

Charm ROSA® Tetracycline-SL (Dilution Confirmation) Test Flow Chart

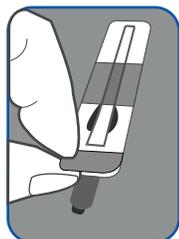


Results in 8 Minutes

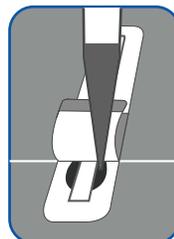
Initial Assay

Detects:
Tetracycline, Chlortetracycline, and Oxytetracycline Drugs

(1) Peel Strip



Verify incubator temperature is 56 ± 1 °C.
Shake sample and label test strip.
Place strip in incubator and peel tape back to "Peel to Here" line.



(2) Add Raw Milk Sample

Slowly pipet 300 µL sample into sample compartment at incubator indicator line (as shown).

Reseal tape over sample compartment.

Close lid and latch and incubate for 8 minutes, but not more than 9 minutes.



(3) Incubate

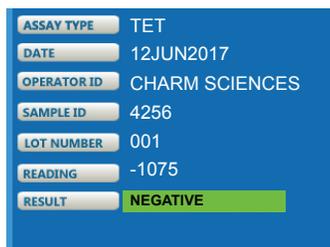
Remove tests from incubator.

Visually inspect for even development.

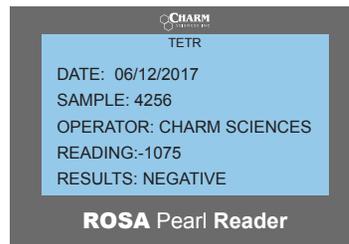
Within 5 minutes insert clean and visually valid test strip in Charm EZ® system or ROSA Pearl Reader in Read-only mode.

(4) Read Results

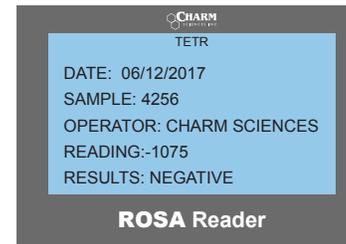
Ex. of Charm EZ Screen



Ex. of ROSA Pearl Reader



Ex. of ROSA Reader Versions 1.05 and higher



Read using Charm EZ System, ROSA Pearl Reader or Rosa Reader version 1.05 or higher.

Refer to manual for complete directions.

Results:

Negative - NOT FOUND - No tetracyclines detected. No further testing required. | **Positive - Initial Positive** - Refer to page 3 or consult with Charm 2400 form. Contact State Lab Evaluation Officer or Charm Sciences technical support for assistance.

Charm ROSA® Tetracycline-SL (Dilution Confirmation) Test Flow Chart

Control Preparation and Daily Performance Monitoring



Results in 8 Minutes

Detects:

Tetracycline, Chlortetracycline, and Oxytetracycline Drugs

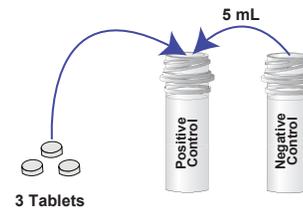
Controls

NEGATIVE CONTROL



Previously tested tetracycline negative milk, which has previously yielded results of -600 or more negative.

POSITIVE CONTROL



Reconstitute 3 tablets with 5 mL Negative Control (raw milk) shake thoroughly and let sit for 5 minutes refrigerated or on ice. Shake thoroughly prior to testing.

If using ROSA Reader Versions 1.05 and higher, or ROSA Pearl Reader, use **ESC 5** reader function to enter **Performance Monitoring Mode**. Use left or right arrow to toggle from Beta-lactam to TETR channel. Refer to manual for complete directions.

The reader will prompt for the calibrators and controls.

- TETR
DATE: 06/12/2017
SAMPLE: PERF TEST
OPERATOR: CHARM SCIENCES

Press ENTER to start.
- TETR
DATE: 06/12/2017
SAMPLE: LOWCAL
OPERATOR: CHARM SCIENCES
READING: -0272
RESULTS: IN RANGE

Insert Low Calibrator, press ENTER.
- TETR
DATE: 06/12/2017
SAMPLE: HIGHCAL
OPERATOR: CHARM SCIENCES
READING: 450
RESULTS: IN RANGE

Insert High Calibrator, press ENTER.
- TETR
DATE: 06/12/2017
SAMPLE: NEGATIVE CONTROL
OPERATOR: CHARM SCIENCES
READING: -1075
RESULTS: VALID

Insert Negative Control, press ENTER. Reading -600 or more negative will give RESULTS: **VALID**
- TETR
DATE: 06/12/2017
SAMPLE: POSITIVE CONTROL
OPERATOR: CHARM SCIENCES
READING: 1045
RESULTS: VALID

Insert Positive Control, press ENTER. Reading more positive than +400 will give RESULTS: **VALID**

If using Charm EZ system, use Menu to enter Performance Monitoring mode and **"Perf Mon"** to enter daily **Performance Check**. Refer to manual for complete directions.

Follow prompts for Performance Test. For complete procedure refer to Operator's Manual.

- Main Menu
Setup Language
Devices Perf. Mon.
Test Setup Archive
Search Exit

Select Perf. Mon.
- Performance Menu
Confirm Later Perf. Mon.
DEL CL Tit Cal. Check
Cert Lab Cfm Perf. Alarm
Exit

Select Perf. Mon.
- Insert Low Calibrator
Dark Pink side facing down and close the door

Follow prompts and insert Low Calibrator.
- Low Calibrator is in Range
Lo Limit = - 160
Answer = - 41.90
Hi Limit = 0

Press OK.
- Insert High Calibrator
Light Pink side facing down and close the door

Follow prompts and insert High Calibrator.
- High Calibrator is in Range
Lo Limit = 110
Answer = 216.29
Hi Limit = 330

Press OK.
- Insert Negative Control
Test Strip

Follow prompts and Press OK.
- ASSAY TYPE TET 12JUN16
OPERATOR ID 02 09:25:45
SAMPLE ID NEGATIVE CONTROL
LOT NUMBER 006
Insert strip and close door to read

Insert Negative Control.
- ASSAY TYPE TET
DATE 12JUN2016
OPERATOR ID 02
SAMPLE ID NEGATIVE CONTROL
LOT NUMBER 006
READING -1500
RESULT VALID

Follow prompt and Continue Confirmation.
- ASSAY TYPE TET 12JUN16
OPERATOR ID 02 09:35:29
SAMPLE ID POSITIVE CONTROL
LOT NUMBER 006
Insert strip and close door to read

Insert Positive Control.
- ASSAY TYPE TET
DATE 12JUN2016
OPERATOR ID 02
SAMPLE ID POSITIVE CONTROL
LOT NUMBER 006
READING 1555
RESULT VALID

Follow prompt and Continue Confirmation.
- Exiting the Performance Monitor
The EZ is ready for operation

Press OK.

Do Not Proceed if Daily Performance Monitoring is INVALID

Daily Performance Monitoring

Charm ROSA® Tetracycline-SL (Dilution Confirmation) Test Flow Chart

Verification of Initial Positive Tanker Sample Done at Same Testing Facility Using Dilution Confirmation Procedure



Results in 8 Minutes

Detects:

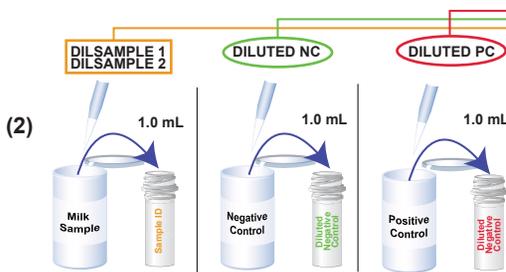
Tetracycline, Chlortetracycline, and Oxytetracycline Drugs

TET-SL Initial Positive Confirmation Procedure



(1) Label three 7 mL screw cap vials; initial positive sample (sample ID), positive control, and negative control.

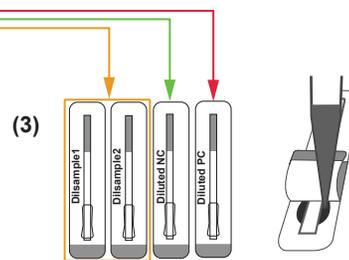
Add 1.0 mL Tetracycline Dilution Buffer to each vial.



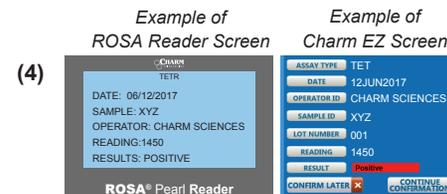
(2) Mix sample/controls.

Add 1.0 mL of milk sample in Sample ID vial. **Add positive control and negative control to the appropriate labeled vial.**

Mix diluted sample/controls.



(3) Label test strips as **Diluted NC** and **Diluted PC**. Label 2 other test strips **Dilsample1** and **Dilsample2**. Perform test (see [Page 1](#)) appropriately from each vial. Pipet two tests from the Diluted Sample vial. Follow [Flow Chart](#) below for interpretation.



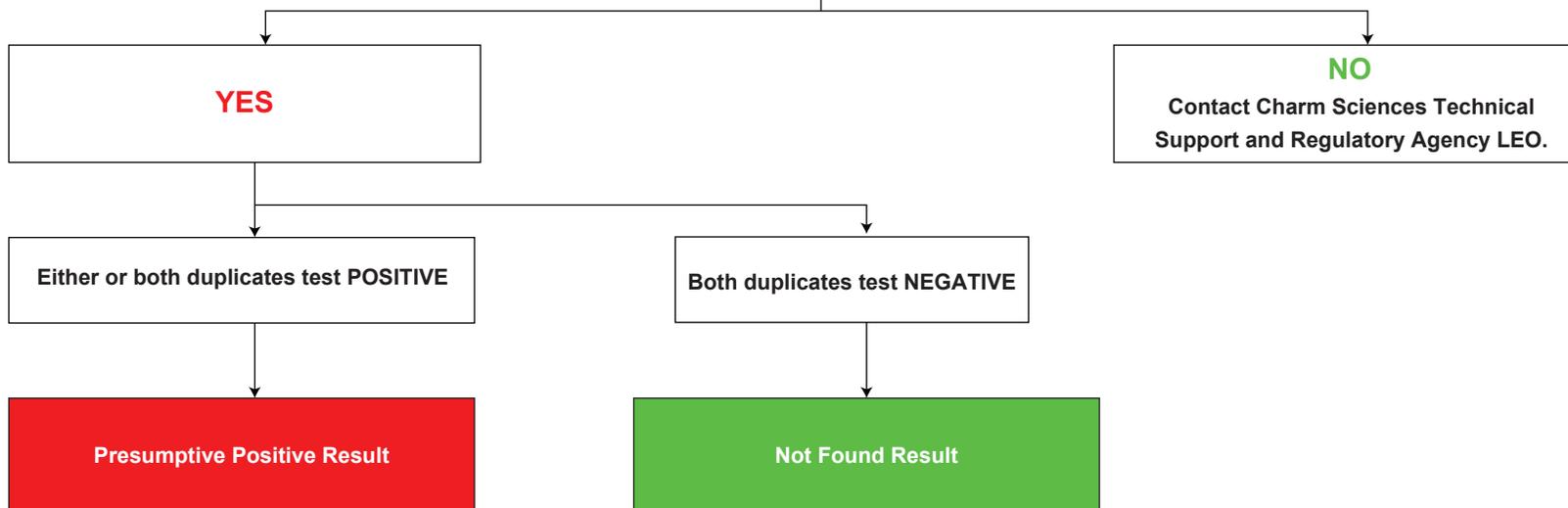
(4) If using the ROSA Pearl Reader, press ESC 5 to enter Performance Monitoring to run controls, then test diluted samples.

If using the Charm EZ system, upon receiving an initial positive result press "Continue Confirmation."

Follow prompts for each strip insertion. If controls are valid and either or both samples are positive, the sample is presumptive positive. Contact State.

Contact Charm Sciences for Further Assistance

Controls give appropriate results



Controls Give Appropriate Results