DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MILK LABORATORY EVALUATION RECORD**	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 GENERAL REQUIREMENTS

(Unless otherwise stated all tolerances are ±5%)

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, 0.5C]** .....
- 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 ±1°C when checked at temperature(s) of use .....
  3. Results recorded/documented and individual devices tagged .....
     - 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 .....

Notes

Laboratory	Lab Number
Location	Date *(mm/dd/yyyy)*

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 ...

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 ±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 ±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 ±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) .....
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 .....

Notes

Laboratory	Lab Number
Location	Date *(mm/dd/yyyy)*

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 sample(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 ..... _____

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

Notes

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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 controls 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 ..... _____

Notes