Drug Residue Testing – 2400 Series Forms - General Requirements

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

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WORK AREA AND STORAGE

Ample work and storage space
- Areas neat, clean and orderly

Well ventilated & 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

THERMOMETERS OR TEMPERATURE MEASURING DEVICES

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.

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 ± 1.0°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

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.

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).

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 AM and PM.
- Corrective action noted if temp unacceptable.

Thermometers on top and bottom shelves of use.

Thermometer bulb/sensor immersed in liquid.

FREEZER

- Size appropriate for work load.
- 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 AM and PM.
  - Corrective action noted if temperature unacceptable.
- Thermometer bulb submerged in anti-freeze liquid.

PIPETTORS

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

PIPETTORS

Accuracy checked every 6 months.

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

Recommend a "spare" (certified labs).

BALANCE/SCALE

- Only needed if using fixed volume pipettor.
- Sensitivity appropriate to use.
- Checked monthly with ASTM 1,2, 3 or Class S or S1 weights (weights need certificate).
  - Within 30 days prior to pipettor accuracy checks.
- Checked annually by a qualified service representative.
- Records maintained.

TANKER SAMPLE REQUIREMENTS

1. Take and record the temperature of tanker.
2. Collect a representative sample for antibiotic testing.
   - Record time of sample collection.
   - May also take a temperature control (TC).
3. Transport samples to lab.
   - Protect samples from contamination.
   - Protect samples from temp abuse.
4. Test samples promptly.
   - Record date/time at start of testing.
   - Check & record temperature of TC.
   - Or use temperature of tanker.
     - If tested "without delay."
   - Sample temperature needs to be °C.

PRODUCER TRACE BACK SAMPLES

- Samples should be accompanied by 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.

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.

INITIAL TESTING OF TANKER SAMPLE

Documentation must show:

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

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.

CONFIRMATION OF PRESUMPTIVE POSITIVE

- Original tanker sample must be forwarded to a certified lab for testing.
- 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 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.

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 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.

POSITIVE DRUG RESIDUE REPORT FORM

- Use most current version (10/2017).
- Section I & 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 WDATCP.

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.

MISCELLANEOUS

- Current safety data sheets.
  - Test kits and positive control.
- Current 2400 series forms (needed for internal audit annually).
- Tanker Disposal form.
- Analyst Training Report form.
  - Annual training/testing of analysts (send to LEOs).
  - Add/remove analysts (send to LEOs).

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