

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> FOOD AND DRUG ADMINISTRATION <b>MILK LABORATORY EVALUATION RECORD</b>	Laboratory	
	Location	
Laboratory Evaluation Officer	Lab Number	Date (mm/dd/yyyy)

List of acceptable entries in columns: **Blank** = No deviations observed; **RO** = Item has been Reviewed or Observed (this entry is for temporary use only and must be replaced with another entry on final record); **X** = Deviation; **N** = Note; **O** = Not Used; **NA** = Not Applicable; **U** = Undetermined

## APPENDIX N BULK MILK TANKER SCREENING PROCEDURES

[Unless otherwise stated all tolerances are  $\pm 5\%$ ]

### GENERAL REQUIREMENTS

1. **Work Area** ..... \_\_\_\_\_
  - a. Ample working space and utilities ..... \_\_\_\_\_
  - b. Clean and well ventilated, test kit used in temperature range specified by manufacturer, reasonably free from dust and drafts ..... \_\_\_\_\_
  - c. Adequate lighting [**NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities, > 50 foot-candles at working surface (pref 100)**]..... \_\_\_\_\_
  - d. Eating and drinking not permitted in immediate testing area ..... \_\_\_\_\_
2. **Storage Space** ..... \_\_\_\_\_
  - a. Cabinets, drawers and shelves adequate ..... \_\_\_\_\_
  - b. Areas neat, clean and orderly ..... \_\_\_\_\_
3. **Temperature Measuring Devices** ..... \_\_\_\_\_
  - a. National Institute of Standards and Testing (NIST) traceable thermometer or other temperature measuring device with certificate. Must be checked annually at ice point ..... \_\_\_\_\_
    1. Reference temperature measuring device identity: ..... \_\_\_\_\_
 

	Serial #	Date of Certificate	Ice Point Date	
a:	_____	_____	_____	_____
b:	_____	_____	_____	_____
    2. Graduation/recording interval not greater than 1.0°C [**NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities, 0.5°C**] ..... \_\_\_\_\_
  - b. Range of test temperature measuring device appropriate for designated use ..... \_\_\_\_\_
    1. Mercury-in-glass (MIG), alcohol/spirit-in-glass (AIG) or electronic/digital thermometers in degrees centigrade ..... \_\_\_\_\_
    2. Plastic lamination recommended for mercury thermometers ..... \_\_\_\_\_
    3. Graduation/recording interval not greater than 1.0°C [**NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities, 0.5°C**] ..... \_\_\_\_\_
  - c. Accuracy of all test temperature measuring devices checked before initial use and annually
    1. Checked against NIST traceable thermometer ..... \_\_\_\_\_
    2. Accurate to  $\pm 1^\circ\text{C}$  when checked at temperature(s) of use ..... \_\_\_\_\_
    3. Results recorded/documented and individual devices tagged ..... \_\_\_\_\_

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- a. Tag includes identification/location, date of check, temperature(s) checked and correction factor(s), as applicable \_\_\_\_\_
  - d. Temperature measuring devices are to be read to the nearest graduation/recording interval, optionally labs may interpolate between graduations \_\_\_\_\_
  - e. Temperature Monitoring Systems (wired/wireless) \_\_\_\_\_
    - 1. The software must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency as stipulated for MIG or AIG thermometers. Optionally, set to register an alert/alarm when out of the acceptable temperature range \_\_\_\_\_
      - a. When temperature(s) are out of acceptable range for greater than two hours, event must be documented and corrective action taken as necessary; maintain records \_\_\_\_\_
    - 2. Optionally, a minimum two-day backup power source (battery/electrical) for the temperature monitoring system and/or all required sensors/probes, remote signal device and monitor/controller may be employed in case of power failure \_\_\_\_\_
    - 3. Temperature monitoring system records for each piece of equipment must be available/accessible for auditing as described in item 3c above \_\_\_\_\_
  - f. Automatic temperature recording instruments, if used, compared weekly against an accurate thermometer; maintain records \_\_\_\_\_
  - g. Temperature measuring device(s) checked for accuracy at another location \_\_\_\_\_
    - 1. Location: \_\_\_\_\_
    - 2. Current and acceptable \_\_\_\_\_
    - 3. Copy of record on-site \_\_\_\_\_
  - h. Dial thermometers not used in the laboratory \_\_\_\_\_
- 4. Refrigeration (Sample \_\_\_\_\_ ) (Reagent \_\_\_\_\_ )** \_\_\_\_\_
- a. Size adequate for workload \_\_\_\_\_
  - b. Maintains samples at 0.0-4.5°C \_\_\_\_\_
  - c. Used for storage of milk or milk products, media and reagents only \_\_\_\_\_
    - 1. Not to be used to store food or drink for consumption \_\_\_\_\_
  - d. Record/download temperature (corrected) daily, from two temperature measuring devices with bulbs or sensor/probe immersed in liquid (in sealed containers) **[NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities, AM and PM]** \_\_\_\_\_
  - e. Temperature measuring devices located on upper and lower shelves of use \_\_\_\_\_
- 5. Freezer ( \_\_\_\_\_ )** \_\_\_\_\_
- a. Size adequate for workload \_\_\_\_\_
  - b. Maintains -15°C or below \_\_\_\_\_
  - c. Used for storage of frozen milk products, controls, media and reagents only \_\_\_\_\_
    - 1. Not to be used to store food or drink for consumption \_\_\_\_\_

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- d. Record/download temperature (corrected) daily, from temperature measuring device with bulb or sensor/probe immersed in liquid (in sealed container) **[NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities, AM and PM]** .....
- 6. Balance, Electronic (if necessary) ( \_\_\_\_\_ )** .....
- a. Weight capability appropriate for intended use .....
- b. Appropriate sensitivity for accuracy check of pipetting devices within a tolerance of  $\pm 5\%$  (0.001g sensitivity appropriate in most instances) .....
- c. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3 weights corresponding to normal use of balance **(At a minimum, Appendix N drug residue testing only laboratories must check the balance calibration within 30 days prior to the pipettor accuracy check)** .....
- 1. Certificate or other verification of authenticity .....
- 2. Free from excessive wear, filth and corrosion .....
- 3. Weights within class tolerance .....
- d. Checked annually by a qualified service representative .....
- 1. Date of Last Check: \_\_\_\_\_ .....
- e. Maintain records .....
- 7. Pipettors, Calibrated, Fixed Volume or Electronic Only [Required for NCIMS Accredited Laboratories and Certified Industry Supervisor Facilities]** .....
- a. Pipettors etched with identification (imprinted serial numbers acceptable) and tagged with date accuracy checked .....
- b. Appropriate tips for pipettor(s) used .....
- c. Follow manufacturer's instructions unless otherwise stated regarding proper technique for use .....
- d. Pipetting devices accuracy checked on-site .....
- e. Pipetting devices accuracy checked at another location .....
- 1. Location: \_\_\_\_\_ .....
- 2. Current and acceptable .....
- 3. Copy of record on-site .....
- f. Check accuracy with ten (10) consecutive measurements, by weight or by volume (>1.0 ml using a class A graduated cylinder), using separate tip for each measurement, every 6 months .....
- g. Average of all 10 measurements must be  $\pm 5\%$  of specified delivery volume, maintain records .....
- h. Or, check accuracy with 10 consecutive readings once every 6 months using the Artel PCS Pipette Calibration System, average of all 10 readings must be  $\pm 5\%$  of specified delivery volume, maintain records/printouts .....
- 1. PCS Calibration System Validation, upon receipt, validate the instrument by following the manufacturer's protocol .....
- 2. PCS Pipette System Quality Control .....
- a. Following manufacturer's Procedure Guide and instrument prompts, perform an instrument calibration every 30 days or just prior to use .....
- b. Record results and file Calibration Certificate (printout) .....

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- 3. Store reagent kits and Instrument Calibrator kits at room temperature ..... \_\_\_\_\_  
     Lot #: \_\_\_\_\_ ..... \_\_\_\_\_  
     Exp. Date: \_\_\_\_\_ ..... \_\_\_\_\_
- 4. Reagent Blanks and Sample Solutions are the same lot ..... \_\_\_\_\_
- 5. PCS Pipette Calibration System Procedure, follow manufacturer’s Procedure Guide and instrument prompts ..... \_\_\_\_\_
- i. Maintain records ..... \_\_\_\_\_
- 8. Deionized Water or Equivalent, or as specified by manufacturer ..... \_\_\_\_\_**

**SAMPLES**

- 9. Sample Requirements ..... \_\_\_\_\_**
- a. Appendix N tanker sample(s) ..... \_\_\_\_\_
  - 1. Prevent contamination with disinfectants from hands or other sources ..... \_\_\_\_\_
  - 2. Ascertain temperature of bulk milk tanker; maintain records ..... \_\_\_\_\_
  - 3. Secure a representative sample for testing. If sample will not be tested without delay, then a temperature control (TC) sample must be taken at the same time, transported, and maintained with the tanker sample(s) until it is tested ..... \_\_\_\_\_
  - 4. Tanker sample(s) tested promptly upon arrival at the testing location (date and time recorded) ..... \_\_\_\_\_
    - a. Determine sample temperature by inserting a pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control ..... \_\_\_\_\_
    - b. Temperature of bulk milk tanker may be used for temperature as received and tested if sample testing begins without delay ..... \_\_\_\_\_
- b. Appendix N Producer Trace Back Samples (Sample(s) not meeting the conditions outlined below may still be tested. The certified laboratory or CIS will document the condition of the samples(s)) ..... \_\_\_\_\_
  - 1. Samples should be accompanied by a temperature control (TC). If no TC, aliquot sample(s) for testing and measure temperature using one of the producer samples ..... \_\_\_\_\_
  - 2. Sample(s) should not be leaking ..... \_\_\_\_\_
  - 3. Tops of samples should be protected from direct contact with ice ..... \_\_\_\_\_
  - 4. Unprotected samples should not be submerged in water and/or ice or slush ..... \_\_\_\_\_

**PERFORMANCE TESTING**

- 10. Performance Testing ..... \_\_\_\_\_**
- a. Run a positive and negative control before use on each new lot of kits, must give appropriate results; maintain records ..... \_\_\_\_\_
- b. Run a negative and positive control **DAILY** (on days testing), at each test site, must give appropriate results; if not, re-run controls (may be necessary to prepare new controls). If problem persists discontinue testing, contact State Regulatory Agency and seek technical assistance; maintain records ..... \_\_\_\_\_

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- c. If available from manufacturer, check instrument calibration with check devices **DAILY** (on days testing), must give appropriate results; if not, discontinue testing and seek technical assistance; maintain records .....
- d. If more than one analyst performs analysis, have different analyst run performance check on rotational basis .....

**FOLLOW-UP ON TEST KIT POSITIVE RESULTS**  
**[Must comply with PMO Appendix N, current revision]**

- 11. Verification of Initial Positive Tanker Samples** .....

  - a. The **SAME** sample is re-tested by the **SAME** analyst using the **SAME** test in **DUPLICATE** along with a positive and negative control .....
  - b. Positive and negative controls give the appropriate result(s) .....
    - 1. If positive and/or negative controls do not give appropriate results, re-run controls and samples. If problem persists seek technical assistance .....
  - c. If one or both duplicates are positive, the tanker sample is **PRESUMPTIVE POSITIVE** and the sample is referred to the designated certified laboratory or Certified Industry Supervisor (CIS) as specified by the facility's protocol as per Agreement with the State Regulatory Agency .....
  - d. Presumptive positive samples must be forwarded to a certified laboratory, not tested by screening facility; producer samples must be tested by a certified laboratory .....
  - e. If both duplicates are negative, milk may be received and processed; record and report as **NOT FOUND** .....
  - f. Complete applicable section of Positive Report form and maintain records of all analyses .....
    - 1. For Presumptive Positive samples, maintain a copy of the Positive Report form and forward the original to the certified laboratory or CIS .....

- 12. Confirmation of Presumptive Positive Tanker Samples [Only in an accredited laboratory or by a CIS (refer to M-a-85 current revision for listing of test kits to assure equivalence)]** .....

  - a. The **SAME** sample [or if it can be demonstrated that the original sample is suspect, a re-sample may be used at the State's discretion] is tested in **DUPLICATE** along with a positive and negative control .....
  - b. Positive and negative controls give the appropriate result(s) .....
    - 1. If positive and/or negative control do not give appropriate results, re-run controls and samples; if problem persists seek technical assistance .....
  - c. If one or both duplicates are positive, the tanker sample is **CONFIRMED POSITIVE**, milk may not be processed, contact State Regulatory Agency .....
  - d. Producer trace back performed on all producer samples from the load, see item 13 .....
  - e. If both duplicates are negative, milk may be received and processed; record and report as **NOT FOUND**, producer trace back is not performed .....
  - f. Complete applicable section of Positive Report form and maintain records of all analyses .....

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1. For Confirmed Positive samples, maintain a copy of the Positive Report form and forward the original to the State Regulatory Agency .....

**13. Trace back of Producers on a Confirmed Positive Tanker [Only performed in an accredited laboratory or by a CIS (refer to M-a-85 current revision for listing of test kits to assure equivalence)] .....**

- a. Samples must be between 0.0 and 4.5°C; maintain records .....
- b. Perform an initial single test on each producer sample .....
- c. Any producer sample that is positive must be re-tested .....
- d. The **SAME** sample is re-tested by the **SAME** analyst using the **SAME** test in **DUPLICATE** along with a positive and negative control .....
- e. Positive and negative controls give the appropriate result(s) .....
  - 1. If positive and/or negative control do not give appropriate results, re-run controls and samples; if problem persists seek technical assistance .....
- f. If one or both duplicates are positive, the producer sample(s) (are) **POSITIVE** .....
- g. If both duplicates are negative, record and report the appropriate producer sample(s) **NOT FOUND** .....
- h. Complete applicable section of Positive Report form and maintain records of all analyses .....
  - 1. For Confirmed Producer Positive samples, maintain a copy of the Positive Report form and forward the original to the State Regulatory Agency .....

**REPORTING AND RECORDS**

**14. Reporting and Records .....**

- a. Report as **Positive (+)** for beta-lactam, specific drug or inhibitor (when a non-specific microbial inhibitor test used without beta-lactamase) when demonstrated .....
- b. Report as **Not Found (NF)** when demonstrated .....
- c. Record test performed, interpretation of unknowns (samples) and controls .....
- d. Records, including all printouts, maintained for 2 years .....

**MISCELLANEOUS**

**15. Miscellaneous .....**

- a. Current Safety Data Sheets (SDS) accessible to analysts .....
- b. Current, applicable survey forms available in laboratory .....
- c. Positive Report forms available with instructions .....
- d. Personnel adequately trained .....
- e. Required split/check sample participation .....

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