STANDARD OPERATING PROCEDURE – Drug Residue Screening

INTRODUCTION
Appendix N of the Grade "A" Pasteurized Milk Ordinance requires that all loads of bulk milk be screened for Beta lactam drug residues prior to receiving. Industry Analysts and Certified Industry Supervisors may perform the initial presumptive testing. However, only Certified Industry Supervisors may perform the confirmatory and trace back testing on presumptive positive tanker loads.

MATERIALS
1. IDEXX Snapshot reader and printer
2. Heating block capable of maintaining 45ºC +/- 5ºC with inserts for SNAP devices and sample tubes
3. Thermometer for the heating block
4. New SNAP Beta-Lactam test kits, which have been stored at 0 to 7ºC and were previously checked for suitability
5. Positive control – penicillin positive control (IDEXX # 98-06513-00) which has been stored at 0 to 30ºC
6. Negative control - beta-lactam negative raw milk which has been stored at 0 to 4.4ºC for less than 72 hours
7. Performance check set, both positive and negative, which has been stored in the dark.
8. 450 µl fixed volume pipettor and tips
9. Timer
10. Sample to be tested and its temperature control. Sample must not have been frozen before testing.
11. Pre-cooled thermometer
12. Copy of the tanker paperwork
13. Copy of the Daily Drug Residue Screening Test Log (BFSLS 500)
14. Copy of the Positive Control Suitability Test form (BFSLS 513A).
15. Copy of the Negative Control Suitability Test form (BFSLS 513B).
16. Copy of the Snap Image Performance Check Set form (BFSLS 534).
17. Copy of a Block Heater Temperature Log (BFSLS 537) for each block heater used.

PREPARATION
1. Turn heating block on. The temperature must have stabilized at 45ºC +/- 5ºC for at least five minutes prior to the initiation of sample testing.
2. Remove the needed number of SNAP devices from the refrigerator. Unused SNAP devices should have a light blue control spot, sample spot and activation circle. Discard devices that do not.
3. Label each SNAP device and its accompanying sample tube, and place the SNAP devices on the heating block. The devices must remain in the heater block for the duration of the test. Do not mix tubes and devices from different lot numbers, and do not use kits past their expiration date.
4. Turn on the Snapshot reader.
   a. From the readers main menu choose “read test”
   b. Make sure that “no” is checked following “read only” and then choose “beta lactam”
   c. Enter the lot number of the SNAP devices and the analyst identification number
5. Record on form BFSLS 500:
   a. Hauler information obtained from the tanker paperwork
   b. Lot number and expiration date of the SNAP devices
   c. Positive control information
   d. Negative control information
   e. Temperature of the heating blocks. Apply the appropriate thermometer correction factor, for example if the thermometer reads 44.0ºC and the correction factor is -0.2ºC then record 43.8ºC.
   f. Date and time of sample collection
TEST PROCEDURE WHEN AN ACCEPTABLE NEGATIVE CONTROL IS AVAILABLE

(previously screened beta-lactam negative raw milk which has been stored at 0 to 4.4°C for less than 72 hours)

1. On the Snapshot reader enter “4444” as the sample identification, then insert the negative performance check device (# 1) into the reader and press “read”.
2. Press “next”, then repeat step 2 with the positive performance check device (# 2), entering “3333” for the sample identification.
3. Remove one vial of positive control from the refrigerator and reconstitute it by adding 1 ml of previously screened negative raw milk. Mix by gently inverting the vial 10 times to ensure that all of the material has dissolved. Let it stand for 10 minutes. Following reconstitution, the positive control must be stored at 0 to 30°C and used within 24 hours.
4. Remove and discard the sample tube caps, making sure the pellets are at the bottom of each tube.
5. Record the time and temperature (in °C) of the sample when analysis was initiated. Use the time indicated on the Snapshot reader, not the time on the wall clock.
6. Shake each raw milk sample, negative control and positive control thoroughly (25 times in 7 seconds through a 1 foot arc) and use within 3 minutes.
7. Avoiding the foam, pre-wet the pipet tip, then pipet 450 µl of each sample and control directly into the bottom of its corresponding tube. Do not allow the liquid to drain down the side of the tube. Use a clean pipet tip for each sample and control.
8. Agitate the sample tubes to dissolve the pellets. Visually confirm that the blue reagent pellets are completely dissolved.
9. Place each sample tube in the heat block next to its SNAP device and incubate for 5 minutes. Use the timer.
10. Pour the entire contents of each sample tube into the well of its corresponding SNAP device. Touch off the last drop on a dry spot in the sample well and then discard the tubes into a biohazard waste bag.
11. When the activation circle begins to turn from blue to white, push the activator firmly until it snaps flush with the body of the SNAP device. Do not let the activation circle turn completely white.
12. Wait 4 minutes, using the timer. The SNAP device remains in the heat block during this time.
13. Immediately remove all SNAP devices from the heat block.
14. On the Snapshot reader enter “2222” for the sample identification, then insert the negative control SNAP device into the reader and press “read”.
15. Press “next”, then repeat step 14 with the positive control SNAP device entering “1111” for the sample identification.
16. Press “next”, then repeat step 14 with each sample SNAP device entering the tanker load identification number as the sample identification.
17. Record on form BFSLS 500:
   a. Results from the performance check devices
   b. Results from the negative and positive controls
   c. Time that the sample device was read, its numerical result, and the interpretation of the result

TEST PROCEDURE WHEN AN ACCEPTABLE NEGATIVE CONTROL IS NOT AVAILABLE

1. When previously screened beta-lactam negative raw milk which has been stored at 0 to 4.4°C for less than 72 hours is not available, a sample of raw milk must be collected and tested prior to reconstituting the positive control.
2. On the Snapshot reader enter “4444” as the sample identification, then insert the negative performance check device (# 1) into the reader and press “read”.
3. Press “next”, then repeat step 2 with the positive performance check device (# 2), entering “3333” for the sample identification.
4. Collect a sample of raw milk. It must have been stored at 0 to 4.4°C for less than 72 hours.
5. Remove and discard a sample tube cap, making sure the pellet is at the bottom of the tube.
6. Shake the raw milk sample thoroughly (25 times in 7 seconds through a 1 foot arc) and use within 3 minutes.
7. Avoiding the foam, pre-wet the pipet tip, then pipet 450 µl of raw milk directly into the bottom of the tube. Use a clean pipet tip and do not allow the liquid to drain down the side of the tube.
8. Agitate the sample tube to dissolve the pellet. Visually confirm that the blue reagent pellet is completely dissolved.
9. Place the sample tube in the heat block next to its SNAP device and incubate for 5 minutes. Use the timer.
10. Pour the entire contents of the sample tube into the well of its corresponding SNAP device. Touch off the last drop on a dry spot in the sample well and then discard the tube into a biohazard waste bag.
11. When the activation circle begins to turn from blue to white, push the activator firmly until it snaps flush with the body of the SNAP device. Do not let the activation circle turn completely white.
12. Wait 4 minutes, using the timer. The SNAP device remains in the heat block during this time.
13. Immediately remove the SNAP device from the heat block.
14. On the Snapshot reader enter “0000” for the sample identification, then insert the SNAP device into the reader and press “read”. If the result is negative, proceed with steps 3 through 17 of the test procedure described above.

CONDITIONS FOR AN INVALID TEST
1. At the completion of the test procedure, if any of the following conditions exist the test is invalid.
   a. The control spot fails to develop color
   b. Blue streaking occurs in the background
   c. The background is the same color as the sample or control spots
   d. The sample or control spots are not uniform in color or exhibit poor spot quality
2. If a test is invalid the sample should be retested with a new SNAP device. Do not put invalid tests in the Snapshot reader.

INTERPRETATION
1. If the result is negative for inhibitory substances, the milk may be accepted and processed.
2. If the result is positive for inhibitory substances:
   a. Place the milk on hold
   b. Refer to the Appendix N notebook for further instructions, paperwork, and state contact numbers.

RECORDKEEPING
1. Forms BFSLS 500, 513A, 513B, 534, and 537 must be completely filled out. Retain the output from the Snapshot printer with form BFSLS 500.
2. Prepare and submit a National Milk Drug Residue Data Base Report Form monthly.

REFERENCES
1. The latest revision of “Appendix N Bulk Milk Tanker Screening Test Form, IDEXX – New Snap® Beta Lactam for Raw Bovine Milk”.
2. The latest revision of “Appendix N Bulk Milk Tanker Screening Test Form, General Requirements”.
3. Appendix N, Section 6 of the Grade “A” Pasteurized Milk Ordinance.
4. Memoranda of information (M-i) and memoranda of interpretation (M-a).
5. SOP 012 Sample Collection

The following individual is responsible for implementation of this SOP and has the overall authority on-site:

Name: ____________________________ Title: __________________________ Date: _______________