

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 CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, > 50 foot-candles at working surface (pref 100)**] _____

2. Storage Space _____

- a. Cabinets, drawers, and shelves adequate _____
- b. Areas neat, clean and orderly _____

3. Thermometers for Use with Test Kits and Laboratory Equipment _____

- a. Thermometer traceable to NIST Certified thermometer _____
 - 1. Traceable thermometer checked at ice point annually _____
- b. Range of thermometers appropriate for designated use _____
- c. Graduation interval not greater than 1.0C [**NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, 0.5C**] _____
- d. Accuracy of test thermometers checked against traceable thermometer annually (including electronic thermometers) _____
 - 1. Accurate to $\pm 1C$ _____
 - 2. Results recorded and thermometers tagged with date, identification, temperature checked and correction (± 0.0 if none) _____
 - 3. Thermometers calibrated on-site _____
 - 4. Thermometers calibrated at another location _____
 - a. Location calibrated: _____
 - b. Calibrations current and acceptable _____
 - c. Copy of calibration record on-site _____

- e. Records maintained _____
- f. Dial thermometers not permitted _____

4. Refrigeration _____

- a. Size adequate for workload _____
- b. Maintains samples at 0-4.4C _____
- c. Reagents stored as per manufacturer instructions _____
- d. Not used to store food or drink for consumption _____
- e. Record temperature daily from 2 thermometers with bulbs submerged in liquid, placed on upper and lower shelves of use [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, AM and PM] _____
- f. NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, dedicated for milk work only, NO PATHOGENS STORED _____

5. Freezer _____

- a. Size adequate for workload _____
- b. Maintains -15C or below _____
- c. Not used to store food or drink for consumption _____
- d. Record temperature daily from thermometer with bulb submerged in anti-freeze liquid, [NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, AM and PM] _____
- e. NCIMS CERTIFIED LABORATORIES and CERTIFIED INDUSTRY SUPERVISORS, dedicated for milk work only, NO PATHOGENS STORED _____

6. Balance, electronic (if necessary) _____

- a. Weight capability appropriate for intended use _____
- b. Accurate to 0.01g for preparations of positive controls _____
- c. Appropriate sensitivity for calibration of pipetting devices within a tolerance of ±5% (0.001g sensitivity appropriate in most instances) _____
- d. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3 weights (**Appendix N drug testing only laboratories may check every 6 months**) _____
- e. Checked annually by a qualified service representative _____

f. Records maintained _____

7. Pipettors, calibrated, fixed volume or electronic only
[Required for NCIMS Certified Laboratories and
Certified Industry Supervisors] _____

a. Calibrate 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 _____

b. Average of all 10 measurements must be $\pm 5\%$ of specified delivery volume, records maintained _____

c. Or, calibrate 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, records/printouts maintained _____

1. Instrument, printer connected by manufacturer supplied cable or instrument connected to computer via serial cable _____

2. Instrument and printer (if applicable) connected to 120v/60Hz power _____

3. Reagent kits and Instrument Calibrator kits stored at room temperature _____

a. Lot # _____ Exp. Date _____ _____

4. Reagent Blanks and Sample Solutions are the same lot _____

5. Certificates of Calibration for Reagent Kit and Instrument Calibrator kit maintained in records _____

6. Instrument Validation Guide available _____

7. PCS Pipette Calibration System Procedure, follow manufacturer's Procedure Guide and instrument prompts _____

a. Uncover and insert Blank into the instrument _____

b. Determine which volumes are to be calibrated _____

c. Select the correct Sample Solution and aliquot sufficient amount into working vessel provided _____

d. Using the Pipettor to be verified, aspirate the Sample Solution from the working vessel and deliver it into the Blank seated in the instrument _____

- e. When appropriate number of measurements are collected, press 'End of Run' button _____
 - f. Record results and file Pipette Calibration Certificate (printout) _____
 - 8. 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) _____
 - 9. PCS Calibration System Validation, upon receipt, validate the instrument by following the manufacturer's protocol _____
 - d. Pipettors etched with identification (imprinted serial numbers acceptable) and tagged with date calibrated _____
 - e. Appropriate tips for pipettor(s) used _____
 - f. Pipetting devices calibrated on-site _____
 - g. Pipetting devices calibrated at another location _____
 - 1. Location calibrated: _____
 - 2. Calibrations current and acceptable _____
 - 3. Copy of calibration record on-site _____
 - h. Records maintained _____
- 8. Deionized Water or Equivalent, or as specified by manufacturer** _____

SAMPLES

- 9. Sample Requirements** _____
- a. Prevent contamination with disinfectants from hands or other sources _____
 - b. Ascertain temperature of bulk milk tanker _____
 - c. If sample will not be tested without delay then a temperature control (TC) sample must be taken, transported and maintained with the tanker sample until it is tested _____

- d. Secure a representative sample for drug residue testing and transport to testing location promptly, preferably on ice to maintain temperature _____
- e. Tanker samples tested promptly upon arriving at the testing location, measure TC when provided _____
 - 1. Temperature of bulk milk tanker may be used for temperature as received and tested if sample testing begins without delay _____
 - 2. If test kit indicates a positive result, confirmation completed (when necessary) within 72 hours of initial collection _____
- f. Record time, date and temperature of samples as received and tested _____
- g. Determine sample temperature by inserting pre-cooled thermometer (pre-cooling of electronic/digital thermometer probes is not necessary) into temperature control (TC), if no TC, aliquot samples for testing and measure temperature using one of the producer samples _____
- h. Do not accept producer samples (about $\frac{3}{4}$ full) that are over filled _____
- i. If raw milk exceeds 4.4C on receipt do not test (samples may be received at 7C if time of receipt is ~~0~~ hours from collection and arrival temperature is equal to or less than temperature of collection) _____

PERFORMANCE TESTING

10. Performance Testing _____

- a. Run a positive and negative control before use on each new lot of kits, must give appropriate results, records maintained _____
- 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, records maintained _____
- 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, records maintained _____

- d. If more than one analyst performs analysis, have different analyst run performance check on rotational basis
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FOLLOW-UP ON TEST KIT POSITIVE RESULTS
[Must comply with M-a-86, 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
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- b. Positive and negative controls give the appropriate result(s)
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- 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
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- 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
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- e. If both duplicates are negative milk may be received and processed, record and report as **NOT FOUND**
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- f. If positive and/or negative controls do not give appropriate results, re-run controls and samples. If problem persists seek technical assistance
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- g. Complete Positive report form and maintain records of all analyses
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1. For Presumptive Positive samples maintain a copy of the positive report form and forward the original to the certified laboratory or CIS
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12. Confirmation of Presumptive Positive Tanker Samples
[Only in a certified 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
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- b. Positive and negative controls give the appropriate result(s)
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- 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. If positive and/or negative control do not give appropriate results, re-run controls and samples, if problem persists seek technical assistance _____
- g. Complete 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 a certified laboratory or by a CIS (refer to M-a-85 current revision for listing of test kits to assure equivalence), this process is also to be followed when doing PMO Section 6 analyses for drugs] _____

- a. Perform an initial single test on each producer sample along with a single positive and negative control for the series _____
- b. Positive and negative controls give the appropriate result(s) _____
- c. If any producer sample is positive the sample is **SUSPECT** and that/those sample(s) 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) _____
- 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. If positive and/or negative control do not give appropriate results, re-run controls and samples, if problem persists seek technical assistance _____
- i. Complete 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. Material safety data sheets (MSDS) on file _____
- 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 _____