APPENDIX N GENERAL TRAINING PROGRAM 2019

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APPENDIX N GENERAL TRAINING PROGRAM

INDEX

FDA 2400 FORMS

APPENDIX N BULK MILK TANKER SCREENING TEST FORM GENERAL REQUIREMENTS (REVISION 10/13)

APPENDIX N BULK MILK TANKER SCREENING TEST FORM IDEXX-NEW SNAP® BETA-LACTAM TEST (raw commingled cow milk , raw commingled camel milk and raw commingled goats milk) (REVISION 3/14)

APPENDIX N BULK MILK TANKER SCREENING TEST FORM CHARM SL (raw commingled cow, sheep, water buffalo and goat milk) AND Charm 3 SL3 (raw commingled cow milk) BETA-LACTAM TESTS (REVISION 3/15)

APPENDIX N BULK MILK TANKER SCREENING TEST FORM NEOGEN BETASTAR® ADVANCED (raw commingled cow milk) BETA-LACTAM TEST (REVISION 1/18)

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

NEOGEN BETASTAR ADVANCED FOR BETA-LACTAMS TEST
(Raw Comingled Cow Milk)
IMS #9-N3

[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. Neogen Corporation Raptor© Integrated Analysis Platform (Manual available). Thermostatically controlled at 65.0 ± 5.0°C _____

Serial Number: _____ _____

1. Temperature checked daily on the screen and printout (day of use), Records maintained (Printout acceptable for daily temperature check) _____

a. Incubator Temperature: _____ _____

b. Annual temperature verification performed; records maintained _____

1. Date of last verification: _____ _____

b. Reader calibrators _____

1. Positive: _____ _____

2. Negative: _____ _____

c. Pipettor – 400 µL and disposable tips (see App. N GR item 7) _____

1. **FOR SCREENING ONLY** - Disposable 400 µL single-use poly-pipets _____

4. Test Kits _____

a. BetaStar Advanced Test for Beta-lactams Kit _____

Lot #: _____ Exp. Date: _____ _____

QC Date: _____ By: _____ _____

5. Sample and control agitation _____

a. 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) _____

6. Reagent Stability and Preparation _____

a. Test Kit including strips are received under ambient temperature _____

b. Strips stored at 18 - 30°C (64 - 86°F), maintain no longer than manufacturer's expiration date _____

c. Negative Control _____

1. Previously negative tested raw milk _____

2. Milk can be screened (previously tested) by the testing location making and/or using the controls _____

3. Negative control must result in a ratio of ≥1.15 for both the beta-lactam and ceftiofur test lines; maintain records _____

Sample ID: _____ Date Tested: _____ _____

Record test line values (Ratio): _____

Beta-lactam line: _____ _____

Ceftiofur line: _____ _____

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

5. 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 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 48 hours. Do not refreeze _____

6. Day of use must result in a ratio of ≥1.15; maintain records _____

Do Not proceed if out of range _____

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

1. Lypholized 5.0 ± 0.5 ppb Penicillin G / 100 ± 10 ppb Desfuroyl ceftiofur _____

   Lot #: _____ Exp. Date: _____ _____

2. Store according to label instructions _____

3. Reconstitute with 1.0 mL of fresh or previously frozen previously screened beta lactam negative raw commingled cow milk _____

4. Positive control must produce a ratio of ≤ 0.85 for both the beta-lactam and ceftiofur test lines; maintain records _____

   Record test line values (Ratio): _____

   Beta-lactam line: _____ _____

   Ceftiofur line: _____ _____

5. Store reconstituted positive control at 0.0-4.5°C for no more than 48 hours _____

6. 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. **Do Not** freeze positive control if it was made with previously frozen negative control _____

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

   a. Thaw slowly 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 _____

7. Day of use must produce a ratio of ≤0.85; maintain records _____

   Do Not proceed if out of range _____

TECHNIQUE

7. Daily Performance and Operation Check _____

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

b. Raptor® Integrated Analysis Platform _____

1. At Raptor® start-up, calibration of camera and LED occurs automatically when instrument is turned on _____

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

3. Annual calibration defines x and y offsets for the Raptor system _____

   a. User performed annual calibration is required every 365 days. Verify annual calibration was performed within last 365 days. Please see user manual for more details _____

      Date of last calibration: _____ _____

4. Daily reader check calibration _____

   a. The reader check calibration must be performed daily in each of three ports in the Raptor System _____

   b. There are three calibration test strips within each cartridge, all positive or all negative _____

   c. Both positive and negative calibration cartridges must read within the limits specified ≤0.85 for positive and ≥1.15 for negative; maintain records _____

   d. Positive Calibrator Ratios: (Specification ≤0.85) _____

      Port 1: _____ Port 2: _____ Port 3: _____ _____

   e. Negative Calibrator Ratios: (Specification ≥1.15) _____

      Port 1: _____ Port 2: _____ Port 3: _____ _____

5. If reader check calibrations are out of range, contact Neogen before proceeding _____

8. Test Procedure _____

a. Make sure hands are clean and dry before handling test kits _____

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

   1. Cartridges that have been removed from the protective storage container must be kept clean and dry _____

   2. Any cartridges removed from the kit that remain unused at the end of the testing day must be discarded _____

c. Cartridges are pre-loaded with one test strip. Up to two more test strips for other residues may be loaded into the cartridge. One cartridge, loaded with up to three test strips, can be used to test one milk sample _____

d. Place cartridge with test strip(s) into any of the three ports. When cartridge is inserted into the port, the port will automatically begin to adjust to the proper temperature _____

e. The bar code on the test device will be read. If the QR (quick response) code for the lot of strips has not been entered into the system, the bar code reader in the front of the reader will turn on automatically. Scan the QR code found on the container storing the test strips _____

f. Instrument will prompt user for the milk sample ID. Scan or enter the sample ID at this time _____

g. Mix milk sample(s)/control(s) (See item 5.a) _____

h. The user will be prompted to add the milk sample when the port reaches 65.0 ± 5.0°C. **Do Not** add milk sample until prompted to do so _____

i. Add 400 uL of mixed sample/control into the back of the cartridge _____

1. Using pipettor (item 3.c) with a new tip for each sample/control and holding pipettor vertically draw up 400 µL avoiding foam and bubbles _____

a. Remove tip from liquid _____

b. While holding the pipettor vertically, expel test portion into cartridge _____

c. After sample is delivered into cartridge, eject pipettor tip into the back of the cartridge to prevent double loading of the same sample or loading a second sample into the same cartridge _____

2. **FOR SCREENING ONLY** - Using a new manufacturer provided single-use 400 µL poly-pipet (item 3.c.1) for each sample/control _____

a. Squeeze top bulb while holding single-use pipet vertically and draw up test portion avoiding foam and bubbles. Insure that pipet shaft is completely full and sample overflows into the bottom half of the overflow reservoir _____

b. Remove tip from liquid _____

c. While holding the single-use pipet vertically, expel test portion slowly into the back of the cartridge. Excess portion should remain in reservoir _____

d. After loading milk sample into the cartridge, leave the used pipet in the back of the cartridge. This will prevent double loading the same sample or loading a second sample into the same cartridge _____

j. Press “Next” after sample has been added. The unit will begin the 5 minute incubation after the system identifies the fluid front of the sample wicking up the device _____

k. After 5 minutes the result will be displayed on the screen, an audible tone will sound, and the test result will automatically print _____

l. Remove cartridge containing test strip(s) from the reader and discard the entire cartridge _____

9. Interpretation with Reader _____

a. If there is a ratio of ≥1.00 on the reader, sample is **a Negative (NF)** _____

b. If there is a ratio of <1.00 on the reader, sample is **an Initial Positive** _____

10. Verification of Initial Positive Tanker Samples (see App. N GR item 11) _____

11. Confirmation of Presumptive Positive Tanker Samples (see App. N GR item 12) [Only in an accredited laboratory or by a CIS] _____

a. For Beta-lactam confirmation, run tests using one Beta-lactam strip per Cartridge _____

12. Traceback of Producer(s) on a Confirmed Positive Tanker (see App. N GR item 13) [Only in an accredited laboratory or by a CIS (refer to M-a-85 current revision for a listing of test kits to assure equivalence)] _____

13. Re-instatement of Producer(s) [Only in an accredited laboratory or by a CIS (refer to M-a-85 current revision for a listing of test kits to assure equivalence)] _____

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

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	2/15
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.

BFSLS 498 (Rev. 1/14)

COMMONWEALTH OF PENNSYLVANIA
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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.

BFSLS 498 (Rev. 1/14)

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)

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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:_**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	-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)

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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			

BFSLS 500a (Rev.1/14)

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	
°C	°C	°C	°C	°C	°C	YES / NO	DEVICE 1 RANGE	
°C	°C	°C	°C	°C	°C	ANALYST ID#	DEVICE 2 RANGE	
INITIALS	INITIALS	INITIALS	INITIALS	INITIALS	INITIALS			

BFSLS 500a (Rev.1/14)

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			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												
1/27	9:05	JR	39.0°F	42-405	PYK8005	37092	45,289 lbs	3.9°C	9:22	9:30	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 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		

BFSLS 500a (Rev.1/14)

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			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												
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		

BFSLS 501a (Rev. 1/14)

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.

BFSLS 501a (Rev. 1/14)

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.

BFSLS 501a (Rev. 1/14)

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.

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_____

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.

BFSLS 503 (Rev. 02/15)

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. 02/15)

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. 02/15)

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**

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**

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**

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

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

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

BFSLS 534a (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-<u>LOW RANGE</u>:** **_____ to _____**	**DEVICE 2- <u>HIGH RANGE</u>:** **_____ 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 534a (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.

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

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: 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 #10)

December 20, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

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 #9), issued August 31, 2016). Revision #9 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 #16), issued December 12, 2018, and adds Tables 2 - 5 for other species milk.

Modifies tables to reflect the acceptance of the following:

- Charm® ROSA® Tetracycline SL Test
- Charm® TRIO Test
- Charm® ROSA® Sulf Test
- Neogen BetaStar® Advanced for Beta-Lactams Test
- Neogen BetaStar® Advanced for Tetracyclines Test

It also modifies the tables to remove the following tests that are no longer available:

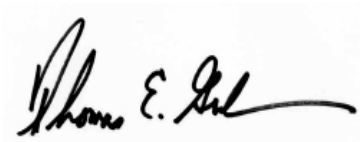
- Neogen BetaStar® Plus Beta Lactam Test
- Charm® II Cloxacillin Test

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 FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers. 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 Website 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 Website, please e-mail your request to Monica.Metz@fda.hhs.gov



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

Monica Metz, Chief
Milk and Milk Products Branch

Table 1: Raw, Commingled Cow Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® *B. stearothermophilus* Tablet Disk Assay Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test DSM Delvotest® P 5 Pack Test (Reader and Visual) DSM Delvotest® P Mini Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® II Tablet Beta-Lactam Test (Competitive Assay)	Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® II Tablet Beta-Lactam Test (Sequential Assay)	Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® II Tablet Beta-Lactam Test[2] (Quantitative Assay)	Charm® 3 SL3 Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® SL Beta-Lactam Test	Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® 3 SL3 Beta-Lactam Test	Charm® 3 SL3 Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Charm® FLUSLBL Flunixin and Beta-Lactam Test	Charm® FLUSLBL Flunixin and Beta-Lactam Test
Charm® II Chloramphenicol Test	Charm® II Chloramphenicol Test

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
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) Charm® ROSA® Tetracycline SL Test (Dilution Protocol) Neogen BetaStar® Advanced for Tetracyclines Test
Charm® ROSA® Tetracycline SL Test (Dilution Protocol)[3]	Charm® II Tetracycline Drug Test (Competitive Assay) Charm® ROSA® Tetracycline SL Test (Dilution Protocol) Neogen BetaStar® Advanced for Tetracyclines Test
Charm® ROSA® Sulf Test	Charm® II Sulfa Drug Test (Competitive Assay) Charm® ROSA® Sulf Test
Charm® TRIO Test[4]	Charm® II Sulfa Drug Test (Competitive Assay) (Sulfa only) Charm® II Tetracycline Drug Test (Competitive Assay) (Tetracyclines only) Charm® 3 SL3 Beta Lactam Test (Beta Lactams only) Charm® ROSA® Tetracycline SL Test (Dilution Protocol) (Tetracyclines only) Charm® ROSA® Sulf Test (Sulfa only) Neogen BetaStar® Advanced for Beta-Lactams Test (Beta-Lactams only) Neogen BetaStar® Advanced for Tetracyclines Test (Tetracyclines only)
DSM Delvotest® P 5 Pack Test (Reader and Visual) Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test DSM Delvotest® P 5 Pack Test (Reader and Visual) DSM Delvotest® P Mini Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
DSM Delvotest® P Mini Test Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test DSM Delvotest® P 5 Pack Test (Reader and Visual) DSM Delvotest® P Mini Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
IDEXX New Snap® Beta-Lactam Test	Charm® II Tablet Beta-Lactam Test (Competitive Assay) Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test Charm® 3 SL3 Beta-Lactam Test Charm® FLUSLBL Flunixin and Beta-Lactam Test IDEXX New Snap® Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Neogen BetaStar® Advanced for Beta-Lactams Test	Charm® 3 SL3 Beta-Lactam Test Neogen BetaStar® Advanced for Beta-Lactams Test
Neogen BetaStar® Advanced for Tetracyclines Test	Charm® II Tetracycline Drug Test (Competitive Assay) Charm® ROSA® Tetracycline SL Neogen BetaStar® Advanced for Tetracyclines Test

[1] This test is not specific for the detection of beta-lactams. While it is not validated to National Conference on Interstate Milk Shipments (NCIMS) standards for any drugs other than beta-lactams, a non-beta-lactam drug residue or other inhibitory substance may cause a positive test result. 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 Test or Delvotest® P Mini Test.

[2] The Charm® II Quantitative Assay detects all six (6) beta-lactam drugs as specified in M-a-85 however with the discontinuance of the Charm® II Cloxacillin Assay it may only be used to screen milk since to complete the determination of a positive result it was necessary to re-test the sample using the Charm II Sequential Assay and as necessary the Charm® II Cloxacillin Test (See FDA/NCIMS 2400 Form N-4 for Charm II Beta Lactam Tests, item 13). Without the Charm® II Cloxacillin Assay in effect it is not possible for the Charm® II Quantitative Assay to be completed and used as an equivalent test for other listed tests that also detect beta-lactam drugs.

[3] For the purposes of equivalency only the use of the dilution protocol option for this test is recognized. Use of undiluted samples with these tests is for initial bulk milk tanker screening only and cannot be used for determining that the test is equivalent to another test.

[4] The Charm® TRIO Test detects multiple drugs. This test may be used for screening only. If testing gives a presumptive (screen) positive further testing must be conducted using a test kit for the specific drug(s) identified. Follow PMO Appendix N protocols to verify the initial positive and if necessary conduct confirmation procedures as specified in the FDA/NCIMS 2400 form.

Table 2: Raw, Commingled Camel Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
IDEXX 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® *B. stearothermophilus* Tablet Disk Assay Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® *B. stearothermophilus* Tablet Disk Assay Charm® II Tablet Beta-Lactam Test (Sequential Assay) Charm® SL Beta-Lactam Test DSM Delvotest® P 5 Pack Test (Reader and Visual) DSM Delvotest® P Mini Test IDEXX New Snap® Beta-Lactam Test
Charm® SL Beta-Lactam Test	Charm® SL Beta-Lactam Test New Snap® Beta-Lactam Test
DSM Delvotest® P 5 Pack Test (Reader and Visual) Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta-Lactam Test Delvotest® P 5 Pack Test (Reader and Visual) Delvotest® P Mini Test New Snap® Beta-Lactam Test
DSM Delvotest® P Mini Test Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta Lactam Test Delvotest® P Mini Test

[1] This test is not specific for the detection of beta-lactams. While it is not validated to National Conference on Interstate Milk Shipments (NCIMS) standards for any drugs other than beta-lactams, a non-beta-lactam drug residue or other inhibitory substance may cause a positive test result. 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 Test or Delvotest® P Mini Test.

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
DSM Delvotest® P Mini Test Not a beta-lactam Specific Test. Refer to Footnote[1].	Charm® SL Beta Lactam Test Delvotest® P Mini Test

[1] This test is not specific for the detection of beta-lactams. While it is not validated to National Conference on Interstate Milk Shipments (NCIMS) standards for any drugs other than beta-lactams, a non-beta-lactam drug residue or other inhibitory substance may cause a positive test result. 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 Delvotest® P Mini Test.

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.

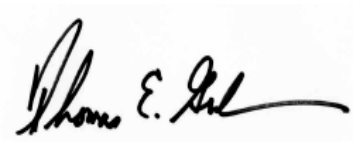
NOTE: FDA recognizes that six (6) Beta lactams are widely used in treating disease in lactating dairy cattle and are the most likely to cause a residue in milk if misused. These are penicillin, ceftiofur, cloxacillin, cephapirin, amoxicillin, and ampicillin. While it is preferred that monitoring for 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

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

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.

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

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

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

NOTICE OF MILK PRODUCER ACTION REPORT

Mail or deliver to the appropriate Region Office within twenty-four (24) hours of this action.

Pennsylvania Department of Agriculture, Region _____
Milk Sanitarian: _____
Region Address: _____
_____
_____

In accordance with Chapter 59a.17, Milk Sanitation, 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 ____/____/____
Reason _____

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.**

Permit Holder _____ FIPS# _____
_____
_____
_____

Signature _____ Date ____/____/____
Approved Inspector or Authorized Agent

BFSLS-431 (Rev. 12/16)

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_____

***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 - 999____
____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: ______________________________

-*

Violative Producer Information

PA Producer Name and Number: ______________________________

Herd Number: ______________________________

Address: ______________________________

____

Out-of-State Producer ID No.: ______________

Cause of Adulterated Bulk Tank: ______________________________

____

____

Drug Used: ______________________________

THIS REPORT MUST BE MAILED WITHIN 72 HOURS OF INITIAL PRESUMPTIVE POSITIVE TEST RESULT.

PERMIT HOLDER: ______________________________

Name FIPS No.

____

Street

____

City State Zip

Signature: ______________________________

Approved Inspector or Authorized Agent

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____

-*

Violative Producer Information

PA Producer Name and Number: __19832___Joe Somebody___________________________

Herd Number: ___10-26-H54_______________________________________

Address: ___ RD 1 Box 94_________________________________
____ Spring Creek, PA 19823_______________________

Out-of-State Producer ID No.: _____________________

Cause of Adulterated Bulk Tank: ___Milked treated cow____________________________

Drug Used: ___Tomorrow______________________________________

THIS REPORT MUST BE MAILED WITHIN 72 HOURS OF INITIAL PRESUMPTIVE POSITIVE TEST RESULT.

PERMIT HOLDER: _____Utters Dairy____42-999_______
Name FIPS No.

_____RD 3 Box 147____
Street

_____Rockville_________________________PA_________________19745______
City State Zip

Signature: ______A. _DeMann____
Approved Inspector or Authorized Agent

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 ____/____/_____ Time ____:____am/pm Temp. ._____°F	_____ FIPS # _____	Load # _____

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 # / Expiration Date	Initial Result (number / interpretation)	Analyst I.D./ Initials
__/___/___ __:___am/pm	_____	_____ Expiration Date _____	FRONT _____ / _____ REAR _____ / _____	_____

PRESUMPTIVE TEST RESULT**

Temperature	Test Method Used	Test Kit Lot # / Expiration Date	Presumptive Result DUPLICATE (number / interpretation)	Analyst I.D./ Initials
_____°C	_____	_____ Expiration Date _____	_____ / _____ _____ / _____	_____

Printout: (enclosed)	Control Results	Charm II Control Point Results	Department Notification:
Yes ☐ No ☐	Positive _____ Negative _____	Control Point _____ Date Established_____ Positive _____ Negative _____ (Average) + _____ -- _____	Phone __ Fax ___ Email ___ Date ___/___/___ Time ___:___am/pm 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 # / Expiration Date	Confirmation Results DUPLICATE (number / interpretation)	Analyst I.D./Initials
___/___/___ ___:___am/pm Temp. Control _____°C	_____	_____ Expiration Date _____	_____/_____ _____/_____	_____

Confirmatory Location	Control Results	Charm II Control Point Results	Department Notification:
_____ _____	Positive _____ Negative _____	Control Point _____ Date Established_____ Positive ____ Negative _____ (Average) + _____ -- _____	Phone __ Fax ___ Email ___ Date ___/___/___ Time ___:___am/pm 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____	_____Utter's Dairy_____	_____18_____
_____	Time _9___:_45___am/pm		Load # _____168123_____
	Temp. ._38___°F	FIPS # __42-995_____	

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 ☒ 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 ☒

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___/_14__ _1__:45__am/pm Temp. Control ___3.7_____°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 ☒

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 __Utter's Dairy_____	**Collection of Sample** Date _2__/_4___/__14__ Time _9__:_45_am/pm Temp.___2.6____°C	**Owner of Milk** ___Utter's Dairy____ FIPS # ___42-995_____	Route # __18_____ Load # ____168123___
Laboratory ID # __42-399_____ **Printout (enclosed):** Yes ☒ No ☐	**Test Method(s) Used** __Charm SL_____ _____	**Test Kit Lot #** ___109_____ **Expiration Date** _____5/2014____	**Department Notification:** 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)
1	42-995	26995	-1459	NF
2	42-995	26845	-1589	NF
3	42-995	26541	+4239	POS
4	42-995	26854	-1259	NF
5	42-995	56771	-2095	NF

Control Results

Positive Control _+1699_____

Negative Control __-1544_____

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 tested 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 and testing 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 and testing 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 using approved test methods and/or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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. of this *Ordinance* 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 using approved test methods or verified screening positive test results using test methods not evaluated by FDA and accepted by the NCIMS 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 or farm

raw milk tanks/silos (only milk offered for sale) 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 using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained or disposed of as determined by the Regulatory Agency.
All presumptive positive test results using approved test methods for drug residues on finished milk and/or milk products shall be reported to the Regulatory Agency in which the testing was conducted.
Industry plant samplers shall be evaluated according to the requirements specified in Section 6. and at the frequency addressed in Section 5. 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 using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS, 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 confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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 confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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.
Upon official notification to the Regulatory Agency and milk producer of a violative individual producer's milk, further farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm 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. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pickup tanker(s) tests negative in accordance with this Appendix.

NOTE: Further farm pickups refer to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker.

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 using approved test methods or a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS.

*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 test results shall be maintained for a minimum of six (6) months by the industry at the location where the test methods were run, and/or another location as directed by the Regulatory Agency and as agreed to by industry. For the laboratory survey, two (2) years of records shall be available at the facility at the time of the survey.

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 using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS, 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 test 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 test 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 (IA) test the samples. Receiving locations that choose to certify all receiving IAs, 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 IAs and Industry Supervisors (ISs) 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. 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 shall be a documented 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 a documented 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 specified drug residue milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads using an approved test method 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 enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CIS). Positive producers shall be handled in accordance with this Appendix.

d. All verified screening test positive loads using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI. of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

e. 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 confirmed positive for drug residues using approved test methods, 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 CIS. Positive producers shall be handled in accordance with this Appendix.

f. 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 verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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. Producer trace back shall be performed as cited in a prior documented

agreement with the Regulatory Agency. (Refer to Section VI. of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

g. 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 shall 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. of this Appendix, as applicable, based on the test method utilized, and has cleared the milk for pick up and/or use.

Sufficient records shall 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.

Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, 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. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer’s milk are prohibited until subsequent testing reveals the milk is free of drug residue. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pickup tanker(s) tests negative in accordance with this Appendix.

NOTE: Further farm pickups refer to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker.

Prevention of the Sale of Milk: Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the Regulatory Agency shall immediately take effective measures to prevent the sale of the milk containing drug residues.

Penalties for Confirmed Positive Milk: 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: When the permit has been suspended as required, 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 confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, 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 for a drug residue using approved test methods 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. of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regards to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS 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 method(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, or M-I-92-11 approved test method, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method, 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 (confirmation) result is obtained when the presumptive positive sample is tested in duplicate, using the same or equivalent (M-I-96-10, latest revision) test method 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 CIS using the same or an equivalent test (M-I-96-10, latest revision).

3. **Producer Trace Back/Permit Suspension Action:** A producer trace back/permit suspension action test is performed after a screening test positive load (confirmation) is identified by an Official Laboratory, Officially Designated Laboratory or CIS using the same or an equivalent (M-I-96-10, latest revision) test method 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 screening test positive (confirmation) 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 method 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 confirmed positive for drug residues using approved test methods, 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 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 (IA):** A person under the supervision of a Certified Industry Supervisor (CIS) or Industry Supervisor (IS) 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 (IS/CIS):** An individual trained by a LEO who is responsible for the supervision and training of Industry Analysts (IAs) 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 (CIS):** An Industry Supervisor (IS) who is evaluated and listed by a LEO as certified to conduct drug residue screening tests using approved test methods at industry drug residue screening sites for *Grade "A" PMO*, Appendix N. enforcement 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).

9. **Verified Screening Positive:** A verified screening positive test is a positive result from an initial testing using test methods not evaluated by FDA and accepted by the NCIMS of a bulk milk pickup tanker and/or raw milk supply that has not been transported in bulk milk pickup tankers, which has been promptly repeated in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result.

10. **Producer Trace Back With Permit Suspension Action Not Required:** A producer trace back test is performed after a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required is identified by a laboratory using the same test method as was used to obtain the verified screening positive load. A verified screening positive producer test result is obtained in the same manner as a verified screening positive for a bulk milk pickup tanker. After an initial positive result is obtained on a producer sample, that sample is then tested in duplicate using the same test method as was used to obtain the initial producer positive result. This testing is performed with positive (+) and negative (-) controls and if either or both of the duplicates are positive and the controls give the proper results, the producer sample is a verified screening positive. (Refer to Section VI. of this Appendix.)

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 verified screening positive for drug residues using only test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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.

CERTIFIED INDUSTRY SUPERVISORS (CISs); EVALUATION AND RECORDS:
Reference: *EML*

1. **Certified Industry Supervisors (CISs)/Industry Supervisors (ISs)/Industry Analysts (IAs):** Regulatory Agencies may choose to allow ISs to be certified. Under this program, these CISs 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) using approved test methods. 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 CISs, ISs and IAs.

The CIS/IS shall report to the LEO the results of all competency evaluations performed on IAs. The names of all CISs, ISs and IAs, 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 CIS and/or IS has established a program that ensures the

proficiency of the IAs they supervise. The LEO shall also verify that each IS and IA 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 IS or IA to demonstrate adequate proficiency to the LEO shall lead to their removal from the LEO list of ISs and/or IAs. 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 CISs and the training requirements for ISs and IAs.)

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 using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, the Regulatory Agency shall be immediately notified. If the bulk milk tanker sample is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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 using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS, 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 using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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. of this *Ordinance*. IAs 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 IS Certification Program.

a. Industry Presumptive Positive Options Using Approved Test Methods: There are two (2) industry options for the milk represented by a presumptive positive sample using approved test methods:

(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 CIS 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 method (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 (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tankers Confirmation). 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 confirmed positive for drug residues using an approved test method, 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 Using Approved Test Methods: Occasionally, an error in sampling or a suspicious test result is discovered after a presumptive result is initially obtained using approved test methods. 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 Using Approved Test Methods: 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 are 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:**

a. All screening test confirmed positive loads using an approved test method 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 CIS. 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 confirmed positive for drug residues using an approved test method, 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.

b. All verified screening positive loads using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be broken down (producer trace back) using the same test method. Verification producer trace back tests shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI. of this Appendix.) Verified screening 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 verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without

additional confirmation required 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 method 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 when using an approved test method or a verified screening positive load when using test methods not evaluated by FDA and accepted by the NCIMS. *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.

TEST METHODS 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 Confirmation Test Methods for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers 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 positive (+) and negative (-) controls by a certified analyst (Official Laboratory, Officially Designated Laboratory or CIS) 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 Test Methods Used by Industry, which have Not been Evaluated by FDA and Accepted by the NCIMS for Bulk Milk Pickup Tanker and/or All Raw Milk Supplies that have Not been Transported in Bulk Milk Pickup Tankers Include the Following Format:
One (1) of the options provided for in Section VI. of this Appendix shall be followed.

e. 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 target testing 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 Method 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 Method 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 TARGET TESTING LEVELS OF DRUG RESIDUES

"Target testing levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the target testing levels. In short, FDA uses the "target testing levels" as prosecutorial guidelines and in full consistency with CNI v. Young.

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.
"Target testing 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. "Target testing 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 "target testing levels" shall be transmitted via Memoranda of Information (M-I's).

V. APPROVED TEST METHODS

Regulatory Agencies and industry shall use test methods from M-a-85, latest revision, 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 lactams 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*. Enforcement action based on each test 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 two (2) or more drug test method**s** have been evaluated by FDA and accepted by the NCIMS for a particular non-Beta lactam drug or drug family, other unevaluated drug test methods for that particular non-Beta lactam drug or drug family are not acceptable for determining a Screening Test Positive (Confirmation) on a milk tank truck load of milk and/or all raw milk supplies that has not been transported in bulk milk pickup tankers. The acceptance of evaluated drug test methods by FDA and the NCIMS for drugs other than Beta lactams does not mandate any additional screening by industry or Regulatory Agencies with the evaluated drug test method, unless it is determined by the Commissioner of FDA that a potential problem exists with other animal drug residues in the milk supply.
New drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance or 25% of the target testing level* for individual drugs, with the exception of the following that may be accepted for Appendix N. and other drug testing:

1. Penicillin G at 2 ppb.
2. Tetracycline drug kits that detect tetracyclines at levels greater than 150 ppb for Chlortetracycline, 119 ppb for Oxytetracycline and 67 ppb for Tetracycline.

*Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

VI. TEST METHODS FOR NON-BETA LACTAMS RESIDUE TESTING THAT HAVE NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION):

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues provided that the following conditions are met:

1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. target testing levels or non-zero tolerances are available, the test method manufacturer's data indicates that testing sensitivity is at or below those concentrations.

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11. An M-I-96-10, latest revision, test method(s) shall be used for confirmation. Whenever the user of the test method and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed.

One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, one (1) of the following two (2) options (1 or 2) shall be used for confirmation:

<u>Option 1:</u>

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, testing shall promptly be repeated in duplicate with positive (+) and negative (-) controls that give the proper results using the same test method on the same sample. The initial test result is verified as a screening positive when one (1) or both of these duplicate retests give a positive result. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency shall take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. Testing for confirmation of that verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall utilize a test method from M-a-85, latest revision, and M-I-92-11, and shall be conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all 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 tanker's confirmation. The verified screening 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 an M-I-96-10, latest revision, test method. 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 proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker's Confirmation). 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. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

Option 2:

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested using a test method from M-a-85, latest revision, and M-I-92-11. The initial positive M-a-85 and M-I-92-11 test is found to be a presumptive positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. 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 conducted in an Official Laboratory, Officially Designated Laboratory or by a CIS at a location acceptable to the Regulatory Agency. Documentation of all 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 tanker's 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 an M-I-96-10, latest revision, test method. 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 proper results, the sample is deemed a Screening Test Positive (Load and/or Raw Milk Supply that has Not been Transported in Bulk Milk Pickup Tanker's Confirmation). 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. Producer trace back, reporting, and enforcement as defined in this Appendix shall occur.

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE:

Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk

milk pickup tankers for non-Beta lactam drug residues provided that the following conditions are met:

1. The test method manufacturer has data indicating the sensitivity and selectivity of the test method; and
2. When U.S. target testing levels or non-zero tolerances are available, the test method manufacturer's data indicates that testing sensitivity is at or below those concentrations.

In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-Beta lactam drug residue. Whenever the user of the test method and the milk supplier agree on voluntary testing for non-Beta lactams using test methods not evaluated by FDA and accepted by the NCIMS, then they shall seek the concurrence of the Regulatory Agency(ies) as to what process shall be followed.

One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, Option 3 shall not be used for non-Beta lactam screening or verification.

Option 3:

If the initial test result from a drug test method that has not been evaluated by FDA and accepted by the NCIMS is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified screening positive by promptly repeating 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. The Regulatory Agency involved (origin and receipt) shall be notified. The appropriate Regulatory Agency may take control of the verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers. A written copy of the verified screening positive test results shall follow the initial Regulatory Agency notification. The verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers shall be disposed of to remove it from the human or animal food chain. Producer trace back shall be conducted by industry using the same drug test method at the direction of the Regulatory Agency as cited in the prior documented agreement. If the initial producer test result from the drug test method is found to be positive, the sample shall promptly be retested in a facility identified in the prior documented agreement using the same drug test method. The initial positive test is found to be a verified producer screening positive by promptly repeating in duplicate with positive (+) and negative (-) controls that give the proper results, using the same test method, on the same sample, with one (1) or both of these duplicate retests giving a positive result. The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups and/or use of the violative individual producer's milk are prohibited until subsequent testing, utilizing the same drug test method or equivalent that has not been evaluated by FDA and accepted by the NCIMS, of a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to

the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pickup tanker(s) test negative in accordance with Appendix N. Whenever a drug residue test is verified screening positive, an investigation may be completed by the Regulatory Agency or its agent to determine the cause of the drug residue and actions taken to prevent future violations.

NOTE: Further farm pickups refer to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker. 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 confirmed positive for drug residues using an approved test method or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required 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.

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.