

5100 Paint Branch Parkway  
College Park, MD 20740-3835

M-I-12-13

October 9, 2012

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Addition of a Claim for Camel Milk to the IDEXX Laboratories, Inc. New SNAP Beta-Lactam Test Kit

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the NCIMS accepted IDEXX Laboratories, Inc. New SNAP Beta Lactam Test Kit for raw, commingled camel milk

The FDA evaluation of the data, presented by IDEXX Laboratories, Inc., indicates that the performance of the test meets the standards established to determine the acceptance of a test for use in testing milk from an additional species, specifically raw, commingled camel milk. The extension of a claim for an additional species can only be conducted for a test kit that has already met the standards for use with raw, commingled cow's milk. These data have been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix N-Drug Residue Testing and Farm Surveillance of the *Grade "A" Pasteurized Milk Ordinance*.

The NCIMS Executive Board on July 30, 2012 accepted the use of this test when used as labeled. Attached is the letter of acceptance from FDA's CVM.

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

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

A handwritten signature in black ink, appearing to read "Robert F. Hennes". The signature is written in a cursive style with a large initial "R".

CAPT Robert F. Hennes, RS, MPH

Attachments: FDA CVM Memorandum of the acceptance of the test kit  
IDEXX New SNAP Test Kit Label Insert



Center for Veterinary Medicine  
Office of Research

Food and Drug Administration  
8401 Muirkirk Road  
Laurel MD 20708

Date: September 28, 2012

From: Philip James Kijak, Ph.D.

Subject: Addition of a Claim for Camel Milk to the IDEXX New SNAP Test Kit

To: Robert F. Hennes, Milk Safety Team

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the IDEXX New SNAP Beta-Lactam Test Kit for use in raw, commingled camel milk.

The study was coordinated by the American Camel Coalition and Camel Milk USA who also provided the control and incurred camel milk samples. The testing was conducted at an independent laboratory. The test kit manufacturer provided the test kits. The protocol for the study was reviewed and approved by CVM. The testing protocol was based on the CVM's "PROTOCOL FOR EVALUATION OF MILK RESIDUE SCREENING TESTS FOR USE WITH OTHER SPECIES".

The testing was done in four (4) groups, one (1) for each drug, with sixty (60) control samples in each group. For all sets of sixty (60) control samples tested, no false positive responses were observed. For the incurred samples, one (1) animal was dosed with penicillin and one (1) animal was dosed with Cephapirin. The milk from both animals was positive initially and becoming negative in the expected manner as the drugs depleted. No problems were observed. The test kit gave acceptable results with the incurred camel milk.

The results of the study were reviewed and accepted by the National Conference on Interstate Milk Shipment's (NCIMS) Laboratory Committee and the 2400 Series Form for the use of the IDEXX New SNAP Beta-Lactam Test Kit for raw, commingled camel milk was approved by the NCIMS Executive Board.

Based on the data generated, it is recommended that the IDEXX New SNAP Test Kit for Amoxicillin, Ampicillin, Ceftiofur, Cephapirin and Penicillin G, is suitable for testing raw, commingled camel milk

Philip J. Kijak  
Digitally signed by Philip J. Kijak  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Philip J. Kijak,  
0.9.2342.19.200300.100.1.1=1300044376  
Date: 2012.09.28 10:58:59 -0400

Philip James Kijak, Ph.D.  
Director, Division of Residue Chemistry  
CVM Office of Research

cc: CFSAN MST/LPET

Attachment: New SNAP Beta-Lactam Kit Label rev. 9/12

11. Remove the device from the heater block and visually inspect the control spot and sample spots.

The test is invalid and the same sample should be retested with a new SNAP device if:

- The control spot fails to develop color.
- Blue streaking occurs in the background or the background is the same color as the sample or control spots.
- The sample or control spots are not uniform in color or exhibit poor spot quality.

**NOTE:** Do not put invalid tests into the reader.



### C. Reading the Results

Results must be read within 30 seconds after final incubation. Insert the SNAP device and follow the instructions for reading (see the SNAPshot or SNAPshot DSR Reader manual for more details).

**NOTE:** Eight SNAP devices can be run simultaneously by one individual. More than eight devices may be run in staggered sets provided all devices are read within 30 seconds after final incubation.

#### Negative Sample

If the ratio is **below or equal to 1.05**, the reader will display a result of "N" or "Negative" and report as "Not Found."

#### Presumptive Positive Sample

If the ratio is **1.06 or higher**, the reader will display a result of "P" or "Positive."

#### Example of SNAPshot Reader Printout

Printout	Description
SNAPshot Reader SNAP Test (or SNAPshot DSR Reader SNAP Test)	Test Type
Beta-Lactam (5 ppb)	Date and Time
6/04/09 12:22 PM	Lot Number
Lot ID: 012345	Technician ID Number
Tech: 9876	Sample Number
Sample: 011	Ratio
Ratio: 0.79	Result
Results: Negative	

#### In the United States for NCIMS Testing:

- Upon initial screen, a positive result indicates an Initial Positive.
- For an invalid result, rerun the sample on a new SNAP device. Do not reinsert the same SNAP device.

#### Retest of Initial Positive Samples

- For milk samples yielding an Initial Positive result, promptly retest the SAME sample in duplicate as described in the Test Procedure section. Test a positive and a negative control along with the duplicate retest samples. **Do not test checksets.**
- The preparation of the positive and negative control samples is described in the **Checksets, Positive and Negative Controls in the United States for NCIMS Testing**<sup>®</sup> section.

**NOTE:** All NCIMS testing must be performed in accordance with Appendix N of the current PMO. All requirements of the PMO must be followed for all additional testing.

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### Interpretation of Retest Results

If the controls test correctly, negative results for both retest samples indicate a **Negative Result** (report as **Not Found**).



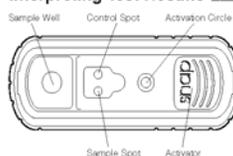
If the controls test correctly and one or both of the retest samples test **Positive**, the sample is a **Beta-lactam Presumptive Positive Test**. In accordance with Appendix N of the PMO, report all presumptive positives to the appropriate regulatory agency.

If either control does not test correctly, then repeat the assay. If either control still does not test correctly, do not continue testing. Contact the appropriate regulatory agency to determine milk status. Contact IDEXX Technical Services for technical assistance.

### Additional Test Information

Samples of this test kit model were independently evaluated by the AOAC Research Institute and were found to perform to the producer's specifications as stated in the test kit's descriptive insert. The producer certifies that this kit conforms in all respects to the specifications originally evaluated by the AOAC Research Institute as detailed in the PERFORMANCE TESTED certificate number 030302.

### Interpreting Test Results



- Negative Result**—The sample spot is darker than or equal to the control spot.
- Positive Result**—The sample spot is lighter than the control spot.

The SNAP test has been approved by AOAC-RI for visual interpretation without a reader. **The Visual Interpretation Procedure for the SNAP device is not acceptable for use in NCIMS milk-regulatory programs.**

**NOTE:** During the AOAC-RI independent evaluation of the New SNAP Beta-Lactam Test Kit, information was provided that demonstrates that the test kit can be used to test frozen milk. For samples that will be frozen, IDEXX recommends freezing and storing the samples at -15°C (5°F) or colder in a nonrost-free freezer. Samples with a noticeable protein precipitation after being thawed are not suitable for testing. Samples should not be stored longer than two months. **The testing of frozen samples is not acceptable for use in NCIMS milk-regulatory programs.**

For technical assistance, call IDEXX Technical Services  
at 1 800 321 0207 (within the U.S. or Canada)  
or 1 207 556 4496, Monday–Friday, 8:00 a.m.–5:00 p.m.

\*SNAP and SNAPshot are trademarks or registered trademarks of IDEXX Laboratories, Inc. or its affiliates in the United States and/or other countries.

Patent information: idexx.com/patents

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## New SNAP<sup>®</sup> Beta-Lactam Test Kit

(penicillin G, amoxicillin, ampicillin, ceftiofur and cephalixin)

Validated for raw, commingled cow and camel milk

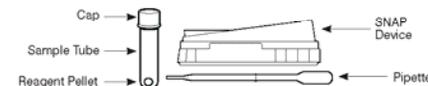


### Product and Intended Use

The New SNAP<sup>®</sup> Beta-Lactam Test is an enzyme-linked receptor-binding assay that detects penicillin G, amoxicillin, ampicillin, ceftiofur and cephalixin residues in raw, commingled cow and camel milk at or below established tolerance and/or safe levels (refer to the Performance Information section). This test also detects cloxacillin at a level above the established tolerance and/or safe level (refer to the Cross-Reactivity section). The top of the New SNAP Beta-Lactam device is marked with "NBL."

### Kit Components

- SNAP device
- Sample tube and cap
- Reagent pellet
- Pipette<sup>1</sup>



<sup>1</sup>Acceptable for Appendix N screening analysts only

### Components Required, But Not Provided (Available Through IDEXX Laboratories)

- Heater block capable of maintaining an operating temperature of 45°C (113°F) ±5°C
- For NCIMS testing, a SNAPshot<sup>®</sup> or SNAPshot<sup>®</sup> DSR Reader with a printer supplied by IDEXX capable of reading a SNAP device

**NOTE:** The New SNAP Beta-Lactam Test is approved only for use with the SNAPshot or SNAPshot DSR Reader for NCIMS testing.

- Positive and negative controls
- For NCIMS laboratories, a calibrated pipette.

### Receipt Condition

For NCIMS purposes, laboratories must receive tests with cold ice packs.

### Storage

All materials must be refrigerated at 0–7°C (32–45°F). Tests can be kept at room temperature (18–29°C/64–84°F) only during the day of use. Remove only the number of tests to be used for the day.

**NOTE:** Discard unused, unrefrigerated devices at the end of the day.

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## Performance Information

### Sensitivity

Parts per billion (ppb)	Dose Response Information				
	Amoxicillin	Ampicillin*	Cefbutor (as DCF)**	Cephapirin*	Penicillin*
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%		
Tolerance/Safe Level (ppb)	10	10	100	20	5
Calculated 90/95% Concentration (ppb)	7.3	5.8	12	11.7	3.0

\*The drugs indicated with an asterisk (\*) have demonstrated a 90/95% sensitivity of this test kit, which is at least 25% less than the tolerance or safe level. Sole reliance on the use of this test kit may result in the rejection of milk that the FDA considers safe for human consumption.

\*\*The test sensitivity for cefbutor was evaluated using milk containing cefbutor and desbutoylcefbutor-related metabolites from treated animals. The cefbutor tolerance is based on measuring the sum of cefbutor- and desbutoylcefbutor-related metabolites in milk as desbutoylcefbutor.

Data presented as percent positive at each concentration.

SENSITIVITY: Based on 30 samples at each milk concentration.

Listed dose response information and calculated 90/95% concentrations are based on cow milk studies. The validation of approved cow's milk kits for additional species is based on an unreviewed study that does not provide full dose response information for the listed drugs with no information on cefbutor. The information provided is sufficient to ensure that the test kit will detect drugs in camel's milk at or below the listed tolerance/safe levels for cow's milk.

### Selectivity

Sixty negative control milk samples were evaluated in an independent laboratory and none of these negative control samples tested positive with SNAP.

### Cross-Reactivity

The New SNAP Beta-Lactam Test Kit cross-reacts with the following drugs at the levels indicated:

	10 ppb	50 ppb	100 ppb
Cloxacillin	0%	100%	100%
Dicloxacillin	0%	100%	100%
Ticarcillin	0%	100%	100%
Cefadroxyl	100%	100%	100%

The New SNAP Beta-Lactam Test Kit *does not cross-react* with the following drugs at levels up to 100 ppb: sulfadiazine, sulfanilamide, sulfathiazole, sulfamethazine, sulfapyridine, sulfadimethoxine, tetracycline, oxytetracycline, chlortetracycline, doxycycline, gentamicin, neomycin, streptomycin, ivermectin, erythromycin, novobiocin, fursemide, trichlormethiazide, chlorothiazide, oxytocin, phenylbutazone, dexamethasone, dipyrone, pirlimycin, tilimicosin, thiabendazole and p-aminobenzoic acid (PABA).

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### Training

The New SNAP Beta-Lactam Test is recommended for use by personnel who have received training by an IDEXX representative. In the United States under NCIMS recommendations, trained individuals should maintain proficiency by regular use and/or state-sponsored training/certification programs. Individuals who have not run a SNAP device in the past six months or who desire additional training should contact IDEXX Technical Services at 1 800 321 0207.

### Operating Instructions

For all NCIMS testing, refer to the current 2400 for IDEXX New SNAP Beta-Lactam (Appendix N Bulk Milk Tanker Screening Test Form).

### Sample Information

- Raw, commingled cow or camel milk must be used.
- Samples must be refrigerated and testing must be completed within 72 hours of sampling.
- Thoroughly mix the sample before testing.
- For NCIMS purposes, milk samples cannot be frozen at any time. The testing of milk samples must be completed within 72 hours of sampling. Completed includes the time from initial test, any necessary retesting of the initial positive, confirmation and/or producer traceback testing.

### Precautions and Warnings

- Do not mix sample tubes and devices from different lot numbers.
- Do not use kits past their expiration dates.
- The SNAP device must be run in a horizontal position.

### Checksets, Positive and Negative Controls in the United States for NCIMS Testing

Positive and negative controls must be run daily prior to testing samples, and with each new lot to verify the performance of the reagents and equipment. Read positive and negative checkset devices. Both devices must read within the limits on the checkset devices.

**NOTE:** Use the checkset with the black skirt for the SNAPshot Reader. Use the checkset with the blue skirt for the SNAPshot DSR Reader.

#### Negative Control (must be run daily):

Use beta-lactam-negative raw milk; milk used for negative control purposes should read less than 0.95 on the IDEXX SNAPshot Reader. Negative control milk can be stored frozen for later use by aliquot and freezing at -15°C (5°F) or colder in a nonfrost-free freezer or in styrofoam container in a frost-free freezer. It must be used within 60 days. Thaw frozen milk at 0-4.4°C. Once thawed, mix thoroughly and do not use the aliquot if noticeable protein precipitation is present after thawing. Thawed negative control milk must be held at 0-4.4°C and can be used for 24 hours. Do not use beyond 24 hours. Milk controls may not be refrozen.

#### Positive Control (must be run daily):

Use the IDEXX Penicillin Positive Control, part #98-06513-00, as directed in the descriptive insert that accompanies the product. The positive control should read greater than 1.2 on the IDEXX SNAPshot Reader.

**NOTE:** If these conditions are not met, rerun the controls. If still not acceptable, contact IDEXX Technical Services.

For technical assistance, call IDEXX Technical Services at 1 800 321 0207 (within the U.S. or Canada) or 1 207 556 4496.

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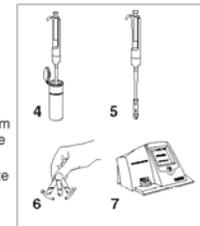
### Test Preparation

- SNAP devices can be kept at room temperature during the day of use.
- A daily temperature check is required. Ensure that the heater block has been preheated and that the temperature has maintained 45°C (113°F) ±5°C for at least five minutes.
- Remove the SNAP device, pipette and sample tube from the bag.
  - NOTE:** An unused SNAP device should have a light-blue control spot, sample spot and activation circle. If the device does not have light-blue control and/or sample spots, discard the device and open a new SNAP device.
- Verify that the reagent pellet is at the bottom of the sample tube. If not, tap the tube to return the pellet to the bottom.
- Shake the milk sample thoroughly.

### Test Procedure

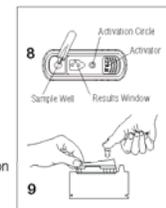
#### A. Preparing the Sample

- Place the SNAP device in the preheated heater block. The device must remain in the heater block for the duration of the test.
- Shake the milk sample thoroughly.
- Remove and discard the sample tube cap.
- With the IDEXX pipette (acceptable for Appendix N screening analysts) or if using a calibrated pipette as pictured (required for NCIMS-certified laboratories), draw up the milk sample (450 µL ±50 µL) to the indicator line.
  - TIP:** When pipetting, take the sample from the middle of the sample container, pipetting away from any bubbles, and slowly draw up the sample to the indicator line on the pipette to avoid air bubbles.
- Carefully add all of the milk sample from the pipette to the tube.
- Shake the sample tube to dissolve the reagent pellet.
- Incubate the sample tube in the heater block at 45°C (113°F) ±5°C for five minutes.
  - NOTE:** Incubation must occur for a minimum of five minutes and no longer than six minutes.



#### B. Testing the Sample

- Pour the entire contents of the sample tube into the sample well of the SNAP device and discard the tube.
  - NOTE:** The sample will flow across the results window toward the blue activation circle.
- When the blue activation circle BEGINS to disappear, push the activator FIRMLY until it snaps flush with the body of the SNAP device.
  - NOTE:** When the edge of the activation circle nearest the sample well begins to turn from dark blue to white, activation should occur. Do not let the circle completely disappear.
- Wait four minutes.
  - NOTE:** The SNAP device must remain in the heater block during color development.



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