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 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 ±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

(APPN/GENREQ-1-Rev. 2/05)
e. Records maintained

f. Dial thermometers not permitted

4. Refrigeration

a. Size adequate for workload

b. Maintains samples at 0-4.4°C

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 -15°C 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

(APPN/GENREQ-2-Rev. 2/05)
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 ±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 ±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 ________

(APPN/GENREQ-3-Rev. 2/05)
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

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

(APPN/GENREQ-4-Rev. 2/05)
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 ¾ 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 ≤3 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

(APPN/GENREQ-5-Rev. 2/05)
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 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

   b. Positive and negative controls give the appropriate result(s)

   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. If positive and/or negative controls 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 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 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

   b. Positive and negative controls give the appropriate result(s)

(APPN/GENREQ-6-Rev. 2/05)
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 analyses ________

(**APPN/GENREQ-7-Rev. 2/05**)

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