Importance of ß-lactams & Tetracyclines Determination

Antibiotic residues in foods pose a serious threat to public health. ß-lactams and tetracyclines are broad spectrum antibiotics used for the treatment and prevention of many bacterial infections. Both categories are widely used in food production, however over use can lead to antibiotic resistance. The monitoring of water sources and food products, such as meat, milk and honey, for antibiotic residues is necessary to ascertain that these compounds are not misused and do not present a danger to human or animal health.

To protect humans, regulatory agencies around the world have imposed regulatory limits regarding the amount of ß-lactams & Tetracyclines that are allowable in human and animal foods. The Unitied States of America has enacted maximum levels for milk (raw milk, milk used in the production of milk based products and heat treated milk): 5-10 ppb for ß-lactams and 300 ppb for tetracyclines.The European Union has enacted maximum levels for milk (raw milk, milk used in the production of milk based products and heat treated milk): 4 ppb for ß-lactams and 100 ppb for tetracyclines.

Performance Data

Sensitivity:

Antibiotics	USA Tolerance/Safe Limit	EU Tolerance/Safe Limit	Strip Sensitivity
ß-lactams			
Penicillin G	5 ppb	4 ppb	2 ppb
Ampicllin	10 ppb	4 ppb	4-8 ppb
Amoxicillin	10 ppb	4 ppb	4-8 ppb
Tetracyclines			
Tetracycline	300 ppb	100 ppb	30-45 ppb
Oxytetracycline	300 ppb	100 ppb	80-90 ppb

General Limited Warranty: Abraxis LLC warrants the products manufactured by the Company, against defects and workmanship when used in accordance with the applicable instructions for a period not to extend beyond the product's printed expiration date. **Abraxis makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.**

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ß-lactams & Tetracyclines

A Screening Test for Rapid Detection of ß-lactams & Tetracyclines in Milk Samples

Product No. 522540

1. General Description

The Abraxis ß-lactams & Tetracyclines Strip Test is designed solely for the preliminary screening of milk samples. This test is suitable for the qualitative screening of ß-lactams at 2 - 4 ppb & Tetracyclines at 30 ppb in milk (see Sample Preparation, Section D). Other conventional methods, such as ELISA, HPLC, or GC/MS, should be used to obtain quantitative results or to confirm positive samples.

2. Safety Instructions

Discard samples according to local, state, and federal regulations.

3. Storage and Stability

The ß-lactams & Tetracyclines Strip Test components and reagents should be stored in refrigerator (4-8°C). Protect from light and moisture. Reagents may be used until the expiration date on the box.

4. Test Principle

The ß-lactams and tetracyclines test strip consists of a membrane strip containing a ß-lactam conjugate and tetracycline conjugate. A Control Line, produced by a different receptor-conjugate reaction, is also present on the membrane strip. The microtiter wells contain colloidal gold labeled receptor, which are preincubated with the milk sample. The colloidal gold labeled receptors move with the milk sample by capillary action along the membrane. In the absence of ß-lactams and/or tetracyclines in the milk sample, the colloidal gold labeled receptor contacts the immobilized ß-lactam and/or tetracycline conjugate on the strip. A reaction occurs forming a visible line. The Control Line is not influenced by the presence or absence of ß-lactams and/or tetracyclines in the milk sample, and therefore, should be present in all reactions. The formation of three visible lines of the same intensity indicates a negative result. If ß-lactams and/or Tetracyclines are present in the milk sample, they compete with the immobilized ß-lactam and/or Tetracycline conjugate in the test area for binding sites on the colloidal gold labeled antibody. If a sufficient amount of ß-lactams and/or Tetracyclines are present in the milk sample, it will fill all of the available binding sites, thus preventing attachment of the labeled receptor to the immobilized ß-lactam and/or Tetracycline conjugate and, therefore no line will develop. If a colored line is not visible in the Test Line region, or if the Test Line is significantly lighter than the Control Line, the milk sample is positive.

5. Limitations of the ß-lactams & Tetracyclines Strip Test

The ß-lactams & Tetracyclines Strip Test is designed for use with milk samples.

Mistakes in handling the test can cause errors. Possible sources for such errors include: inadequate storage conditions of the test strip or reagents, inaccurate volumes of sample, extract or reagents, too long or too short incubation times, and extreme temperatures (lower than 10°C or higher than 30°C) during the test performance.

The Abraxis ß-lactams & Tetracyclines Strip Test provides preliminary qualitative screening results. Reasonable judgment should be applied to any test results, particularly when preliminary positive results are obtained. Other conventional methods, such as ELISA, HPLC, or GC/MS should be used to obtain quantitative results or to confirm positive samples.

A. Warnings and Precautions

1. Prior to use ensure that the product has not expired by verifying that the date of use is prior to the expiration date on the label.
2. Unused microtiter wells should be resealed in the packet with desiccant and stored protected from light and moisture.
3. Use reasonable judgment when interpreting results.
4. As the sample or extract runs through the test strip, the membrane may become tinted pink. This does not invalidate the test or cause inaccurate results.

B. Reagents and Materials Provided

1. 6 packets, each containing 8 test strips and 8 microtiter wells coated with colloidal gold labeled enzyme-linked receptors (total 48 tests)
2. 12 X 8 microtiter well holder
3. Disposable droppers

C. Additional Reagents and Materials (not provided)

1. Timer
2. Micropipette (1000 μL) with disposable tips

D. Sample Preparation

1. *Milk* - Adjust to room temperature. Proceed to Strip Test Procedure, Section E.

Note: do not use abnormal looking milk or expired samples.

E. Strip Test Procedure

1. Prepare sample according to Sample Preparation instructions (Section D).
2. Open the packet containing the 8-test strips and the microtiter 8-well strip. Remove the required number of wells (1 per sample) and place in holder. Use within one hour. Place the remaining wells in the container and reseal.
3. Using the dropper, add 6 drops (approx. 200 μL) of the sample into the well containing the receptor enzyme reagent and mix by aspirating and expelling from the dropper.
4. Sufficiently dissolve the reagent within the milk in 5 minutes until the sample milk becomes a consistent pink color.
5. Insert the blue stripe end of test strip into the sample well and allow the sample to diffuse through the strip.
6. Remove strip and interpret the results *within 5 minutes* according to the Interpretation of Results criteria (Section F).

F. Interpretation of Results

C = Control Line
B = ß-Lactams
T = Tetracyclines
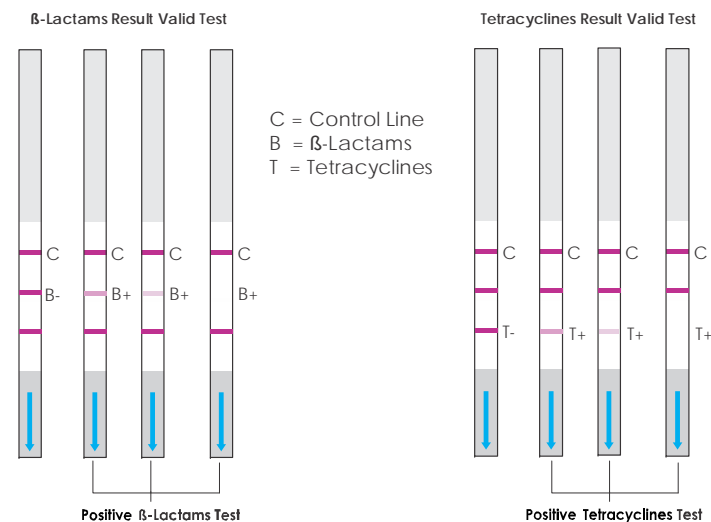
ß-lactam Negative: B line darker than or equal to C line.

Tetracycline Negative: T line darker than or equal to C line.

ß-lactam Negative & Tetracycline Negative: B & T lines are present and darker than or equal to C line.

ß-lactam Positive*: B line is not present or lighter than C line.

Tetracycline Positive*: T line is not present or lighter than C line.

Invalid: C line not present.

*See "Performance Data" for the range of sensitivity ppb (ng/mL) values obtained with the strip on the last page.

Note: Control line is a quality indicator and always present. If the control line is not present it is an invalid test. Please repeat assay with a new strip. Illustration is for demonstration of test line intensity range only, since overall intensity may vary slightly with different lots of reagents, samples, extracts, etc. Results should be determined *within 5 minutes* after completion of the strip test procedure. Interpretation of the results beyond the 5 minutes may produce inaccurate results.