APPENDIX
N
GENERAL TRAINING PROGRAM

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APPENDIX N GENERAL TRAINING PROGRAM

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FDA 2400 FORMS

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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 _____

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

IDEXX - NEW SNAP® BETA-LACTAM TEST
(Raw Commingled Cow, Raw Commingled Camel, and Raw Commingled Goat Milk)
IMS # 9-I1

[Unless otherwise stated all tolerances are ±5%]

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Heater block with SNAP insert thermostatically controlled at 45±5°C _____

1. Check temperature by placing standardized temperature measuring device in a tube containing liquid (bulb submersed); maintain records _____

2. Or, use 6-inch partial immersion thermometer placed directly into small thermometer well in middle of heating unit; maintain records _____

3. Temperature measuring device for each incubator (App. N GR item 3) _____

b. IDEXX Readers for SNAP devices, with printer or data download capability _____

1. SNAPshot® Reader _____

a. Check Set, Part Number 87-05856-01 (black skirt) _____

2. SNAPshot® DSR Reader _____

a. Check Set, Part Number 87-14761-00 (blue skirt) _____

c. Pipettor - 450 µL and disposable tips (see App. N GR item 7) _____

d. Or single use 450 µL poly-pipet with indicator line to measure amount of sample, supplied by manufacturer **(screening only)** _____

e. Timer _____

4. Reagents _____

a. SNAP Kit _____

Lot #: _____ Exp Date: _____ _____

QC Date: _____ By: ___ _____

1. Sample tubes containing reagent pellet _____

b. Positive Control _____

1. IDEXX Penicillin Positive Control _____

Lot #: _____ Exp Date: _____ _____

c. Negative Control _____

1. Previously tested negative raw milk (item 5.d) _____

5. Reagent stability _____

a. Kits must be received within 72 hours if shipped non-refrigerated; over 72 hours must be shipped refrigerated _____

b. Store kits at 0-7°C, maintain no longer than manufacturer's expiration date _____

c. Positive Control- Manufacturer supplied, maintain no longer than manufacturer's expiration date _____

1. Store according to label instructions _____

2. Reconstitute as per manufacturer's instructions with fresh or frozen previously screened beta-lactam negative raw milk.

3. Positive control must produce greater than 1.2 on the IDEXX reader; maintain records _____

Reader value: _____ _____

4. Store reconstituted positive control at 0.0-4.5°C for no more than 24 hours _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

d. Negative Control - beta-lactam negative raw milk (fresh or frozen) _____

1. Negative control must produce less than 0.95 on the IDEXX reader; (SNAP Test Negative Control can be any of the approved species milk); maintain records _____

Sample ID: _____ Date Tested: _____ _____

Reader value: _____ _____

2. Store fresh negative control milk at 0.0-4.5°C for no more than 72 hours _____

3. Negative control milk frozen for later use _____

a. Aliquot within 24 hours and freeze at –15°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

b. Thaw frozen milk at 0.0-4.5°C _____

c. Once thawed mix thoroughly, **Do Not** use if noticeable protein precipitation is present after thawing _____

d. Thawed negative control milk held at 0.0-4.5°C and used within 24 hours _____

4. Milk controls may not be refrozen _____

6. Daily Performance and Operation Checks (see App. N GR item 10) _____

a. Read Performance Check Set (Device #1 as Negative and Device #2 as Positive) _____

b. Both devices must read within the limits as indicated on the storage box label of the check set devices _____

Positive Range: _____ Negative Range: _____ _____

c. If check sets fail, call IDEXX before proceeding _____

TECHNIQUE

7. Test Procedure _____

a. Set out required number of SNAP devices, sample tubes and pipets for the samples to be tested _____

1. Discard unused, un-refrigerated devices at the end of the day _____

b. Pre-warm heater block(s) to 45±5°C, and maintain 45±5°C range for at least 5 min before beginning the test _____

1. Check initial pre-heating with a temperature measuring device (see App**.** N GR item 3); maintain records _____

2. Continuous use block heaters, check temperature daily with temperature measuring device (see App**.** N GR item 3); maintain records _____

c. Label each device and sample tube _____

d. Place device(s) on incubator block(s) _____

e. Verify that blue reagent pellet is in bottom of tube before removing cap. If not in bottom, tap to bring down _____

f. Remove and discard sample tube cap(s) _____

g. Mix milk sample(s)**/**control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (samples must be in appropriate containers to allow the use of vortexing) _____

h. Add 450 uL of mixed sample/control to corresponding tube(s) _____

1. Using Pipettor (item 3.c) with a new tip for each sample/control draw up 450 µL avoiding foam and bubbles _____

a. Remove tip from liquid _____

b. While holding the pipettor vertically, expel test portion to sample tube _____

2. Using a new manufacturer provided single-use 450 µL poly-pipet (item 3d.) for each sample/control **(Screening Only)** _____

a. Draw up 450 uL of sample to indicator line, avoiding foam and bubbles _____

b. Remove tip from liquid _____

c. While holding poly-pipet vertically, expel test portion to sample tube _____

i. Agitate sample tube(s) to dissolve reagent pellet _____

j. Place tube(s) in heater block next to device with the corresponding ID _____

k. Incubate tube(s) for 5 min (use timer) at 45±5°C _____

l. After incubation, pour contents of each tube into sample well of corresponding device _____

m. Watch blue activation circle, as it begins to disappear push the activator firmly until it "snaps" flush with the body of the SNAP device (device remains on heater block) _____

n. Incubate device for 4 min (use timer) at 45±5°C _____

o. At the end of incubation, visually inspect the control and test spots. The test is invalid and the same sample should be retested with a new SNAP device if: _____

1. The control spot fails to develop color _____

2. Blue streaking occurs in the background or the background is the same color as the sample or control spots _____

3. The sample or control spots are not uniform in color or exhibit poor spot quality _____

p. Insert only valid tests in the reader **IMMEDIATELY (no longer than 30 sec)** after completion of incubation _____

8. Interpretation with Idexx Reader for SNAP Devices _____

a. IDEXX Reader for SNAP devices automatically prints results as Positive or Negative (NF) _____

9. Verification of Initial Positive Tanker Samples (see App. N GR item 11); Confirmation of Presumptive Positive Tanker Samples (see App. N GR item 12); and Traceback of Producer(s) on a Confirmed Positive Tanker (see App. N GR item 13) _____

10. Reporting (see App. N GR item 14) _____

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

CHARM® SL (Raw Commingled Cow, Sheep, Water Buffalo and Goat Milk), IMS #9-C13
AND
Charm 3 SL3 (Raw Commingled Cow Milk), IMS #9-C15

BETA-LACTAM TESTS

[Unless otherwise stated all tolerances are ±5%]

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Charm Sciences Strip Incubator:
56±1°C 8 min timer - SL beta-lactam test;
56±1°C 3 min with internal timer – SL3 beta-lactam test
56±1°C Charm EZ display when message "Add milk to strip and close door" _____

1. Clean, properly maintained and located on a level surface _____

2. Check temperature daily (day of use); maintain records _____

   a. Charm EZ printout acceptable for daily temperature check (annual accuracy check required); maintain records _____

3. Temperature measuring device for each incubator (App N. GR item 3) _____

4. Lid closed (slightly sprung so that timer not active) when not running tests _____

5. Incubator Temperature: _____ _____

6. Timer if not included in incubator
   Incubation Time of internal timer: _____ _____

b. ROSA® Reader, ROSA Pearl Reader (with or without ROSA Barcode option), Charm EZ or Charm Sciences equivalent with print out or download of data; manual available _____

Serial Number: _____ _____

1. SL beta-lactam test - ROSA Reader V1.03 or higher (or if ROSA Pearl Reader or Charm EZ see 3.b.2) _____

a. Calibrators _____

Range(s)	Result	
Low: _____	_____	_____
High: _____	_____	_____

b. Maintain records _____

2. SL3 beta-lactam test - ROSA Pearl Reader V3.00 or higher or Charm EZ _____

a. Calibrators - Low and High for use in all assay channels _____

Range(s)	Result	
Low: _____ (darker magenta)	_____	_____
High: _____ (lighter pink)	_____	_____

b. Maintain records _____

3. Calibrator serial numbers match reader SN _____

4. **Do not proceed if out of range.** Manufacturer should be contacted for corrective actions _____

5. Printer or computer link for hardcopy download _____

c. Pipettor - 300 µL and disposable tips (see App. N GR item 7) _____

d. Or single use 300 µL ROSA-pipet with overflow bulb to accurately measure amount of sample, supplied by manufacturer **(screening only)** _____

e. Optional Centrifuge (Not applicable to SL3 beta-lactam test) - mini or equivalent (1200-2000 x g) for frozen controls _____

4. Reagents _____

a. Test Strips (EZ Compatible for Charm EZ) _____

Lot #: _____ Exp. Date: _____ _____

QC Date: _____ By: _____ _____

b. Positive Control _____

1. Lyophilized or tablet 5 ppb Penicillin G beta-lactam tests _____

Lot #: _____ Exp Date: _____ _____

c. Negative Control _____

1. Previously negative tested raw milk (item 5.d) _____

5. Reagent stability _____

a. SL3 reagents must be received within 72 hours if shipped non-refrigerated; over 72 hours must be refrigerated. (Not applicable to the SL reagents) _____

b. Store reagents at 0.0-4.5°C, desiccant blue, maintain no longer than manufacturer's expiration date _____

1. **Do not use if desiccant indicator is white or pink** _____

c. Positive Control - Manufacturer supplied, maintain no longer than manufacturer's expiration date _____

1. Reconstitute with Negative Control (raw milk), tested +400 or more positive, used within 48 hours when maintained at 0.0-4.5°C _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

2. Or, aliquot within 24 hours and freeze at –15°C or colder in a non frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation** _____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

c. For **SL ONLY**, centrifuge 3 min and cool _____

1. Test portion below fat layer without mixing _____

3. Day of use, must produce +400 or greater reading; maintain records _____

Test Value: _____ _____

Do not proceed if out of range _____

d. Negative Control - raw milk tested –600 or more negative;
(SL Test Negative Control can be any of the approved species milk) _____

Sample ID: _____ Test Value: _____ _____

Date tested: _____ _____

1. Use within 72 hours when maintained at 0.0-4.5°C _____

2. Or, aliquot within 24 hours and freeze at –15°C or colder in a non frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation** _____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

c. For SL **ONLY**, centrifuge 3 min and cool _____

1. Test portion below fat layer without mixing _____

3. Day of use must produce –600 or more negative; maintain records _____

Do not proceed if out of range _____

TECHNIQUE

6. Daily Performance and Operation Check _____

a. See App. N GR items 10.b-d _____

b. If using ROSA reader Versions 1.05 and higher, or ROSA-Pearl, use ESC 5 reader function to enter performance monitoring mode of reader; if using Charm EZ, use Menu to enter Performance Monitoring mode and “Perf Mon” to enter daily performance check; refer to manual for directions _____

c. Check Calibrators; items 3.b.1 or 3.b.2 _____

d. Positive and negative controls must give appropriate readings prior to any sample analysis (see App. N GR item 10.a) _____

e. Controls in-range when in performance monitoring mode, ROSA reader version 1.05 and higher, ROSA Pearl or Charm EZ _____

f. **Do not proceed if out of range** _____

7. Test Procedure _____

a. Set out required number of test strips and place them in a dry labeled container at room temperature, or take out strips as needed _____

1. Discard unused test strips at the end of the day _____

b. Label test strips, one for each test sample and each control. Avoid crushing sample compartment(s) _____

c. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (samples/controls must be in appropriate containers to allow the use of vortexing) _____

1. Centrifuge sheep milk sample(s)/controls that have been previously frozen; refer to 5.c.2.a-c and 5.d.2.a-c _____

d. Place strip into appropriate incubator _____

e. While holding strip flat, peel back plastic (to ‘peel to here’ line) to expose sample pad compartment. Avoid lifting the wick and sponge under tape _____

1. For multiple samples, complete steps 7.d-g for each sample/control, before starting test of next sample _____

2. Complete all samples within 2 min (1 min 15 sec for SL3 test) of placing first strip in incubator _____

f. Add 300 µL of mixed sample/control to corresponding strip _____

1. Using pipettor (item 3.c) with new tip for each sample/control, draw up 300 µL avoiding foam or bubbles _____

   a. Remove tip from liquid _____

   b. While holding the pipettor vertically, expel test portion slowly into either side well of appropriate strip _____

2. Using new manufacturer-provided ROSA-pipet (item 3.d) for each sample/control **[Screening only]** _____

   a. Squeeze top bulb while holding vertically with bulb and overflow reservoir side pointing down, draw up test portion avoiding foam and bubbles. Sample should completely fill pipet shaft and overflow into the bottom half of the overflow reservoir _____

   b. Remove tip from liquid _____

   c. While holding the ROSA-pipet vertically, expel test portion slowly into either side well of appropriate strip. Excess portion should remain in reservoir _____

g. Re-seal plastic firmly around sample pad compartment _____

h. ROSA Reader and Charm EZ (read only mode) _____

1. Close lid and latch ROSA incubator to start automatic timer in the incubator. If no automatic timer in incubator, set external timer for 8 min for SL. For SL test, incubate 8 min not to exceed 9 min. For SL3 test, incubate 3 min not to exceed 3 min and 30 sec _____

2. At end of incubation visually inspect C (Control) line. An absent C line, a partial C line or an indistinct C line indicates an invalid test; and the sample/control must be re-tested _____

3. Insert only valid test(s) in reader _____

   a. ROSA reader set to appropriate channel

      1. SLBL slow blink for SL beta-lactam test _____

      2. SLBL solid (no blink) for SL3 beta-lactam test _____

      3. Press ENTER, reading and interpretation appear in 5 sec, read strips within 5 min (3 min with SL3) of completion of incubation. Strips may be held vertically, sample compartment down while waiting to be read _____

b. Charm EZ automatically sets channel when color coded strip inserted _____

1. Close door; reading and interpretation appear in 5 sec, read strips within 5 min (3 min with SL3) of completion of incubation. Strips may be held vertically, sample compartment down while wait to read _____

i. Charm EZ (incubate and read mode) _____

1. Charm EZ automatically sets channel and incubator temperature when color coded strip inserted. Optionally enter sample ID _____

2. Peel strip (7.e) and add milk (7.f) _____

3. Close door to begin _____

4. Charm EZ automatically prompts for further testing when positive _____

8. Interpretation with Reader _____

a. If there is a negative or zero reading on the reader, sample is **a Negative (NF)** _____

b. If there is a positive reading on the reader, sample is **an Initial Positive** _____

9. Verification of Initial Positive Tanker Samples (see App. N GR item 11); Confirmation of Presumptive Positive Tanker Samples (see App. N GR item 12); and Traceback of Producer(s) on a Confirmed Positive Tanker (see App. N GR item 13) _____

10. Reporting (see App. N GR item 14) _____

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

CHARM® FLUSLBL (Raw Commingled Cow Milk)
FLUNIXIN and BETA-LACTAM TEST
IMS #9-C16

[Unless otherwise stated all tolerances are ±5%]

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Charm Sciences Strip Incubator:
56±1°C 8 min timer
56±1°C Charm EZ display when message 'Add milk to strip and close door' _____

1. Clean, properly maintained and located on a level surface _____

2. Check temperature daily (day of use); maintain records _____

a. Charm EZ printout acceptable for daily temperature check (annual accuracy check required); maintain records _____

3. Temperature measuring device for each incubator (App N. GR item 3) _____

4. Lid closed (slightly sprung so that timer not active) when not running tests _____

5. Incubator Temperature: _____ _____

b. ROSA® Reader, ROSA Pearl Reader (with or without ROSA Barcode option), Charm EZ or Charm Sciences equivalent with print out or download of data; manual available _____

Serial Number: _____ _____

1. ROSA Reader V1.07 or higher
(or if ROSA Pearl Reader or Charm EZ see 3.b.2) _____

a. Calibrators _____

Range(s)	Result	
Low: _____	_____	_____
High: _____	_____	_____

b. Maintain records _____

2. ROSA Pearl Reader V3.00 or higher or Charm EZ _____

a. Calibrators - Low and High for use in all assay channels _____

Range(s)	Result	
Low: _____ (darker magenta)	_____	_____
High: _____ (lighter pink)	_____	_____

b. Maintain records _____

3. Calibrator serial numbers match ROSA reader SN _____

4. **Do not proceed if out of range.** Manufacturer should be contacted for corrective actions _____

5. Printer or computer link for hardcopy download _____

c. Pipettor - 300 µL and disposable tips (see App. N GR item 7) _____

d. Or single use 300 µL ROSA-pipet with overflow bulb to accurately measure amount of sample; supplied by manufacturer **(screening only)** _____

4. Reagents _____

a. Test Strips (EZ Compatible for Charm EZ) _____

Lot #: _____ Exp. Date: _____ _____

QC Date: _____ By: _____ _____

b. Positive Control (labeled as 2 ppb Flunixin and 5 ppb Penicillin G Standard) _____

1. 5 ppb Penicillin G Standard _____

Lot #: _____ Exp. Date: _____ _____

2. 2 ppb Lyophilized Flunixin _____

Lot #: _____ Exp. Date: _____ _____

3. Or, alternative to 4.b.1-4.b.2, 5 ppb Penicillin G and 2 ppb Flunixin tablet _____

4. Preparation _____

a. Add 10.0 mL negative raw milk (item 5.d) to Flunixin control (item 4.b.2), and allow to rehydrate for 5 min _____

b. Add 8.0 mL of reconstituted Flunixin control (item 4.b.4.a) to Positive Control (item 4.b.1), and allow to rehydrate for 5 min _____

c. Or, alternative to 4.b.4.a and 4.b.4.b, add 5.0 mL negative milk (item 5.d) to Flunixin and Penicillin G tablet (item 4.b.3), and allow to rehydrate for 5 min _____

c. Negative Control _____

1. Previously negative tested raw milk (item 5.d) _____

5. Reagent stability _____

a. FLUSLBL reagents received refrigerated _____

b. Store reagents at 0.0-4.5°C, desiccant blue, maintain no longer than manufacturer's expiration date _____

1. **Do not use if desiccant indicator is white or pink** _____

c. Positive Control - Manufacturer supplied; maintain no longer than manufacturer's expiration date _____

1. Reconstituted Control (4.b.4), tested +400 or more positive; use within 48 hours when maintained at 0.0-4.5°C _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

2. Or, aliquot within 24 hours and freeze at =15°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 3 weeks _____

Lab Date prep: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation** _____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

3. Day of use, must produce +400 or greater reading; maintain records _____

Test Value: _____ _____

Do not proceed if out of range _____

d. Negative Control - raw milk tested –400 or more negative with FLUSLBL test _____

Sample ID: _____ Test Value: _____ _____

Date tested: _____ _____

1. Used within 72 hours when maintained at 0.0-4.5°C _____

2. Or, aliquot within 24 hours and freeze at –15°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 3 weeks _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation** _____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

3. Day of use must produce –400 or more negative with FLUSLBL test: maintain records _____

Do not proceed if out of range _____

TECHNIQUE

6. Daily Performance and Operation Check _____

a. See App. N GR items 10.b-d _____

b. If using ROSA reader Version 1.07 and higher, or ROSA Pearl, use ESC 5 reader function to enter performance monitoring mode of reader; if using Charm EZ, use Menu to enter Performance Monitoring mode and "Perf Mon" to enter daily performance check; refer to manual for directions _____

c. Check Calibrators, items 3.b.1 & 3.b.2 _____

d. Positive and negative controls must give appropriate readings prior to any sample analysis (see App. N GR item 10.a) _____

e. Controls in-range when in performance monitoring mode, ROSA reader version 1.07 and higher, ROSA Pearl or Charm EZ _____

1. If out of range, manufacturer should be contacted for corrective action, 800-343-2170 _____

f. **Do not proceed if out of range** _____

7. Test Procedure _____

a. Set out required number of test strips for samples to be tested in one day and place them in a dry labeled container at room temperature, or take out strips as needed _____

1. Discard unused test strips at the end of the day _____

b. Label test strips, one for each test sample and each control. Avoid crushing sample compartment(s) _____

c. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (samples/controls must be in appropriate containers to allow the use of vortexing) _____

d. Place strip into appropriate incubator _____

e. While holding strip flat, peel back plastic (to 'peel to here' line) to expose sample pad compartment. Avoid lifting the wick and sponge under tape _____

1. For multiple samples, complete steps 7.d-g for each sample/control, before starting test of next sample _____

2. Complete all samples within 2 min of placing first strip in incubator _____

f. Add 300 µL of mixed sample/control to corresponding strip _____

1. Using pipettor (item 3.c) with new tip for each control/sample, draw up 300 µL avoiding foam or bubbles _____

   a. Remove tip from liquid _____

   b. While holding the pipettor vertically, expel test portion slowly into either side well of appropriate strip _____

2. Using new manufacturer-provided ROSA-pipet (item 3.d) for each control/sample **[Screening only]** _____

   a. Depress top bulb while holding vertically with bulb and overflow reservoir side pointing down, draw up test portion avoiding foam and bubbles. Sample should completely fill pipet shaft and overflow into the bottom half of the overflow reservoir _____

   b. Remove tip from liquid _____

   c. While holding the ROSA-pipet vertically, expel test portion slowly into either side well of appropriate strip. Excess portion should remain in reservoir _____

g. Re-seal plastic firmly around sample pad compartment _____

h. ROSA Reader and Charm EZ (read only mode) _____

1. Close lid and latch ROSA incubator to start automatic timer in the incubator. If no automatic timer in incubator, set external timer for 8 min not to exceed 9 min _____

2. At end of incubation visually inspect C (Control) line. An absent C line, a partial C line or an indistinct C line indicates an invalid test, and the sample/control must be re-tested _____

3. Insert only valid test(s) in reader _____

   a. ROSA reader set to appropriate channel _____

      1. Press ENTER; reading and interpretation appear in 5 sec, read strips within 5 min of completion of incubation. Strips may be held vertically, sample compartment down while waiting to be read _____

CHARM® II BETA-LACTAM ASSAYS

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

Competitive (Raw Commingled Cow Milk and Pasteurized White Milks) IMS #9-C2
Sequential (Raw Commingled Cow and Goat Milk) IMS #9-C3
Quantitative (Raw Commingled Cow Milk) IMS #9-C4
Cloxacillin (Raw Commingled Cow Milk) IMS #9-C9

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Analyzer heater for 13 x 100 mm tubes _____

1. 85±2°C for Competitive Assay ____ _____

2. 65±2°C for Sequential Assay ____ _____

3. 55±2°C for Quantitative Assay ____ _____

4. 35±2°C for Cloxacillin Assay ____ _____

5. Temperature checked by electronic display, or by placing accuracy checked temperature measuring device in tube containing liquid (bulb submersed) in heating unit; maintain records _____

6. Or, use 6 inch partial immersion thermometer placed directly into small thermometer well in middle of heating unit; maintain records _____

7. Temperature measuring device for each incubator (App. N item 3) _____

b. Mixer, Maxi-mixer II or equivalent _____

c. Centrifuge, Whisperfuge® or Heraeus® (3400 rpm) or equivalent _____

d. Scintillation counter, Charm II or equivalent _____

e. Scintillation fluid dispenser, set to dispense 3 mL _____

1. Check every six (6) months with Class A graduated cylinder and record; maintain records _____

f. Cotton swabs _____

g. Borosilicate test tubes, 13 x 100 mm _____

h. Plastic stoppers for tubes _____

i. Pipettors - Fixed Volume or Electronic (see App. N GR item 7) _____

1. 300 µL and appropriate tips _____

2. 5.0 mL and appropriate tips _____

j. Timer _____

4. Reagents _____

a. Scintillation fluid – Optifluor or equivalent supplied by manufacturer of test kits _____

b. Competitive, Sequential or Quantitative Assay _____

1. Reagent blister packages: microbial binder (green) tablet, tracer reagent (yellow) tablet _____

Lot #: _____ Exp. Date: _____

2. 0.008 IU/mL Penicillin G standard _____

Lot #: _____ Exp. Date: _____

3. Zero control standard _____

Lot #: _____ Exp. Date: _____

c. Cloxacillin Assay _____

1. Reagent blister packages: microbial/antibody binder (white) tablet, tracer reagent (blue) tablet _____

Lot #: _____ Exp. Date: _____

2. 10 ppb Cloxacillin standard _____

Lot #: _____ Exp. Date: _____

3. Zero control standard _____

Lot #: _____ Exp. Date: _____

5. Reagent stability _____

a. All tablet reagents stored at -15°C or below _____

b. Positive Control – Lyophilized 0.008 IU/mL penicillin G or 10 ppb cloxacillin standard for Cloxacillin assay _____

1. Reconstitute with 100 mL (measured) Negative Control (allow to sit 15 min prior to use or aliquotting) _____

   Lab Prep. Date: _____ Lab Exp. Date: _____

2. For Quantitative Only: Dilute reconstituted 0.008 IU/mL Penicillin G standard 1:4 with Zero Control Standard _____

3. Use within 48 hours when stored at 0.0-4.5°C _____

4. Or, aliquot within 24 hours and freeze at -15°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer**;** use within 2 months _____

   Lab Prep. Date: _____ Lab Exp. Date: _____

   a. Thaw and use within 24 hours. Store at 0.0-4.5°C _____

c. Negative Control – Lyophilized Zero Control Standard (ZCS) or alternatively, raw milk qualified to test similar to ZCS _____

Lab Prep. Date: _____ Lab Exp. Date: _____

1. Reconstitute ZCS according to manufacture instructions (allow to sit 15 min prior to use or aliquotting) _____

   a. To qualify raw milk, test sample 3 times and average results. Average must be within +/-10% of ZCS _____

      Lab Prep. Date: _____ Lab Exp Date: _____ _____

2. Use within 48 hour when stored at 0.0-4.5°C _____

3. Or, aliquot within 24 hours and freeze at -15°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

   Lab Prep. Date: _____ Lab Exp. Date: _____

   a. Thaw and use within 24 hours. Store at 0.0-4.5°C _____

d. Scintillation fluid expires six (6) months after opening _____

   Date Opened: _____ Lab Exp. Date: _____ _____

TECHNIQUE

6. Control Point and Negative Control Average to be determined for each new lot of reagents. Steps 6, 7, and 8 are for the various Charm beta-lactam screening methods and it is operator choice which method is followed _____

a. Competitive Assay Control Point (CP) and Negative Control Average _____

1. Run six 0.008 IU/mL Pen G _____

2. Run three Negative Controls _____

Penicillin G		Negative Control	
1.	_____	1.	_____
2.	_____	2.	_____
3.	_____	3.	_____
4.	_____	Av.	_____
5.	_____		
6.	_____		
Av.	_____		
+15%	_____		
CP	_____		_____

b. Sequential Assay Control Point (CP) and Negative Control Average _____

1. Run six 0.008 IU/mL Pen G _____

2. Run three Negative Controls _____

Penicillin G		Negative Control	
1.	_____	1.	_____
2.	_____	2.	_____
3.	_____	3.	_____
4.	_____	Av.	_____
5.	_____		
6.	_____		
Av.	_____		
+25%	_____		
CP	_____		_____

c. Quantitative Assay Control Point (CP) and Negative Control Average

1. Run six Negative Controls

2. Run three 0.002 IU/mL Pen G (1 part 0.008 IU/mL and 3 parts Negative Control) _____

Negative Control		Penicillin G	
1.	_____	1.	_____
2.	_____	2.	_____
3.	_____	3.	_____
4.	_____	Av.	_____
5.	_____		
6.	_____		
Av.	_____		
–15%	_____		
CP	_____		_____

d. Cloxacillin Assay Control Point (CP) and Zero Control Average _____

1. Run six 10 ppb Cloxacillin

2. Run three Negative Controls _____

Cloxacillin		Negative Control	
1.	_____	1.	_____
2.	_____	2.	_____
3.	_____	3.	_____
4.	_____	Av.	_____
5.	_____		
6.	_____		
Av.	_____		
+15%	_____		
CP	_____		_____

7. Acceptability of Control Point Determinations _____

a. If any of the 6 control point determinations deviate from the average, redo that determination _____

1. For Competitive Assay cannot deviate by more than ±15% _____

2. For Sequential Assay cannot deviate by more than ±25% _____

3. For Quantitative Assay cannot deviate by more than ±15% _____

4. For Cloxacillin Assay cannot deviate by more than ±15% _____

b. If the re-determined value is within the allowed deviation recalculate the average and proceed with testing _____

c. If the value is not within allowed deviation, run another set of 6 standards _____

d. A common control point for multiple analysts may be used _____

1. Control point determination performed by one analyst only _____

2. Control point determination rotated and inclusive of all certified/approved analysts _____

3. If daily performance check fails and is not resolved by using fresh controls, technique should be reviewed for consistency and corrective action taken as necessary _____

8. Daily Performance and Operation Check (also see App. N GR item 10) _____

a. The negative control tests ±20% (±15% for Quantitative Assay) established for each new kit lot _____

b. The positive control tests less than or equal to the control point _____

c. If these conditions are not met re-determine control point(s) _____

1. Conditions met, proceed with testing _____

2. Conditions not met, discontinue testing and seek technical assistance _____

9. Beta-lactam (all except Cloxacillin) Test Procedures _____

a. Label test tubes, one for each test sample _____

b. Add 1 green tablet to each tube _____

c. Add 300 µL water to each tube _____

d. Breakup tablets in tubes by mixing tubes 10 times on mixer in a rise and fall motion in 10 sec, if necessary continue mixing, green tablets must be completely suspended before proceeding _____

e. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting, use within 3 min (samples must be in appropriate container to allow the use of vortexing) _____

f. Add 5.0 mL of mixed sample/control to corresponding tube _____

1. Using pipettor (item 3.i.2) with new tip for each sample/control, draw up 5 mL avoiding foam or bubbles _____

2. Remove tip from liquid _____

3. Expel test portion into appropriate tube _____

g. Competitive Assay _____

1. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

   a. Add yellow tablet to each tube _____

   b. Vortex tubes 10 times in a rise and fall motion in 10 sec (yellow tablets do not breakup) _____

2. Incubate tubes for 3 min at 85±2°C _____

3. Remove tubes and centrifuge for 3 min, optionally for 5 min (same time used to determine control point) _____

4. Skip to item 11 _____

h. Sequential Assay _____

1. Vortex tubes 10 times in a rise and fall motion in 10 sec _____

2. Incubate tubes for 2 min at 65±2°C _____

3. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

   a. Add yellow tablet to each tube _____

   b. Vortex tubes as in item 9.h.1 above _____

4. Incubate tubes for 2 min at 65±2°C _____

5. Remove tubes and centrifuge for 3 min, optionally for 5 min (same time used to determine control point) _____

6. Skip to item 11 _____

i. Quantitative Assay _____

1. Vortex tubes 10 times in a rise and fall motion in 10 sec _____

2. Incubate tubes for 7 min at 55±2°C _____

3. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

   a. Add yellow tablet to each tube _____

   b. Vortex tubes as in item 1 above _____

4. Incubate tubes for 2 min at 55±2°C _____

5. Remove tubes and centrifuge for 3 min, optionally for 5 min (same time used to determine control point) _____

6. Skip to item 11 _____

10. Cloxacillin Test Procedure _____

a. Competitive Assay _____

1. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting, use within 3 min (samples must be in appropriate containers to allow the use of vortexing) _____

2. Fill identified test tubes ¾ full with milk samples, avoiding foam and bubbles, and centrifuge for 5 min _____

3. Cool tubes to 0.0-4.5°C _____

4. Label empty test tubes, one for each test sample _____

5. Add 1 white tablet to each new empty tube _____

6 Add 300 µL water to each tube _____

7. Breakup tablets in tubes by vortexing tubes 10 times on mixer in a rise and fall motion in 10 sec, if necessary continue vortexing, white tablets must be completely suspended before proceeding _____

8. Draw up 5.0 mL of centrifuged sample/control from below the fat layer _____

a. Use new tip for each sample/control _____

b. Remove tip from liquid _____

c. Expel test portion into appropriate tube _____

9. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

a. Add blue tablet to each tube _____

b. Vortex tubes 10 times in a rise and fall motion in 10 sec (blue tablets do not breakup) _____

10. Incubate tubes for 3 min at 35±2°C _____

11. Remove tubes and centrifuge for 5 min _____

11. After Centrifugation Step in Beta-Lactam (9.g.3, 9.h.5, and 9.i.5) and Cloxacillin (10.a.11) Test Procedures _____

a. Immediately pour off milk _____

b. While still draining tubes, remove fat ring with 2 or more cotton swabs, continue until dry, do not touch pellet (do not go much below the fat ring) _____

c. Add 300 µL of water to tubes and break up pellets using vortex mixer _____

d. Pellets must be completely suspended before proceeding to next step _____

e. Add 3 mL of scintillation fluid to each tube, cap and vortex until uniformly mixed _____

f. Count tubes on scintillation counter for 1 min using [14C] channel _____

g. Record counts as counts per minute (CPM) _____

12. Interpretation _____

a. If the beta-lactam assay (not applicable to Cloxacillin Assay) result the analyzer is at least 50 points greater than the control point, then the sample result is Negative (NF) _____

b. If Cloxacillin assay result is greater than the control then the sample is Negative (NF) _____

c. If the beta-lactam assay result in the analyzer is less than or equal to the control point then the sample is Presumptive Positive _____

d. If the beta-lactam assay (not applicable to Cloxacillin Assay) result in the analyzer is less than 50 points greater than the control point, then the sample must be re-counted _____

1. If on re-count the result is greater than the control point, then the sample is Negative (NF) _____

2. If on re-count the result is equal to or less than the control point, then the sample is Presumptive Positive _____

13. Verification of Initial Positive Samples (see App. N GR item 11); Confirmation of Presumptive Positive Samples (see App. N GR item 12); and Producer Traceback (see App. N GR item 13). For Quantitative Assay: PROMPTLY retest the SAME sample using the Sequential Assay or Competitive Assay, and when these beta-lactam assays give Not Found [NF] the Cloxacillin Assay is required _____

14. Reporting (see App. N GR item 14) _____

15. Handling of Exempt Quantities of Radioactive Materials _____

a. No mouth pipetting _____

b. No smoking, eating or use of cosmetics while reagents are being handled _____

c. NRC (Nuclear Regulatory Commission) licensed facilities must meet requirements as they relate to the use of gloves, other protective measures, and handling of wastes _____

d. Wash hands thoroughly after handling reagents _____

e. Wipe up spills immediately and thoroughly _____

f. Properly dispose of all contaminated waste _____

CHARM® II COMPETITIVE ASSAYS

FOR SULFONAMIDES (IMS #9C-10), TETRACYCLINES (IMS #9C-12) AND CHLORAMPHENICOL (IMS #9C-11)

APPENDIX N BULK MILK TANKER SCREENING TEST FORM (Raw Commingled Cow Milk)

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Analyzer heater for 13 x 100 mm tubes _____

1. 85±2ºC for Sulfonamide Assay ____ _____

2. 35±2ºC for Tetracycline Assay ____ _____

3. Check temperature by electronic display, or by placing accuracy checked temperature measuring device in tube containing liquid (bulb submersed) in heating unit; maintain records _____

4. Or, use 6 inch partial immersion thermometer placed directly into small thermometer well in middle of heating unit; maintain records _____

5. Temperature measuring device for each incubator (App. N GR item 3) _____

b. Ice-water bath, 0.0-4.5ºC for Chloramphenicol Assay _____

c. Mixer, Maxi-mixer II or equivalent _____

d. Centrifuge, Whisperfuge® or Heraeus® (3400 rpm) or equivalent _____

e. Scintillation counter, Charm II or equivalent _____

f. Scintillation fluid dispenser, set to dispense 3 mL _____

1. Checked every six (6) months with Class A graduated cylinder and record; maintain records _____

g. Cotton swabs (not applicable for Chloramphenicol Assay) _____

h. Borosilicate test tubes, 13 x 100 mm _____

i. Plastic stoppers for tubes _____

j. Pipettors – Fixed Volume or electronic (see App. N GR item 7) _____

1. 300 µL and appropriate tips _____

2. 5.0 mL and appropriate tips _____

3. 1.0 mL and appropriate tips (not applicable Sulfa Drug Assay) _____

k. Timer _____

4. Reagents _____

a. Scintillation fluid – Optifluor or equivalent supplied by manufacturer of test kits _____

b. Sulfonamide Assay (Competitive Assay) _____

1. Reagent blister packages: microbial/antibody binder (white) tablet, tracer reagent (pink) tablet _____

Lot #: _____ Exp. Date: _____ _____

2. 10 ppb Sulfamethazine standard or multi-standard _____

Lot #: _____ Exp. Date: _____ _____

3. Zero control standard _____

Lot #: _____ Exp. Date: _____ _____

c. Chloramphenicol Assay (Chloramphenicol and other Amphenicols) _____

1. Reagent blister packages: reagent (white tablet), tracer reagent (green tablet) and Charcoal (black tablet) _____

Lot #: _____ Exp. Date: _____ _____

2. 1 ppb Chloramphenicol standard or multi-standard _____

Lot #: _____ Exp. Date: _____ _____

3. Zero control standard _____

Lot #: _____ Exp. Date: _____ _____

d. Tetracycline Assay (Competitive Assay) _____

1. Reagent blister packages: microbial/antibody binder (white) tablet, tracer reagent (orange) tablet _____

Lot #: _____ Exp. Date: _____ _____

2. 30 ppb Oxytetracycline standard or multi-standard _____

Lot #: _____ Exp. Date: _____ _____

3. Zero control standard _____

Lot #: _____ Exp. Date: _____ _____

5. Reagent stability _____

a. All tablet reagents stored at –15ºC or below _____

b. Positive Control – Lyophilized 10 ppb Sulfamethazine, 30 ppb Oxytetracycline and 1 ppb Chloramphenicol standards _____

1. Reconstitute with 100 mL (measured) Negative Control (allow to sit 15 min prior to use or aliquotting); use within 48 hours at 0.0-4.5ºC _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

2. Or, aliquot within 24 hours and freeze at –15ºC or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw and use within 24 hours. Store at 0.0-4.5ºC _____

c. Negative Control – Lyophilized Zero Control Standard (ZCS) or alternatively raw milk qualified to test similar to ZCS _____

1. Reconstitute ZCS according to manufacture instructions. (Allow to sit 15 min prior to use or aliquotting) _____

a. To qualify raw milk, test sample 3 times and average results. Average must be within +/-10% of ZCS _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

2. Use within 48 hours when stored at 0.0-4.5ºC _____

3. Or, aliquot within 24 hours and freeze at –15ºC or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw and use within 24 hours. Store at 0.0-4.5ºC _____

d. Scintillation fluid expires six (6) months after opening _____

Date opened: _____ Lab Exp. Date: _____ _____

TECHNIQUE

6. Control point and Zero Control Average to be determined for each new lot of reagents _____

a. Sulfonamide Assay Control Point (CP) and Negative Control Average _____

1. Run six 10 ppb Sulfamethazine

Sulfamethazine	
1.	_____
2.	_____
3.	_____
4.	_____
5.	_____
6.	_____
Av.	_____
+24%	_____
CP.	_____

2. Run three Negative Controls

Negative Control	
1.	_____
2.	_____
3.	_____
Av.	_____

_____

b. Chloramphenicol Assay Control Point (CP) and Negative Control Average _____

1. Run six 1 ppb chloramphenicol

Chloramphenicol	
1.	_____
2.	_____
3.	_____
4.	_____
5.	_____
6.	_____
Av.	_____
+25%	_____
CP.	_____

2. Run three Negative Controls

Negative Control	
1.	_____
2.	_____
3.	_____
Av.	_____

_____

c. Tetracycline Assay Control Point (CP) and Negative Control Average _____

1. Run six 30 ppb Oxytetracycline

2. Run three Negative Controls

Oxytetracycline		Negative Control	
1.	_____	1.	_____
2.	_____	2.	_____
3.	_____	3.	_____
4.	_____	Av.	_____
5.	_____		
6.	_____		
Av.	_____		
+23%	_____		
CP.	_____		_____

7. Acceptability of control point determinations _____

a. If any of the 6 control point determinations deviate from the average, redo that determination _____

1. For Sulfonamide Assay cannot deviate by more than ±24% _____

2. For Tetracycline Assay cannot deviate by more than ±23% _____

3. For Chloramphenicol Assay cannot deviate by more than ±25% _____

b. If the re-determined value is within the allowed deviation recalculate the average and proceed with testing _____

c. If the value is not within allowed deviation then another set of 6 standards must be run _____

d. A common control point for multiple analysts may be used _____

1. Control point determination performed by one analyst only _____

2. Control point determination rotated and inclusive of all certified/approved analysts _____

3. If daily performance check fails and is not resolved by using fresh controls, technique should be reviewed for consistency and corrective action taken as necessary _____

8. Daily Performance and Operation Check (also see App. N GR item 10) _____

a. The Negative Control tests ±30% (20% Chloramphenicol Assay) established for each new lot of kits _____

b. The positive control tests less than or equal to the control point _____

c. If these conditions are not met re-determine control point(s) _____

1. Conditions met; proceed with testing _____

2. Conditions not met; discontinue testing and seek technical assistance _____

9. Test Procedures _____

a. Sulfonamide Assay _____

1. Label test tubes, one for each test sample _____

2. Add 1 white tablet to each tube _____

3. Add 300 µL water to each tube _____

4. Breakup tablets in tubes by vortexing tubes 10 times in a rise and fall motion in 10 sec, white tablets must be completely broken apart or continue vortexing before proceeding _____

5. Mix milk sample(s)**/**control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (samples/controls must be in appropriate containers to allow the use **o**f vortexing) _____

6. Add 5 mL of mixed sample/control to corresponding tube _____

a. Using pipettor (item 3**.j.**2) with new tip for each sample/control, draw up 5 mL avoiding foam or bubbles _____

b. Remove tip from liquid _____

c. Expel test portion into appropriate tube _____

7. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

a. Add pink tablet to each tube _____

b. Vortex tubes 10 times in a rise and fall motion in 10 sec (pink tablets do not breakup) _____

8. Incubate tubes for 3 min at 85±2ºC _____

9. Remove tubes and centrifuge for 3 min; optionally for 5 min (use same time used to determine control point) _____

10. After centrifugation, immediately pour off milk _____

11. While still draining tubes, remove fat ring with 2 or more cotton swabs, continue until dry, do not touch pellet (do not go much below the fat ring) _____

12. Add 300 µL of water to tubes and break up pellets using vortex mixer _____

13. Pellets must be completely suspended before proceeding to next step _____

14. Add 3 mL of scintillation fluid to each tube, cap and vortex until uniformly mixed _____

15. Count tubes on scintillation counter for 1 min using [3H] channel _____

16. Record counts as counts per minute (CPM) _____

b. Chloramphenicol Assay _____

1. Label test tubes, one for each test sample _____

2. Add 1 white tablet to each tube _____

3. Add 300 µL water to each tube _____

4. Breakup tablets in tubes by vortexing tubes 10 times in a rise and fall motion in 10 sec, white tablets must be completely broken apart or continue vortexing before proceeding _____

5. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting, use within 3 min (samples/controls must be in appropriate containers to allow the use **o**f vortexing) _____

6. Add 1.0 mL of mixed sample/control to corresponding tube _____

   a. Using pipettor (item 3**.j.**3) with new tip for each sample/control, draw up 1 mL avoiding foam and bubbles _____

   b. Remove tip from liquid _____

   c. Expel test portion into appropriate tube _____

7. The following steps must be completed within 40 sec (all assay tubes being assayed) _____

   a. Add 1 green tablet to each tube _____

   b. Vortex tubes as in 4 above _____

   c. Add black tablet to each tube _____

   d. Vortex tubes as in 4 above _____

8. Incubate tubes in an ice bath (50% ice, 50% water) at 0.0-4.5ºC for 3 min _____

9. Remove tubes and centrifuge for 5 min _____

10. Using 300 µL pipettor immediately add 300 µL of centrifuged sample to a new labeled tube (remove by avoiding fat and without disturbing pellet)

11. Use fresh tip for each sample _____

12. Add 3 mL of scintillation fluid to each tube, cap and vortex until uniformly mixed _____

13. Count tubes on scintillation counter for 1 min using [3H] channel _____

14. Record counts as counts per minute (CPM) _____

c. Tetracycline Assay _____

1. Label test tubes, one for each test sample _____

2. Add 1 white tablet to each empty tube _____

3. Add 300 µL water to each tube _____

4. Breakup tablets in tubes by vortexing tubes 10 times in a rise and fall motion in 10 sec, white tablets must be completely broken apart or continue vortexing before proceeding _____

5. Mix sample(s)/control(s) by shaking 25 times in 7 sec through 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min. Dilute 1 mL of sample with 9 mL of Zero Control, repeat mixing. **Controls are not diluted before testing** _____

6. Add 5.0 mL diluted milk sample or undiluted control to corresponding tube _____

   a. Using pipettor (item 3**.j.**2) with new tip for each sample/control, draw up 5 mL avoiding foam or bubbles _____

   b. Remove tip from liquid _____

   c. Expel test portion into appropriate tube _____

7. The following steps must be completed within 40 sec (all sample tubes being assayed) _____

   a. Add orange tablet to each tube _____

   b. Vortex tubes 15 times in a rise and fall motion in 20 sec (orange tablets do not breakup) _____

8. Incubate tubes for 3 min at 35±2ºC _____

9. Remove tubes and centrifuge for 5 min _____

10. After centrifugation immediately pour off milk _____

11. While still draining tubes, remove fat ring with 2 or more cotton swabs, continue until dry, do not touch pellet (do not go much below the fat ring) _____

12. Add 300 µL of water to tubes and break up pellets using vortex mixer _____

13. Pellets must be completely suspended before proceeding to next step _____

14. Add 3 mL of scintillation fluid to a tube, cap and vortex until uniformly mixed. Count tubes on scintillation counter for 1 min using [3H] channel _____

15. Repeat step 14 with each tube to be analyzed. _____

16. Record counts as counts per minute (CPM) _____

10. Interpretation _____

a. If the number of the measured activity in the analyzer is greater than the control point, then the sample is Negative (NF) _____

b. If the number of the measured activity in the analyzer is less than or equal to the control point then the sample is Presumptive Positive _____

11. Verification of Initial Positive Samples (see App. N GR item 11); Confirmation of Presumptive Positive Samples (see App. N GR item 12);and Producer Traceback (see App. N GR item 13) _____

12. Reporting (see App. N GR item 14) _____

13. Handling of Exempt Quantities of Radioactive Materials _____

a. No mouth pipetting _____

b. No smoking, eating or use of cosmetics while reagents are being handled _____

c. Nuclear Regulatory Commission (NRC) licensed facilities must meet requirements as they relate to the use of gloves, other protective measures, and handling of wastes _____

d. Wash hands thoroughly after handling reagents _____

e. Wipe up spills immediately and thoroughly _____

f. Properly dispose of all contaminated waste _____

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

Neogen BetaStar® Plus (Raw Commingled Cow Milk) Beta-Lactam Test
IMS# 9-N1

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Heater Block, 47.5±2.0ºC _____

1. Check temperature daily (day of use); maintain records _____

2. Temperature measuring device must be supplied by manufacturer and meet all App. N GR item 3 requirements _____

3. Temperature measuring device for each incubator (App. N GR item 3) _____

b. Accuscan® III Reader (software V 3.551 or higher) with Accuscan III program installed, with printout or download of data. Manual available _____

Serial Number: _____ _____

1. Printer or computer link for hardcopy download _____

2. Maintain records _____

c. Pipettor – 200 µL and disposable tips (see App. N GR item 7) _____

d. Or single use 200 µL Poly-pipet with overflow bulb to accurately measure amount of sample, supplied by manufacturer **(screening only)** _____

e. Timer _____

4. Reagents _____

a. BetaStar Plus Test Kit

Lot #: _____ Exp. Date: _____ _____

QC Date: _____ By: _____ _____

1. Kit contains lyophilized receptor vials, dipsticks, and Poly-pipets (item 3.d) _____

   a. Verify that first 5 characters of the lot code on the dipstick tube, dipstick and vial matches the first 5 characters of the Test Kit lot code _____

      Kit Lot #: _____ _____

2. Verify acceptable status of the moisture indicator card in the dipstick tube prior to use. If all of the dots on the indicator card have changed from blue to pink, do not use the kit _____

b. Positive Control _____

   1. Lyophilized 5 ppb Penicillin G/100ppb Desfuroylceftiofur _____

      Lot #: _____ Exp. Date: _____ _____

c. Negative control _____

   1. Previously tested negative raw milk (item 5.d) _____

5. Reagent Stability (frozen standards are not allowed) _____

a. Test Kit including reagents and dipsticks received refrigerated in insulated chest with cold pack block shipped overnight _____

b. Store reagents and dipsticks at 0.0-4.5**º**C, maintain no longer than manufacturer's expiration date _____

c. Positive Control – Manufacturer supplied, maintain no longer than manufacturer's expiration date _____

   1. Reconstituted with 1 mL of raw commingled cow milk tested at 2.0 or higher ratio with BetaStar Plus Beta Lactam test**;** use within 48 hours and maintain at 0.0-4.5**º**C _____

      Lab Prep Date: _____ Lab Exp Date: _____ _____

   2. Day of use, must produce 0.85 or lower ratio reading; maintain records _____

      Test Value: _____

      Do not proceed if out of range _____

d. Negative Control – raw commingled cow milk tested at 2.0 or higher ratio reading with BetaStar Plus Beta-Lactam test. Maintain at 0.0-4.5ºC and use within 72 hours _____

Sample ID: _____ Test Value: _____ _____

Date Tested: _____ _____

Do not proceed if out of range _____

TECHNIQUE

6. Daily Performance and Operation Check _____

a. See App. N GR item 10 _____

b. Accuscan III Reader Calibration _____

1. The reader calibration occurs automatically when the Accuscan III Program (V3.551 or higher) is initiated on the reader _____

   a. The Accuscan III program must be re-initiated daily prior to use, when the unit is turned off, or when the unit goes off if the battery charge is too low _____

2. If the reader calibration is unsuccessful, the reader will not operate. A warning message will prompt the user "Calibration unsuccessful. Contact Neogen." _____

3. Calibrator cartridges must be read daily. There are two calibrators, one as Positive and one as Negative. Each calibrator has a line for both beta-lactam and Ceftiofur _____

4. Both lines on each of the calibration cartridges must read within the limits as indicated on the cartridge device _____

   Positive Calibrator Readings: _____

   Beta-lactam: _____ _____

   Ceftiofur: _____ _____

   Negative Calibrator Reading: _____ _____

   Beta-lactam: _____ _____

   Ceftiofur: _____ _____

5. If Calibrators are out of range, contact Neogen before proceeding _____

6. Maintain records _____

7. Test Procedure [Precautions – when handling BetaStar Plus test, make sure hands are clean and dry. This will protect against contamination of test reagents] _____

a. The test is designed for use under normal ambient environmental conditions (15-30ºC). Remove the kit from the refrigerator. Remove the number of test vials required and the dipstick container. Immediately return the balance of the kit to the refrigerator. Allow the dipstick container to equilibrate to room temperature (15-30ºC) for 10-15 min prior to opening to prevent condensation _____

b. Remove the number of dipsticks required and return the dipstick container to the refrigerator _____

c. A maximum of 4 tests can be run at one time. If more than one sample is being run, all milk samples should be prepared prior to inserting into the heater block and beginning the incubation period _____

d. Any receptor vials or dipsticks removed from the kit that remain unused at the end of the testing day must be discarded _____

e. Dipsticks that have been removed from the dipstick container must be kept clean and dry _____

f. Label one vial and one dipstick for each test sample and each control _____

g. Gently tap the vial on a hard surface in order to assure all solid material is in bottom of vial _____

h. Mix milk sample**(s)/**control**(s)** 25 times in **7** sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (sample must be in appropriate containers to allow the use of vortexing) _____

i. Carefully remove the cap and rubber stopper from the vial _____

j. Pipette 200 µL milk sample into the vial _____

1. **Certified laboratories must,** utilize a fixed volume pipettor _____

a. Attach a 200 µL pipette tip to the pipettor _____

b. Draw up sample, avoiding foam and bubbles _____

c. Deliver the sample into the vial by depressing the plunger _____

d. Replace the rubber stopper in the vial _____

2. Using new manufacturer-provided Poly-pipet (item 3.d) for each sample/control **[Screening only]** _____

   a. Squeeze top bulb while holding vertically with bulb and overflow reservoir side pointing down, draw up test portion avoiding foam and bubbles. Sample should completely fill pipet shaft and overflow into the bottom half of the overflow reservoir _____

   b. Remove tip from liquid _____

   c. While holding the Poly-pipet vertically, expel test portion slowly into the vial. Excess portion should remain in reservoir _____

   d. Replace the rubber stopper in the vial _____

k. Mix the milk and the reagents thoroughly by inverting the vial twice and swirling in a circular motion until all solids are in solution _____

l. Remove and discard stopper from vial and place the vial into the heater block and incubate at 47.5 ± 2.0ºC for 3 min, not to exceed 3 min and 30 sec _____

m. At the completion of the 3 min incubation, place labeled dipstick into the vial in the heater block. The arrows on the dipstick must be oriented downward in the vial _____

n. Incubate the dipstick in the vial for 2 min, not to exceed 2 min and 30 sec at 47.5 ± 2.0ºC _____

o. At the completion of the 2 min incubation, remove the dipstick from the vial and visually inspect the control line; an absent, partial or indistinct control line indicates an invalid test and the sample/control must be re-test. **CAUTION: Insert only valid test(s) into the Reader** _____

p. Place the dipstick arrows first, into the holder, and insert the holder into the Accuscan III reader (software V3.551 or higher) _____

q. Read dipsticks within 3 min of completion of the incubation _____

8. Interpretation with Reader _____

a. If there is a negative reading (ratio > 1.0) on the reader, sample is Negative (NF) _____

b. If there is a positive reading (ratio ≤ 1.0) on the reader, sample is an Initial Positive _____

9. Verification of Initial Positive Tanker Samples (see App. N GR item 11); Confirmation of Presumptive Positive Tanker Samples (see App. N GR item 12); and Traceback of Producer(s) on a Confirmed Positive Tanker (see App. N GR item 13) _____

10. Reporting (see App. N GR item 14) _____

a. Maintain reader tapes or computer print outs _____

QC FORMS

BFSLS#	NAME OF RECORD	REVISION DATE
497	Monthly Analytical Balance Check Records	1/14
498	Monthly Electronic Balance Check Records	1/14
500	Daily Drug Screening Test Log	1/14
500a	Daily Drug Screening Test Log	1/14
501a	Temperature Records - Block Heater	1/14
501b	Temperature Records - Freezer	1/14
501c	Temperature Records - Refrigerator	1/14
503	Semi-Annual Pipettor Accuracy Check	12/13
513	Test Kit Suitability Check for Drug Residue Testing	1/14
513A	Positive Control Suitability Check	7/11
513B	Negative Control Suitability Check	7/11
515	Thermometer Accuracy Check Log	12/13
515a	Thermometer Accuracy Check Log	12/13
528	Appendix N Training Log	1/14
528a	Appendix N Training Session(New Analyst)	2/15
534	SNAP Image Performance Check Set	7/09
534a	SNAPshot DSR Performance Check Set	5/15
535	ROSA Control Strips log	7/09

BFSLS 497 (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

MONTHLY ANALYTICAL ELECTRONIC BALANCE CHECK RECORDS

Year:_____

Make/ Model/Type:_____ Serial # or ID#:_____

Date(s) Serviced: _____

Date	Analysts ID# or Initials		Actual Scale Readings								Comments
		10 mg	50 mg	100 mg	200 mg	300 mg	500 mg	1 g	5 g	10g	

1. Electronic only, sensitive to 0.1g for general laboratory purposes and to 0.0001g for pipettor checks and antibiotics.
2. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3, weights. Certificate of authenticity or other verification, required.
3. Check weights that correspond to normal use of balance and maintain records. Record actual display reading of balance.
4. Checked at least annually by a qualified representative for good working order with proof of check in laboratory.

BFSLS 497 (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:__**Utter's Dairy**_____

MONTHLY ANALYTICAL ELECTRONIC BALANCE CHECK RECORDS

Year:__**2013, 2014**_____

Make/ Model/Type:__**Mettler Toledo**_____ Serial # or ID#:____**1002894**_____

Date(s) Serviced: _**8/15/12,8/18/13**_____

Date	Analysts ID# or Initials		Actual Scale Readings								Comments
		10 mg	50 mg	100 mg	200 mg	300 mg	500 mg	1 g	5 g	10g	
11/25/13	J. Michaels, #02	0.0099g	0.0501g	0.1001g	0.2003g	0.2997g	0.4997g	1.0000g	5.0001g	10.0001	√ Cleaned area & balance
12/15/13	A. Thomas	0.0100g	0.0495g	0.1002g	0.1995g	0.2996g	0.4996g	0.9995g	4.9998g	10.0000	√ Cleaned area & balance
1/23/14	J. Michaels, #02	0.0099g	0.0501g	0.1000g	0.2001g	0.2999g	0.5000g	1.0001g	4.9997g	9.9998	√ Cleaned area & balance

1. Electronic only, sensitive to 0.1g for general laboratory purposes and to 0.0001g for pipettor checks and antibiotics.
2. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3, weights. Certificate of authenticity or other verification, required.
3. Check weights that correspond to normal use of balance and maintain records. Record actual display reading of balance.
4. Checked at least annually by a qualified representative for good working order with proof of check in laboratory.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
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LABORATORY DIVISION

Facility/Laboratory Name:_____

MONTHLY MILK/MEDIA ELECTRONIC BALANCE CHECK RECORDS

Year:_____

Make/ Mode/ Type:_____ Serial # or ID#:_____

Date(s) Serviced: _____

Date	Analysts ID# or Initials	Actual Scale Readings							Comments
		1 gm	5 gm	10 gm	25 gm	50 gm	100 gm	150 gm	

1. Electronic only, sensitive to 0.1g for general laboratory purposes and to 0.0001g for pipettor checks and antibiotics.
2. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3, weights. Certificate of authenticity or other verification, required.
3. Check weights that correspond to normal use of balance and maintain records. Record actual display reading of balance.
4. Checked at least annually by a qualified representative for good working order with proof of check in laboratory.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:___**Northpoint Laboratory**_____

MONTHLY MILK/MEDIA ELECTRONIC BALANCE CHECK RECORDS

Year:_**2013, 2014**_____

Make/ Mode/ Type:__**Ohaus Scout**_____ Serial # or ID#:___**21198**_____

Date(s) Serviced: __**4/12/12, 4/19/13**_____

Date	Analysts ID# or Initials	Actual Scale Readings							Comments
		1 gm	5 gm	10 gm	25 gm	50 gm	100 gm	150 gm	
11/20/13	J. Smith	1.02g	5.00g	9.99g	25.01g	50.01g	99.98g	150.02g	√ cleaned balance
12/15/13	A. Jones	1.01g	5.02g	9.99g	25.00g	50.02g	100.01g	149.99g	√ cleaned balance
1/18/14	A. Jones	1.02g	5.01g	10.00g	25.01g	50.01g	99.99g	150.03g	√ cleaned balance

1. Electronic only, sensitive to 0.1g for general laboratory purposes and to 0.0001g for pipettor checks and antibiotics.
2. Checked monthly with Class S or S1, or equivalent ASTM 1, 2, or 3, weights. Certificate of authenticity or other verification, required.
3. Check weights that correspond to normal use of balance and maintain records. Record actual display reading of balance.
4. Checked at least annually by a qualified representative for good working order with proof of check in laboratory.

BFSLS 500 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

SCREENING TEST USED_____

DAILY DRUG SCREENING TEST LOG

FACILITY/LABORATORY NAME:_____ FDA ID# _____ YEAR_____

ADDRESS:_____

SAMPLE COLLECTED			TANKER TEMP. °F	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL °C	TIME START TESTING	TIME READ RESULT	RESULT (NUMERICAL VALUE)	INTERP. (POS/NF)	ANALYST ID#
DATE (mm/dd)	TIME	SAMPLER ID											

A VALID POSITIVE AND NEGATIVE CONTROL MUST BE RUN EACH DAY SCREENING TEST IS PERFORMED WITH RESULTS RECORDED.

COMMERCIAL POSITIVE CONTROL		RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION		READER PERFORMANCE CHECKS	
MFG		LOT#		ID (i.e. SILO #)		LOT#		IDEXX	ROSA
LOT #		DATE PREP'D		DATE PREP'D		EXPIRATION DATE		DEVICE 1:	LOW:
DATE RECEIVED		TIME PREP'D		TIME PREP'D:				DEVICE 2:	HIGH:
DATE OPENED		FROZEN DATE		FROZEN DATE		LEVEL CHECK (Charm SL or SL3 only)			
EXPIRATION DATE		THAW DATE		THAW DATE		Satisfactory?		Analysts ID #	
COMMENTS:		EXPIRATION DATE		EXPIRATION DATE		Yes	No		
		NUMERICAL RESULT		NUMERICAL RESULT					

BFSLS 500 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

SCREENING TEST USED_Charm SL_____

DAILY DRUG SCREENING TEST LOG

FACILITY/LABORATORY NAME:__Utter's Dairy_____ FDA ID# _42-689_____ YEAR____2014_____

ADDRESS:_____

SAMPLE COLLECTED			TANKER TEMP. °F	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL °C	TIME START TESTING	TIME READ RESULT	RESULT (NUMERICAL VALUE)	INTERP. (POS/NF)	ANALYST ID#
DATE (mm/dd)	TIME	SAMPLER ID											
1/27	09:05	JR	39.0°F	42-405	PYK8005	37092	45,289 lbs	3.9°C	09:22	09:30	-2698	Not Found	JK
1/27	10:15	MJ	38.0°F	Hilltop 42-341	XFT8736	38112	35,599 lbs	3.3°C	10:20	10:28	-1831	Not Found	JM
1/27	10:45	MJ	37.5°F	42-405	XFK5592	38561	37, 268 lbs	3.2C	10:51	10:59	-1587	Not Found	JK

A VALID POSITIVE AND NEGATIVE CONTROL MUST BE RUN EACH DAY SCREENING TEST IS PERFORMED WITH RESULTS RECORDED.

COMMERCIAL POSITIVE CONTROL		RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION		READER PERFORMANCE CHECKS	
MFG	Charm Sciences	LOT#	18A	ID (i.e. SILO #)	37090	LOT#	127	IDEXX	ROSA
LOT #	18A	DATE PREP'D	1/26/14	DATE PREP'D	1/26/14	EXPIRATION DATE	4/2014	DEVICE 1: NA	LOW:-0987
DATE RECEIVED	12/29/13	TIME PREP'D	09:00AM	TIME PREP'D:	9:55AM			DEVICE 2: NA	HIGH:+1156
DATE OPENED	1/6/14	FROZEN DATE	1/26/14	FROZEN DATE	NA	LEVEL CHECK (Charm SL or SL3 only)			
EXPIRATION DATE	5/2014	THAW DATE	1/27/14	THAW DATE	NA	Satisfactory?		Analysts ID #	
COMMENTS:		EXPIRATION DATE	1/28/14	EXPIRATION DATE	1/29/14	Yes	No	JR	
		NUMERICAL RESULT	+2598	NUMERICAL RESULT	-1697	X			

BFSLS 500 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

SCREENING TEST USED_IDEXX New Snap_____

DAILY DRUG SCREENING TEST LOG

FACILITY/LABORATORY NAME:__Utter's Dairy_____ FDA ID# _42-689_____ YEAR____2014_____

ADDRESS:_4242 Wide lane, Hometown PA 19856_____

SAMPLE COLLECTED			TANKER TEMP. °F	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL °C	TIME START TESTING	TIME READ RESULT	RESULT (NUMERICAL VALUE)	INTERP. (POS/NF)	ANALYST ID#
DATE (mm/dd)	TIME	SAMPLER ID											
1/27	09:05	JR	39.0°F	42-405	PYK8005	37092	45,289 lbs	3.9°C	09:22	09:30	0.67	Not Found	JK
1/27	10:15	MJ	38.0°F	Hilltop 42-341	XFT8736	38112	35,599 lbs	3.3°C	10:20	10:28	0.71	Not Found	JM
1/27	10:45	MJ	37.5°F	42-405	XFK5592	38561	37, 268 lbs	3.2C	10:51	10:59	0.59	Not Found	JK

A VALID POSITIVE AND NEGATIVE CONTROL MUST BE RUN EACH DAY SCREENING TEST IS PERFORMED WITH RESULTS RECORDED.

COMMERCIAL POSITIVE CONTROL		RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION		READER PERFORMANCE CHECKS	
MFG	IDEXX	LOT#	EH598	ID (i.e. SILO #)	37090	LOT#	DA188	IDEXX	ROSA
LOT #	EH598	DATE PREP'D	1/27/14	DATE PREP'D	1/26/14	EXPIRATION DATE	5/14/14	DEVICE 1: 0.73	LOW: NA
DATE RECEIVED	12/25/13	TIME PREP'D	09:00AM	TIME PREP'D:	9:55AM			DEVICE 2: 1.56	HIGH: NA
DATE OPENED	1/2/14	FROZEN DATE	NA	FROZEN DATE	1/26/14	LEVEL CHECK (Charm SL or SL3 only)			
EXPIRATION DATE	4/1/14	THAW DATE	NA	THAW DATE	1/27/14	Satisfactory?		Analysts ID #	
COMMENTS:		EXPIRATION DATE	1/28/14	EXPIRATION DATE	1/28/14	Yes	No		
		NUMERICAL RESULT	5.01	NUMERICAL RESULT	0.87	NA			

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

DAILY DRUG SCREENING TEST LOG

SCREENING TEST USED _____ YEAR _____

FACILITY/LABORATORY NAME: _____ FDA ID# _____

ADDRESS: _____

SAMPLE COLLECTED			TANKER TEMP. (°F)	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL (°C) 0.0-4.5C	TIME START TESTING	TIME READ RESULTS	RESULTS (NUMERICAL VALUE)	INTERP. (POS/NF)	NAME/ID#	COMMENTS
DATE (mm/dd)	TIME	Sampler ID												

A POSITIVE AND NEGTIVE CONTROL MUST BE RUN EACH DAY THAT SCREENING TEST IS PERFORMED WITH RESULTS MAINTAINED.

COMMERCIAL POSITIVE CONTROL		RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION	READER PERFORMANCE CHECKS	
MFG.		LOT #		ID (i.e. SILO #):		LOT#:	ROSA SERIAL #:	
LOT #		DATE PREP'D		DATE PREP'D:			LOW STRIP RESULT	
DATE RECEIVED:		TIME PREP'D:		TIME PREP'D:		EXPIRATION DATE:	HIGH STRIP RESULT	
DATE OPENED:		FROZEN DATE		FROZEN DATE			LOW RANGE	
LOT EXPIRES ON:		THAW DATE		THAW DATE			HIGH RANGE	
		EXPIRES:		EXPIRES:				
		NUMERICAL RESULT:		NUMERICAL RESULT:				
HEATER BLOCK TEMPERATURE		FRIDGE TEMPERATURE	0.0-4.5C	FREEZER TEMPERATURE	< -15.0C	LEVEL CHECK	IDEXX	
HEATER BLOCK SN#		FRIDGE SN#		FREEZER SN#		(Charm ROSA only)	DEVICE 1 RESULT	
AM	PM	AM	PM	AM	PM	SATISFACTORY?	DEVICE 2 RESULT	
ºC	ºC	ºC	ºC	ºC	ºC	YES / NO	DEVICE 1 RANGE	
ºC	ºC	ºC	ºC	ºC	ºC	ANALYST ID#	DEVICE 2 RANGE	
INITIALS	INITIALS	INITIALS	INITIALS	INITIALS	INITIALS			

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

DAILY DRUG SCREENING TEST LOG

SCREENING TEST USED: IDEXX New Snap

YEAR: 2014

FACILITY/LABORATORY NAME: Utter's Dairy

FDA ID#: 42-689

ADDRESS: 4242 Wide Lane, Hometown PA 19856

SAMPLE COLLECTED DATE (mm/dd)	TIME	Sampler ID	TANKER TEMP. (°F)	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL (°C) 0.0-4.5C	TIME START TESTING	TIME READ RESULTS	RESULTS (NUMERICAL VALUE)	INTERP. (POS/NF)	NAME/ID#	COMMENTS
1/27	9:05	JR	39.0ºF	42-405	PYK8005	37092	45,289 lbs	3.9ºC	9:22	9:30	0.67	Not Found	JK	
1/27	10:15	MJ	38.0ºF	Hilltop 42-341	XFT8736	38112	35,599 lbs	3.3ºC	10:20	10:28	0.71	Not Found	JM	
1/27	10:45	MJ	37.5ºF	42-405	XFK5592	38561	37, 268 lbs	3.2C	10:51	10:59	0.59	Not Found	JK	

A POSITIVE AND NEGTIVE CONTROL MUST BE RUN EACH DAY THAT SCREENING TEST IS PERFORMED WITH RESULTS MAINTAINED.

COMMERCIAL POSITIVE CONTROL			RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION	READER PERFORMANCE CHECKS	
MFG.	IDEXX		LOT #	EH598	ID (i.e. SILO #):	37090	LOT#: DA188	ROSA / SERIAL #:	
LOT #	EH598		DATE PREP'D	1/27/2014	DATE PREP'D:	1/26/2014		LOW STRIP RESULT	
DATE RECEIVED:	12/25/2013		TIME PREP'D:	09:00AM	TIME PREP'D:	9:55AM	EXPIRATION DATE: 5/14/2014	HIGH STRIP RESULT	
DATE OPENED:	1/2/2014		FROZEN DATE	NA	FROZEN DATE	1/26/2014		LOW RANGE	
LOT EXPIRES ON:	4/1/2014		THAW DATE	NA	THAW DATE	1/27/2014		HIGH RANGE	
			EXPIRES:	1/28/2014	EXPIRES:	1/28/2014			
			NUMERICAL RESULT:	5.01	NUMERICAL RESULT:	0.87			
HEATER BLOCK TEMPERATURE		40-50C	FRIDGE TEMPERATURE	0.0-4.5C	FREEZER TEMPERATURE	< -15.0C	LEVEL CHECK	IDEXX	
HEATER BLOCK SN#	12578		FRIDGE SN#	S1985E58	FREEZER SN#		(Charm ROSA only)	DEVICE 1 RESULT	0.73
AM	PM		AM	PM	AM	PM	SATISFACTORY?	DEVICE 2 RESULT	1.56
47.8ºC	46.5ºC		1.2ºC	1.5ºC	-15.5ºC	-16.1ºC	YES / NO	DEVICE 1 RANGE	0.58-0.88
ºC	ºC		2.5ºC	2.6ºC	ºC	ºC	ANALYST ID#	DEVICE 2 RANGE	1.25-1.85
INITIALS JR	INITIALS MJ		INITIALS JR	INITIALS MJ	INITIALS JR	INITIALS MJ	NA		

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

DAILY DRUG SCREENING TEST LOG

SCREENING TEST USED: Charm SL

YEAR: 2014

FACILITY/LABORATORY NAME: Utter's Dairy

FDA ID#: 42-689

ADDRESS: 4242 Wide lane, Hometown PA 19856

SAMPLE COLLECTED DATE (mm/dd)	TIME	Sampler ID	TANKER TEMP. (°F)	OWNER OF MILK/ FIPS #	COMPLETE TANKER LICENSE PLATE NUMBER	BILL OF LADING #	POUNDS	LAB. TEMP. CONTROL (°C) 0.0-4.5C	TIME START TESTING	TIME READ RESULTS	RESULTS (NUMERICAL VALUE)	INTERP. (POS/NF)	NAME/ID#	COMMENTS
1/27	9:05	JR	39.0°F	42-405	PYK8005	37092	45,289 lbs	3.9°C	9:22	9:30	-2698	Not Found	JK	
1/27	10:15	MJ	38.0°F	Hilltop 42-341	XFT8736	38112	35,599 lbs	3.3°C	10:20	10:28	-1831	Not Found	JM	
1/27	10:45	MJ	37.5°F	42-405	XFK5592	38561	37, 268 lbs	3.2C	10:51	10:59	-1587	Not Found	JK	

A POSITIVE AND NEGTIVE CONTROL MUST BE RUN EACH DAY THAT SCREENING TEST IS PERFORMED WITH RESULTS MAINTAINED.

COMMERCIAL POSITIVE CONTROL			RECONSTITUTED POSITIVE CONTROL		PRE-TESTED NEGATIVE CONTROL		TEST KIT INFORMATION	READER PERFORMANCE CHECKS	
MFG.	Charm Sciences		LOT #	18A	ID (i.e. SILO #):	37090	LOT#: 127	ROSA SERIAL #:	Q13598744
LOT #	18A		DATE PREP'D	1/26/2014	DATE PREP'D:	1/26/2014		LOW STRIP RESULT	-987
DATE RECEIVED:	12/29/2013		TIME PREP'D:	09:00AM	TIME PREP'D:	9:55AM	EXPIRATION DATE: 4/2014	HIGH STRIP RESULT	1156
DATE OPENED:	1/6/2014		FROZEN DATE	1/26/2014	FROZEN DATE	NA		LOW RANGE	-0851 to-1103
LOT EXPIRES ON:	May-14		THAW DATE	1/27/2014	THAW DATE	NA		HIGH RANGE	0996 - 1397
			EXPIRES:	1/28/2014	EXPIRES:	1/29/2014			
			NUMERICAL RESULT:	2598	NUMERICAL RESULT:	-1697			
HEATER BLOCK TEMPERATURE		55-57C	FRIDGE TEMPERATURE	0.0-4.5C	FREEZER TEMPERATURE	< -15.0C	LEVEL CHECK	IDEXX	
HEATER BLOCK SN#	12578		FRIDGE SN#	S1985E58	FREEZER SN#		(Charm ROSA only)	DEVICE 1 RESULT	
AM	PM		AM	PM	AM	PM	SATISFACTORY?	DEVICE 2 RESULT	
56.8ºC	56.5ºC		1.2ºC	1.5ºC	-15.5ºC	-16.1ºC	YES / NO	DEVICE 1 RANGE	
ºC	ºC		2.5ºC	2.6ºC	ºC	ºC	ANALYST ID#	DEVICE 2 RANGE	
INITIALS JR	INITIALS MJ		INITIALS JR	INITIALS MJ	INITIALS JR	INITIALS MJ	JR		

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (BLOCK HEATER)

Facility/Laboratory Name_____

Heater Block Make/ Model_____ Unit ID#_____

Testing Procedure Used _____ Temp. Range of Use:_____

MONTH/YEAR_____

Day	Temperature AM	Analysts Initials/ID#	Temperature PM	Analysts Initials/ID#
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

1. Temperature are checked each day of use prior to use.
2. All temperature readings need to be made to the nearest 0.1˚C.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (BLOCK HEATER)

Facility/Laboratory Name_**Utter's Dairy**_____

Heater Block Make/ Model **LAB-LINE MULTI-BLOK HEATER/2052** ___ Unit ID#__**Block#1**_____

Testing Procedure Used _**IDEXX NEW SNAP** _____ Temp. Range of Use**:**_**45±5°C** _____

MONTH/YEAR__January 2014_____

Day	Temperature AM	Analysts Initials/ID#	Temperature PM	Analysts Initials/ID#
1				
2	45.9°C	JK		
3				
4	45.0°C	AT		
5				
6	45.8°C	AT		
7				
8				
9	45.3°C	JM		
10				
11	45.1°C	JK		
12				
13	44.9°C	JK		
14				
15				
16	44.8°C	AT		
17				
18	45.3°C	AT		
19				
20	45.0°C	AT		
21				
22				
23	45.1°C	JK		
24				
25	45.0°C	JM		
26				
27	44.8°C	JK		
28				
29				
30	44.9°C	AT		
31				

1. Temperatures are checked each day of use prior to use.
2. All temperature readings need to be made to the nearest 0.1˚C.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (BLOCK HEATER)

Facility/Laboratory Name_**Utter's Dairy**_____

Heater Block Make/ Model **ROSA Incubator** ___ Unit ID#__**RR0795**_____

Testing Procedure Used _**Charm SL** _____ Temp. Range of Use:_**56±1°C** _____

MONTH/YEAR__January 2014_____

Day	Temperature AM	Analysts Initials/ID#	Temperature PM	Analysts Initials/ID#
1				
2	56.1°C	JK	56.0°C	AS
3				
4	56.1°C	AT		
5				
6	56.1°C	AT		
7				
8				
9	56.1°C	JM	55.9°C	AS
10				
11	56.1°C	JK		
12				
13	56.9°C	JK		
14				
15				
16	56.1°C	AT	56.6°C	AS
17				
18	56.3°C	AT		
19				
20	56.0°C	AT		
21				
22				
23	56.1°C	JK	55.9°C	AS
24				
25	56.0°C	JM		
26				
27	55.8°C	JK		
28				
29				
30	55.9°C	AT	55.7°C	JT
31				

1. Temperatures are checked each day of use prior to use.
2. All temperature readings need to be made to the nearest 0.1˚C.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (FREEZER)

Facility/Laboratory Name_____

Make/ Model_____ Unit ID# or Serial No. _____

MONTH/YEAR_____ **Temp. Range: < -15ºC**

Day	Temperature AM		Analysts Initials/ID#	Temperature PM		Analysts Initials/ID#
Thermometer location (shelf)	(top)	(bottom)		(top)	(bottom)	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

1. Temperatures are to be checked daily for screening-only locations; temperatures are checked twice daily (AM and PM) for CIS and Milk Industry locations.
2. All temperature readings need to be made to the nearest 0.1˚C.

BFSLS 501b (Rev 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (FREEZER)

Facility/Laboratory Name___ **Utter's Dairy**_____

Make/ Model___Revco_____ Unit ID# or Serial No. ___**REL5004E**_____

MONTH/YEAR___**January 2014**_____ **Temp. Range: < -15ºC**

Day	Temperature AM		Analysts Initials/ID#	Temperature PM		Analysts Initials/ID#
Thermometer location (shelf)	(top)	(bottom)		(top)	(bottom)	
1	-15.5	-16.3	JK	-18.0	-22.0	JM
2	-17.5	-21.1	JK	-16.5	-21.5	JK
3	-17.5	-22.0	AT	-18.5	-19.5	JK
4	-18.0	-22.0	JM	-18.0	-19.0	AT
5	-16.5	-21.5	AT	-20.6	-22.0	JM
6	-18.5	-19.5	JK	-19.5	-20.2	AT
7	-18.0	-19.0	AT	-16.5	-18.5	JK
8	-20.6	-22.0	AT	-15.5	-16.3	AT
9	-19.5	-20.2	JK	-17.5	-21.1	AT
10	-16.5	-18.5	JM	-17.5	-22.0	JK
11	-15.5	-16.3	JK	-18.5	-19.5	JK
12	-17.5	-21.1	JK	-18.0	-19.0	JK
13	-17.5	-22.0	AT	-20.6	-22.0	JK
14	-18.0	-22.0	JM	-19.5	-20.2	AT
15	-16.5	-21.5	AT	-16.5	-18.5	JM
16	-18.5	-19.5	JK	-15.5	-16.3	AT
17	-18.0	-19.0	AT	-15.5	-16.3	JK
18	-20.6	22.0	AT	-17.5	-21.1	AT
19	-19.5	-20.2	JK	-17.5	-22.0	AT
20	-16.5	-18.5	JM	-18.0	-22.0	JK
21	-15.5	-16.3	JK	-16.5	-21.5	JM
22	-15.5	-16.3	JK	-16.5	-21.5	JK
23	-17.5	-21.1	JK	-18.5	-19.5	JK
24	-17.5	-22.0	AT	-18.0	-19.0	AT
25	-18.0	-22.0	JM	-20.6	-22.0	JM
26	-16.5	-21.5	AT	-19.5	-20.2	AT
27	-18.5	-19.5	JK	-16.5	-18.5	JK
28	-18.0	-19.0	AT	-15.5	-16.3	AT
29	-20.6	-22.0	AT	-15.5	-16.3	AT
30	-19.5	-20.2	JK	-17.5	-21.1	JK
31	-16.5	-18.5	JM	-17.5	-22.0	JM

1. Temperatures are to be checked daily for screening-only locations; temperatures are checked twice daily (AM and PM) for CIS and Milk Industry locations.
2. All temperature readings need to be made to the nearest 0.1˚C.

BFSLS 501c (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (REFRIGERATOR)

Facility/Laboratory Name_____

Make/ Model_____ Unit ID#_____

MONTH/YEAR_____ **Temp. Range: 0.0ºC to 4.5ºC**

Day	Temperature AM		Analysts Initials/ID#	Temperature PM		Analysts Initials/ID#
Thermometer location (shelf)	(top)	(bottom)		(top)	(bottom)	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

1. Temperatures are to be checked daily for screening-only locations; temperatures are checked twice daily (AM and PM) for CIS and Milk Industry locations.
2. All temperature readings need to be made to the nearest 0.1˚C.

BFSLS 501c (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

TEMPERATURE RECORDS (REFRIGERATOR)

Facility/Laboratory Name___ Utter's Dairy_____

Make/ Model___Revco_____ Unit ID# or Serial No. ___REL5004E_____

MONTH/YEAR___January 2014_____ **Temp. Range: 0.0ºC to 4.5ºC**

Day	Temperature AM		Analysts Initials/ID#	Temperature PM		Analysts Initials/ID#
Thermometer location (shelf)	(top)	(bottom)		(top)	(bottom)	
1	2.5	3.0	JK	2.5	3.0	JK
2	2.5	3.1	JK	2.6	3.1	JK
3	2.7	3.0	AT	2.5	3.0	AT
4	2.5	3.0	JM	2.6	3.1	JM
5	2.6	3.1	AT	2.5	3.0	AT
6	2.5	3.0	JK	2.7	3.1	JK
7	2.6	3.1	AT	2.5	3.0	AT
8	2.5	3.0	AT	2.5	3.0	AT
9	2.7	3.1	JK	2.5	3.1	JK
10	2.5	3.0	JM	2.7	3.0	JM
11	2.5	3.0	JK	2.7	3.0	JK
12	2.5	3.1	JK	2.5	3.0	JK
13	2.7	3.0	AT	2.6	3.1	JK
14	2.5	3.0	JM	2.5	3.0	AT
15	2.6	3.1	AT	2.6	3.1	JM
16	2.5	3.0	JK	2.5	3.0	AT
17	2.6	3.1	AT	2.7	3.1	JK
18	2.5	3.0	AT	2.5	3.0	AT
19	2.7	3.1	JK	2.5	3.0	AT
20	2.5	3.0	JM	2.6	3.1	JK
21	2.5	3.0	JK	2.5	3.0	JM
22	2.6	3.1	JK	2.5	3.0	JK
23	2.5	3.0	JK	2.5	3.1	JK
24	2.6	3.1	AT	2.7	3.0	AT
25	2.5	3.0	JM	2.5	3.0	JM
26	2.7	3.1	AT	2.6	3.1	AT
27	2.5	3.0	JK	2.5	3.0	JK
28	2.5	3.0	AT	2.6	3.1	AT
29	2.5	3.1	AT	2.5	3.0	AT
30	2.7	3.0	JK	2.7	3.1	JK
31	2.5	3.0	JM	2.5	3.0	JM

1. Temperatures are to be checked daily for screening-only locations; temperatures are checked twice daily (AM and PM) for CIS and Milk Industry locations.
2. All temperature readings need to be made to the nearest 0.1˚C.

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

SEMI-ANNUAL PIPETTOR ACCURACY CHECK

Test Kit for Use: _____

Calibration Location: ☐ On-site ☐ Other Name: _____

Date:		Date:		Date:		Date:	
Pipettor ID:		Pipettor ID:		Pipettor ID:		Pipettor ID:	
Analyst:		Analyst:		Analyst:		Analyst:	
Balance used (SN#):		Balance used (SN#):		Balance used (SN#):		Balance used (SN#):	
Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]
1		1		1		1	
2		2		2		2	
3		3		3		3	
4		4		4		4	
5		5		5		5	
6		6		6		6	
7		7		7		7	
8		8		8		8	
9		9		9		9	
10		10		10		10	
Average		Average		Average		Average	

1. Check accuracy with ten (10) consecutive weighings once every 6 months.
2. Use with an analytical balance that reads to four decimal points.
3. Pipet and dispense as used during normal test procedure.
4. If pipettor specified volume is ≥ 1.0 mL, measurements may be by volume using class A graduated cylinder.
5. Average of all 10 weighing must be ±5% of pipettor specified delivery volume.
6. If accuracy check fails (>5%), pipettor is to be taken out of service.
7. Individual pipettors must be etched or imprinted with identification and tagged with the average volume and date of accuracy check.

BFSLS 503 (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:__Utter's Dairy_____

SEMI-ANNUAL PIPETTOR ACCURACY CHECK

Test Kit for Use: _CHARM SL , Finnpipette 300µl _

Calibration Location: ☑ On-site ☐ Other Name: _____

Date: 1/15/14		Date: 7/25/14		Date: 1/20/15		Date:	
Pipettor ID: J44426		Pipettor ID: J44426		Pipettor ID: J44426		Pipettor ID:	
Analyst: A Thomas		Analyst: A Thomas		Analyst: J. Michaels_		Analyst:	
Balance used (SN#): 10226978		Balance used (SN#): 10226978		Balance used (SN#): 10229978		Balance used (SN#):	
Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]
1	.2922	1	.3205	1	.3278	1	
2	.2988	2	.3111	2	.3021	2	
3	.2921	3	.3125	3	.3098	3	
4	.2890	4	.3075	4	.3542	4	
5	.2980	5	.3061	5	.3134	5	
6	.3054	6	.3041	6	.3062	6	
7	.3214	7	.3126	7	.3076	7	
8	.3232	8	.3116	8	.3057	8	
9	.2998	9	.3128	9	.3322	9	
10	.2960	10	.3180	10	.3032	10	
	3.017		3.1168		3.1622		
Average	.3017	Average	.3117	Average	.3162	Average	

1. Check accuracy with ten (10) consecutive weighings once every 6 months.
2. Use with an analytical balance that reads to four decimal points.
3. Pipet and dispense as used during normal test procedure.
4. If pipettor specified volume is ≥ 1.0 mL, measurements may be by volume using class A graduated cylinder.
5. Average of all 10 weighing must be ±5% of pipettor specified delivery volume.
6. If accuracy check fails (>5%), pipettor is to be taken out of service.
7. Individual pipettors must be etched or imprinted with identification and tagged with the average volume and date of accuracy check.

BFSLS 503 (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:__Utter's Dairy_____

SEMI-ANNUAL PIPETTOR ACCURACY CHECK

Test Kit for Use: _ IDEXX New Snap, Eppendorf 450µl _

Calibration Location: ☑ On-site ☐ Other Name: _____

Date: 1/15/14		Date: 7/25/14		Date: 1/20/15		Date:	
Pipettor ID: 9588463		Pipettor ID: 9588463		Pipettor ID: 9588463		Pipettor ID:	
Analyst: A Thomas		Analyst: A Thomas		Analyst: J. Michaels_		Analyst:	
Balance used (SN#): 10226978		Balance used (SN#): 10226978		Balance used (SN#): 10229978		Balance used (SN#):	
Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]	Reading #	Weight(gm)[4]
1	.4773	1	.4596	1	.4719	1	
2	.4611	2	.4593	2	.4601	2	
3	.4645	3	.4570	3	.4592	3	
4	.4712	4	.4596	4	.4594	4	
5	.4646	5	.4616	5	.4722	5	
6	.4628	6	.4575	6	.4621	6	
7	.4497	7	.4493	7	.4730	7	
8	.4708	8	.4524	8	.4709	8	
9	.4672	9	.4509	9	.4690	9	
10	.4578	10	.4593	10	.4652	10	
	4.647		4.567		4.663		
Average	.4647	Average	.4567	Average	.4663	Average	

EXAMPLE

1. Check accuracy with ten (10) consecutive weighings once every 6 months.
2. Use with an analytical balance that reads to four decimal points.
3. Pipet and dispense as used during normal test procedure.
4. If pipettor specified volume is ≥ 1.0 mL, measurements may be by volume using class A graduated cylinder.
5. Average of all 10 weighing must be ±5% of pipettor specified delivery volume.
6. If accuracy check fails (>5%), pipettor is to be taken out of service.
7. Individual pipettors must be etched or imprinted with identification and tagged with the average volume and date of accuracy check.

BFSLS 513 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: _____

TEST KIT SUITABILITY CHECK FOR DRUG RESIDUE TESTING

Test Method Used: _____

Date Received	Lot Number	Expiration Date	Date Tested [1]	Date Start Using [2]	Control Results/Interpretation				Analyst ID or Initials
					POSITIVE CONTROL		NEGATIVE CONTROL		
					Result / Interpretation	Suitability Check Date[3]	Result / Interpretation	Suitability Check Date[3]	

1. 'Date tested' is the date the first positive and negative control is run to check the suitability of the new lot.
2. 'Date Start Using' is the date this lot of kits is put into use, testing controls & trucks.
3. Suitability check date the POS/NEG control that was used to check the new kit was first tested and found suitable.

BFSLS 513 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: __Utter's Dairy_____

TEST KIT SUITABILITY CHECK FOR DRUG RESIDUE TESTING

Test Method Used: _Charm SL_____

Date Received	Lot Number	Expiration Date	Date Tested [1]	Date Start Using [2]	Control Results/Interpretation				Analyst ID or Initials
					POSITIVE CONTROL		NEGATIVE CONTROL		
					Result / Interpretation	Suitability Check Date[3]	Result / Interpretation	Suitability Check Date[3]	
12/15/13	127	4/2014	12/16/13	12/20/13	+1954 / POS	12/16/13	-1149 / NF	12/15/13	JM
1/8/14	128	6/2014	1/10/14	1/11/14	+2257 / POS	1/10/14	-2087 / NF	1/8/14	JM

1. 'Date tested' is the date the first positive and negative control is run to check the suitability of the new lot.
2. 'Date Start Using' is the date this lot of kits is put into use, testing controls & trucks.
3. Suitability check date the POS/NEG control that was used to check the new kit was first tested and found suitable.

BFSLS 513 (Rev.1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: __Utter's Dairy_____

TEST KIT SUITABILITY CHECK FOR DRUG RESIDUE TESTING

Test Method Used: _IDEXX New Snap_____

Date Received	Lot Number	Expiration Date	Date Tested [1]	Date Start Using [2]	Control Results/Interpretation				Analyst ID or Initials
					POSITIVE CONTROL		NEGATIVE CONTROL		
					Result / Interpretation	Suitability Check Date[3]	Result / Interpretation	Suitability Check Date[3]	
12/15/13	MT995	6 FEB 14	12/16/13	12/20/13	5.69 / POS	12/16/13	0.76 / NF	12/15/13	JM
1/8/14	KD143	30 APR 14	1/10/14	1/11/14	3.30 / POS	1/10/14	0.67 / NF	1/8/14	JM

1. 'Date tested' is the date the first positive and negative control is run to check the suitability of the new lot.
2. 'Date Start Using' is the date this lot of kits is put into use, testing controls & trucks.
3. Suitability check date the POS/NEG control that was used to check the new kit was first tested and found suitable.

BFSLS 513A (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

Positive Control Suitability Test

Positive Control Information											Test Kit Information			
Manufacturer	Lot #	Mfg. Expiration Date	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Positive Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date

BFSLS 513A (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:___Utter's Dairy_____

Positive Control Suitability Test

Positive Control Information / Test Kit Information

Manufacturer	Lot #	Mfg. Expiration Date	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Positive Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date
Charm Sciences	**18D**	**2/2014**	**12/16/13**	**12/17/13**	**12/16/13**	**08:35**	**08:45**	**+1954/POS**	**JM**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Charm Sciences	**18D**	**2/2014**	**12/23/13**	**12/24/13**	**12/23/13**	**09:30**	**09:40**	**+2155/POS**	**AT**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Charm Sciences	**18F**	**5/2014**	**12/30/13**	**12/31/13**	**12/30/13**	**08:20**	**08:30**	**+1874/POS**	**AT**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Charm Sciences	**18F**	**5/2014**	**1/10/14**	**1/11/14**	**1/10/14**	**09:15**	**09:25**	**+2358/POS**	**JM**		**Charm SL**	**Charm Sciences**	**128**	**6/2014**

EXAMPLE

BFSLS 513A (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

Positive Control Suitability Test

Positive Control Information											Test Kit Information			
Manufacturer	Lot #	Mfg. Expiration Date	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Positive Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date
IDEXX	EK669	2/16/14	12/16/13	12/17/13	12/16/13	08:35	08:45	5.69/Pos	JM		SNAP	IDEXX	MT995	2/6/14
IDEXX	EK669	2/16/14	12/23/13	12/24/13	12/23/13	09:30	09:40	4.17/POS	AT		SNAP	IDEXX	MT995	2/6/14
IDEXX	EK669	2/16/14	12/30/13	12/31/13	12/30/13	08:20	08:30	6.68/POS	AT		SNAP	IDEXX	MT995	2/6/14
IDEXX	EK669	2/16/14	1/10/14	1/11/14	1/10/14	09:15	09:25	3.30/POS	JM		SNAP	IDEXX	KD143	4/30/14

EXAMPLE

BFSLS 513B (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

Negative Control Suitability Test

Negative Control Information

Test Kit Information

Source (bulk tank, silo, tanker, etc)Date	ID # (tanker license #, silo#, etc)	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Negative Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date

BFSLS 513B (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:__ Utter's Dairy_____

Negative Control Suitability Test

Negative Control Information										Test Kit Information			
Source (bulk tank, silo, tanker, etc)/Date	ID # (tanker license #, silo#, etc)	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Negative Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date
Tanker	**1235587**	**12/16/13**	**12/17/13**	**12/16/13**	**08:35**	**08:45**	**-2087/NF**	**JM**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Tanker	**1235568**	**12/23/13**	**12/24/13**	**12/23/13**	**09:30**	**09:40**	**-1822/NF**	**AT**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Tanker	**1235621**	**12/30/13**	**12/31/13**	**12/30/13**	**08:20**	**08:30**	**-1597/NF**	**AT**		**Charm SL**	**Charm Sciences**	**127**	**4/2014**
Tanker	**1235649**	**1/10/14**	**1/11/14**	**1/10/14**	**09:15**	**09:25**	**-2144/NF**	**JM**		**Charm SL**	**Charm Sciences**	**128**	**6/2014**

BFSLS 513B (Rev. 7/11)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

Negative Control Suitability Test

Negative Control Information

Test Kit Information

Source (bulk tank, silo, tanker, etc)Date	ID # (tanker license #, silo#, etc)	Date Prepared	Expiration Date	Date Tested	Start Test Time	Read Results Time	Test Results Negative Control	Analyst ID# or Initials		Test Kit Used	Manufacturer	Lot #	Mfg. Expiration Date
Tanker	**1235587**	**12/16/13**	**2/16/14**	**12/16/13**	**08:35**	**08:45**	**0.69/NF**	**JM**		**SNAP**	**IDEXX**	**MT995**	**2/6/14**
Tanker	**1236489**	**12/23/13**	**2/23/14**	**12/23/13**	**09:30**	**09:40**	**0.77/ NF**	**AT**		**SNAP**	**IDEXX**	**MT995**	**2/6/14**
Tanker	**1236954**	**12/30/13**	**2/30/14**	**12/30/13**	**08:20**	**08:30**	**0.68/ NF**	**AT**		**SNAP**	**IDEXX**	**MT995**	**2/6/14**
Tanker	**1237259**	**1/10/14**	**3/10/14**	**1/10/14**	**09:15**	**09:25**	**0.80/ NF**	**JM**		**SNAP**	**IDEXX**	**KD143**	**4/30/14**

EXAMPLE

BFSLS 515 (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____ **Year**_____

THERMOMETER ACCURACY CHECK LOG

Date NIST Tested	NIST	Serial /ID Number	Range	Graduation Interval	Calibration points	Ice point result	Correction Factor[7] °C	Analyst

Date Tested	Test thermometer Location of use	Serial Number	Lab ID	Temp range of use °C	Temp of Test Thermometer °C	Temp and ID of NIST Reference Thermometer °C	Correction Factor °C	Analyst

1. **To be done before initial use and at least annually thereafter.**
2. **National Institute of Standards and Testing (NIST) Certified thermometer, or equivalent, with a certificate of calibration.**
3. **Range of test thermometers appropriate for designated use.**
4. **Accuracy of test thermometers checked against certified thermometer.**
5. **Accurate to ± 1.0°C when checked at temperature(s) of use.**
6. **Results recorded and thermometers tagged with the following information: Identification, date of check, temperature of check, correction factor(s) and analyst ID.**
7. **If NIST has a correction other than 0.0°C, use form BFSLS 515a.**

BFSLS 515 (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____ **Year**_____

THERMOMETER ACCURACY CHECK LOG

Date NIST Tested	NIST	Serial /ID Number	Range	Graduation Interval	Calibration points	Ice point result	Correction Factor[7] °C	Analyst
1/6/14	NIST 1	F95-389	-1 to 101C	0.2	0,32,45,64,85	0.0C	0.0	JM
1/8/14	NIST 2	3697	-50 to 10C	0.2	-30, -15, 0	0.0C	0.0	JM

Date Tested	Test thermometer Location of use	Serial Number	Lab ID	Temp range of use °C	Temp of Test Thermometer °C	Temp and ID of NIST Reference Thermometer °C	Correction Factor °C	Analyst
1/6/14	Sampling	J3398	TC1	0.0-4.5	0.2	0.0 / NIST 1	-0.2	JM
1/6/14	Sample receiving	J6689	TC2	0.0-4.5	0.0	0.0 / NIST 1	0.0	JM
1/6/14	Fridge, top shelf	Ertco 14479	F1	0.0-4.5	0.6	0.0 / NIST 1	-0.6	JM
1/6/14	Fridge, bottom shelf	Ertco 1245	F2	0.0-4.5	-0.2	0.0 / NIST 1	+0.2	JM
1/7/14	Incubator, top shelf	Ertco 6695	I1	31-33	31.5	32.1 / NIST 1	+0.6	JM
1/7/14	Incubator, bottom shelf	Ertco 1176	I2	31-33	31.9	32.1 / NIST 1	+0.2	JM
1/7/14	Charm SL heater block	Ertco 5572	HB1	55-57	56.2	56.0 / NIST 1	-0.2	JM
1/8/14	Freezer	Fisher F669	FZ1	<-15.0	-18.2	-18.6 / NIST 2	-0.4	JM

1. **To be done before initial use and at least annually thereafter.**
2. **National Institute of Standards and Testing (NIST) Certified thermometer, or equivalent, with a certificate of calibration.**
3. **Range of test thermometers appropriate for designated use.**
4. **Accuracy of test thermometers checked against certified thermometer.**
5. **Accurate to ± 1.0°C when checked at temperature(s) of use.**
6. **Results recorded and thermometers tagged with the following information: Identification, date of check, temperature of check, correction factor(s) and analyst ID.**
7. **If NIST has a correction other than 0.0°C, use form BFSLS 515a.**

BFSLS 515a (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____ Year _____

THERMOMETER ACCURACY CHECK LOG

Date NIST Tested	NIST	Serial /ID Number	Range	Graduation Interval	Calibration points	Ice point result	Correction Factor °C	Analyst ID

Date Tested	Test Thermometer Location of use	Serial Number	Lab ID	Temp range of use °C	Temp of Test Thermometer °C	Read Temp and ID of NIST Reference Thermometer °C	Adjusted NIST Reading °C	Correction Factor of Test Thermometer °C	Analyst ID

1. **To be done before initial use and at least annually thereafter.**
2. **National Institute of Standards and Testing (NIST) Certified thermometer, or equivalent, with a certificate of calibration.**
3. **Range of test thermometers appropriate for designated use.**
4. **Accuracy of test thermometers checked against certified thermometer.**
5. **Accurate to ± 1.0°C when checked at temperature(s) of use.**
6. **Results recorded and thermometers tagged with the following information: Identification, date of check, temperature of check, correction factor(s) and analyst ID.**

BFSLS 515a (Rev. 12/13)

COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____ Year _____

THERMOMETER ACCURACY CHECK LOG

Date NIST Tested	NIST	Serial /ID Number	Range	Graduation Interval	Calibration points	Ice point result	Correction Factor °C	Analyst ID
1/6/14	NIST 1	F95-389	-1 to 101C	0.2	0,32,45,64, 85	0.0C	0.0	JM
1/8/14	NIST 2	3697	-50 to 10C	0.2	-30, -15, 0	0.3C	-0.3	JM

Date Tested	Test Thermometer Location of use	Serial Number	Lab ID	Temp range of use °C	Temp of Test Thermometer °C	Read Temp and ID of NIST Reference Thermometer °C	Adjusted NIST Reading °C	Correction Factor of Test Thermometer °C	Analyst ID
1/6/14	Sampling	J3398	TC1	0.0-4.5	0.2	0.0 / NIST 1	0.0	-0.2	JM
1/6/14	Sample receiving	J6689	TC2	0.0-4.5	0.0	0.0 / NIST 1	0.0	0.0	JM
1/6/14	Fridge, top shelf	Ertco 14479	F1	0.0-4.5	0.6	0.0 / NIST 1	0.0	-0.6	JM
1/6/14	Fridge, bottom shelf	Ertco 1245	F2	0.0-4.5	-0.2	0.0 / NIST 1	0.0	+0.2	JM
1/7/14	Incubator, top shelf	Ertco 6695	I1	31-33	31.5	32.1 / NIST 1	32.1	+0.6	JM
1/7/14	Incubator, bottom shelf	Ertco 1176	I2	31-33	31.9	32.1 / NIST 1	32.1	+0.2	JM
1/7/14	Charm SL heater block	Ertco 5572	HB1	55-57	56.2	56.0 / NIST 1	56.0	-0.2	JM
1/8/14	Freezer	Fisher F669	FZ1	<-15.0	-18.2	-18.6 / NIST 2	-18.9	-0.7	JM

1. To be done before initial use and at least annually thereafter.
2. National Institute of Standards and Testing (NIST) Certified thermometer, or equivalent, with a certificate of calibration.
3. Range of test thermometers appropriate for designated use.
4. Accuracy of test thermometers checked against certified thermometer.
5. Accurate to ± 1.0°C when checked at temperature(s) of use.
6. Results recorded and thermometers tagged with the following information: Identification, date of check, temperature of check, correction factor(s) and analyst ID.

BFSLS 528 (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:_____

Annual Appendix N Training Log

Name	PDA Analyst #	Position (CIS or IS or IA)	Date of Initial Training[1]	Date of On-site Review by IS[2]	Date of On-site review by State LEO[3]	Annual Split Sample Participation Date	Results from Split Samples (Pass/Fail)

Notes:

1. Date of the initial training for Industry Analyst (IA) to gain approval for testing.
2. Date of annual in-house training and observation of the IA by the Supervisor.
3. Date of audit with state LEO. Audit participation is optional for IA's and mandatory for all Industry Supervisors.
4. All IA's and Supervisory must have a successful participation in the annual split samples to maintain approval/certification.

BFSLS 528 (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name:___Utter's Dairy_____

Annual Appendix N Training Log

Name	PDA Analyst #	Position (CIS or IS or IA)	Date of Initial Training[1]	Date of On-site Review by IS[2]	Date of On-site review by State LEO[3]	Annual Split Sample Participation Date	Results from Split Samples (Pass/Fail)
Alyssa Thomas	03	IA	4/15/12	3/1/13	NA	3/12/13	PASS
Jeff Michaels	02	IA	10/19/13	3/1/13	NA	3/12/13	PASS
Jason Kirk	01	CIS	NA	NA	6/15/13	3/12/13	PASS
Alice Stone	04	CIS	3/3/12	NA	6/15/13	3/12/13	PASS

EXAMPLE

Notes:

1. Date of the initial training for Industry Analyst (IA) to gain approval for testing.
2. Date of annual in-house training and observation of the IA by the Supervisor.
3. Date of audit with state LEO. Audit participation is optional for IA's and mandatory for all Industry Supervisors.
4. All IA's and Supervisory must have a successful participation in the annual split samples to maintain approval/certification.

BFSLS 528a (2/15)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

APPENDIX N TRAINING SESSION
APPROVAL REQUEST FOR NEW ANALYST

The following individuals have participated in training at: (Facility) _____ in (Town) _____PA, concerning the Appendix N Testing Program for Drug Residues for (test)_____.

This training was held on_____, 20____ by _____
Information and materials presented dealt with the review of the (current) Pasteurized Milk Ordinance (PMO) - Appendix N Testing Program for Drug Residues, Industry Analyst, Industry Supervisor and Certified Industry Supervisor responsibilities. FDA 2400 forms and product inserts, along with quality control records, were used to evaluate approved methods for testing for animal drug residues. Each analyst properly demonstrated testing procedure of approved Appendix N method used at this facility.

The undersigned have been trained in the Appendix N requirements. They understand the responsibilities associated with this testing procedure.

DETERMINED BY FACILITY TRAINER			DETERMINED BY LABORATORY EVALUATION OFFICER		
Name of Participant (print)	**SIGNATURE of Participant**	**Date Trained**	**Classification**	**Status**	**PDA #**

Classification: IA= Ind. Analyst, IS = Ind. Supervisor, CIS = Certified Ind. Supervisor Status: F^A-Fully Approved, C^A = Conditionally Approved, P^A = Provisionally Approved

_____
Facility Supervisor Signature

_____
Date

_____
State Laboratory Evaluation Officer Signature

_____
Date Approved

BFSLS 528a (2/15)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

APPENDIX N TRAINING SESSION
APPROVAL REQUEST FOR NEW ANALYST

The following individuals have participated in training at: (Facility) ___Utter's Dairy_____ in (Town) _Hometown_____PA, concerning the Appendix N Testing Program for Drug Residues for (test)___Charm SL_____.

This training was held on_____October 15_____, 2015____ by ___John Doe CIS 22_____
Information and materials presented dealt with the review of the (current) Pasteurized Milk Ordinance (PMO) - Appendix N Testing Program for Drug Residues, Industry Analyst, Industry Supervisor and Certified Industry Supervisor responsibilities. FDA 2400 forms and product inserts, along with quality control records, were used to evaluate approved methods for testing for animal drug residues. Each analyst properly demonstrated testing procedure of approved Appendix N method used at this facility.

The undersigned have been trained in the Appendix N requirements. They understand the responsibilities associated with this testing procedure.

DETERMINED BY FACILITY TRAINER			DETERMINED BY LABORATORY EVALUATION OFFICER		
Name of Participant (print)	SIGNATURE of Participant	Date Trained	Classification	Status	PDA #
Jeff Michaels		10/19/12	IS	Ca	03

Classification: IA= Ind. Analyst, IS = Ind. Supervisor, CIS = Certified Ind. Supervisor Status: F^A-Fully Approved, C^A = Conditionally Approved, P^A = Provisionally Approved

_____ Facility Supervisor Signature

_____ Date

_____ State Laboratory Evaluation Officer Signature

_____ Date Approved

BFSLS 534 (Rev. 7/09)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: _____

SNAPSHOT PERFORMANCE CHECK SET

YEAR:_____ MONTH:_____

SERIAL # OF PERFORMANCE CHECK SET:_____

DAY	**DEVICE 1:C/S _____** **-.15_____ +.15_____**	**DEVICE 2:C/S _____** **-.30_____ +.30_____**	**ANALYST ID# OR INITIALS**
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

1. Performance Check Set needs to be done day of use along with a positive and negative control.

BFSLS 534 (Rev. 7/09)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: **WIDE CREEK FARMS**

SNAPSHOT PERFORMANCE CHECK SET

YEAR: **2013** MONTH: **December**

SERIAL # OF PERFORMANCE CHECK SET: **SNAP001347**

DAY	DEVICE 1:C/S = 0.73 -.15 = .58 +.15 = .88	DEVICE 2:C/S = 1.55 -.30 = 1.25 +.30 = 1.85	ANALYST ID# OR INITIALS
1	.77	1.58	AT, #03
2	.76	1.58	JK, #01
3	.77	1.58	AT, #03
4	.77	1.59	AT, #03
5	.76	1.58	JM, #02
6	.77	1.58	AT, #03
7	.77	1.59	JK, #01
8	.77	1.58	JK, #01
9	.77	1.58	JK, #01
10	.77	1.58	JM, #02
11	.76	1.58	AT, #03
12	.77	1.58	JK, #01
13	.77	1.58	AT, #03
14	.77	1.58	AT, #03
15	.77	1.58	JM, #02
16	.77	1.58	AT, #03
17	.77	1.58	JK, #01
18	.77	1.58	JK, #01
19	.77	1.58	JK, #01
20	.77	1.58	JM, #02
21	.77	1.58	AT, #03
22	.77	1.58	AT, #03
23	.77	1.59	JK, #01
24	.77	1.58	AT, #03
25	.79	1.58	AT, #03
26	.77	1.58	JM, #02
27	.77	1.58	AT, #03
28	.77	1.58	JK, #01
29	.77	1.58	JK, #01
30	.77	1.58	JK, #01
31	.77	1.58	JM, #02

EXAMPLE

1. Performance Check Set needs to be done day of use along with a positive and negative control.

BFSLS 534 (Rev. 5/15)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: _____

SNAPSHOT DSR PERFORMANCE CHECK SET

YEAR:_____ MONTH:_____

SERIAL # OF PERFORMANCE CHECK SET:_____

DAY	**DEVICE 1-LOW RANGE:** _____ **to** _____	**DEVICE 2- HIGH RANGE:** _____ **to** _____	**ANALYST ID# OR INITIALS**
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

1. Performance Check Set needs to be done day of use along with a positive and negative control.

BFSLS 534 (Rev. 5/15)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: __Utter's Dairy_____

SNAPSHOT DSR PERFORMANCE CHECK SET

YEAR:__2015_____ MONTH:__January_____

SERIAL # OF PERFORMANCE CHECK SET:___87-14762-00_____

DAY	DEVICE 1-LOW RANGE: _0.69_____ to __0.75____	DEVICE 2- HIGH RANGE: _1.51_____ to __1.75____	ANALYST ID# OR INITIALS
1			
2	0.70	1.64	JS
3	0.70	1.64	JS
4	0.70	1.64	JS
5	0.70	1.64	SM
6			
7	0.71	1.64	SM
8	0.70	1.64	SM
9			
10	0.70	1.64	JS
11	0.70	1.64	SM
12			
13			
14	0.70	1.63	JS
15	0.70	1.64	JS
16	0.70	1.64	SM
17	0.70	1.64	JS
18	0.72	1.65	SM
19			
20			
21	0.70	1.64	JS
22	0.70	1.64	SM
23			
24	0.70	1.64	JS
25	0.71	1.64	SM
26			
27			
28	0.70	1.64	SM
29	0.70	1.63	JS
30	0.70	1.64	JS
31	0.70	1.64	SM

1. Performance Check Set needs to be done day of use along with a positive and negative control.

BFSLS 535 (Rev. 7/09)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: _____

CHARM ROSA READER (ROSA Reader, ROSA Pearl Reader or Charm Sciences equivalent)

PRIMARY CALIBRATION STRIPS

YEAR_____ MONTH_____

SERIAL # OF PRIMARY CALIBRATION STRIPS_____

DAY	LOW RANGE: -20% _____ +20%_____	HIGH RANGE: -20% _____ +20%_____	ANALYST ID# OR INITIALS
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

1. Primary Calibration Strips need to be done day of use along with a positive and negative control.
2. Primary Calibration Strips match ROSA serial number. Calibration strips are specific to an individual reader. Do not interchange strips between different readers.

BFSLS 535 (Rev. 7/09)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
LABORATORY DIVISION

Facility/Laboratory Name: **WIDE CREEK FARMS**

CHARM ROSA READER (ROSA Reader, ROSA Pearl Reader or Charm Sciences equivalent)

PRIMARY CALIBRATION STRIPS

YEAR **2012** MONTH **October**

SERIAL #(S) OF PRIMARY CALIBRATION STRIPS **RR0795** **(CHARM SL)**

DAY	LOW RANGE: -20% -1063 +20% -1594	HIGH RANGE: -20% +1297 +20% +1945	ANALYST ID# OR INITIALS
1	-1246	+1391	JK
2			
3	-1445	+1685	JK
4			
5	-1330	+14	AT
6			
7	-1455	-15	JM
8	-1501	+1667	JM
9			
10			
11	-1422	+1333	JK
12			
13	-1456	+1785	JK
14			
15	-1099	+1469	JK
16			
17			
18	-1363	+1537	AT
19			
20	-1489	+1372	JM
21			
22			
23	-1125	+1403	AT
24	-1199	+1743	JM
25			
26			
27	-1099	+1899	AT
28			
29	-1159	+1589	AT
30			
31	-1426	+1900	JK

EXAMPLE

1. Primary Calibration Strips need to be done day of use along with a positive and negative control.
2. Primary Calibration Strips match ROSA serial number. Calibration strips are specific to an individual reader. Do not interchange strips between different readers.

APPENDIX N

MEMOS

pennsylvania
DEPARTMENT OF AGRICULTURE

BUREAU OF FOOD SAFETY & LABORATORY SERVICES

Date: February 4, 2014

Subject: New FDA 2400 Form Changes

To: All Pennsylvania Approved Dairy Laboratories/Facilities

From: Michael F. Hydock, Chief
Laboratory Division

IMPLEMENTATION DATE: Immediately

Enclosed is one (1) original copy of the revised FDA-2400 form series for the following procedures that may apply to your laboratory/facility:

1. FORM FDA/NCIMS 2400a-4 Petrifilm™ Aerobic & Coliform Count Rev. 1/14
2. FORM FDA/NCIMS 2400d Direct Microscopic Somatic Cell Count Rev. 1/14
3. FORM FDA/NCIMS 2400h-2 Bentley SomacountTM Rev. 1-14
4. FORM FDA/NCIMS 2400h-3 Foss 5000-FC Rev. 1/14
5. FORM FDA/NCIMS 2400h-4 SomaScope™ MKII/Smart Rev 1/14
6. FORM FDA/NCIMS 2400h-5 Foss Minor Rev. 1/14
7. FORM FDA/NCIMS 2400n-4 Charm® II Beta-Lactam Assays Rev. 1/14
8. FORM FDA/NCIMS 2400n-5 Charm® II Combined Non-Beta-Lactam Assays rev. 1/14

These forms have been reviewed and approved by the LPET in conjunction with the NCIMS Laboratory Committee.

In the case of these forms there are NO procedure changes. The changes in these forms are mainly the result of Conference actions (IMS#s, footer FDA/NCIMS 2400x Form and 4.5C). In addition there are some editorial and format changes/fixes.

All laboratory surveys conducted after today shall be conducted using these new forms.

If you have any questions please contact me at 717-772-3236 or email mhydock@pa.gov

cc. L. Johnson
cc. J. Martin

pennsylvania
DEPARTMENT OF AGRICULTURE

BUREAU OF FOOD SAFETY & LABORATORY SERVICES

Date: January 27, 2014

Subject: Laboratory Quality Control Forms Revised 12/13 and 1/14

To: Pennsylvania Approved Laboratories and Screening Facilities

From: Michael F. Hydock, Chief
BFSLS – Laboratory Division

EFFECTIVE IMMEDIATELY

Enclosed is a packet of the Laboratory Quality Control Forms Revised 12/13 or 1/14.
The forms are as follows:

1.	BFSLS 495	Incubator Temperature Log	(Revision 12-13)
2.	BFSLS 501a	Temperature Record Block Heater	(Revision 1-14)
3.	BFSLS 501b	Temperature Record Freezer	(Revision 1-14)
4.	BFSLS 501c	Temperature Record Refrigerator	(Revision 1-14)
5.	BFSLS 510	Refrigerator Temperature Log	(Revision 12-13)
6.	BFSLS 515	Thermometer Accuracy check	(Revision 12-13)
7.	BFSLS 515a	Thermometer Accuracy check	(Revision 12-13 -New Form)
8.	BFSLS 532	Freezer Temperature Log	(Revision 12-13)
9.	BFSLS 532a	Freezer Temperature Log	(Revision 12-13)
10.	BFSLS 497	Monthly Analytical Balance Check Records	(Revison1-14)
11.	BFSLS 498	Monthly Milk-Media Electronic Balance Check Records	(Revison1-14)
12.	BFSLS 500	Drug Screening Test Log	(Revison1-14)
13.	BFSLS 500a	Daily Screening Log	(Revison1-14)
14.	BFSLS 503	Semi-annual Pipettor Accuracy Check	(Revison 2-15)
15.	BFSLS 513	Test Kit Suitability Check	(Revison1-14)
16.	BFSLS 528	Appendix N Training Log	(Revison1-14)
17.	BFSLS 528a	Appendix N Training Sheet New Analyst	(Revison 2-15)
18.	BFSLS 480	Microbiological Suitable Water (MS)	(Revision
19.	BFSLS 485	Daily pH Meter Maintenance	12-13)
20.	BFSLS 485b	Daily pH Meter Calibration Log	(Revision
21.	BFSLS 486	Stock Phosphate Buffer(Purchased)	12-13)
22.	BFSLS 486b	Stock Phosphate Buffer(Lab Prepared)	(Revision
23.	BFSLS 490	Quarterly Percent Weight Loss Records-Agar Method	12-13)
24.	BFSLS 490a	Quarterly Percent Weight Loss Records-Petrifilm Method	(Revision
25.	BFSLS 492	Dilution Blank Checks	12-13)
26.	BFSLS 492a	Pre-Dispensed Rinse Solution Checks for Gallon Containers	(Revision
27.	BFSLS 492b	Pre-Dispensed Rinse Solution Checks for Half Pint, Pint, & Quart Containers	12-13) (Revision 12-13)
28.	BFSLS 492c	Pre-Dispensed Rinse Solution Checks for Half Gallon Containers	(Revision 12-13)
29.	BFSLS 493	Autoclave Sterilization Record	(Revision 12-13)
30.	BFSLS 493a	Autoclave Sterilization Record - Waste Only	(Revision 12-13)
			12-13)
			(Revision
			12-13)
			(Revision 12-13)

31.	BFSLS 494	Hot Air Oven Sterilization Record	(Revision 12-13)
32.	BFSLS 503b	Volume Check Continuous Pipetting Outfit	(Revision 1-14)

If your laboratory/facility is using an older revision of the above forms, they are to be replaced with the current revision and used immediately for recording laboratory/facility required records. The forms and reports must be maintained and available for review during a laboratory/facility evaluation. If you desire to make any change in the format of these forms, a request outlining the change(s) must be submitted to the Laboratory Division for review and acceptance prior to initiating the change(s). A written response will be sent to the laboratory/ facility from BFSLS-Laboratory Division granting or not granting any change(s) in the format as acceptable for use as an official record form.

If you have any questions, call me at (717) 787-4315.

Thank you for your cooperation.

cc. J. Rakowski

pennsylvania
DEPARTMENT OF AGRICULTURE

BUREAU OF FOOD SAFETY & LABORATORY SERVICES

Date: October 25, 2013

Subject: New FDA 2400 Form Changes - Effective Immediately

To: All Pennsylvania Approved Dairy Laboratories/Facilities

From: Michael F. Hydock, Chief
Laboratory Division

IMPLEMENTATION DATE: NOVEMBER 1, 2013

Enclosed is one (1) original copy of the revised FDA-2400 form series for the following procedure that applies to your laboratory/facility:

1. FORM FDA/NCIMS 2400n Appendix N - General Requirements rev. 10/13
2. FORM FDA/NCIMS 2400n-1 Charm® SL/SL3 rev. 10/13

These forms has been reviewed and approved by the LPET in conjunction with the NCIMS Laboratory Committee.

General Conference changes: Add IMS# to the top of each method, change 4.4C to 4.5C where specified and recognize the efforts of the NCIMS in the revision of these forms in the footer of each form, FDA/NCIMS 2400 form.

1. Appendix N General Requirements (FORM FDA/NCIMS 2400n): Clarification of balance calibration checks (item 6.c), clarification on use of pipettors (item 7.c), specifies need to record date and time of tanker testing (item 9.4), clarifies interpretation of positive and negative controls prior to reading duplicate test results for presumptive (item 11.b.1), BMT confirmation (item 12.b.1) and producer traceback (item 13.e.1) testing, and fixes producer traceback procedure so that there is an initial screen of producers on a load prior to running the samples in duplicate with controls (item 13.a-g).

2. Charm SL/SL3 BL Test (FORM FDA/NCIMS 2400n-1): Adds EZ reader wording including allowance to use EZ reader to incubate and read (item 7) and removes SL6 (no longer an approved method).

All laboratory surveys conducted **after November 1, 2013** shall be conducted using these new forms.

If you have any questions please contact me at 717-772-3236 or email mhydock@pa.gov

cc. L. Johnson
cc. J. Martin

pennsylvania
DEPARTMENT OF AGRICULTURE

BUREAU OF FOOD SAFETY & LABORATORY SERVICES

Date: October 25, 2013

Subject: New FDA 2400 Form Changes - Effective Immediately

To: All Pennsylvania Approved Dairy Laboratories/Facilities

From: Michael F. Hydock, Chief
Laboratory Division

IMPLEMENTATION DATE: NOVEMBER 1, 2013

Enclosed is one (1) original copy of the revised FDA-2400 form series for the following procedure that applies to your laboratory/facility:

1. FORM FDA/NCIMS 2400n Appendix N - General Requirements rev. 10/13
2. FORM FDA/NCIMS 2400n-2 IDEXX New Snap® Beta-Lactam Test rev. 10/13

These forms has been reviewed and approved by the LPET in conjunction with the NCIMS Laboratory Committee.

General Conference changes: Add IMS# to the top of each method, change 4.4C to 4.5C where specified and recognize the efforts of the NCIMS in the revision of these forms in the footer of each form, FDA/NCIMS 2400 form.

1. Appendix N General Requirements (FORM FDA/NCIMS 2400n): Clarification of balance calibration checks (item 6.c), clarification on use of pipettors (item 7.c), specifies need to record date and time of tanker testing (item 9.4), clarifies interpretation of positive and negative controls prior to reading duplicate test results for presumptive (item 11.b.1), BMT confirmation (item 12.b.1) and producer traceback (item 13.e.1) testing, and fixes producer traceback procedure so that there is an initial screen of producers on a load prior to running the samples in duplicate with controls (item 13.a-g)

2. IDEXX New Snap BL Test (FORM FDA/NCIMS 2400n-2): Adds approval for testing raw camel and raw goat milk, and allows test kits to be shipped and received without refrigeration as long as shipping is less than 72 hour (item 3.f). Reminder: IDEXX has announced that they are no longer able to service the old SNAPshot reader as of October 31, 2013. The old readers may still be used as long as they continue to work as specified in the 2400 form.

All laboratory surveys conducted **after November 1, 2013** shall be conducted using these new forms.

If you have any questions please contact me at 717-772-3236 or email mhydock@pa.gov

cc. L. Johnson
cc. J. Martin

pennsylvania
DEPARTMENT OF AGRICULTURE

BUREAU OF FOOD SAFETY & LABORATORY SERVICES

Date: June 15st, 2012

Subject: Appendix N Positive Drug Residue Dumping Procedure for Multi-Compartment Tankers

To: Milk Receiving Locations conducting Appendix N Drug Residue Testing
Milk Sanitarian Supervisors
Milk Sanitarians

From: Dr. Lydia Johnson | Director
Bureau of Food Safety & Laboratory Services
Pennsylvania Department of Agriculture
2301 North Cameron Street | Harrisburg, PA 17110
Phone: 717.787.4315 | Fax: 717.787.1873

In response to the recent questions raised concerning dumping of milk from multi-compartment tankers, the Pennsylvania Department of Agriculture (PDA) is adopting the following procedure effective June 1st, 2012. This policy rescinds any prior PDA policies or memorandums concerning dumping of Appendix N positive testing milk on multi-compartment tankers. This policy is intended to align PDA's policy with the interpretation of FDA as stated in the answer to question number 72 c) contained in M-I-12-9.

- If all compartments test negative, all compartments may be received.
- If all compartments test presumptive positive and are confirmed positive, all compartments must be dumped.
- When one compartment tests presumptive positive and the other compartment(s) test negative, the milk from the negative compartments(s) shall not be unloaded until the confirmatory tests and producer trace back tests are completed and a positive producer is confirmed.
- If milk from the bulk milk tank of the confirmed positive producer has been split between compartments, that milk is considered adulterated and must also be dumped.
- If a producer has multiple bulk milk tanks, only the compartments with milk from individual tank samples confirmed positive needs to be dumped.

Your cooperation is appreciated. If you have any questions or concerns, please contact me.

DHHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-96-10 (Revision #9)

August 31, 2016

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Drug Residue Test Methods For Confirmation Of Presumptive Positive Results And Initial Producer Trace Back

This coded memorandum replaces and rescinds the previous revision of this coded memorandum (M-I-96-10 (Revision #8), issued March 22, 2012). Revision #8 will be identified in the next Index of Memoranda of Information (M-I) as "INACTIVE".

This revision reflects changes made to M-a-85 (Revision #15), issued August 29, 2016, and also adds Tables 2 - 5 for other species milk.

Modifies Tables to reflect the acceptance of the following:

- New Snap® Beta Lactam Test approval for raw, commingled camel milk (M-I-12-13, issued 10/9/2012) and raw, commingled goat milk (M-I-13-7, issued 10/31/2013)

It also modifies the Tables to remove the following Tests that are no longer available:

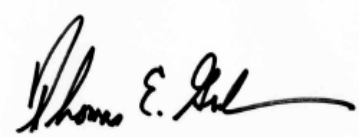
- Charm Sciences, Inc. Charm® SL6 Beta Lactam Test; and
- DSM Delvotest SP/Delvotest SP mini.

The following Tables have been developed by FDA's Center for Veterinary Medicine (CVM) to demonstrate those screening Tests that have been accepted under the requirements of Appendix N of the *Grade "A" Pasteurized Milk Ordinance* (PMO) to determine whether presumptive positive milk tank truck and/or raw milk supplies that have not been transported in a milk tank truck results are screening positive (load or raw milk supplies that have not been transported in a bulk milk pickup tanker confirmation). These Tables may also be used to determine an appropriate initial producer trace back test to identify the positive producer(s) who contributed the milk containing drug(s) on a positive milk tank truck load. These Tables do not include any

additional requirements for testing and are a reference for which Tests are appropriate to test samples from a producer(s), which has contributed milk containing drug(s) to a positive milk tank truck.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your region. This memorandum should be widely distributed to representatives of the dairy industry, State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.



Thomas Graham, PhD, Team Leader
Laboratory Proficiency & Evaluation Team

Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Milk and Milk Products Branch

Table 1: Raw, Commingled Cow Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
BetaStar® Plus Beta Lactam Test	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® II Tablet Beta Lactam Test (Competitive Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® 3 SL3 Beta Lactam Test
Charm® *B. stearothermophilus* Tablet Disk Assay Not a Beta lactam Specific Test. Refer to Footnote[1].	BetaStar® Plus Beta Lactam Test Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P Mini New Snap® Beta Lactam Test
Charm® II Tablet Beta Lactam Test (Competitive Assay)	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test
Charm® II Tablet Beta Lactam Test (Sequential Assay)	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test
Charm® II Tablet Beta Lactam Test (Quantitative Assay)	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® II Tablet Beta Lactam Test (Competitive Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® 3 SL3 Beta Lactam Test

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® II Test for Cloxacillin (Competitive Assay)	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® 3 SL3 Beta Lactam Test
Charm® SL Beta Lactam Test	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test
Charm® 3 SL3 Beta Lactam Test	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® II Tablet Beta Lactam Test (Competitive Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) + Charm® II Test for Cloxacillin in Milk (Competitive Assay) Charm® 3 SL3 Beta Lactam Test
Charm® FLUSLBL Flunixin and Beta Lactam Test	Charm® FLUSLBL Flunixin and Beta Lactam Test
Charm® II Chloramphenicol Test	Charm® II Chloramphenicol Test
Charm® II Sulfa Drug Test (Competitive Assay)	Charm® II Sulfa Drug Test (Competitive Assay)
Charm® II Tetracycline Drug Test (Competitive Assay)	Charm® II Tetracycline Drug Test (Competitive Assay)
Delvotest P 5 Pack (Reader and Visual) Not a Beta lactam Specific Test. Refer to Footnote[1].	BetaStar® Plus Beta Lactam Test Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P Mini New Snap® Beta Lactam Test

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Delvotest P Mini Not a Beta lactam Specific Test. Refer to Footnote[1].	BetaStar® Plus Beta Lactam Test Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P Mini New Snap® Beta Lactam Test
New Snap® Beta Lactam Test	BetaStar® Plus Beta Lactam Test Charm® II Tablet Beta Lactam Test (Competitive Assay) Charm® II Tablet Beta Lactam Test (Sequential Assay) Charm® II Tablet Beta Lactam Test (Quantitative Assay) Charm® SL Beta Lactam Test Charm® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test

[1]These Tests are not specific for Beta lactams. While they are not validated to NCIMS standards for any drugs other than Beta lactams, a non-Beta lactam drug residue can cause a positive test. A negative or not found (NF) test result using one (1) of the Beta lactam specific Tests to follow-up or confirm a positive result with this test kit will require re-testing the sample using the Charm® *B. stearothermophilus* Tablet Disk Assay, Delvotest P 5 Pack or Delvotest P Mini. Any of the listed confirmation test options, other than the four (4) identified in the Tables, are Beta lactam specific Tests.

Table 2: Raw, Commingled Camel Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
New Snap® Beta Lactam Test	New Snap® Beta Lactam Test

Table 3: Raw, Commingled Goat Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® SL Beta Lactam Test	Charm® SL Beta Lactam Test New Snap® Beta Lactam Test
Delvotest P 5 Pack (Reader and Visual) Not a Beta lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P Mini New Snap® Beta Lactam Test
Delvotest P Mini Not a Beta lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P Mini New Snap® Beta Lactam Test
New Snap® Beta Lactam Test	Charm® SL Beta Lactam Test New Snap® Beta Lactam Test

[1]These Tests are not specific for Beta lactams. While they are not validated to NCIMS standards for any drugs other than Beta lactams, a non-Beta lactam drug residue can cause a positive test. A negative or not found (NF) test result using one of the Beta lactam specific Tests to follow-up or confirm a positive result with this test kit will require re-testing the sample using the Charm® *B. stearothermophilus* Tablet Disk Assay, Delvotest P 5 Pack or Delvotest P Mini. Any of the listed confirmation test options, other than the four (4) identified in the Tables, are Beta lactam specific Tests.

Table 4: Raw, Commingled Sheep Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® SL Beta Lactam Test	Charm® SL Beta Lactam Test

Table 5: Raw, Commingled Water Buffalo Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® SL Beta Lactam Test	Charm® SL Beta Lactam Test
Delvotest P Mini Not a Beta lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta Lactam Test Delvotest P Mini

[1]These Tests are not specific for Beta lactams. While they are not validated to NCIMS standards for any drugs other than Beta lactams, a non-Beta lactam drug residue can cause a positive test. A negative or not found (NF) test result using one of the Beta lactam specific Tests to follow-up or confirm a positive result with this test kit will require re-testing the sample using the Charm® *B. stearothermophilus* Tablet Disk Assay, Delvotest P 5 Pack or Delvotest P Mini. Any of the listed confirmation test options, other than the four (4) identified in the Tables, are Beta lactam specific Tests.

DHHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-a-85 (Revision #15)

August 29, 2016

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Beta Lactam And Other Test Methods For Use Under Appendix N And Section 6 Of The *Grade "A" Pasteurized Milk Ordinance* (PMO)

This coded memorandum replaces and rescinds the previous revision of this coded memorandum (M-a-85 (Revision #14), issued March 22, 2012). Revision #14 will be identified in the next Index of Memoranda of Interpretation (M-a) as "INACTIVE".

This revision addresses the following changes**:**

- The discontinuance of the Charm Sciences, Inc. Charm® SL6 Beta Lactam Test as Charm Sciences is no longer manufacturing the test kit;
- The discontinuance of the DSM Delvotest SP/Delvotest SP mini as DSM no longer markets this test kit in the United States; and
- The acceptance of the New Snap® Beta Lactam Test for testing raw, commingled goat and camel milk.

The individual Test Tables presented in this revision provide data points that were derived from testing at least thirty (30) samples at each concentration for each drug detected.

The attached information is summarized from the evaluation of data submitted by test sponsors. Information related to the protocol used in this evaluation is available from Dr. Phillip J. Kijak, FDA's Center for Veterinary Medicine (CVM), (240) 402-6689. Additional information regarding the performance of these Tests may be available from the test kit manufacturers.

Label claims for these new approved Tests were evaluated for use on raw, commingled cow, goat, sheep, water buffalo or camel milk samples as indicated in the individual Test Tables. All the information presented in the attached Tables is based on the evaluation of the tests using raw, commingled cow milk. For Tests with a label claim for additional species, the test sponsor provided data to demonstrate that the performance

of the Test is equivalent to the performance for cow milk. The evaluation protocol did not measure the performance of these Tests in the assay of drug residues in other milk matrices, i.e., pasteurized milk or milk taken from individual cows, although claims for such use are made by some of the manufacturers of these Tests.

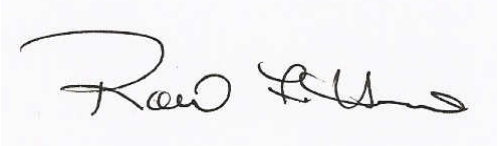
> **NOTE:** FDA recognizes that six (6) Beta lactams are widely used in treating disease in lactating dairy cattle and are the most likely to cause a residue in milk if misused. These are penicillin, ceftiofur, cloxacillin, cephapirin, amoxicillin, and ampicillin. While it is preferred that monitoring for Beta lactams include all of these drugs, at this time, the Agency is recommending that methods be utilized that have been shown to detect at least four (4) of the six (6) Beta lactams identified above.
>
> Testing for drug residue(s) in compliance with the provisions of Sections 6 and 7 of the PMO may be accomplished by the use of any accepted Appendix N Test for raw milk or an accepted Section 6 Test for raw and pasteurized milk.

The NCIMS Executive Board has agreed that future updates to M-a-85 that add, delete or revise these Tests will not require a public comment period or follow the protocol established in the Procedures document for the issuance of M-a's.

Copies of this coded memorandum are enclosed for distribution to Regional Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your region. This memorandum should be widely distributed to representatives of the dairy industry, State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations and other interested parties and also will be available on the FDA Web site at http:// www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@.fda.hhs.gov.

Thomas Graham, PhD, Team Leader
Laboratory Proficiency & Evaluation Team



Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Milk and Milk Products Branch

ATTACHMENT TO M-a-85 (REVISION #15)

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
Beta lactams

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE OR TARGET LEVEL	10 ppb	10 ppb	100 ppb[2]	20 ppb	10 ppb	5 ppb
SCREENING TEST						
BETASTAR® Plus BETA LACTAM TEST	5.5	5.2	80	19.0	8.2	4.7
CHARM® *B. stearothermophilus* TABLET DISK ASSAY [4, 5, 6]	7.5	6.7	ND[3]	11.7	50[7]	3.8
CHARM® II TABLET BETA LACTAM TEST (COMPETITIVE ASSAY) [4]	7.5	5.7	47	4.2	70[7]	3.0
CHARM® II TABLET BETA LACTAM TEST (SEQUENTIAL ASSAY) [6]	8.1	6.6	58	4.1	50[7]	3.4
CHARM® II TABLET BETA LACTAM TEST (QUANTITATIVE ASSAY) [8]	8.1	6.6	58	4.1	8.5	3.4
CHARM® II TEST FOR CLOXACILLIN IN MILK (COMPETITIVE ASSAY) [4, 9]	ND[3]	ND[3]	ND[3]	ND[3]	8.5	ND[3]
CHARM® SL BETA LACTAM TEST [10,11,12]	5.6	8.5	77	13.7	50[7]	3.6
CHARM® 3 SL3 BETA LACTAM TEST	8.4	8.0	79	20.0	8.6	3.8
CHARM® FLUSLBL FLUNIXIN AND BETA LACTAM TEST [13]	5.9	6.8	63	13.4	NA[14]	2.0
DELVOTEST P 5 PACK (READER) [4, 15]	4.6	4.0	ND[3]	8.2	NA[14]	2.1
DELVOTEST P 5 PACK (VISUAL) [4, 5, 16]	4.6	4.0	ND[3]	8.2	NA[14]	2.1
DELVOTEST P MINI[5, 6, 11]	7.7	5.1	NA[14]	7.0	30[7]	3.1
NEW SNAP® BETA LACTAM TEST KIT [17, 18, 19]	7.3	5.8	12	11.7	50[7]	3.0

Continued on next page

FOOTNOTES:

1. Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each Test in the following Tables and should be considered when selecting drug residue monitoring tests. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory. The data is based on detection in raw, commingled cow milk for the test kits listed.
2. The ceftiofur tolerance is based on measuring the sum of ceftiofur and desfuroylceftiofur related metabolites in milk as desfuroylceftiofur. The screening test detection concentrations for ceftiofur were evaluated using milk containing ceftiofur and desfuroylceftiofur related metabolites from treated animals. Due to the approval of “Spectramast”, an intramammary ceftiofur product, the target level of 50 ppb as parent ceftiofur is no longer used.
3. ND indicates “Not Detected” at or below tolerance.
4. This Test is acceptable for use to detect Beta lactam residues when used with pasteurized cow whole and skim milk.
5. Refer to M-I-01-4, Issued July 2, 2001, for certification requirements to use this visual test.
6. This Test is acceptable for testing raw, commingled goat milk.
7. 90/95% concentrations were not determined for sensitivities significantly above the tolerance/target level.
8. Test sensitivity when presumptive positive milk samples are verified in accordance with label directions using the Charm® II Tablet Beta Lactam Test (Sequential Assay) and the Charm® II Test for Cloxacillin in Milk (Competitive Assay).
9. For Appendix N bulk milk tanker screening, this Test must be used in combination with other approved screening methods in order to detect at least four (4) of the six (6) targeted Beta lactam drugs.
10. The Charm® SL Beta Lactam Test is acceptable for testing raw, commingled goat milk (M-I-03-3, issued 2/25/2003).
11. The Charm® SL Beta Lactam Test, Delvotest P/Delvotest P Mini and are acceptable for testing raw, commingled water buffalo milk (M-I-09-6, issued October 16, 2009).
12. The Charm® SL Beta Lactam Test is acceptable for testing raw, commingled sheep milk (M-I-09-7, issued 11/3/2009).
13. The Charm® FLUSLBL Flunixin and Beta Lactam Test is a multi-class test. The information listed here is only for the performance of the test kit in detecting Beta lactam drug residues. For information on flunixin, refer to MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS NSAIDs on page 15.
14. NA indicates “Data Not Available”.
15. The DelvoScan Reader option for the Delvotest 5 P Pack has not been validated in fat-free chocolate, whole chocolate, half & half, and heavy cream and pasteurized goat milk.
16. The Delvotest 5 P Pack (VISUAL) is acceptable to detect ampicillin, amoxicillin, cephapirin and penicillin residues in cow fat-free chocolate, whole chocolate, half & half, and heavy cream and pasteurized goat milk.
17. The visual reading option is not available with the New Snap® Beta Lactam Test.

FOOTNOTES:

18. The New Snap® Beta Lactam Test is acceptable for testing raw, commingled camel milk (M-I-12-13, issued 10/9/2012).
19. The New Snap® Beta Lactam Test is acceptable for testing raw, commingled goat milk (M-I-13-7, issued 10/31/2013).

BETASTAR® PLUS BETA LACTAM TEST
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**10**	**5**
DRUG CONCENTRATION (ppb)						
1						0
2	0	0			0	0
3						0
4	0	0		0	0	0
5	27	10				100
6	100	100			0	
8	100	100		0	83	
10	100	100			100	
12				0		
15				63		
20			0	100		
40			0			
60			20			
80			90			
100			100			

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

CHARM® *B. stearothermophilus* TABLET DISK ASSAY
DRUG CONCENTRATION RESPONSE [1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**20**	**5**
DRUG CONCENTRATION (ppb)				
1				0
2	0	0	0	0
3				0
4	10	3	0	55
5				100
6	30	67		
8	90	100	0	
10	100	100		
14			100	
20			100	

[1]Percent positive
[2]Based on 30 samples at each concentration

CHARM® II TABLET BETA LACTAM TEST (COMPETITIVE ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**5**
DRUG CONCENTRATION (ppb)					
1					10
2	3	3		30	67
3					97
4	10	43		100	100
5			0		100
6	83	97			
8	100	100		100	
10	100	100	20		
14				100	
20			43	100	
40			100		
60			97		
80			100		
100			100		

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

CHARM® II TABLET BETA LACTAM TEST (SEQUENTIAL ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**5**
DRUG CONCENTRATION (ppb)					
1					0
2	0	0		3	10
3					80
4	20	10		100	100
5			0		100
6	23	83			
8	93	97		100	
10	100	100	0		
14				100	
20			3	100	
40			67		
60			97		
80			100		
100			100		

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

CHARM® II TABLET BETA LACTAM TEST (QUANTITATIVE ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**10**	**5**
DRUG CONCENTRATION (ppb)						
1						0
2	0	0		3	0	10
3						80
4	20	10		100	3	100
5			0			100
6	23	83			17	
8	93	97		100	87	
10	100	100	0		100	
14				100		
20			3	100		
40			67			
60			97			
80			100			
100			100			

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

CHARM® II TEST FOR CLOXACILLIN IN MILK (COMPETITIVE ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	CLOXACILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**
DRUG CONCENTRATION (ppb)	
2	0
4	3
6	17
8	87
10	100

[1]Percent positive
[2]Based on 30 samples at each concentration

CHARM® SL BETA LACTAM TEST
DRUG CONCENTRATION RESPONSE [1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**5**
DRUG CONCENTRATION (ppb)					
1					0
2	3	3			13
3					73
4	70	13		0	100
5			0		100
6	100	83			
8	100	100		50	
10	100	97[4]	0		
12				97	
16				100	
20			0	100	
40			0		
60			23		
80			100		
100			100		

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites
[4]All statistical models used to calculate 90/95 allow for a single negative result at tolerance

CHARM® 3 SL3 BETA LACTAM TEST
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**10**	**5**
DRUG CONCENTRATION (ppb)						
1						0
2	0	0			0	0
3						13
4	0	0		0	0	97
5						100
6	3	23			13	
8	83	97		0	93	
10	100	100			100	
12				3		
16				83		
20			0	100		
40			0			
60			50			
80			100			
100			100			

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

CHARM® FLUSLBL FLUNIXIN AND BETA LACTAM TEST[1]
DRUG CONCENTRATION RESPONSE[2,3]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[4]**	**20**	**5**
DRUG CONCENTRATION (ppb)					
1					0
2	0	0			20
3					97
4	13	10		0	100
5					100
6	90	43			
8	97	97		3	
10	100	100			
12				67	
16				97	
20			0	100	
40			37		
60			97		
80			100		
100			100		

[1]Beta lactam data only. See separate listing under NSAIDs for flunixin drug concentration response on page 15.
[2]Percent positive
[3]Based on 30 samples at each concentration
[4]Total parent and desfuroylceftiofur related metabolites

DELVOTEST P 5 PACK (VISUAL AND READER)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**20**	**5**
DRUG CONCENTRATION (ppb)				
1				3
2	10	7	3	60
3				100
4	100	97	100	100
5				100
6	100	100		
8	100	100	100	
10	100	100		
14			100	
20			100	

[1]Percent positive
[2]Based on 30 samples at each concentration

DELVOTEST P MINI
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**20**	**5**
DRUG CONCENTRATION (ppb)				
1				0
2	33	3	0	0
3				100
4	47	70	7	100
5				100
6	93	100		
8	97	100	100	
10	100	97[3]		
14			100	
20			100	

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]All statistical models used to calculate 90/95 allow for a single negative result at tolerance

NEW SNAP® BETA LACTAM TEST KIT
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	PENICILLIN
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**100[3]**	**20**	**5**
DRUG CONCENTRATION (ppb)					
1					7
2	0	0		0	37
3					93
4	20	37		0	100
5			7		100
6	70	100			
8	100	100		0	
10	100	100	90		
12				100	
20			100	100	
40			100		
60			100		
80			100		
100			100		

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]Total parent and desfuroylceftiofur related metabolites

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

DRUG	FLUNIXIN[2]
TOLERANCE/TARGET LEVEL (ppb)	2 ppb
SCREENING TEST	
CHARM® FLUSLBL FLUNIXIN AND BETA LACTAM TEST	1.9

[1]Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each Test in the following Table. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.
[2]As 5-hydroxyflunixin, the major metabolic form of flunixin and the chemical marker of flunixin in milk.

CHARM® FLUSLBL FLUNIXIN AND BETA LACTAM TEST[1]
DRUG CONCENTRATION RESPONSE[2,3]

DRUG	FLUNIXIN[4]
TOLERANCE/TARGET LEVEL (ppb)	**2**
DRUG CONCENTRATION (ppb)	
0.4	30
0.8	70
1.0	
1.2	97
1.6	97
2.0	100

[1]Flunixin data only. See separate listing under Beta lactams for Beta lactam drug concentration response on page 12.
[2]Percent positive
[3]Based on 30 samples at each concentration
[4]As 5-hydroxyflunixin, the major metabolic form of flunixin and the chemical marker of flunixin in milk.

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
SULFONAMIDES

DRUG	SULFADIMETHOXINE	SULFAMETHAZINE	SULFATHIAZOLE	SULFADIAZINE
TOLERANCE/TARGET LEVEL (ppb)	10 ppb	10 ppb	10 ppb	10 ppb
SCREENING TEST				
CHARM® II SULFA DRUG TEST (COMPETITIVE ASSAY)	4.0	9.4	7.3	4.9

[1]Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following Table. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.

CHARM® II SULFA DRUG TEST (COMPETITIVE ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	SULFADIMETHOXINE	SULFAMETHAZINE	SULFATHIAZOLE	SULFADIAZINE
TOLERANCE/TARGET LEVEL (ppb)	**10**	**10**	**10**	**10**
DRUG CONCENTRATION (ppb)				
2	97	7	0	40
4	100	80	57	100
6	100	97	100	100
8	100	100	100	100
10	100	100	100	97[3]

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]All statistical models used to calculate 90/95 allow for a single negative result at tolerance

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
TETRACYCLINES

DRUG	CHLORTETRACYCLINE	OXYTETRACYCLINE	TETRACYCLINE
TOLERANCE/TARGET LEVEL (ppb)	**300 ppb (Chlortetracycline + Tetracycline + Oxytetracycline)**		
DRUG CONCENTRATION (ppb)			
CHARM® II TETRACYCLINE DRUG TEST (COMPETITIVE ASSAY)	257	119	67

[1]Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following Table. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.

CHARM® II TETRACYCLINE DRUG TEST (COMPETITIVE ASSAY)
DRUG CONCENTRATION RESPONSE[1,2]

DRUG	Chlortetracycline	Oxytetracycline	Tetracycline
TOLERANCE/TARGET LEVEL	**300 ppb (Chlortetracycline + Tetracycline + Oxytetracycline)**		
DRUG CONCENTRATION (ppb)			
20			0
30			7
40			37
60		13	93
70		37	
90	17		
100		87	
120	20		
150		100	
160	77		
230	93		
300	97[3]	100	100

[1]Percent positive
[2]Based on 30 samples at each concentration
[3]All standard statistical models used to calculate 90/95 allow for a single negative result at tolerance

Pennsylvania Department of
AGRICULTURE
Bureau of Food Safety and Laboratory Services

Date: January 20, 2006

Subject: Reporting procedures for **Presumptive Test Results, Screen Test Positive Loads** and **Producer Trace Back** (M-a-86 Rev 3, Issued July 23, 2001)

To: All Pennsylvania Approved Appendix N Screening and/or Confirmatory Laboratories /Facilities.

From: Michael F. Hydock
Chief, Laboratory Division

To achieve uniformity the procedure for reporting **Presumptive Test Results**, **Screen Test Positive (load confirmation)** and **Producer Trace Back tests** for drug residues are as follows:

1. All presumptive test results (positive or negative) must be reported to the State Regulatory Agency **prior to** further testing or movement of the bulk milk tanker to a confirmatory test location.

2. **Methods of Reporting:**

   A. During the hours of 8:00 am to 4:00 pm, report presumptive test results (positive or negative) to the Pennsylvania Department of Agriculture, Division of Milk Sanitation, Harrisburg using this phone number **(717) 787-4315 or FAX, as previously instructed**. After notification, use the Appendix N testing procedure protocol that the testing location is accredited for in accordance with the current M-a-86. **Fax or mail completed report forms to the Division of Milk Sanitation within 72 hours of INITIAL TESTING. Fax number, 717-787-1873.**

   B. Over weekends or non-office hours, report presumptive test results (positive or negative) loads using this phone number **(717) 787-4315 (Please leave message with the automated attendant).** After notification, use the Appendix N testing procedure protocol that the testing location is accredited for in accordance with the current M-a-86. **Fax or mail completed form reports to the Division of Milk Sanitation within 72 hours of INITIAL TESTING. Fax number, 717-787-1873.**

Screening Only Locations:
For Presumptive Tested Loads send the current form, BFSLS-477 (Rev 01/06) a copy of the Bill of Lading, and a photocopy of the corresponding printout, if possible.

Confirmatory Locations:
For Screen Test Positive Loads and Producer Trace Back tests send the current form, BFSLS–477 (Rev 01/06), BFSLS-502 (Rev 01/06), AFC-476 (Rev. 08/01), copy of the Bill of Lading, and a photocopy of the printout, if possible.

Note: **Presumptive positive tanker samples must accompany all other producer samples, with the corresponding paperwork to the confirmatory testing location.**

cc . J. Dell

2301 North Cameron Street, Harrisburg, PA 17110-9408
717-787-4315 FAX: 717-787-1873 www. agriculture.state.pa.us

Pennsylvania Department of
AGRICULTURE
Bureau of Food Safety and Laboratory Services
Laboratory Division

Date: September 19, 2005

Subject: Change in Address/Location and Personnel.

To: All Pennsylvania Approved Laboratories and Appendix N Testing Facilities.

From: Michael F. Hydock, Chief
Laboratory Division

EFFECTIVE OCTOBER 1, 2005

To Maintain certification, all Pennsylvania Approved Laboratories and Appendix N Testing Facilities **must notify the Laboratory Division in writing with in 5 days**, of **any changes** made in the **address/location and/or personnel.**

Policy Purpose:

- To maintain the correct information for on-site survey certification and Laboratory/Facility status changes for each Pennsylvania Approved Dairy Laboratory/Facility.
- To maintain a current list of certified laboratory analysts based on periodic review of the laboratory/facility personnel's status.
- To determine if a **major change in personnel** will likely affect the facility's Quality Assurance Program. If a major change in quality assurance records/training does occur, an INTERIM on-site evaluation by a certified Laboratory Evaluation Officer, may be justified to determine compliance.

Failure to comply with this policy will result in **decertification of the laboratory/facility and/or analysts** conducting testing of dairy products for regulatory compliance.

Responses should be mailed to the following address:

Commonwealth of Pennsylvania
Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, Pa.17110-9408
Attention: Michael F. Hydock, Chief, Laboratory Division

If you have any questions call me at (717) 787-4315 Ext. 207

Cc: B. McLean
J. Dell

APPENDIX N REPORTING FORMS

BFSLS#	NAME OF RECORD SHEET	REVISION DATE
431	Notice of Milk Action Report	2/00
472	Emergency Laboratory Report - Drug Residue/Phosphatase	5/09
476	Bulk Milk Pick-Up Tanker Information	8/01
477	Appendix N Bulk Milk Tanker Positive Drug Residue Test Report	1/14
502	Producer Trace-Back for Positive Confirmed Loads Test Report	1/14

BFSLS-431 (Rev. 2/00)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
DIVISION OF MILK SANITAITON

NOTICE OF MILK PRODUCER ACTION REPORT

Pennsylvania Department of Agriculture, Region _____
Milk Sanitarian: _____
Region Address: _____
_____
_____

In accordance with Chapter 59.31. Milk Sanitation and Standards, you are hereby advised of the following producer action:

Producer No. _____
Herd No. _____
Producer Name _____
Address: _____
_____

Action Taken:

Initial Instatement* Date ____/____/____
Previous Handler _____

Suspension* Date ____/____/____
Reason _____
Reinstatement Date ____/____/____

Handler Initiated Termination** Date ____/____/____

Producer Initiated Termination** Date ____/____/____

Reason _____

***Attach a copy of the Dairy Farm Sanitation Report.**
****Attach a copy of the Dairy Farm Sanitation Report and include a copy of the producer record. Mail or deliver to the appropriate Region Office within twenty-four (24) hours of this action.**

Permit Holder _____ FIPS# 42 - _____
_____
_____

Signature _____ Date ____/____/____
Approved Inspector or Authorized Agent

BFSLS-431 (Rev. 2/00)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
DIVISION OF MILK SANITAITON

NOTICE OF MILK PRODUCER ACTION REPORT

Pennsylvania Department of Agriculture, Region _6____
Milk Sanitarian: __D. State_____
Region Address: __PO Box 5184_____
__Harrisburg, PA 17110_____
_____

In accordance with Chapter 59.31. Milk Sanitation and Standards, you are hereby advised of the following producer action:

Producer No. ___19832_____
Herd No. __10-26-H54_____
Producer Name __Joe Somebody_____
Address: __RD 1 Box 94_____
__Spring Creek, PA 19823_____

Action Taken:

Initial Instatement* Date ____/____/____
Previous Handler _____

Suspension* Date _10_/_30_/_07
Reason ___Antibiotics_____
Reinstatement Date _11_/_02_/_07_

Handler Initiated Termination** Date ____/____/____

Producer Initiated Termination** Date ____/____/____

Reason _Milked treated cow_____

EXAMPLE

***Attach a copy of the Dairy Farm Sanitation Report.**
****Attach a copy of the Dairy Farm Sanitation Report and include a copy of the producer record. Mail or deliver to the appropriate Region Office within twenty-four (24) hours of this action.**

Permit Holder ____Utters Dairy_____ FIPS# 42 - 995____
____RD 3 Box 147_____
____Rockville, PA 19745_____

Signature ____A. DeMann_____ Date _11_/_03_/_07_
Approved Inspector or Authorized Agent

BFSLS 472 (8/09)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
DIVISION OF MILK SANITATION
2301 NORTH CAMERON STREET, PA 17110-9408
FAX 717-787-1873

EMERGENCY LABORATORY REPORT

(Drug Residue / Phosphatase)

Please use this form to report ***all positive official monthly test results***, which require an immediate report to the Department of Agriculture, and then send this report to the address shown above. Phone notification of positive drug residues during off hours, holidays, and weekends may be made to **717-787-4315** (via voicemail system). If this positive test result involves a producer who also is a raw or pasteurized jugger, please include this information with your phone call report.

Positive phosphatase results or drug residue results in finished products will now require phone call notification to the Harrisburg office at 717-787-4315.

In accordance the *Section 59.309*, Milk Sanitation Standards, you are hereby advised of the following positive result:

Drug Residue ☐ Test Kit Used _____ Lot # _____

Phosphatase ☐ Fluorophos _____ Charm_____

Pathogens ☐ Confirmed Type_____

REPORTING INFORMATION

Producer Name / Address _____
or _____
Finished Product ID Code _____

Producer No. & Herd No. / Sell By Code_____
Date Sampled _____ Temperature Control _____
Date and Time of Analysis _____ Temperature Control _____

RESULTS FOUND

Initial Result (Values / Interpretation) _____

Confirmatory Test(s) Used_____

Confirmation Results (Values / Interpretation) _____

RECORD KEEPING INFORMATION

Date/Time PDA was notified by phone _____ Date Report was mailed _____

Approved Inspector _____

Permit Holder _____ BTU No. _____

LABORATORY _____

SIGNATURE _____
Laboratory Director

This report must be mailed (Received in Harrisburg) within 48 hours from initial notification

BFSLS 472 (8/09)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
DIVISION OF MILK SANITATION
2301 NORTH CAMERON STREET, PA 17110-9408
FAX 717-787-1873

EMERGENCY LABORATORY REPORT

(Drug Residue / Phosphatase)

Please use this form to report ***all positive official monthly test results***, which require an immediate report to the Department of Agriculture, and then send this report to the address shown above. Phone notification of positive drug residues during off hours, holidays, and weekends may be made to **717-787-4315** (via voicemail system). If this positive test result involves a producer who also is a raw or pasteurized jugger, please include this information with your phone call report.

Positive phosphatase results or drug residue results in finished products will now require phone call notification to the Harrisburg office at 717-787-4315.

In accordance the *Section 59.309*, Milk Sanitation Standards, you are hereby advised of the following positive result:

Drug Residue [x] Test Kit Used **_Delvo 5-pak_____** Lot # **_07I23/I__**

Phosphatase [ ] Fluorophos _____ Charm_____

Pathogens [ ] Confirmed Type_____

REPORTING INFORMATION

Producer Name / Address **__Bob Nokandu_____**
or **__RR 1 Box 168_____**
Finished Product ID Code **__Ronks, PA_____**

Producer No. & Herd No. / Sell By Code**___47-10002693_____**
Date Sampled **__11/8/13_____** Temperature Control **__2.9C_____**
Date and Time of Analysis **__11/8/13__12:30PM_____** Temperature Control **__3.1C_____**

RESULTS FOUND

Initial Result (Values / Interpretation) **___Purple - Pos_____**

Confirmatory Test(s) Used**_____Delvo 5-pak_____**

Confirmation Results (Values / Interpretation) **_____Purple-Pos_____**

RECORD KEEPING INFORMATION

Date/Time PDA was notified by phone **__11/8/13__2:00PM_____** Date Report was mailed **__11/8/13__**

Approved Inspector **___Z. Kennedy_____**

Permit Holder **____Utter's Dairy_____** BTU No. **_____42-995_____**

LABORATORY **___Quality Laboratory_____**

SIGNATURE **___Michael Peters _____**
Laboratory Director

This report must be mailed (Received in Harrisburg) within 48 hours from initial notification

AFC-476 (Rev.08/01)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
DIVISION OF MILK SANITATION
2301 N. CAMERON STREET
HARRISBURG, PA 17110-9408

In accordance with the provisions of The Pennsylvania Drug Residue Testing Program, I am submitting the following information regarding positive drug residue tests involving a producer under my supervision.

Bulk Milk Pick-up Tanker Information

Tanker License Plate Number: _____ Date Report Mailed: _____

_____/_____	_____/_____	_____/_____
Presumptive Test Used /Date	Screen Test Used /Date	Producer Trace Back Test /Date
_____	_____	_____
Presumptive Test Location	Screen Test Location	Producer Trace Back Location
_____	_____	_____
Presumptive Test Result (Duplicate)	Screen Test Result (Duplicate)	Producer Trace Back Result (Triplicate)

Disposition of _____

Adulterated Tanker: _____

Date and Location: _____

-*-*-*

AFC-476 (Rev.08/01)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
DIVISION OF MILK SANITATION
2301 N. CAMERON STREET
HARRISBURG, PA 17110-9408

In accordance with the provisions of The Pennsylvania Drug Residue Testing Program, I am submitting the following information regarding positive drug residue tests involving a producer under my supervision.

Bulk Milk Pick-up Tanker Information

Tanker License Plate Number: _YR-0935_____ Date Report Mailed: _1-7-08_____

IDEXX SNAP____/1-5-08	__Charm SL_____/1-5-08_	_Charm SL_____/1-5-08_____
Presumptive Test Used /Date	Screen Test Used /Date	Producer Trace Back Test /Date
Mountainside Dairy_____	__Utters Dairy_____	_____Utters Dairy_____
Presumptive Test Location	Screen Test Location	Producer Trace Back Location
2.31, 2.43_____	_+2351. +2153_____	__+2147, +2044, +2189_____
Presumptive Test Result (Duplicate)	Screen Test Result (Duplicate)	Producer Trace Back Result (Triplicate)

Disposition of Adulterated Tanker: __Dumped at Lee Oswald Manure pit_____

Date and Location: __1-6-08 Rockville PA_____

_*_*_*

BFSLS-477 (REV. 01-14)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
LABORATORY DIVISION
2301 N. CAMERON STREET
HARRISBURG, PA 17110-9408
Office (717) 787-4315 Fax (717) 787-1873

APPENDIX N BULK MILK TANKER *POSITIVE* DRUG RESIDUE TEST REPORT

Receiving Location	Collection of Sample	Owner of Milk	Route #
_____	Date ____/____/_____	_____	Load # _____
_____	Time ____:____am/pm		
	Temp. ._____°F	FIPS # _____	

Milk Hauler	Rejection Information	Weight of Load	Tanker License Plate # / State
_____	Positive compartment:	_____	_____
	Single _____ Front_____ Rear_____		

INITIAL TEST RESULT

Date /Time	Test Method Used	Test Kit Lot #	Initial Result (number / interpretation)	Analyst I.D./ Initials
__/___/___	_____	_____	FRONT _____ / _____	_____
__:___am/pm		Expiration Date _____	REAR _____ / _____	

PRESUMPTIVE TEST RESULT**

Temperature	Test Method Used	Test Kit Lot #	Presumptive Result DUPLICATE (number / interpretation)	Analyst I.D./ Initials
_____°C	_____	_____	_____ / _____	_____
		Expiration Date _____	_____ / _____	

Printout: (enclosed)	Control Results	Charm II Control Point Results	Department Notification:
Yes ☐	Positive _____	Control Point _____	Phone __ Fax ___ Email ___
No ☐	Negative _____	Date Established_____	Date ___/___/___
		Positive _____ Negative _____	Time ___:___am/pm
		(Average) + _____ -- _____	Reported By: _____
			Who contacted_____

Disposition of Load (secure initial test sample, secure tanker, attach weight slip)

Seal numbers: _____ Sent to: _____

Dumped / Diverted Where? _____

Analyst _____ Supervisor _____ Date _____

Received ☐
Condemned ☐
Rejected ☐

Comments:
_____
_____

SCREENING TEST (CONFIRMATION) RESULTS

Date / Time Tested	Test Method Used	Test Kit Lot #	Confirmation Results DUPLICATE (number / interpretation)	Analyst I.D./Initials
___/___/___	_____	_____	_____/_____	_____
___:___am/pm		Expiration Date _____	_____/_____	
Temp. Control _____°C				

Confirmatory Location	Control Results	Charm II Control Point Results	Department Notification:
_____	Positive _____	Control Point _____	Phone __ Fax ___ Email ___
_____	Negative _____	Date Established_____	Date ___/___/___
		Positive ____ Negative _____	Time ___:___am/pm
		(Average) + _____ -- _____	Reported By: _____
			Who contacted_____

Disposition of Load (secure initial test sample, secure tanker, attach weight slip)

Seal numbers: _____ Sent to: _____

Dumped / Diverted Where? _____

Received ☐
Condemned ☐

CERTIFIED ANALYST/SUPERVISOR _____ DATE _____

**SCREENING FACILITIES - A COPY OF THIS REPORT MUST ACCOMPANY THE TRUCK AND PRODUCER SAMPLES TO THE CONFIRMATION LOCATION, BE KEPT ON FILE AT THE SCREENING LOCATION, AND ALSO BE SENT TO THE PENNSYLVANIA DEPARTMENT OF AGRICULTURE WITHIN 72 HOURS OF INITIAL TESTING.

BFSLS-477 (REV. 01-14)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
LABORATORY DIVISION
2301 N. CAMERON STREET
HARRISBURG, PA 17110-9408
Office (717) 787-4315 Fax (717) 787-1873

APPENDIX N BULK MILK TANKER *POSITIVE* DRUG RESIDUE TEST REPORT

Receiving Location	Collection of Sample	Owner of Milk	Route #
Brown Cow Dairy	Date 2/4/14 Time 9:45 am/pm Temp. 38 °F	Utter's Dairy FIPS # 42-995	18 Load # 168123

Milk Hauler	Rejection Information	Weight of Load	Tanker License Plate # / State
My-T-Trucks	Positive compartment: Single _____ Front X Rear _____	52,269	PT-3698F

INITIAL TEST RESULT

Date /Time	Test Method Used	Test Kit Lot #	Initial Result (number / interpretation)	Analyst I.D./ Initials
2/4/14 9:55 am/pm	IDEXX Snap	KD159 Expiration Date 4/2/14	FRONT 6.58 / POS REAR 0.75 / NF	JT

PRESUMPTIVE TEST RESULT**

Temperature	Test Method Used	Test Kit Lot #	Presumptive Result DUPLICATE (number / interpretation)	Analyst I.D./ Initials
3.2 °C	IDEXX Snap	KD159 Expiration Date 4/2/14	5.95 / POS 6.12 / POS	JT

Printout: (enclosed)	Control Results	Charm II Control Point Results	Department Notification:
Yes [X] No [ ]	Positive 3.59 Negative 0.72	Control Point _____ Date Established _____ Positive _____ Negative _____ (Average) + _____ -- _____	Phone __ Fax ___ Email X Date 2/4/14 Time 10:30 am/pm Reported By: JT Who contacted M. Hydock

Disposition of Load (secure initial test sample, secure tanker, attach weight slip)
Seal numbers: 0134, 1121,1139 Sent to: Utter's Dairy for confirmation
Dumped / Diverted Where? _____
Analyst J. Thompson Supervisor F. James Date 2/4/14

Received [ ]
Condemned [ ]
Rejected [X]

Comments:

SCREENING TEST (CONFIRMATION) RESULTS

Date / Time Tested	Test Method Used	Test Kit Lot #	Confirmation Results DUPLICATE (number / interpretation)	Analyst I.D./Initials
2/4/1
1:45 am/pm Temp. Control _____ °C	Charm SL	109 Expiration Date 5/2014	+2689 / POS +2548 / POS	S. M

Confirmatory Location	Control Results	Charm II Control Point Results	Department Notification:
Utter's Dairy	Positive +1659 Negative -1452	Control Point _____ Date Established _____ Positive ____ Negative _____ (Average) + _____ -- _____	Phone __ Fax X Email ___ Date 2/4/14 Time 3:00 am/pm Reported By: J. W Who contacted M. Hydock

Disposition of Load (secure initial test sample, secure tanker, attach weight slip)
Seal numbers: 899,1574 Sent to: A. Stoltzfus manure pit
Dumped / Diverted Where? Ronks, PA

Received [ ]
Condemned [X]

CERTIFIED ANALYST/SUPERVISOR Sam Marshal / James Williams DATE 2/4/14

**SCREENING FACILITIES - A COPY OF THIS REPORT MUST ACCOMPANY THE TRUCK AND PRODUCER SAMPLES TO THE CONFIRMATION LOCATION, BE KEPT ON FILE AT THE SCREENING LOCATION, AND ALSO BE SENT TO THE PENNSYLVANIA DEPARTMENT OF AGRICULTURE WITHIN 72 HOURS OF INITIAL TESTING.

BFSLS-502 (REV. 01/14)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
LABORATORY DIVISION
2301 N. CAMERON STREET
HARRRISBURG, PA 17110-9408
Office (717) 787-4315 Fax (717) 787-1873

PRODUCER TRACE-BACK FOR POSITIVE CONFIRMED LOADS (DRUG RESIDUE) TEST REPORT

Confirmatory Location _____	Collection of Sample Date ____/____/_____ Time ___:____am/pm Temp._____°F	Owner of Milk _____ FIPS # _____	Route # _____ Load # _____
Laboratory ID # _____ Printout (enclosed): Yes ☐ No ☐	Test Method(s) Used _____ _____	Test Kit Lot # _____ Expiration Date _____	Department Notification: Phone __ Fax ___ Email ___ Date ___/___/___ Time ___:___am/pm Reported By: _____ Who contacted_____

Comments:

Samples Received: Date: ___/___/___ Time: ___:___am/pm Temp. : _____°C. Analyst Initials _____

Samples Tested: Date: ___/___/___ Time: ___:___am/pm Temp. : _____°C. Analyst Initials _____

PRODUCER TRACE-BACK INFORMATION TEST RESULTS

Sample #	FIPS #	Producer #	Result (#)	Interpretation (POS or NF)	Control Results
					Positive Control _____
					Negative Control _____
					Charm II Control Point Results Control Point _____ Date Established_____ Positive _____ Negative _____ (Average) + _____ -- _____
					Producer Confirmation
					Positive Producer(s)
					DUPLICATE RESULTS (number / interpretation) _____/_____ _____/_____ Positive Control _____ Negative Control _____

CERTIFIED ANALYST / SUPERVISOR _____ DATE _____

**A COPY OF BFSLS-477 MUST ACCOMPANY THIS REPORT AND BE SENT WITHIN 48 HOURS OF TRACE-BACK RESULTS. A COPY MUST BE KEPT ON FILE AT THE CONFIRMATORY LOCATION.

BFSLS-502 (REV. 01/14)

PENNSYLVANIA DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES
LABORATORY DIVISION
2301 N. CAMERON STREET
HARRRISBURG, PA 17110-9408
Office (717) 787-4315 Fax (717) 787-1873

PRODUCER TRACE-BACK FOR POSITIVE CONFIRMED LOADS (DRUG RESIDUE) TEST REPORT

Confirmatory Location	Collection of Sample	Owner of Milk	
__Utter's Dairy_____	Date _2__/_4___/__14__ Time _9__:_45_am/pm Temp.___2.6____°C	___Utter's Dairy____ FIPS # ___42-995_____	Route # __18_____ Load # ____168123___

Laboratory ID #	Test Method(s) Used	Test Kit Lot #	Department Notification:
__42-399_____ Printout (enclosed): Yes ☒ No ☐	__Charm SL_____ _____	___109_____ Expiration Date _____5/2014____	Phone __ Fax X___ Email ___ Date _2__/_4__/_14__ Time _3__:_00__am/pm Reported By: _J. W_____ Who contacted_M. Hydock__

Comments:

Samples Received: Date: _2_/_4_/_14_ Time: _1__:_30__am/pm Temp. : _2.5___°C. Analyst Initials _SM__

Samples Tested: Date: _2_/_4_/_14_ Time: _2__:_00__am/pm Temp. : _2.3___°C. Analyst Initials _SM__

PRODUCER TRACE-BACK INFORMATION TEST RESULTS

Sample #	FIPS #	Producer #	Result (#)	Interpretation (POS or NF)	Control Results
1	42-995	26995	-1459	NF	Positive Control _+1699_____
2	42-995	26845	-1589	NF	Negative Control __-1544_____
3	42-995	26541	+4239	POS	
4	42-995	26854	-1259	NF	
5	42-995	56771	-2095	NF	Charm II Control Point Results Control Point _____ Date Established_____ Positive _____ Negative _____ (Average) + _____ -- _____
					Producer Confirmation
					Positive Producer(s)
					DUPLICATE RESULTS (number / interpretation) __+4369___/___POS_____ __+4254__/__POS_____ Positive Control __+1854_____ Negative Control __-1584_____

CERTIFIED ANALYST / SUPERVISOR Sam Marshal / James Williams_____ DATE _____2/4/14_____

**A COPY OF BFSLS-477 MUST ACCOMPANY THIS REPORT AND BE SENT WITHIN 48 HOURS OF TRACE-BACK RESULTS. A COPY MUST BE KEPT ON FILE AT THE CONFIRMATORY LOCATION.

GRADE "A" PASTEURIZED MILK ORDINANCE (PMO)

– APPENDIX N

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6 of this *Ordinance*. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (Refer to Section 6 of this *Ordinance*.)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Bulk milk pickup tanker samples confirmed positive for drug residues shall be retained as determined necessary by the Regulatory Agency.

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

NOTE: On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted by the Regulatory Agency where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency in which the dairy farm is located as specified in Appendix B and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.

All presumptive positive test results for drug residues from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been

transported in bulk milk pickup tankers, farm raw milk tanks/silos (only milk offered for sale) or finished milk or milk product samples shall be reported to the Regulatory Agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues shall be retained or disposed of as determined by the Regulatory Agency.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. THE EXAMINATION OF MILK AND MILK PRODUCTS and at the frequency addressed in Section 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS of this *Ordinance*.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues, the Regulatory Agency in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.

When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Further pickups or use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if the initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

Records of all sample results shall be maintained for a minimum of six (6) months by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers, which contains milk from another Regulatory Agency's jurisdiction, is found to be presumptive positive for drug residues it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from which the milk originated.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving Industry Analysts and Industry Supervisors successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I. INDUSTRY RESPONSIBILITIES of this Appendix for drug residues?
4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers and of the trace back to the farm of origin?
5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

a. There should be an agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be "timely" for example by telephone or fax, and supported in writing.

b. The ultimate disposition should either be prearranged in an agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted Beta lactam milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

d. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be positive (confirmed) for drug residues, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

e. The suspension and discontinuance of farm bulk milk tank pick up and/or the use of raw milk supplies that have not been transported in bulk milk pickup tankers is the responsibility of the industry; under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records should be maintained by industry and/or the Regulatory Agency that:

1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and

2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. ENFORCEMENT of this Appendix and has cleared the milk for pick up and/or use.

Sufficient records should be reviewed to assure that all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 of this *Ordinance.*

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under

FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Suspension: Any time milk is found to test as a confirmed positive for a drug residue, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties: Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement: The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up: Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.*

Permit Revocation: After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. Permits of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a positive tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records shall indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?
4. What screening and/or confirmatory test(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?
6. Which producer(s) was responsible?
7. Record of negative test results prior to subsequent milk pickup from the violative producer(s).

III. TESTING PROGRAM FOR DRUG RESIDUES ESTABLISHED DEFINITIONS:

For purposes of this Appendix the following definitions are to be used:

1. **Presumptive Positive:** A presumptive positive test is a positive result from an initial testing of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers using an M-a-85 (latest revision) approved test, which has been promptly repeated in duplicate with positive and negative controls that give the proper results using the same test, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

2. **Screening Test Positive (Load or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation):** A screening test positive result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test as that used for the presumptive positive, with a positive and negative control that give the proper results, and either or both of the duplicates are positive. A screening test positive (load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers confirmation) is to be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Action:** A producer trace back/permit action test is performed after a screening test positive load is identified by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor using the same or an equivalent (M-I-96-10, latest revision) test as was used to obtain the screening test positive (load confirmation). A confirmed producer test positive result is obtained in the same manner as a confirmation (screening test positive) for a load. After an initial positive result (producer presumptive positive) is obtained on a producer sample, that sample is then tested in duplicate using the same test as was used to obtain the producer presumptive positive result. This testing is performed with a positive and negative control and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is confirmed as positive.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

4. **Individual Producer Load:** An individual producer bulk milk pickup tanker is a bulk milk pickup tanker, or a compartment(s) of a bulk milk pickup tanker, that contains milk from only one (1) dairy farm.

5. **Individual On-Farm Producer/Processor's Raw Milk Supply:** An individual on-farm producer/processor's raw milk supply may be transported in bulk milk pickup tankers; and/or their raw milk supply may be stored in a farm bulk milk tank(s)/silo(s) on the dairy farm that directly feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system or piped from the a farm bulk milk tank(s)/silo(s) to a raw milk tank(s) and/or silo(s) in the milk plant that feeds the batch (vat) pasteurizer(s) or constant-level tank of a HTST pasteurization system; and/or other raw milk storage containers.

6. **Industry Analyst:** A person under the supervision of a Certified Industry Supervisor or Industry Supervisor who is assigned to conduct screening of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

7. **Industry Supervisor/Certified Industry Supervisor:** An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts who test milk tank trucks and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for Appendix N. drug residue requirements.

8. **Certified Industry Supervisor:** An Industry Supervisor who is evaluated and listed by a LEO as certified to conduct drug residue screening tests at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. regulatory actions (confirmation of bulk milk pickup tankers, farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, producer trace back and/or permit actions).

CERTIFIED INDUSTRY SUPERVISORS; EVALUATION AND RECORDS:
Reference: *EML*

1. **Certified Industry Supervisors/Industry Supervisors/Industry Analysts:** Regulatory Agencies may choose to allow Industry Supervisors to be certified. Under this program, these Certified Industry Supervisors may officially confirm presumptive positive bulk milk pickup tanker loads and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, and confirm producer milk for regulatory purposes (producer trace back/permit action). In the implementation of Appendix N. of this *Ordinance*, the LEO shall use the appropriate Appendix N. FDA/NCIMS 2400 Form when evaluating Official Laboratories, Officially Designated Laboratories or Certified Industry Supervisors, Industry Supervisors and Industry Analysts.

The Certified Industry Supervisor/Industry Supervisor shall report to the LEO the results of all competency evaluations performed on Industry Analysts. The names of all Certified Industry Supervisors, Industry Supervisors and Industry Analysts, as well as their training and evaluation status, shall be maintained by the LEO and updated as replacement, additions and/or removals occur. The LEO shall verify (document) that each Certified Industry Supervisor and/or Industry Supervisor has established a program that ensures the proficiency of the Industry Analysts they supervise. The LEO shall also verify that each Industry Supervisor and Industry Analyst has demonstrated proficiency in performing drug residue analysis at least biennially. Verification may include an analysis of split samples and/or an on-site performance evaluation or another proficiency determination that the LEO and the FDA Laboratory Proficiency Evaluation Team (LPET) agree is appropriate.

Failure by the Industry Supervisor or Industry Analyst to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of Industry Supervisors and/or Industry Analysts. Reinstatement of their testing status shall only be possible by completing retraining and/or successfully analyzing split samples and/or passing an on-site evaluation or otherwise demonstrating proficiency to the LEO. (Refer to the *EML*, which describes the certification requirements for Certified Industry Supervisors and the training requirements for Industry Supervisors and Industry Analysts.)

2. **Sampling and Testing of Bulk Milk Pickup Tankers:** The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample shall be representative. The sample analysis shall be completed before the milk is processed.

3. **Sampling and Testing of Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers:** All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), or other raw milk storage container(s) supply. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

4. **Bulk Milk Pickup Tanker Unloaded Prior to Negative Test Result:** If the bulk milk pickup tanker is unloaded and commingled prior to obtaining a negative test result and the screening test is presumptive positive, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive, then the commingled milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the commingled milk. The milk shall be disposed of under the supervision of the Regulatory Agency.

5. **Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Processed Prior to Negative Results:** If the raw milk supply that has not been transported in bulk milk pickup tankers is processed prior to obtaining a negative test result and the screening test is presumptive positive, the Regulatory Agency shall be immediately notified. If the sample of the raw milk supply that has not been transported in bulk milk pickup tankers is confirmed positive, then the processed milk is adulterated and unacceptable for human consumption regardless of any subsequent test results from the raw milk supply and/or pasteurized milk or milk products. The processed milk shall be disposed of under the supervision of the Regulatory Agency.

BULK MILK PICKUP TANKER AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS SCREENING TEST:

1. **Performance Tests/Controls:** Each lot of test kits purchased shall be tested by positive (+) and negative (-) controls, as defined in the SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN RAW BULK MILK PICKUP TANKERS of this Section, in each screening facility prior to its initial use and each testing day thereafter. Records of all positive (+) and negative (-) control performance tests shall be maintained.

2. **Initial Drug Testing Procedures:** The following procedures apply to testing bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues following the provisions of Appendix N. Industry analysts may screen tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and receive or reject milk. Milk plants, receiving stations, transfer stations and other screening locations may choose to participate in the Industry Supervisor Certification Program.

   a. Industry Presumptive Positive Options: There are two (2) industry options for the milk represented by a presumptive positive sample:

1) The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the presumptive positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be in an Official Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor at a location acceptable to the Regulatory Agency. Documentation of prior testing shall be provided to the analyst performing the load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation. The presumptive positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers may be re-sampled, at the direction of the Regulatory Agency, prior to analysis with the same or equivalent test (M-I-96-10, latest revision), as was used to obtain the presumptive positive result. This analysis shall be done in duplicate with positive (+) and negative (-) controls. If either or both of the duplicate samples are positive and the positive (+) and negative (-) controls give the correct reactions, the sample is deemed a Screening Test Positive (Confirmed Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers). A written copy of the test results shall be provided to the Regulatory Agency. The milk, which that sample represents, is no longer available for sale or processing into human food.

2) The owner of the presumptive positive milk may reject the load and/or raw milk supply that has not been transported in bulk milk pickup tankers without further testing. At that time the milk represented by the presumptive positive test is not available for sale or processing into human food. The milk cannot be re-screened. The Regulatory Agency involved (origin and receipt) shall be notified. Under this option, producer trace backs shall be conducted for the reject load.

NOTE: When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

3. **Re-Sampling:**

a. Presumptive Results: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained. When this happens, the Regulatory Agency may allow the industry to re-sample the bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers. The reasons that made the re-sampling necessary shall be clearly documented in testing records and reported to the Regulatory Agency. This written record shall be provided to the Regulatory Agency and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

b. Screening Test Results: Re-sampling or additional analysis of screening test results should be discouraged. However, the Regulatory Agency may direct re-sampling and/or analysis, when it has determined that procedures for sampling and/or analysis did

not adhere to accepted NCIMS practices (*SMEDP*, FDA/NCIMS 2400 Forms, Appendix N. and the applicable FDA interpretative or informational memoranda). This decision by the Regulatory
Agency shall be based on objective evidence. A Regulatory Agency allowing re-sampling shall plan a timely follow-up to identify the problem and initiate corrective action to ensure the problem that led to the need for re-sampling is not repeated. If re-sampling and/or analysis is necessary, it shall include a review of the samplers, analysts, and/or laboratories to identify the problem(s) and initiate corrective action to ensure the problem(s) is not repeated. The reasons that made the re-sampling or analysis necessary shall be clearly documented in testing records maintained by the Regulatory Agency, and shall be maintained with the record of the testing for that load and/or raw milk supply that has not been transported in bulk milk pickup tankers.

4. **Producer Trace Back:** All screening test positive (confirmed) loads shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit action) shall be performed in an Official Laboratory, Officially Designated Laboratory or by a Certified Industry Supervisor. Positive producers shall be handled in accordance with this Appendix.

NOTE: When a farm bulk milk tank(s)/silos, milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is used for a milk plant's raw milk supply(ies) that has not been transported in bulk milk pickup tankers, is found to be positive (confirmed) for drug residues, the farm of origin for the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Assuring Representative Samples From Individual-Producer Loads And Multiple-Farm Tank Loads From An Individual Producer: Representative samples shall be secured from each farm storage tank(s)/silo(s) of milk prior to loading onto a bulk milk pickup tanker and/or other raw milk supply transportation method at the dairy farm. The representative sample(s) shall travel with the bulk milk pickup tanker and/or other raw milk supply transportation method to a designated location acceptable to the Regulatory Agency.

Record Requirements: Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo, or other raw milk storage container(s), etc. used for the storage of raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test, if the analysis results are positive the record shall show:
   a. The identity of each producer contributing to the positive load;
   b. Who at the Regulatory Agency was notified;
   c. When did this notification take place; and
   d. How was this notification accomplished.
6. Follow-up testing if initial test was positive/any and all controls (+/-);

7. Site where test was performed; and
8. Prior test documentation shall be provided for a presumptive positive load.

*Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.

SCREENING TESTS NECESSARY TO IMPLEMENT THE PROVISIONS OF APPENDIX N. FOR BULK MILK PICKUP TANKERS AND/OR ALL RAW MILK SUPPLIES THAT HAVE NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS:

1. **Performance Tests/Controls (+/-):**
   a. Each lot of kits purchased is tested by positive (+) and negative (-) controls.
   b. Each screening facility runs a positive (+) and negative (-) control performance test each testing day.
   c. All NCIMS Approved Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Screening Tests Include the Following Format: All presumptive positive test results shall be repeated in duplicate as soon as possible at the direction of the Regulatory Agency on the same sample with single positive (+) and negative (-) controls by a certified analyst (Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor) using the same or equivalent test (M-I-96-10, latest revision). If the duplicate tests are negative, with appropriate (+/-) control results, the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers is reported as negative. If one (1) or both duplicate test(s) is positive (+), the test result is reported to the Regulatory Agency in which the testing was conducted, as a screening test positive (confirmed).
   d. All positive (+) controls used for drug residue testing kits are labeled to indicate a specific drug and concentration level for that drug.
      (1) For tests that have been validated and only detect Penicillin, Ampicillin, Amoxicillin and Cephapirin, the positive (+) control is Pen G @ 5 ± 0.5 ppb.
      (2) For test kits validated for the detection of Cloxacillin, the positive (+) control may be Cloxacillin @ 10 ± 1 ppb.
      (3) For test kits validated for one (1) drug residue only, the positive (+) control is ± 10% of the safe level/tolerance of the drug residue detected.
2. **Work Area:**
   a. Temperature within specifications of the test kit manufacturer's labeling.
   b. Adequate lighting for conducting the test kit procedure.
3. **Test Kit Thermometers:**
   a. Thermometer traceable to a NIST Certified Thermometer.
   b. Graduation interval not greater than 1°C.
   c. Dial thermometers are not used to determine the temperatures of samples, reagents, refrigerators, or incubators in milk laboratories.
4. **Refrigeration:**
   a. Test kit reagent storage temperature specified by manufacturer.

5. **Balance (Electronic):**
   a. 0.01 g for preparation of positive (+) controls.
   b. Balance with appropriate sensitivity for calibration of pipetting devices within a tolerance of ± 5%. These devices may be calibrated at another location acceptable to the LEO.
6. **Screening Test Sampling Requirements:**
   a. Temperature of milk in the bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers determined and recorded.
   b. Representative bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sample for drug residue testing collected.
   c. Samples tested within seventy-two (72) hours of collection.
7. **Screening Test Volumetric Measuring Devices:**
   a. Single use devices provided by kit manufacturers are acceptable for Appendix N. screening analysts.
   b. NCIMS Certified Laboratories require calibrated pipetting/dispensing devices. These devices may be calibrated at another location acceptable to the LEO.
   c. Measuring devices with tips bearing calibration lines provided by test kit manufacturers are acceptable for Appendix N. screening.

IV. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutorial guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding. They do not dictate any result; they do not limit FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.
"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules.

Notification, changes or additions of "safe levels" shall be transmitted via Memoranda of Information (M-I's).

V. APPROVED METHODS

Regulatory Agencies and industry shall use tests from the most recent revision of M-a-85 for analysis of bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for Beta lactam residues, following the testing procedures specified in Section III of this Appendix. AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this *Ordinance*. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6 of this *Ordinance*.

One (1) year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk. The acceptance of evaluated tests does not mandate any additional screening by industry with the evaluated method.

M-a-86, Revision 3 Flowchart
For Antibiotic Residue Analysis

Incoming tankers are screened for antibiotic residues either by an approved industry analyst(s) or by a certified analyst.
Daily monitoring performed on assays with readers – monitoring must be valid before proceeding.
POSITIVE AND NEGATIVE CONTROL REACTIONS ARE VALID.

Sample Reaction after initial analysis:

Negative → Report as **"Not Found" (NF)** and milk can be processed.

Positive → Promptly retest the same initial sample in duplicate using the **same assay** with a positive and a negative control. After incubation **and** both control reactions give the proper reactions:

- If both duplicate samples yield negative (NF) results, then: → Report as **"Not Found" (NF)** and milk can be processed.
- If one or both duplicate samples yield a positive result, the tanker must be confirmed and regulatory is immediately notified of the "**Presumptive Positive**" result.

Only certified analysts can continue the assay beyond this point.

Using the same initial positive sample*:
Optionally, rerun the reader performance controls where applicable.
Promptly run a positive control, a negative control and same initial positive sample in duplicate on the same or equivalent assay.
Both controls give proper results before proceeding.
NOTE**:** Controls and samples can be incubated at the same time, but control reactions must be determined before reading the sample results.

- If both duplicate samples yield a negative (NF) result, then the tanker can be processed.
- If either one or both duplicate samples yield a positive result, the tanker load is a "**Screening Test Positive** (Confirmed Load)."
  The tanker represented by the sample **cannot** be processed, retested or offered for sale.
  Producer trace back must be conducted.
  ↓
  Using the same or equivalent assay, test the producers that made up the "**Screening Test Positive**" tanker.
  Positive producer samples are confirmed using the same procedure as for the tanker sample.

*The Presumptive Positive Load can be re-sampled at the direction of the state Regulatory Agency prior to load confirmation. Records must indicate the reason for re-sampling the tanker and the regulator contacted.