

**APPENDIX N BULK MILK TANKER SCREENING TEST FORM  
GENERAL REQUIREMENTS**

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

**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
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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 \_\_\_\_\_
    - 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  $\pm 5\%$  (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) \_\_\_\_\_

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 \_\_\_\_\_