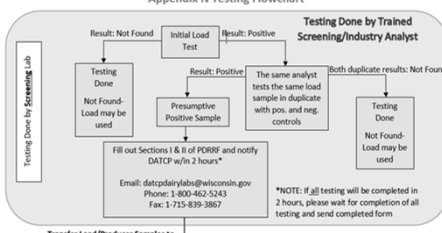
---

---

---

**APPENDIX N FLOWCHART**


Appendix N Testing Flowchart



\*NOTE: If all testing will be completed in 2 hours, please wait for completion of all testing and send completed form

**Top box is for the Screening Lab**

- Presumptive Positive to Verified Positive Load
- Trained Screening/ Industry Analyst
- Notify DATCP within two hours



WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

18

---

---

---

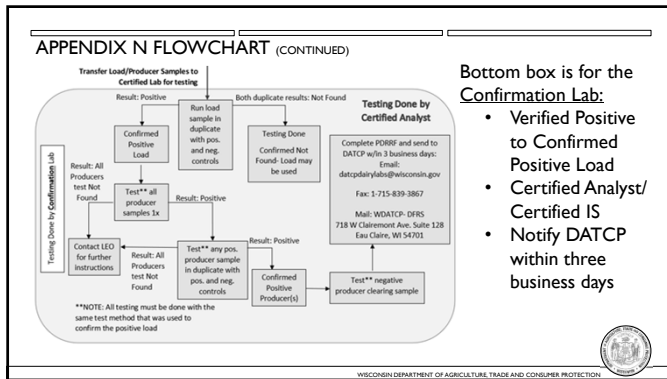
---

---

---

---

---



19

**DIRECT MILK SHIPMENTS REJECTED FOR DRUG RESIDUE**

**Collecting a clearing sample at a licensed dairy plant**

- Sample taken at facility with a lab using the same or equivalent test.
- Sampling shall be done in accordance with ATPC 65.72(3)(c).
- Direct loads that are shipped to be tested as a clearing sample shall be shipped no more than 24 hours after the initial confirmed positive.
- Clearing samples tested within 24 hours may be "offered for sale" when screened negative.
- Loads shipped after 24 hours that test positive will be considered a second violation under ATPC 65.922(4).

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

20

**DIRECT MILK SHIPMENTS REJECTED FOR DRUG RESIDUE**

**Collecting a clearing sample when approved on the farm**

- Sampled in accordance with ATPC 82.12(2m)
- From a properly agitated tanker that is located in a suitable shelter adjacent to, but not in the milkinghouse ("suitable shelter" shall meet milkinghouse standards)
- Using a division approved inline milk sampling device installed on the milk pipeline

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

21

REPORTS AND RECORDS

Report a positive result interpretation as POS.


- Not just a + sign (contrary to 2400 forms)

Report a negative result interpretation as NF for "not found".

Keep all written records and printouts for at least two years.

Legibility of records is critical.

- No write-overs or whiteout.
- If you make a mistake, strike out the incorrect information with a single line (example), initial it, and write correct info next to it.



22

---

---

---

---

---


---

---

---

POSITIVE DRUG RESIDUE REPORT FORM

- Use most current version (10/2017)
- Section I and II to be filled out by screening lab
- Original copy must go to certified lab doing the load confirmation (screening lab keep a copy)
- Certified lab completes sections III (load confirmation test data) and V (positive producer test data)
- Section IV – disposition of milk
- Section VI – negative recheck (producer) to resume shipping
- Forward completed form to DATCP



23

---

---

---

---

---


---

---

---

MISCELLANEOUS

- Heater block temperature to be documented each day of testing (thermometer to be in block when testing)
- If using Charm EZ reader for incubating test strips, the EZ printout is acceptable for the daily temperature documentation
  - Charm thermometer needed for annual accuracy check of the Charm EZ incubator/reader unit
- Heater block needs to be level
- Positive and negative control information to be documented
  - Positive control – lot #, date made, expiration date
  - Negative control – source, date tested, expiration date



24

---

---

---

---

---

---


---

---



MISCELLANEOUS

- Current safety data sheets
  - Test kits and positive control
- Current 2400 series forms (needed for annual internal audit)
- Tanker Disposal form
- Analyst Training Report form (send to LEOs)
  - Annual training/testing of analysts
  - Within 30 days, any addition/removal of analysts

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

25

---

---


---

---

---

---

---



Kate Angeles, Mary Wegner, Laura Traas, and Natasha Lepak

Laboratory Evaluation Officers – Division of Food and Recreational Safety

Email: [datcpleo@wisconsin.gov](mailto:datcpleo@wisconsin.gov) Website: [datcp.wi.gov](http://datcp.wi.gov)

WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION (DATCP)

Fall 2025 Workshop

26

---

---

---

---

---

---

---