

**APPENDIX N  
GENERAL  
REQUIREMENTS  
(REV. 10/13)**

# ITEM 1: WORK AREA

- ▣ Ample working space and utilities
- ▣ Clean and well ventilated, test kits used in temperature range specified by manufacturer
- ▣ Adequate lighting : meaning greater than 50 foot candles at working surface, but preferably 100 foot candles
- ▣ Eating and drinking not permitted in immediate testing area





## ITEM 2: STORAGE SPACE

- ▣ Cabinets, drawers, shelves adequate
- ▣ Areas neat, clean, and orderly

# ITEM 3: THERMOMETERS

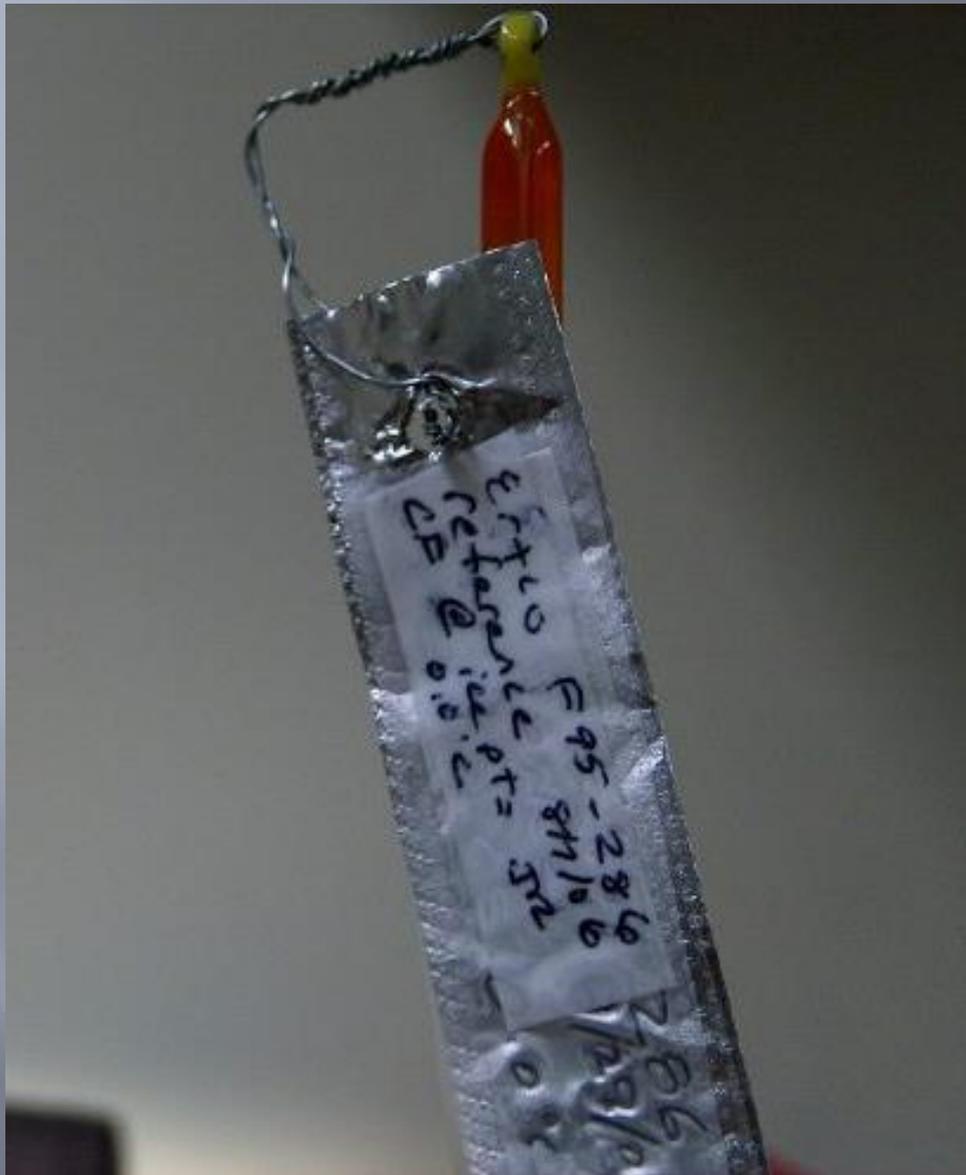
- ▣ Thermometers traceable to NIST certified thermometer. Certified thermometer must have current valid certificate available.
- ▣ NIST thermometer checked at ice point, annually, preferably just before checking test thermometers
- ▣ Range of thermometers appropriate for designated use
- ▣ Graduation not greater than 1.0°C for Screening Only facilities; Milk Industry and CIS facilities 0.5°C



Mercury in glass NIST certified thermometer

Digital NIST certified thermometer





NIST thermometer tagged with results of ice point check

# ITEM 3: THERMOMETERS

- ▣ Accuracy of test thermometers checked against certified NIST thermometer before initial use and annually, with a correction factor not to exceed  $\pm 1.0^{\circ}\text{C}$
- ▣ Results recorded on BFSLS 515 (Rev 1/14) Thermometer Accuracy Check Log
- ▣ If certified NIST thermometer has a correction factor at ice point, use form BFSLS 515a and record raw and corrected NIST thermometer temperatures

## ITEM 3: THERMOMETERS

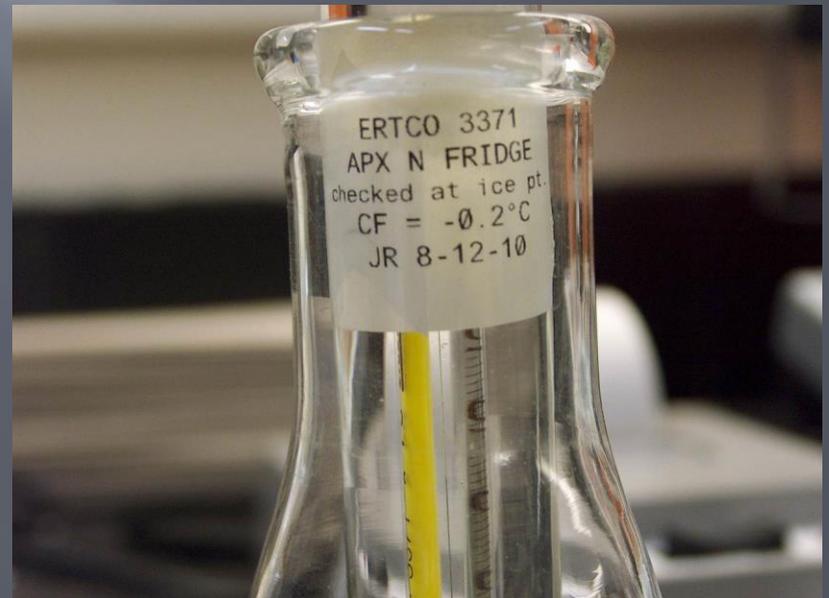
- ▣ Accuracy check records must be current and acceptable whether checked onsite or at another location
- ▣ Thermometer tagged with date, identification/location, temperature checked, analyst doing check and any applicable correction factor (0.0°C, if none)

# ITEM 3: THERMOMETERS

- ▣ Dial thermometers are not permitted in the testing area / laboratory!
- ▣ Automatic temperature recording instruments, if used, are to be compared weekly against an accurate thermometer with results recorded



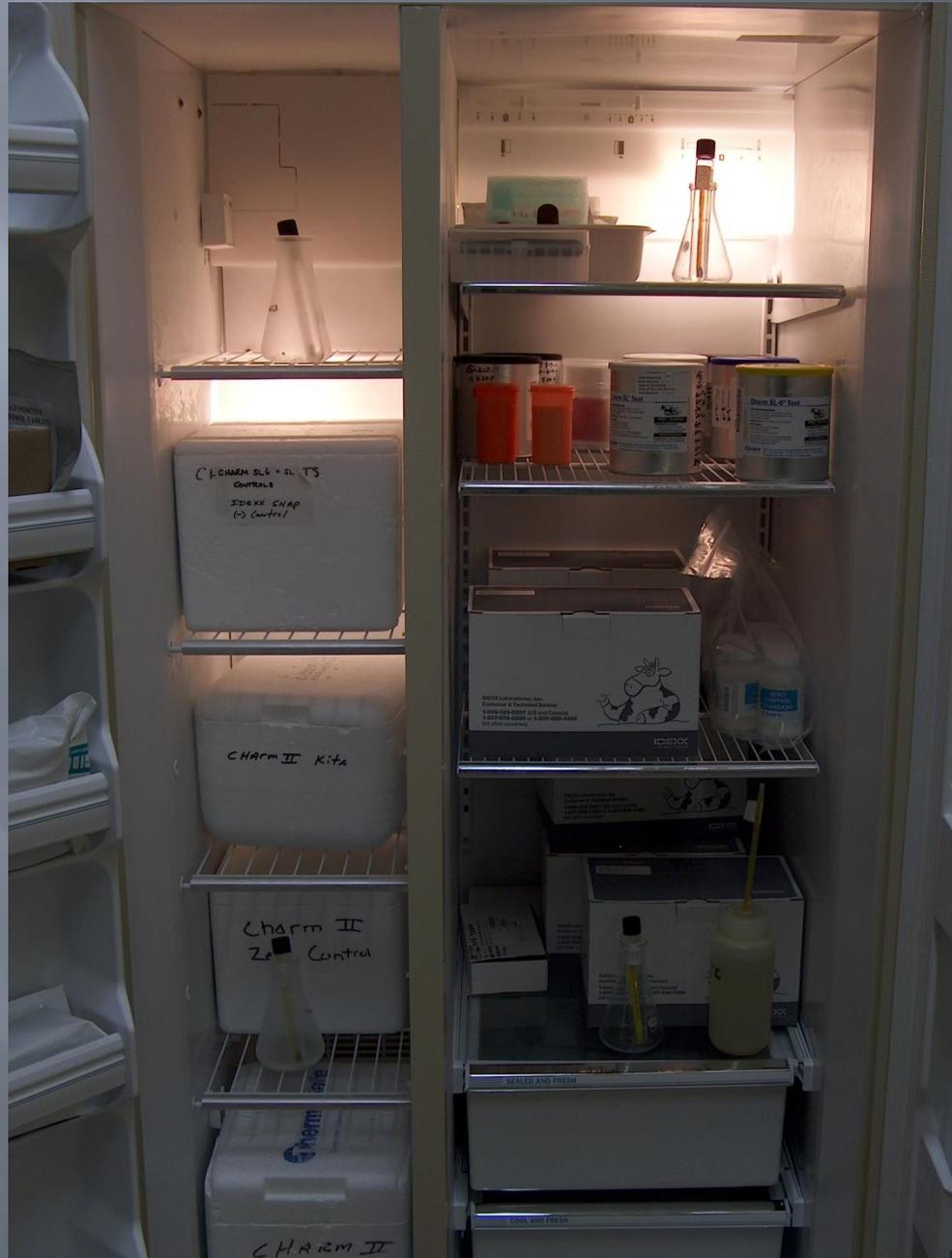
LabID#34  
122570582  
Apx N TC  
CF at 0.0C=+0.2C  
JR 8/5/13



ERTCO 3371  
APX N FRIDGE  
checked at ice pt.  
CF = -0.2°C  
JR 8-12-10

# ITEM 4: REFRIGERATION

- ▣ Size adequate for workload
- ▣ Must maintain samples at 0-4.5°C; if not, take corrective action and document correction and rechecked temperature
- ▣ Reagents must be stored according to manufacturer's instructions
- ▣ Not to be used to store food or drink for consumption



# ITEM 4: REFRIGERATION

- ▣ Record temperatures twice daily (AM and PM) using two thermometers with bulbs submerged in liquid, placed on upper and lower shelves of the refrigerator
- ▣ Screening only labs have the option of recording temperature once daily
- ▣ Temperatures are to be read and recorded to the nearest 0.1°C.

## ITEM 5: FREEZER

- ▣ Size adequate for workload
- ▣ Maintain temperature  $-15.0^{\circ}\text{C}$  or below; if not, take corrective action and document correction and rechecked temperature.
- ▣ Reagents must be stored according to manufacturer's instructions
- ▣ Not to be used to store food or drink for consumption

## ITEM 5: FREEZER

- ▣ Record temperatures twice daily (AM and PM) using thermometer(s) with bulbs submerged anti-freeze liquid
- ▣ Screening only labs have the option of recording temperature once daily
- ▣ Temperatures are to be read and recorded to the nearest 0.1°C

## ITEM 6: BALANCE

- ▣ Weight capability appropriate for intended use
- ▣ Appropriate sensitivity for accuracy check of pipetting devices within a tolerance of  $\pm 5\%$
- ▣ Balance checked monthly with Class S or S1, or equivalent ASTM 1, 2, 3 weights with results recorded on BFSLS 497, rev. 1/14
- ▣ Weights have a valid certificate or other verification of authenticity
- ▣ Balance checked annually by a qualified service representative with records maintained



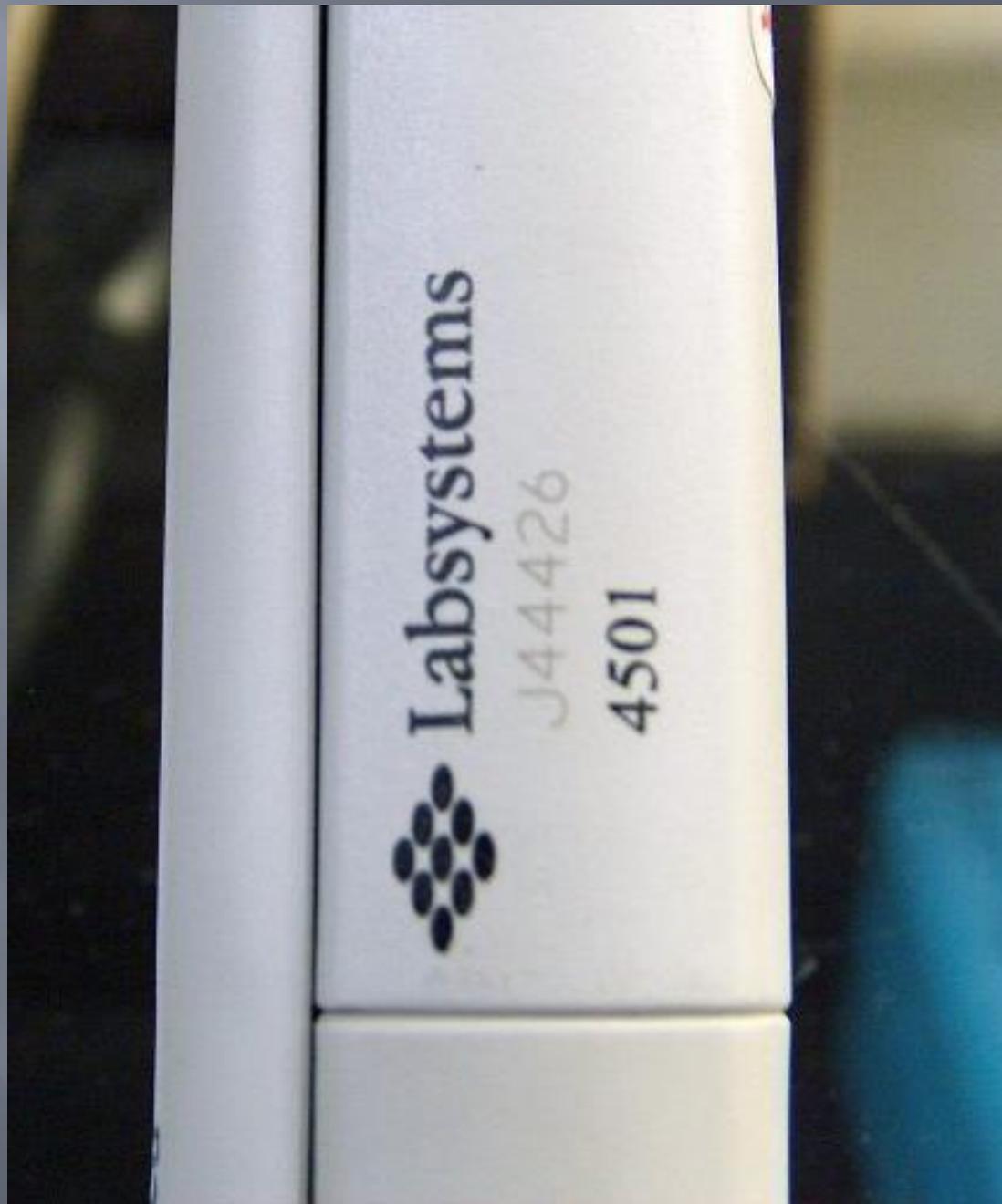
# ITEM 7: PIPETTORS

- ▣ Checked for accuracy every 6 months with ten (10) consecutive measurements by weight using a separate tip for each measurement or, by volume using a Class A graduate for pipettors of >1.0 ml
- ▣ Average of all ten measurements must be  $\pm 5\%$  of the specified delivery volume

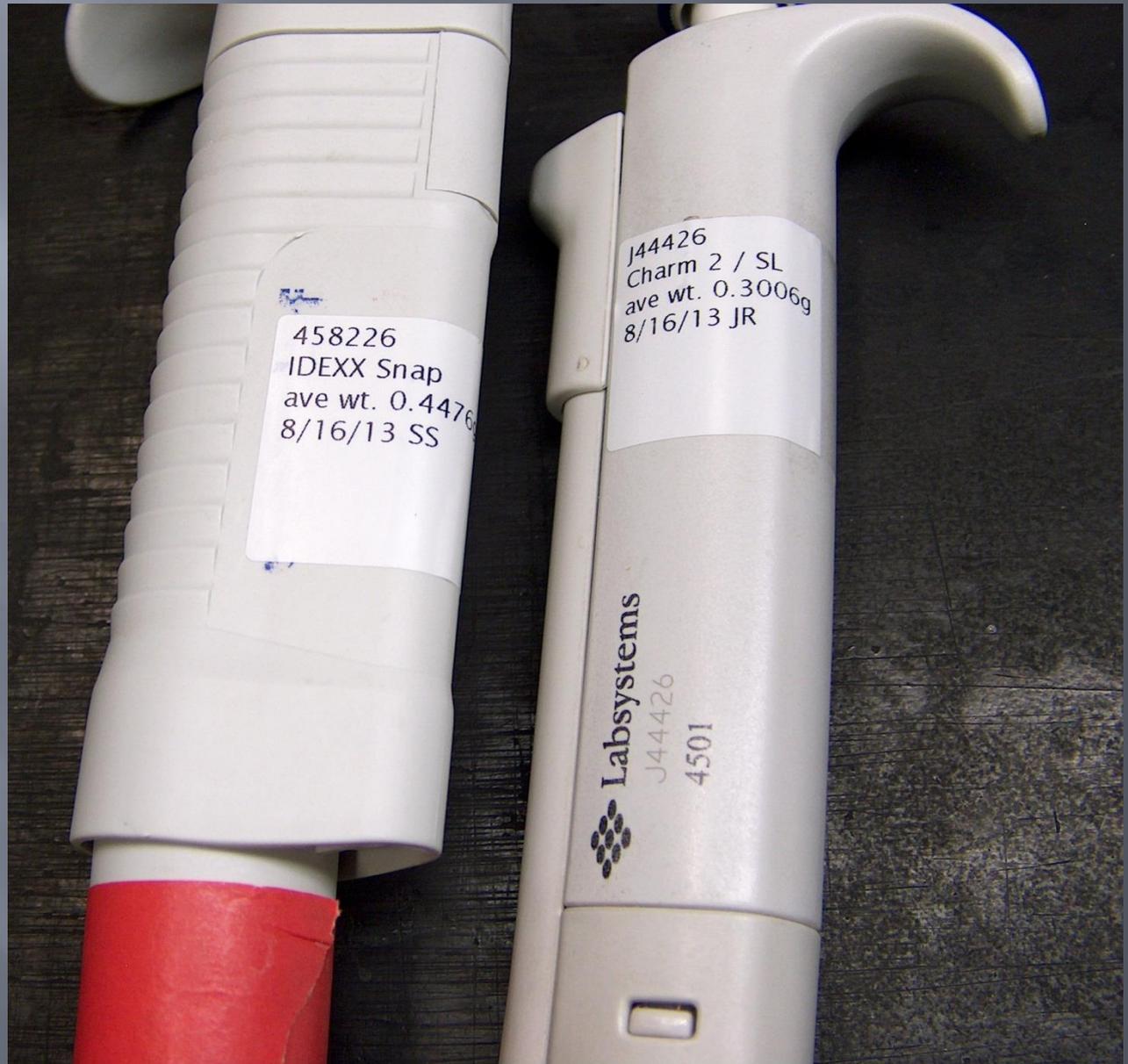
# ITEM 7: PIPETTERS

- ▣ Pipettors must be etched with identification; Imprinted serial numbers are acceptable
- ▣ Pipettors are tagged with the date and analyst of accuracy check
- ▣ Accuracy check records must be current and acceptable whether checked onsite or at another location
- ▣ Records maintained on BFSLS 503, rev. 1/14

Pipettor with  
imprinted serial  
number



Pipettors tagged  
with date & results  
of accuracy check  
and analyst



# ITEM 9: SAMPLE REQUIREMENTS

- ▣ Prevent contamination with disinfectants from hands or other sources
- ▣ Pipet tips ,disposable pipets, and/or test kits must be decontaminated before discarding, i.e. soaking in a sanitizing solution overnight or autoclaving (sanitizer used in plant should be sufficient , ex. 200ppm chlorine or 25ppm iodine)



Container with 200ppm bleach solution and appropriate test kit



Waste bag for use in autoclave

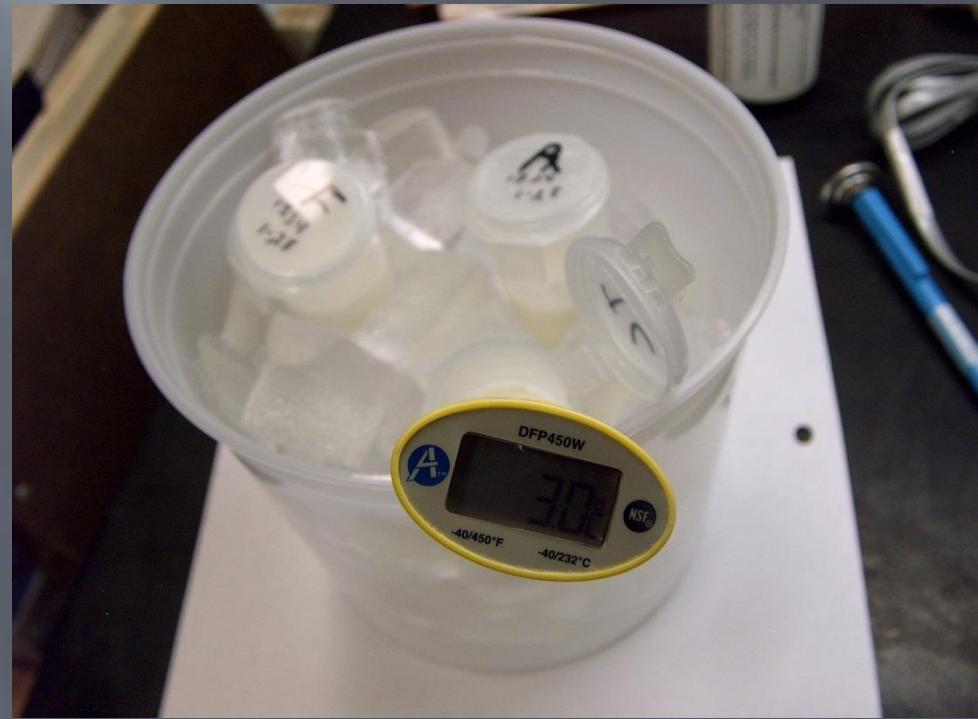
# ITEM 9: SAMPLE REQUIREMENTS

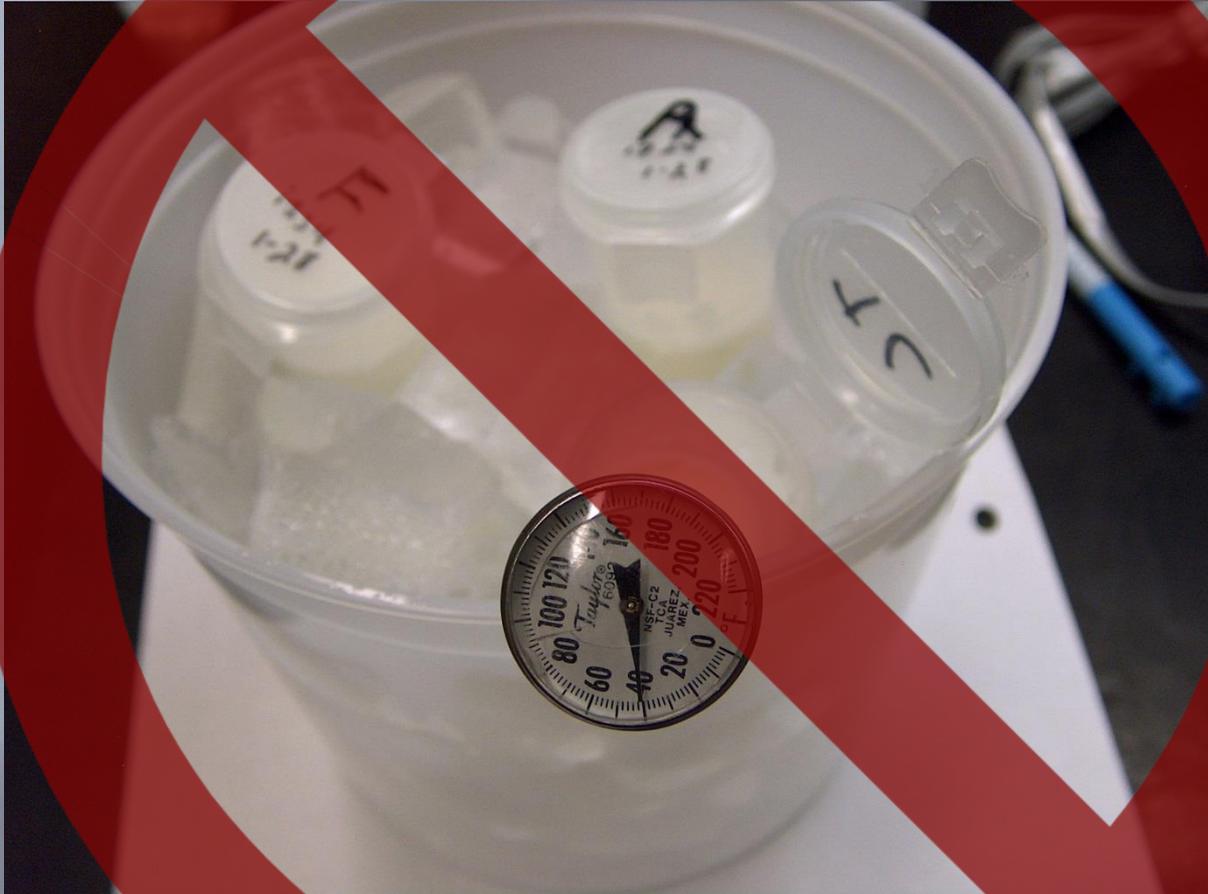
- ▣ Ascertain temperature of bulk milk tanker
- ▣ A TC (temperature control) sample must be taken, transported, and maintained with the tanker sample until it is tested
- ▣ Secure a representative sample for drug residue testing and transport promptly to testing location on ice to maintain temperature
- ▣ Record date, time and temperature of sampling



Ice water bath for samples with Temperature Control (TC) sample

TC temperature determined using digital thermometer





DO NOT USE DIAL THERMOMETERS!

# ITEM 9: SAMPLE REQUIREMENTS

- ▣ Tanker samples tested promptly upon arriving at the testing location, measure TC provided
- ▣ If test kit indicates a positive result, confirmation must be completed within 72 hours of initial collection(time of truck sampling)

# ITEM 9: SAMPLE REQUIREMENTS

- ▣ Record date, time, and temperature of samples as tested
- ▣ Determine sample temperature by inserting a digital thermometer or pre-cooled glass into TC (temperature control)
- ▣ If no TC, aliquot samples for testing and measure temperature using one of the producer samples(avoid as routine practice)

## Digital probe TC thermometers



Glass TC thermometer kept in alcohol solution. Kept in the fridge when not in use (pre-cooled).



# ITEM 9: SAMPLE REQUIREMENTS

- ▣ DO NOT accept samples that :
  - are over-filled (more than  $\frac{3}{4}$  full)
  - are leaking
  - have the tops of samples (seals) in direct contact with ice (should be using 'floater' racks)
  - are unprotected and submerged in water and/or ice or slush

# ITEM 9: SAMPLE REQUIREMENTS

- ▣ If raw milk samples exceed  $4.5^{\circ}\text{C}$  on receipt, DO NOT TEST.
- ▣ However, samples may be received  $>4.5^{\circ}\text{C}$  but  $< 7^{\circ}\text{C}$  if time of receipt is  $\leq 3$  hours from collection and arrival temperature is equal to or less than the temperature of collection.
  - Document temperature violation
  - Avoid as routine practice

# ITEM 10: PERFORMANCE TESTING

- ▣ Run a positive and negative control on each new lot of kits before use. Controls must give appropriate results, with records maintained (BFSLS 513 Rev. 1/14).
- ▣ Run a negative and positive control DAILY (on days of testing) and when first prepared. Controls must give appropriate results, with records maintained (BFSLS 513a Rev 7/11, BFSLS 513b Rev 7/11).

# ITEM 10: PERFORMANCE TESTING

- ▣ If controls do not give appropriate results, re-run controls (may be necessary to make new controls).
- ▣ If problem persists, discontinue testing, contact one of the Laboratory Evaluation Officers and seek technical assistance from the manufacturer.

# ITEM 10: PERFORMANCE TESTING

- ▣ If available from manufacturer, check instrument calibration with check devices DAILY (on days of testing), with records maintained (BFSLs 534 SNAP Rev 7/09, BFSLs 534a SNAPShot Rev 5/15 & BFSLs 535 Rosa Reader Rev 7/09).
- ▣ Devices must give appropriate results. If not, discontinue testing and seek technical assistance from the manufacturer.

IDEXX check devices



Charm ROSA  
Reader check  
devices

# ITEM 10: PERFORMANCE TESTING

- ▣ If more than one analyst performs analysis, have a different analyst run performance checks on rotational basis.

ITEMS: 11-13 INITIAL, PRESUMPTIVE,  
CONFIRMATION, & PRODUCER TRACEBACK OF  
SAMPLES

- ▣ This is addressed in the Appendix N Flow Chart Presentation

# ITEM 14: REPORTING & RECORDS

- ▣ Report Positive results as 'Positive (+) for Beta-Lactam'
- ▣ Report Negative results as 'Not Found (NF)'
- ▣ Report tests performed, interpretation of unknowns (samples) and controls (BFSLS 500 rev. 1/14 or BFSLS 500a rev. 1/14)

# ITEM 14: REPORTING & RECORDS

- ▣ Records, including all printouts, must be maintained for 2 years and be available for the LEO to review during the biennial evaluation

APX N DAILY QC

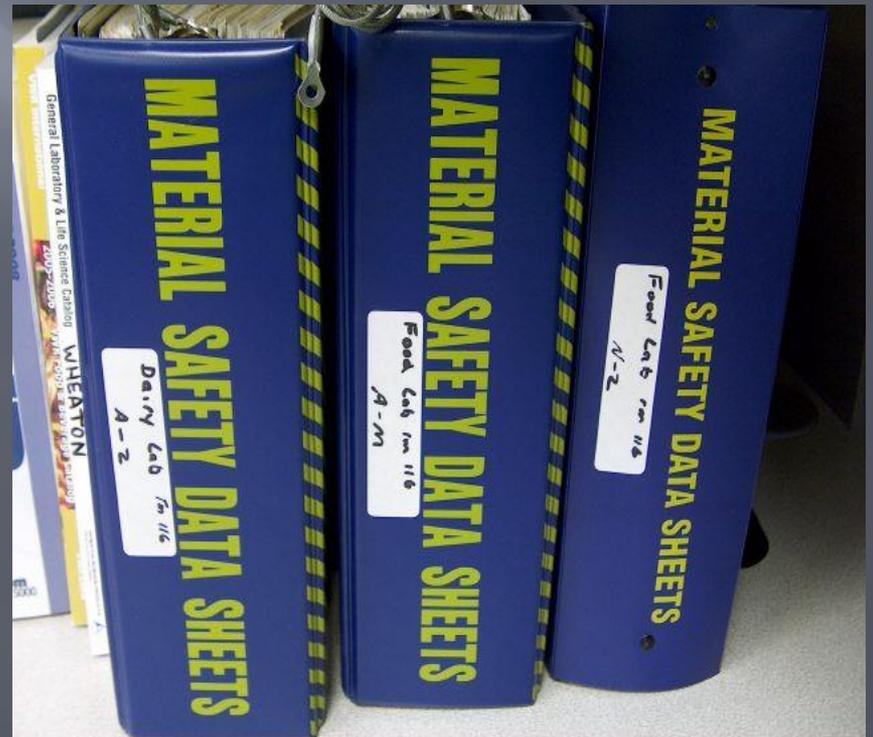
ROOM 115

TESTING REFERENCE MAN

APPENDIX N

# ITEM 15: MISCELLANEOUS

- ▣ Current Safety Data Sheets (SDS) accessible to analysts
- ▣ Current, applicable survey forms (2400 forms) available in the laboratory
- ▣ Positive Report Forms available with instructions



# ITEM 15: MISCELLANEOUS

- ▣ Personnel adequately trained
- ▣ If an analyst does not have a PA analyst number (PA#) assigned then no training documentation has been approved by PDA
- ▣ If no training documentation has been approved by PDA, the analyst in question cannot conduct testing
- ▣ All IA's (Industry Analysts) are to receive re-training annually from an IS or CIS. (BFSLS 528 rev 1/14)

# ITEM 15: MISCELLANEOUS

- ▣ Required split sample participation annually if receiving more than 200,000 pounds of milk a week (March Splits)
- ▣ Facilities receiving less than 200,000 pounds of milk a week will be required to test check samples brought by the LEO to each on-site evaluation

Please email  
QUESTIONS OR  
COMMENTS to  
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