# 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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