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:



- b. Blue streaking occurs in the background or the background is the same color as the sample or control spots.
- c. 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 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 Beta-Lactam (5 ppb) Test Type 6/04/06 12:22 PM Date and Time 012345 Lot Number Lot ID: 9876 Technician ID Number Tech: Sample: 011 Sample Number Ratio: 0.79 Ratio **Results:** Negative Result

### 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" 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.

### 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<sup>K</sup> certificate number 030302.

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

test frozen milk. For samples that will be frozen, IDEXX recommends freezing and

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-monitoring programs.

storing the samples at -15°C (5°F) or colder in a nonfrost-free freezer. Samples with

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.

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## **Interpreting Test Results**



for use in NCIMS milk-monitoring programs.

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.

# **IDEXX** Laboratories)

# **Receipt Condition**

### Storage

All materials must be refrigerated at  $0^{\circ}-7^{\circ}C$  ( $32^{\circ}-45^{\circ}F$ ). 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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LICENSE NUMBER 030302

The New SNAP\* Beta-Lactam Test is an enzyme-linked receptor-binding assay that detects penicillin G, amoxicillin, ampicillin, ceftiofur and cephapirin residues in raw, commingled cow 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 base of the New SNAP Beta-Lactam Test is marked with "NBL."

# Kit Components

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

LABORATORIES

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<b>New SNAP<sup>*</sup> Beta-Lactam Test Kit</b> (penicillin G, amoxicillin, ampicillin, ceftiofur and cephapirin) Validated for raw, commingled cow milk	snap*

# Product and Intended Use



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

# **Components Required (Not Provided: Available through**

 Block heater capable of maintaining an operating temperature of 45°C (113°F) ±5°C For NCIMS testing, a SNAPshot\* 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 Reader for NCIMS testing.

Positive and negative controls

For NCIMS-certified laboratories, a calibrated pipette is required.

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

# Performance Information

### Sensitivity

#### Dose Response Information

Parts per billion (ppb)	Amoxicillin	Ampicillin*	Ceftiofur (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 ceftiofur was evaluated using milk containing ceftiofur- and desfuroylceftiofur-related metabolites from treated animals. The ceftiofur tolerance is based on measuring the sum of ceftiofur- and desfuroylceftiofur-related metabolites in milk as desfurov/ceftiofur

Data presented as percent positive at each concentration.

SENSITIVITY: Based on 30 samples at each milk concentration

### 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, furosemide, trichlormethiazide, chlorothiazide, oxytocin, phenylbutazone, dexamethasone, dipyrone, pirlimycin, tilmicosin, thiabendazole and p-aminobenzoic acid (PABA).

### 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 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 and the testing must be completed within 72 hours of sampling.

### **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.

### 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 and 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.

# **Test Preparation**

- least five minutes.

# Test Procedure

#### A. Preparing the Sample

**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.

- to the tube.
- reagent pellet.

## B. Testing the Sample

- 10. Wait four minutes.

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

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.

1. Place the SNAP device in the preheated heater block. The device must remain in the heater block for the duration of the test.

2. Shake the milk sample thoroughly.

3. 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  $\mu$ L ±50  $\mu$ L) to the indicator line.

5. Carefully add all of the milk sample from the pipette

6. Shake the sample tube to dissolve the

7. 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

8. 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.

9. 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.

NOTE: The SNAP device must remain in the heater block during color development.



