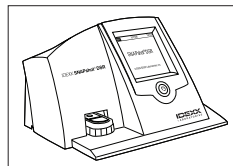


11. Remove the device from the heater block and visually inspect the control spot and sample spots.

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)	
Beta-Lactam (5 ppb)	Test Type
6/04/09 12:22 PM	Date and Time
Lot ID: 012345	Lot Number
Tech: 9876	Technician ID Number
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**).

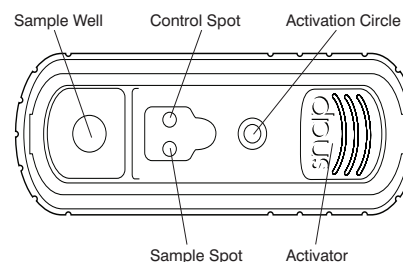
If the controls test correctly and one or both of the retest samples test **Positive**, the sample is a “**Beta-lactam Presumptive Positive Test.**” In accordance with Appendix N of the PMO, report all presumptive positives to the appropriate regulatory agency.

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 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 nonfrost-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

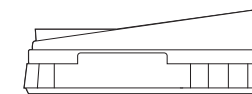
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Tel: 1 207 556 4496 or 1 800 321 0207 • Fax: 1 207 556 4630

New SNAP* Beta-Lactam Test Kit

(penicillin G, amoxicillin, ampicillin, ceftiofur and cephalosporin)
Validated for raw, commingled cow, camel and goat milk

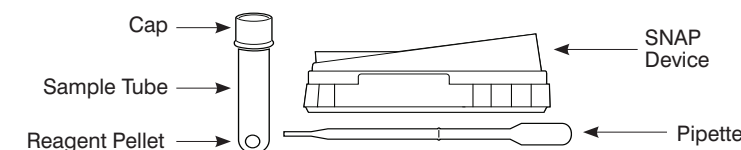


Product and Intended Use

The New SNAP* Beta-Lactam Test is an enzyme-linked receptor-binding assay that detects penicillin G, amoxicillin, ampicillin, ceftiofur and cephalosporin residues in raw, commingled cow, camel and goat 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†



†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* or SNAPshot* 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 within 72 hours when shipped ambient. Refrigerate immediately upon receipt.

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.

Performance Information

Sensitivity

Parts per billion (ppb)	Dose Response Information				
	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 desfuroylceftiofur.

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 abbreviated study that does not provide full dose response information for the listed drugs with no information on ceftiofur. The information provided is sufficient to ensure that the test kit will detect drugs in camel's and goat'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%
Ticarillin	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, camel or goat 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 0–4.5°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 0–4.5°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.

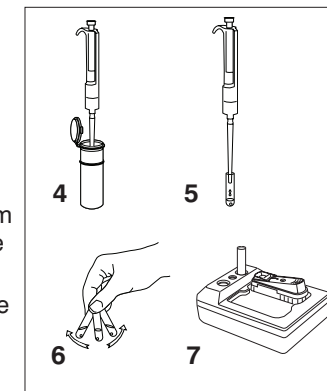
Test Preparation

- 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.

