DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MILK LABORATORY EVALUATION RECORD**	Laboratory Location	
Laboratory Evaluation Officer	Lab Number	Date *(mm/dd/yyyy)*

List of acceptable entries in columns: **Blank** = No deviations observed; **RO** = Item has been Reviewed or Observed (this entry is for temporary use only and must be replaced with another entry on final record); **X** = Deviation; **N** = Note; **O** = Not Used; **NA** = Not Applicable; **U** = Undetermined

APPENDIX N BULK MILK TANKER SCREENING TEST PROCEDURES
IDEXX - NEW SNAP® BETA-LACTAM TEST
(Raw Commingled Cow, Camel and 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 immersed); 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 ..... ___

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4. Reagents ..... ___
- a. SNAP Kit ..... ___
  - Lot #: _____ Exp. Date: _____ ..... ___
  - QC Date: _____ By: _____ ..... ___
  - 1. Sample tubes containing reagent pellet ..... ___
- b. Positive Control ..... ___
  - 1. IDEXX Penicillin G 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 ..... ___

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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 µL 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 3 d) for each sample/control **(Screening Only)** ..... ___
   a. Draw up 450 µL 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 ..... ___

Notes

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) ..... ___

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