APPENDIX N BULK MILK TANKER SCREENING TEST FORM
GENERAL REQUIREMENTS

[Unless otherwise stated all tolerances ±5%]

1. Work Area _____

a. Ample working space and utilities _____

b. Clean 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 _____

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 3.c 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 _____

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 _____

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 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 kit 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 is 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 is positive the tanker sample is **CONFIRMED POSITIVE**, milk may not be processed, contact State Regulatory _____

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 _____

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 is positive the producer sample(s) is (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 analysis _____

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 _____