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

FDA/NCIMS Revision 10/13

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

Notes

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 ..... ___

Notes

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) ..... ___

Notes

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 ..... ___

Notes

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 ..... ___

Notes

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

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 ..... ___

Notes