

Operator's Manual: Charm® MRL Beta-lactam and Tetracycline DIP Test for Raw Commingled Cow Milk

Kit Information

Introduction

The Charm MRL Beta-lactam and Tetracycline DIP Test is an immunoreceptor assay utilizing lateral flow technology. Beta-lactam and tetracycline drugs interact with colored beads in the lateral flow test strip, and the color intensity in the test and control zones is read visually. The test is designed for use by dairy, intake, laboratory, field, and regulatory personnel.

Kit Contents and Materials Needed

Supplied with Kits	Equipment
<ul style="list-style-type: none"> DT-MRLBLTET DIP Test Strips 300 µL Pipets Sample Vials Operator's Manual 	<ul style="list-style-type: none"> Charm DIP Test Incubator 300 µl Pipet (optional)

Charm DIP Test equipment available only from Charm Sciences Inc.
For details and ordering information see **Order Codes and Kit Contents**.

Sensitivity and Selectivity

Beta-lactam and tetracycline-free raw milk yields negative results at least 99% of the time.

Table 1. Sensitivity – Detection Ranges in Cow Milk at 0 to 7°C

Beta-lactam Drug	Detection Range [†] (ppb*)	EU / CODEX MRL (ppb*)	Tetracycline Drug	Detection Range [†] (ppb*)	EU / CODEX MRL (ppb*)
Amoxicillin	2 to 3	4	Chlortetracycline	25 to 75	100 / 100
Ampicillin	2 to 3	4	Doxycycline	50 to 100	None ^ø
Cefacetrole	25 to 50	125	Oxytetracycline	20 to 60	100 / 100
Cefalonium	2 to 4	20	Tetracycline	25 to 75	100 / 100
Cefazolin	8 to 10	50			
Cefoperazone	1 to 2	50			
Cefquinome	10 to 20	20			
Ceftiofur and Metabolites [^]	25 to 50	100 / 100			
Cefuroxime	75 to 100	None			
Cephapirin	4 to 8	60 [§]			
Cloxacillin	3 to 6	30			
Dicloxacillin	2 to 4	30			
Nafcillin	20 to 30	30			
Oxacillin	3 to 6	30			
Penicillin G	1 to 3	4 / 4			

[†] Positive at least 95% of the time.
* parts per billion, µg/kg or µg/L
[^] Ceftiofur parent drug sensitivity is approximately 1/2 that reported in the table.
[§] U.S. tolerance is 20 ppb cephalosporins.
^ø Not for use in animals from which milk is produced for human consumption.

Storage

Store DT-MRLBLTET DIP test strips refrigerated (defined as 0 to 7°C or 0 to 4.5°C for US certified labs). See **Reagents and Storage** for details.

Charm Sciences, Inc.

659 Andover Street, Lawrence, Massachusetts, 01843-1032, USA
Tel: +1.978.687.9200 | Fax: +1.978.687.9216 | Email: info@charm.com | www.charm.com
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Interferences and Cross Reactivity

There are no known interferences from drugs at 100 ppb in the following animal drug families: aminoglycosides, amphenicols, fluoroquinolones, macrolides/lincosamides, nitrofurans, sulfa drugs/sulfonamides, or chlorothiazide, dexamethasone, dipyrone, flunixin, furosemide, ivermectin, novobiocin, oxytocin, PABA, phenylbutazone, trichlormethiazide, and thiabendazole. Other beta-lactam and tetracycline drugs are detected. There are no interferences from somatic cells at 10^6 SCC/ml or bacteria at 3×10^5 CFU/ml.

Training

- For questions contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com.

Reagents and Storage

Test Strips

- Store test strips refrigerated in tightly closed supplied foil bag.
- In high humidity, limit condensation by opening bag after it has warmed to room temperature (20 to 30 minutes from the time the container is removed from refrigerator).
- Inspect desiccant indicator in test strip bag. Beads inside desiccant packets should be blue. Do not use test strips if blue beads have turned purple or pink.
- Remove from bag the number of test strips to be used in one day and return container to refrigerated storage.
- Keep removed test strips at room temperature during daily use for up to 2 hours. Unused test strips should be discarded.

Negative Control

- Use beta-lactam and tetracycline negative raw, commingled milk as a Negative Control for performance monitoring and to reconstitute Positive Tablet for use as the Positive Control.
- Qualified Negative Control should yield a strong visual negative (both lower test lines are darker than upper control line). See **Interpretation**.
- Store Negative Control refrigerated for up to 72 hours.
- See **Retest of Initial Positive** for Negative Control performance specifications.
- Use 300 μ L of Negative Control in Step 2 of **Procedure**.

Positive Control (purchased separately)

- Use MRLBLTET/TET Positive Tablet to make a 4.0 ± 0.4 ppb penicillin G and 100 ± 20 ppb oxytetracycline Positive Control for performance monitoring.
- Store Positive Tablets refrigerated in the closed zip-lock moisture resistant foil bag provided.
- Reconstitute one Positive Tablet with 5.0 mL of Negative Control (see above). Shake well. Allow to stand refrigerated or on ice for 5 minutes. Mix before use.
- Positive Control should yield strong visual positive (both lower test lines are lighter than upper control line). See **Interpretation**.
- Store reconstituted Positive Control refrigerated for up to 48 hours.
- Use 300 μ L of Positive Control in Step 2 of **Procedure**.

Performance Check

- Test one Negative Control and one Positive Control prior to testing actual samples to verify performance of test strips.
- If Controls do not perform as specified, discontinue use and contact Charm Sciences for assistance.

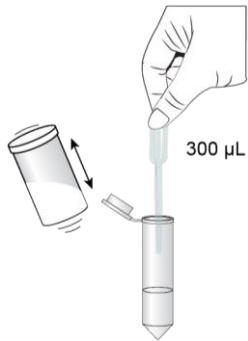
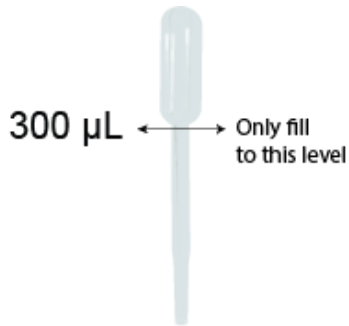
Precautions

- High fat samples (greater than 6.5%) may cause invalid results including false negatives at Detection Range levels.

Sample and Test Information

- Raw, commingled milk must be cool (0 to 15 °C) for testing.
- Test refrigerated samples within 5 days of milking.
- Test may be performed at ambient temperatures of 10 to 30 °C in naturally circulating air.

DT-MRLBLTET Test for Milk – Procedure



Step 1

- **Mix all samples well before testing.**

Step 2

- Using supplied 300 µL pipet, draw up sample to the top of the tube / bottom of the bulb. Avoid foam and bubbles.
- Holding pipet vertically, **pipet 300 µL** ($\pm 15 \mu\text{L}$) sample or Control into sample vial.

Step 3

- Place vial into $56 \pm 1 \text{ } ^\circ\text{C}$ DIP Test incubator.

Step 4

- Add DIP test strip (arrows pointing down) into vial with sample or control.

Step 5

- Allow the sample or Control to wick up the test strip for 10 minutes.

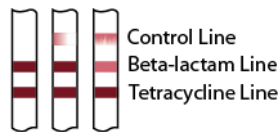
Step 6

- Remove strip from vial. Interpret results.

Interpretation

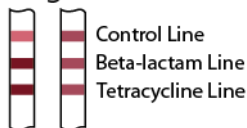
Hold test strip 30 to 60 cm away with arrows pointing down. Compare each lower test line intensity to upper Control line intensity.

Invalid



Invalid – Upper control line is absent, partial, or unevenly colored, or either lower test line is smeared. Test result is invalid and sample should be retested.

Negative



Negative - Both lower Beta-lactam and Tetracycline test lines are **same as or darker** than upper Control line.

Positive



Positive – **Either or both** lower Beta-lactam and Tetracycline test line is clearly **lighter** than upper Control line, or test line(s) is absent.

Order Codes and Kit Contents

KITS

DT-MRLBLTET-20K:

- (1) foil bag of 20 DT-MRLBLTET test strips
- (20) 300 µL pipets
- (20) sample vials
- (1) Operator's Manual

NOT SUPPLIED WITH KIT

DT-INC4-NT-56 (4 place Charm DIP Test Incubator, 56°C)

LF-PGOT-5-TBLK (five MRLBLTET/TET Positive Tablets, 4 ppb Penicillin G and 100 ppb Oxytetracycline)

Warranty Information

Charm Sciences, Inc. ("Charm") warrants each reagent product, including but not limited to test kits, to be free from defects in materials and workmanship and to be free from deviations from the specifications and descriptions of Charm's reagent products appearing in Charm's product literature, when stored under appropriate conditions and given normal, proper and intended usage, until the expiration of such reagent product's stated shelf life, or, if none is stated, for one year from the date of delivery of such reagent product to the end-user purchaser. **THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER STATUTORY, EXPRESS, IMPLIED (INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE).** The warranty provided herein may not be altered except by express written agreement signed by an officer of Charm. Representations, oral or written, which are inconsistent with this warranty are not authorized and if given, should not be relied upon. In the event of a breach of the foregoing warranty, Charm's sole obligation shall be to replace any reagent product or part thereof that proves defective in materials or workmanship within the warranty period, provided the customer notifies Charm promptly of any such defect prior to the expiration of said warranty period. The exclusive remedy provided herein shall not be deemed to have failed of its essential purpose so long as Charm is willing to replace any nonconforming reagent product or part. **Charm shall not be liable for consequential, incidental, special or any other indirect damages resulting from economic loss or property damages sustained by any customer from the use of its reagent products.** Except for Charm's obligation set forth above to replace any reagent product that proves defective within the warranty period, Charm shall not be liable for any damages of any kind arising out of or caused by any incorrect or erroneous test results obtained while using any such reagent product, whether or not caused by a defect in such reagent product.