



Operator's Manual (for Canada):

Charm MRL TRIO Test for Beta-lactams, Sulfonamides, and Tetracyclines in Raw Commingled Cow Milk

Kit Information

Introduction

The Charm MRL TRIO® Test is an immunoreceptor assay utilizing Rapid One Step Assay (ROSA®) lateral flow technology. Beta-lactams, sulfonamides, and tetracyclines interact with colored beads in the lateral flow test strip, and the color intensity in the test and control zones is read visually or measured by the Charm EZ® System. The MRL TRIO test detects beta-lactams, sulfonamides, and tetracyclines at or below the US Target Level/Tolerance and Canadian MRL (Maximum Residue Limit), refer to Table 1. The test is designed for use by dairy, intake, laboratory, field, and regulatory personnel.

Kit Contents and Materials Needed

Supplied with Kits	Disposables	Equipment
<ul style="list-style-type: none"> MRL TRIO Test Strips TRIO Positive Tablet (supplied with 100K only) Operator's Manual 	<ul style="list-style-type: none"> Pipet Tips or ROSA Pipets 	<ul style="list-style-type: none"> Charm EZ System Printer (optional) 300 µL Pipet (optional) ROSA Incubator (optional)

Charm equipment available only from Charm Sciences, Inc.

Positive control may be purchased separately as needed [LF-TRIO-PT-1-TBL].

Storage

Store MRLTRIO test strips and TRIO Positive Tablet refrigerated (defined as 0 to 7°C or 0 to 4.5°C for US certified labs). See **Reagents and Storage** for details.

Sensitivity and Selectivity

Beta-lactam, sulfonamide, and tetracycline free raw milk yields negative results at least 90% of the time with 95% confidence. Independent laboratory evaluation false positive rate was less than 0.3% (2 positives of 690 negative tests).

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

Beta-lactam Drug	Detection Level† (ppb*)	US Target Level or Tolerance / Canadian MRL (ppb*)	Sulfonamide Drug	Detection Level† (ppb*)	US Target Level or Tolerance / Canadian MRL (ppb*)
Amoxicillin ^Ω	3.5	10 / None	Sulfadimethoxine	2.2 [∞]	10 / 10 [∞]
Ampicillin	8.8	10 / 10	Sulfamethazine	6.2	10 / 10 [∞]
Ceftiofur and Metabolites [^]	50	100 / 100	Tetracycline Drug	Detection Level† (ppb*)	US Target Level or Tolerance / Canadian MRL (ppb*)
Cephapirin	14.5	20 / 20	Chlortetracycline	34	300 / 100
Cloxacillin	8.5	10 / None	Oxytetracycline	53	300 / 100
Penicillin G	2.0	5 / 6 ^{&}	Tetracycline	42	300 / 100

† Positive at least 90% of the time with 95% confidence as determined by probit analysis of independent laboratory dose response.

* parts per billion or ng/mL.

^Ω Amoxicillin is hypersensitive to US Tolerance. The US NCIMS criteria of detecting within 50% of Tolerance is not met; therefore, US confirmation of beta-lactam drug presumptive positives is performed with Charm 3 SL3 Beta-lactam Test.

[^] Ceftiofur parent drug sensitivity is approximately 1/2 that reported in the table.

[&] Canadian MRL for penicillin G is 0.01 IU/mL, equivalent to 6 ppb.

[∞] Canadian MRL for sulfonamides are singly or in combination with other MRL listed sulfonamides. MRL TRIO Test is hypersensitive to sulfadimethoxine Canadian MRL.

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Table 2. Sensitivity – Percent of Detection (POD) [†] of 30 replicates at each concentration in Cow Milk						
Beta-lactam Drug	Level Tested (ppb*)	POD [†] Percent Positive	Sulfonamide Drug	Level Tested (ppb*)	POD [†] Percent Positive	
Amoxicillin	1.0	3%	Sulfadimethoxine	1.0	33%	
	2.0	60%		2.0	97%	
	3.0	97%		3.0	100%	
	4.0	100%		4.0	100%	
	6.0	100%		10.0	100%	
	8.0	100%		Sulfamethazine	2.0	0%
	10.0	100%			4.0	67%
Ampicillin	2.0	0%	Tetracycline Drug	6.0	97%	
	4.0	3%		8.0	97%	
	6.0	70%		10.0	100%	
	8.0	97%		Level Tested (ppb*)	POD[†] Percent Positive	
	10.0	100%				
Ceftiofur and Metabolites [^]	20	0%	Chlortetracycline	10	10%	
	40	27%		20	63%	
	50	93%		40	83%	
	60	100%		60	97%	
	80	100%		100	100%	
	100	100%		120	97%	
Cephapirin	4.0	0%	Oxytetracycline	180	100%	
	8.0	30%		240	100%	
	12.0	90%		300	100%	
	16.0	100%		30	7%	
	20.0	100%		40	30%	
Cloxacillin	2.0	0%	Tetracycline	50	63%	
	4.0	33%		60	93%	
	6.0	80%		80	100%	
	8.0	100%		100	100%	
	10.0	100%		120	100%	
Penicillin G	0.5	0%		180	100%	
	1.0	0%		240	100%	
	1.25	10%		300	100%	
	1.5	40%		15	60%	
	2.0	93%		20	97%	
	3.0	100%		30	100%	
	4.0	100%		60	100%	
	5.0	100%		100	100%	
[†] Percent of 30 replicates that test positive at each concentration determined by manufacturer. [*] parts per billion or ng/mL. [^] Ceftiofur parent drug sensitivity is approximately 1/2 that reported in the table.			120	100%		
			180	100%		
			240	100%		
			300	100%		

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, chlorothiazide, dexamethasone, dipyrone, flunixin, furosemide, ivermectin, minocycline, novobiocin, oxytocin, PABA, phenylbutazone, sulfabenzamide, sulfacetamide, sulfadoxine, sulfaguanidine, sulfanilamide, sulfanitran, sulfisoxazole, trichlormethiazide, and thiabendazole. Other beta-lactams, sulfonamides, and tetracyclines are detected; see Table 3, Intra-family Cross Reactivity.

There are no interferences from somatic cells at 10⁶ SCC/mL or bacteria at 3 x 10⁵ CFU/mL.

Table 3. Intra-family Cross Reactivity – Detection Level† in Cow Milk at 0 to 7°C

Beta-lactam Drug	Detection Level† (ppb*)	Sulfonamide Drug	Detection Level† (ppb*)
Cefacetile	30	Sulfachlorpyridazine	1
Cefadroxil	750	Sulfadiazine	5
Cefalexin	750	Sulfaethoxypyridazine	7
Cefalonium	10	Sulfamerazine	4
Cefazolin	20	Sulfamethizole	2
Cefoperazone	2	Sulfamethoxazole	8
Cefquinome	40	Sulfamethoxypyridazine	5
Cefuroxime	125	Sulfapyridine	8
Dicloxacillin	10	Sulfaquinoxaline	8
Nafcillin	100	Sulfathiazole	1
Oxacillin	25	Tetracycline Drug	Detection Level† (ppb*)
Penethamate	2^	Doxycycline	250
Piperacillin	1		

† Positive with high confidence.

* parts per billion or ng/mL.

^ Penethamate is rapidly converted to benzylpenicillin (penicillin G), the marker residue.

Training

- Equipment setup and use can be self-taught from the manual.
- Proficiency samples are available for validation.
- 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 container.
- To open test strip container, remove and save plastic lid with foil lined foam insert to reseal container. Lift foil tab and peel foil seal off container. Completely remove and discard foil seal.
- In high humidity, limit condensation by opening container 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 container. Beads inside desiccant packets should be blue. Do not use test strips if blue beads have turned purple or pink.
- Remove from container the number of test strips to be used in one day; use supplied plastic lid to immediately reseal container tightly and return to refrigerated storage.
- Keep removed test strips at room temperature during daily use. It is good practice to protect room temperature strips from humidity by storing them in a closed dry container at room temperature. Unused test strips after 24 hours should be discarded.

Negative Control

- Use beta-lactam, sulfonamide, and tetracycline negative raw commingled milk as a Negative Control for performance monitoring and to reconstitute Positive Control.
- Qualified Negative Control should yield a reading less than (more negative than) –600 negative result on Charm EZ system.
- Store Negative Control refrigerated for up to 72 hours.
- See **Retest of Initial Positive** for Negative Control performance specifications.
- Use 300 µL of Negative Control in **Procedure**.

Positive Control

- Use TRIO Positive Tablet to make a 4 ppb penicillin G, 10 ppb sulfadimethoxine, and 100 ppb oxytetracycline Positive Control.
- Store tablets refrigerated, closed in the supplied moisture resistant foil bag.
- Using a clean vial, reconstitute 1 Positive Tablet with 5.0 mL of Negative Control (see above). Shake well. Allow to stand refrigerated or on ice for 10 minutes. Mix before use.
- Store reconstituted Positive Control refrigerated for up to 48 hours.
- See **Daily Performance Check** for Positive Control performance specifications.
- Use 300 µL of Positive Control in **Procedure**.

Long-Term Sample and Control Storage





- Mix controls, aliquot 0.5 mL portions (or more) into clean vials, label, and freeze.
- Freeze reconstituted Positive Control within 6 hours of preparation.
- Freeze aliquots at -15°C or below for up to 1 month.
- Thaw frozen aliquots slowly (overnight in refrigerator or with cool water) and shake well. Store Controls refrigerated and use within 24 hours of thawing. Noticeable protein precipitation indicates an unsuitable sample for MRL TRIO testing. Discard any unused thawed sample. **Do not refreeze.**
- For long term preservation of samples, freezing -15°C or lower is recommended. **US NCIMS does not permit the freezing of samples.**

Daily Performance Check

- Daily and before retesting “initial positive” samples, check Charm EZ system performance using the supplied Calibration Strips. On Charm EZ system, go to menu and follow on-screen instructions. Calibration Strips must test within range.
- Test one Negative Control and one Positive Control prior to testing actual samples to verify performance of test strips and equipment.
- Negative Control must be RESULT NEGATIVE and with a READING less than (more negative than) -600 on the Charm EZ system.
- Positive Control must be RESULT POSITIVE and with a READING greater than +400 on Charm EZ system. Re-make/retest control if it tests out of range. Do not proceed and contact Charm Sciences Inc. if still out of range.
- If Calibration Strips or Controls do not perform in specified ranges, discontinue use and contact Charm Sciences for assistance.

Precautions

- High fat samples (greater than 6.0%) may cause invalid results. Do not read invalid test strips in the Charm EZ system.
- Debris on test strips may alter the Charm EZ system optics. Keep equipment clean and wipe dust and milk off test strips before inserting in Charm EZ system.
- ROSA Incubator or Charm EZ system must be clean and level. ROSA Incubator or Charm EZ system temperature must be $56 \pm 1^\circ\text{C}$. The temperature indicator should match ROSA Incubator temperature. A daily thermometer check is recommended. Keep ROSA Incubator lid lowered, but not latched, unless performing procedure.
- ROSA Incubators may take more than 10 minutes to reach proper temperature, depending on ambient temperature.
- The Charm EZ system may take up to 3 minutes to reach proper temperature, depending on ambient temperature.
- Turning on the Charm EZ system without the SD Card or the Slide Mechanism properly inserted will result in an error message.
- If testing individual cow samples or frozen milk containing precipitates, centrifuge (3 minutes at 1200 ± 200 g) and use skim portion below fat layer as the milk sample for testing. **US NCIMS does not permit the freezing of samples or recognize the testing of individual cow samples.**
- Not validated for use with pasteurized whole milk.
- When more than one family of drug is identified as causing a positive in a sample, it is recommended to confirm individually with tests specific to each family detected positive. This will avoid potential false-positive-family results that may occur as cross over from true positive results from the other detected family.

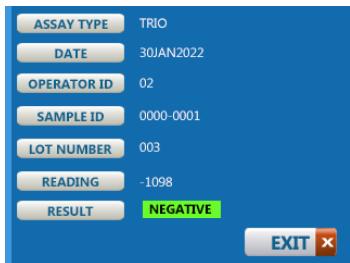
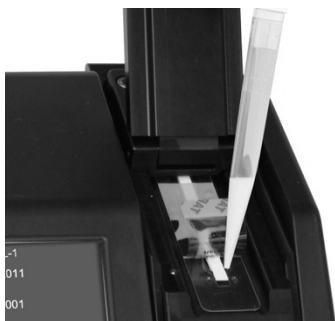
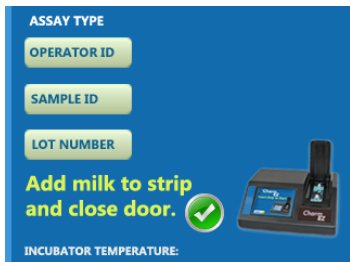
<p>Charm EZ </p> <p>This strip is not Charm EZ compatible. Remove strip and insert correct type.</p>	<ul style="list-style-type: none"> • The Charm EZ system is not compatible with all Charm test strips. • Older, non-compatible test strips will result in an error message when inserted into the Charm EZ system. • For a complete list of Charm EZ Compatible® tests contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com.
<p>Charm EZ </p> <p>Test has previously been run (lines detected) or reader lens is dirty. Check lens and run another strip.</p>	<ul style="list-style-type: none"> • Debris on test strips may alter the Charm EZ system optics. • Keep equipment clean and wipe dust and milk off test strips before inserting in Charm EZ system. • At the beginning of each assay run the Charm EZ system checks to make sure the strip inserted has not been previously run and the optics lens is clean.
<p>Charm EZ </p> <p>ERROR. Door was opened during assay. Remove used strip and discard.</p>	<ul style="list-style-type: none"> • Do not open the door on Charm EZ system while an assay is in progress. • Opening the door will invalidate the results and this will result in an error message. • Remove the test strip and restart the assay.
<p>Charm EZ </p> <p>Flow error detected. Run another test and check volume dispensed.</p>	<ul style="list-style-type: none"> • The Charm EZ systems monitors the assay progress during the incubation. • Damaged strips are detected by the system and will result in an error message. • Remove the strip and restart the assay.

Sample and Test Information

- Raw, commingled milk must be refrigerated or cool (0 to 7°C) for testing.
- Test refrigerated samples within 5 days of milking.
- Testing of milk samples must be completed within 72 hours of sampling. Completed includes the time required to finish the initial testing, any necessary re-testing of the initial positive, confirmation, and/or producer trace back testing.
- To preserve samples or controls after testing, freeze samples at -15°C or below. See **Long-Term Sample and Control Storage**. Milk being tested for NCIMS purposes may **not be frozen** at any time during testing process.
- Test may be performed at ambient temperatures of 10 to 35°C in naturally circulating air. After incubation, test strip results are stable at room temperature for 3 minutes. Over several hours positive results will become more positive while negative results will remain stable. If refrigerated, results are stable for 1 hour. If frozen at -15°C or below, results are stable for 1 week. **The refrigeration or freezing of incubated strips is not recognized by the US NCIMS.**

MRL TRIO Test for Milk Procedure with Charm EZ System Incubation

Use MRL TRIO test strips. Re-shape dented sample compartments to fit into Charm EZ system.

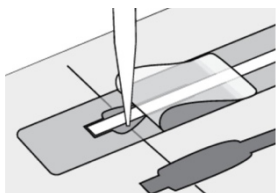
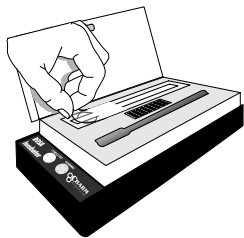


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|----------------|---|
| Step 1 | <ul style="list-style-type: none"> Power up Charm EZ system and wait for Insert Strip to Start Screen. |
| Step 2 | <ul style="list-style-type: none"> Mix all samples before testing. |
| Step 3 | <ul style="list-style-type: none"> Label test strip(s) with sample identification; test strip(s) may be placed in Charm EZ system to avoid crushing sample compartment. |
| Step 4 | <ul style="list-style-type: none"> Place test strip in Charm EZ system. The Charm EZ system will automatically read the test strip and adjust the Assay Type and incubator to the required temperature. Wait for incubator temperature to turn green. |
| Step 5 | <ul style="list-style-type: none"> Tap the touch screen to enter the Operator ID, Sample ID, or Lot Number information. |
| Step 6 | <ul style="list-style-type: none"> Holding test strip flat in Charm EZ system, use tab to expose sample compartment by peeling tape to “Peel to Here” line. Avoid lifting the test strip and sponge under tape. |
| Step 7 | <ul style="list-style-type: none"> Using 300 μL pipet, draw up sample, avoiding foam and bubbles. Holding pipet vertically, slowly pipet 300 μL (\pm 15 μL) sample into sample compartment at indicator line (as shown). |
| Step 8 | <ul style="list-style-type: none"> Reseal tape over sample compartment. Do not press hard over center of the sample compartment. |
| Step 9 | <ul style="list-style-type: none"> Close door on Charm EZ system. This will start the 3-minute timer. Do not open the door while the assay is in progress. |
| Step 10 | <ul style="list-style-type: none"> Assay Results will appear on the screen automatically at the end of the incubation period. Remove test strip(s) from Charm EZ system to return to the Insert Strip to Start Screen. |

MRL TRIO Test for Milk Procedure with ROSA Incubator

Check that ROSA Incubator temperature is $56 \pm 1^\circ\text{C}$.

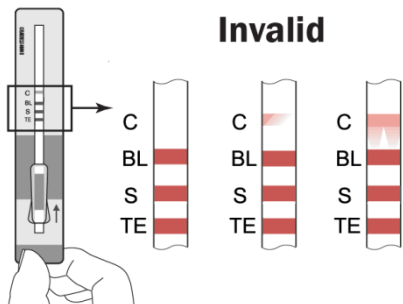
Use MRL TRIO test strips. Re-shape dented sample compartments to fit into ROSA Incubator.



- | | |
|---------------|---|
| Step 1 | <ul style="list-style-type: none"> • Mix all samples before testing. |
| Step 2 | <ul style="list-style-type: none"> • Label test strip(s) with sample identification. Avoid crushing sample compartment. |
| Step 3 | <ul style="list-style-type: none"> • Place test strip in ROSA Incubator. • Holding test strip flat in ROSA Incubator, use TAB to expose sample compartment by peeling tape back to “Peel to Here” line. Avoid lifting the test strip and sponge under tape. |
| Step 4 | <ul style="list-style-type: none"> • Using 300 μL pipet, draw up sample. Avoid foam and bubbles. • Holding pipet vertically, slowly pipet 300 μL ($\pm 15 \mu\text{L}$) sample or Control into sample compartment at ROSA Incubator indicator line (as shown). |
| Step 5 | <ul style="list-style-type: none"> • Reseal tape over sample compartment. Do not press hard over center of the sample compartment. • When performing multiple tests in a ROSA Incubator: <ul style="list-style-type: none"> ○ Peel, pipet and reseal before starting next test strip. ○ Complete all test strips within 1 minute. |
| Step 6 | <ul style="list-style-type: none"> • Close lid on ROSA Incubator and latch. Timer starts and red-light illuminates. |
| Step 7 | <ul style="list-style-type: none"> • Incubate for 3 minutes, but not more than 4 minutes. • At 3 minutes, a beeper and alternating yellow and red blinking lights start. |
| Step 8 | <ul style="list-style-type: none"> • Remove test strip(s) from ROSA Incubator. Do not squeeze sample compartment. Hold test strip with sample compartment in the down position until interpreted. • Read within 3 minutes of completing incubation. • Lower ROSA Incubator lid. Do not re-latch. |

Visual Inspection

Hold test strip vertically with sample compartment in down position. Do not squeeze the sample compartment. Wipe foreign matter (dust, etc.) off test strip.



The test is **INVALID** if any of the following are observed:

- **C** (Control) line is missing.
- **C** line is smeared or uneven.
- **C**, **BL** (Beta-lactam), **S** (Sulfonamide), or **TE** (Tetracycline) line is obscured by sample or Control.
- Beads do not flow past **TE**, **S**, **BL**, or **C** lines.

Re-test INVALID samples. DO NOT INTERPRET OR PUT INVALID TEST STRIPS IN CHARM EZ SYSTEM.

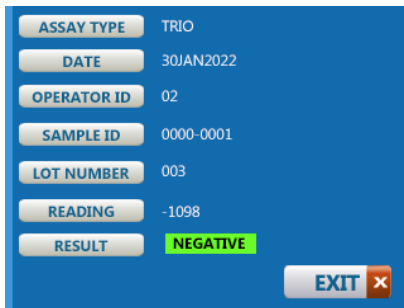
Interpretation



Within 3 minutes of completing incubation, insert clean and visually valid test strip into Charm EZ system as shown. Slide test strip completely into slot until it stops.

If desired, enter **SAMPLE** and/or **OPERATOR**. Close door to read. A numerical value (**READING**) and an interpretation (**RESULT**) are displayed on screen.

Results are stored in memory and can be recalled to the display and downloaded to printer or computer.



Negative - If **READING** is a negative number or zero, the Charm EZ system will display **RESULT NEGATIVE**. Report as "Not Found".

Positive - If **READING** is a positive number, the Charm EZ system will display **RESULT POSITIVE**. Sample should be retested. See **Retest of Initial Positive**. Charm EZ system will display additional information to indicate for which drug(s) the sample was positive:

- BL = Positive for beta-lactams only.
- S = Positive for sulfonamides only.
- TE = Positive for tetracyclines only.
- BLS = Positive for beta-lactams and sulfonamides.
- BLTE = Positive for beta-lactams and tetracyclines.
- STE = Positive for sulfonamides and tetracyclines.
- BLSTE = Positive for beta-lactams, sulfonamides, and tetracyclines.

Retest of Initial Positive

Due to hypersensitivity to US tetracycline Tolerances, in USA do not retest TE initial positives using MRL TRIO test. Perform retest of TE initial positives in US following the Confirmation of Initial Positives of the Charm Tetracycline-SL Dilution Confirmation protocol, see **Confirmation of Multiple Family Positive Samples, Confirmation of Presumptive Beta-Lactam Positive (USA), and Confirmation of Initial Tetracycline Positive (USA)**.

1. Test "initial positive" samples with MRL TRIO test in duplicate along with one Negative Control and one Positive Control.
2. Negative Control must yield **RESULT NEGATIVE** with **READING** less (more negative) than -600 on Charm EZ system.
3. Positive Control must yield **RESULT POSITIVE** with **READING** greater than +400 on Charm EZ system.
4. If either Control is not within range, repeat testing of "initial positive" with Controls. If either Control is still not within range after retest, discontinue testing and contact Charm Sciences.

If both Controls are within range and either or both of the retested samples are **RESULT POSITIVE**, the sample is a "MRL TRIO-Presumptive Positive Test" for the detected drug Beta-Lactam, Sulfonamide, and/or Tetracycline, see **Confirmation of Multiple Family Positive Samples, Confirmation of Presumptive Beta-Lactam Positive (USA), and Confirmation of Initial Tetracycline Positive (USA)**.

Confirmation of Multiple Family Positive Samples, Confirmation of MRL TRIO-Presumptive Beta-Lactam Positive (USA), and Confirmation of Initial Tetracycline Positive (USA)

When more than one family of drugs are identified as causing a positive in a sample, confirm each drug family BL, S and TE individually with tests specific to each family detected: Charm 3 SL3 test for BL, Charm Sulfa Test for S, and Charm Tetracycline Test for TE (if in US, Charm ROSA Tetracycline-SL (Dilution Confirmation) Test). This will avoid potential false-positive-family results that may occur as cross over from true positive results from the other detected family.

In USA due to hypersensitive amoxicillin detection, all beta-lactam presumptive positive samples are confirmed using the Charm 3 SL3 test procedure.

1. Select and label the appropriate test(s) based on the positive result, BL, S, and/or TE. For multiple test positive results perform a confirmation for each positive result, BL and/or S and/or TE.
2. For each positive family, test the "presumptive positive" sample(s) (or "initial positive" sample in the case of TE in the US) in duplicate along with one Negative Control and one Positive Control.
3. Negative Control must yield **RESULT NEGATIVE** with **READING** less (more negative) than -600 on Charm ROSA Reader or Charm EZ system.
4. Positive Control must yield **RESULT POSITIVE** with **READING** greater than +400 on ROSA Reader or Charm EZ system.
5. If either Control is not within range, repeat testing of sample in duplicate with Controls. If either Control is still not within range after retest, discontinue testing and contact Charm Sciences.

If both Controls are within range and either or both of the retested samples are **RESULT POSITIVE**, the sample is positive for the specific family of antibiotics tested: "Beta-lactam, Sulfonamide, and/or Tetracycline Positive Test".

KITS	NOT SUPPLIED WITH KIT
LF-MRLTRIO-40NSK: <ul style="list-style-type: none"> (1) container of 40 MRL TRIO test strips (1) Operator's Manual LF-MRLTRIO-100K: <ul style="list-style-type: none"> (1) container of 100 MRL TRIO test strips (5) TRIO Positive Tablets (1) Operator's Manual LF-TRIO-PT-1-TBL: <ul style="list-style-type: none"> (1) TRIO Positive Tablets 	1-MLT-96 (box of 96 disposable pipet tips, 200-1000 µL) 1-MLT-960 (10 boxes of 96 disposable pipet tips, 200-1000 µL) 1-MLT-BG (bag of 1,000 disposable pipet tips, 200-1000 µL) LF-ROSA-PIPET-500 (500 disposable ROSA- pipets, 300 µL) LF-ROSA-PIPET-5000 (5000 disposable ROSA-pipets, 300 µL) PIP-300UL-1STOP-M (300 µL fixed volume pipet) LF-INC4-ADJUSTABLE: 4 place ROSA incubator with adjustable time and temperature LF-ROSA-EZ (Charm EZ System)

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.