

CHARM SL & SL-3 BETA-LACTAM TESTS (Rev. 08/14)



**ITEMS 1&2:
see Appendix N General
requirements items 1-9 and 15**

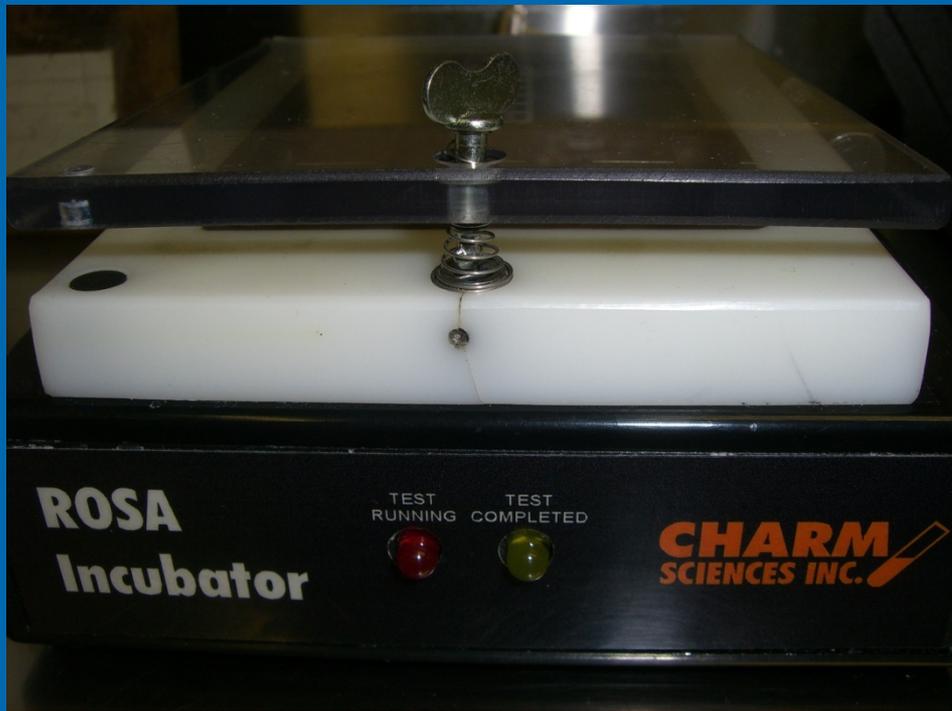


ITEM 3: EQUIPMENT

- Strip Incubator,
 - $56\pm 1^{\circ}\text{C}$ 8 min timer - SL beta-lactam test;
 - $56\pm 1^{\circ}\text{C}$ 3 min timer - SL-3 beta-lactam test
 - $56\pm 1^{\circ}\text{C}$ Charm EZ
- Incubator level, temperature checked daily (day of use), records maintained
- Lid closed, but slightly sprung ajar, when not running tests

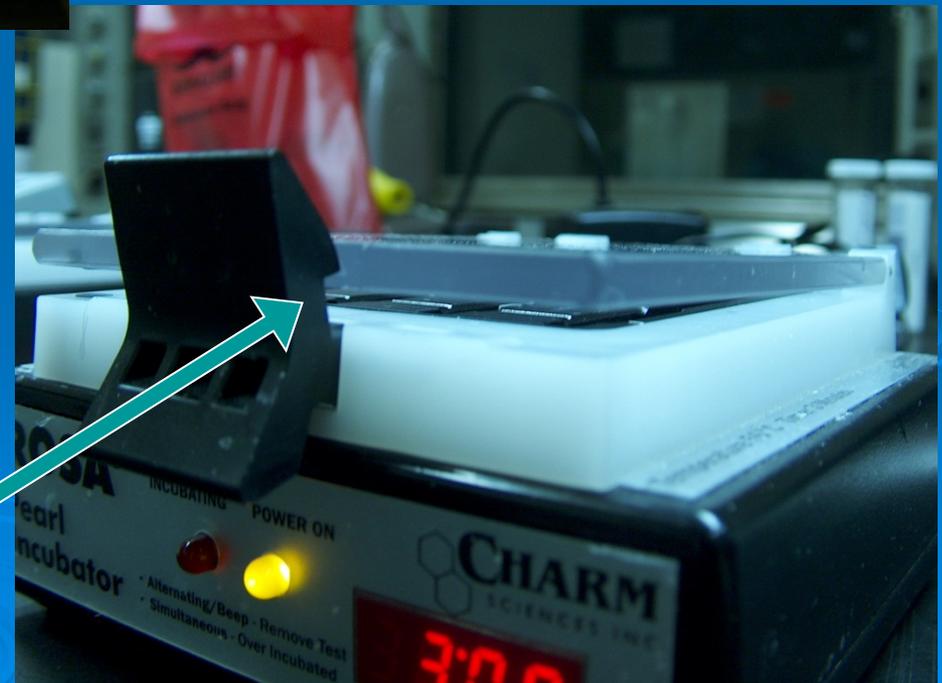


Level placed on internal heated portion of strip incubator



Older style strip incubator.
Lid kept open by spring.

Newer style strip incubator
-Toggle type latch. Lid kept
open by latch in groove in
the lid.

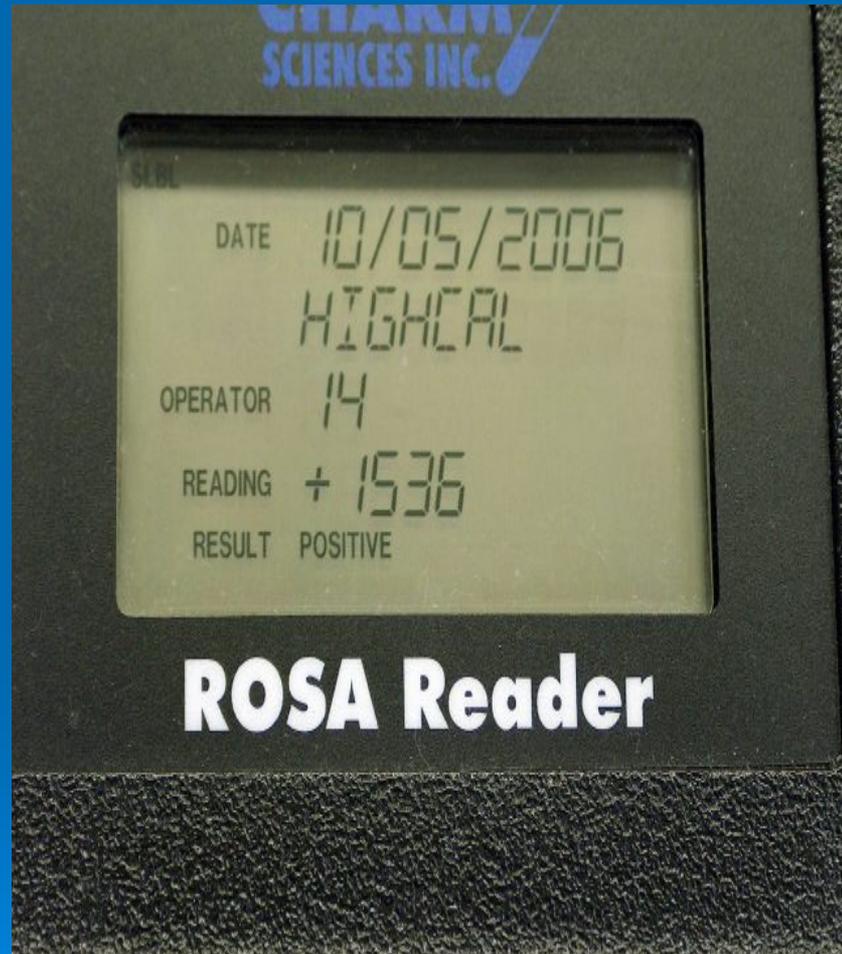


ITEM 3: EQUIPMENT

- ROSA® Reader, ROSA Pearl Reader; manual available
 - SL-5 beta-lactam test - ROSA Reader V1.03 or higher
 - SL-3 beta-lactam test - ROSA Pearl Reader V3.00 or higher
- Calibrators:
 - 2 line for SL-5
 - solid color for SL-3



SL-5



SL-3

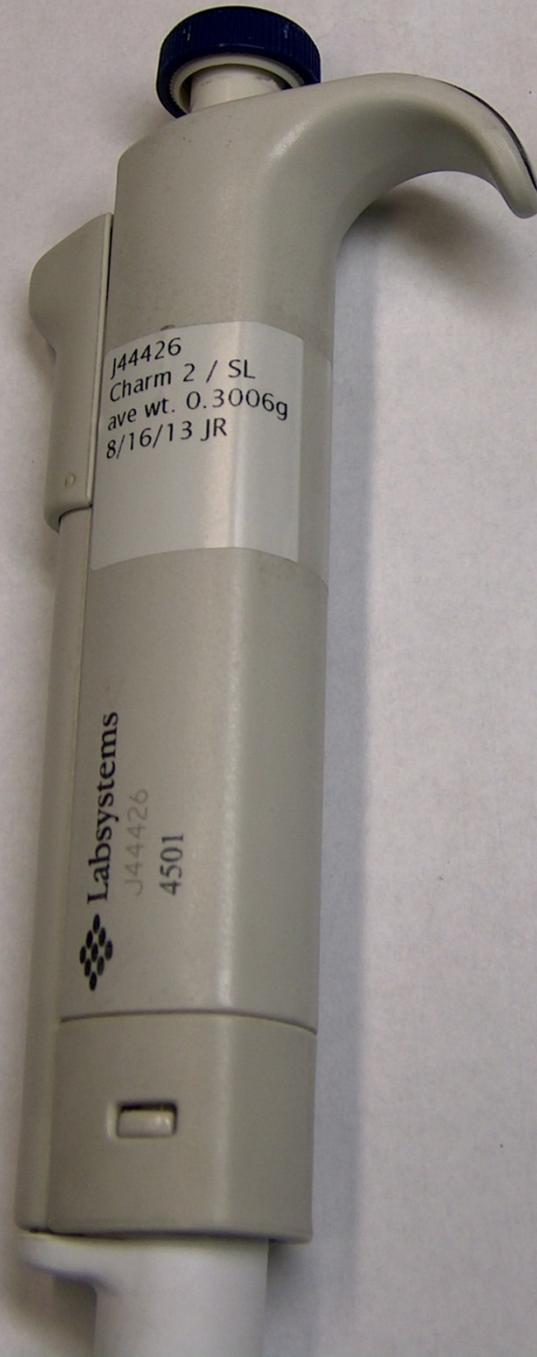
ITEM 3: EQUIPMENT

- Calibrator serial number must match ROSA Reader serial number
- DO NOT PROCEED if calibrators are out of range, contact manufacturer for corrective actions
- Printer or copier link for hardcopy, records maintained

ITEM 3: EQUIPMENT

- Fixed-volume pipettor with disposable tips set to dispense 300 μ l
- Or single use 300 μ l poly-pipet with overflow bulb to accurately measure the amount of sample, supplied by the manufacturer (Screening locations only)

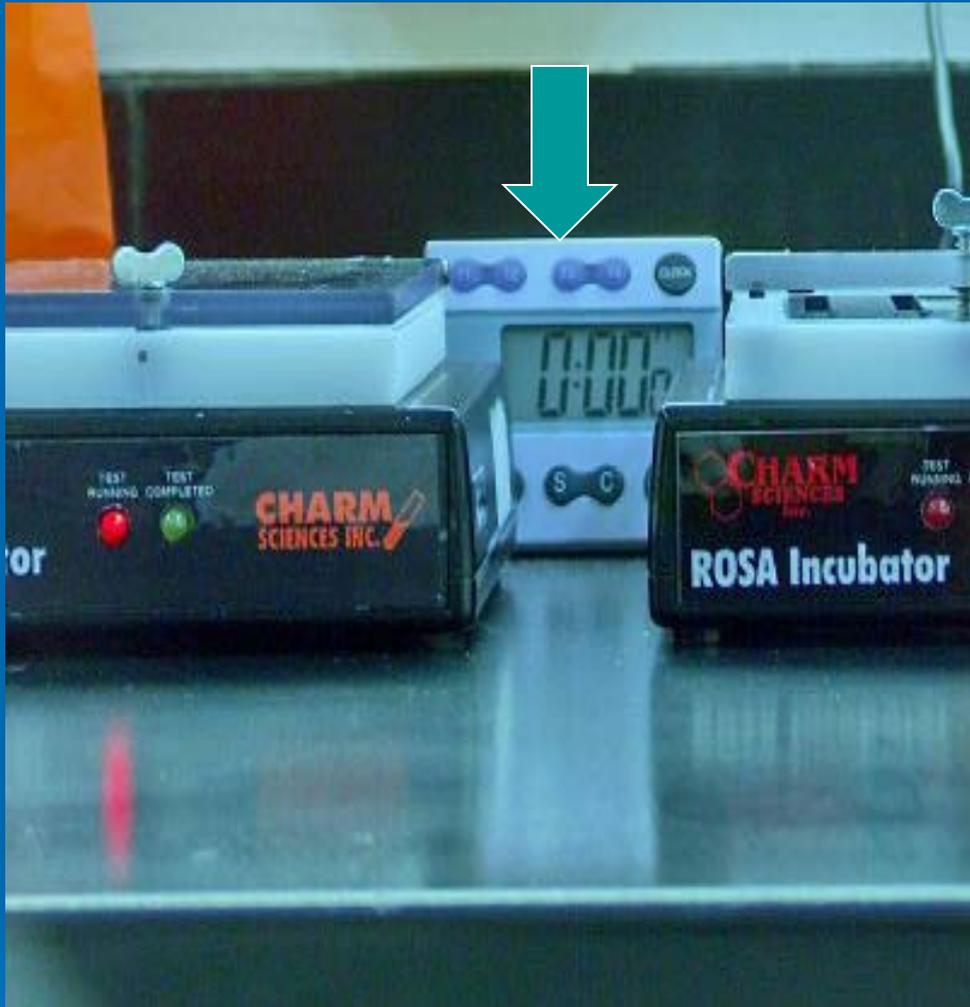
Fixed-volume
pipettor



Single use poly pipet –
supplied by Charm
Sciences

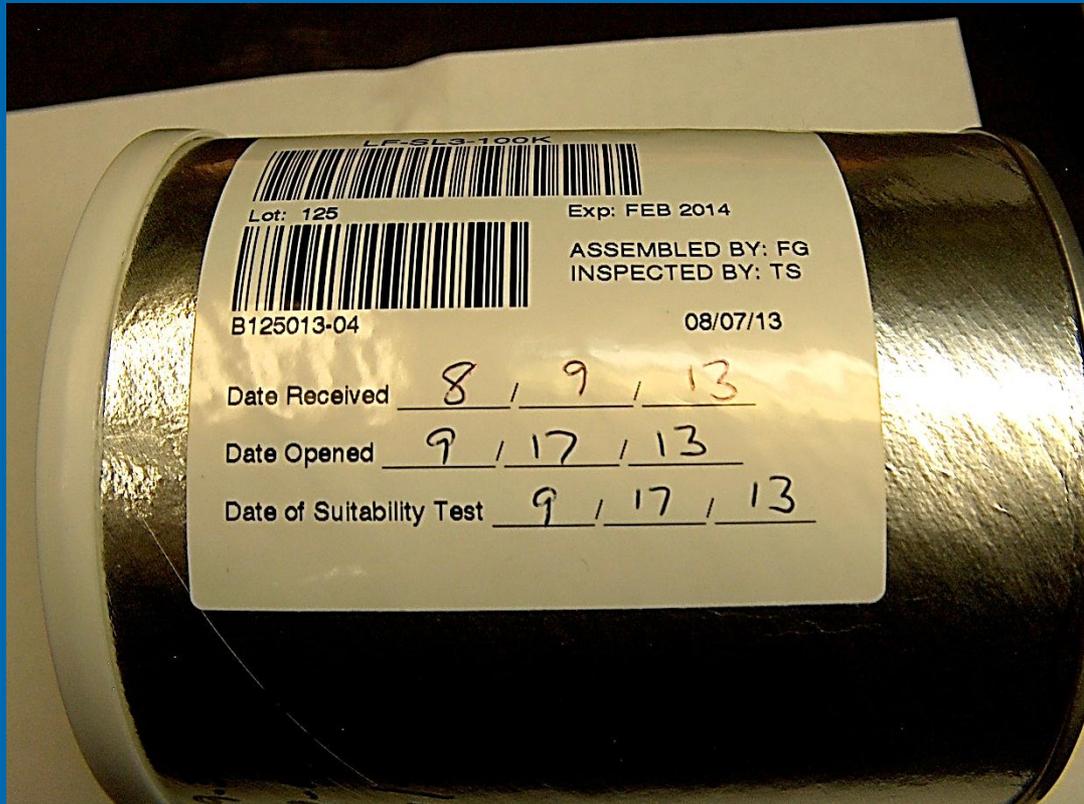
ITEM 3: EQUIPMENT

- Optional Timer- required if not built into the Incubator
- Optional Centrifuge-Charms SL only, mini or equivalent (1200-2000 x g) for frozen controls



ITEM 4: REAGENTS

- Test strips container must be labeled with date received, date opened, and date of suitability
- Positive Control:
 - 5ppb Pen-G for SL-5 and SL-3
- Negative Control is previously tested inhibitor-free raw milk



Charm test kit container labeled with date received, date opened, and suitability check date

Positive and negative control aliquots



ITEM 5: REAGENT STABILITY

- SL-3 reagents must be received within 72 hours if shipped non-refrigerated
- Reagents stored at 0-4.5°C, maintain no longer than manufacturer's expiration date
- **Do not use if desiccant indicator is white or pink**



Blue desiccant.
Kit/control o.k. for use

Pink desiccant.
Kit/control not acceptable
for use - discard

ITEM 5: REAGENT STABILITY

Positive Control

- Positive Control-manufacturer supplied, maintained for no longer than manufacturer's expiration date
- Reconstituted with pre-tested inhibitor free raw milk (negative control), use within 48 hours when maintained at 0-4.5°C
- Positive control may be frozen (within 24 hours of preparation) and stored in a non-frost-free freezer, or in a insulated foam container in a frost-free freezer, for no more than 2 months at -15°C or below

ITEM 5: REAGENT STABILITY

Positive Control

- Frozen controls: thaw, mix, cool (0.0-4.5°C) and use within 24 hours (do not refreeze)
- For SL-5 only, centrifuge thawed control for 3 minutes. Use middle layer.
- Test for suitability each time prepared and or day of use, must produce +400 or greater with records maintained (BFSLS 513a, Rev. 7/11)

ITEM 5: REAGENT STABILITY

Negative Control

- Negative Control-previously tested inhibitor-free raw milk
- Test for suitability each time must produce -600 or greater with records maintained (BFSL 513b, Rev 7/11)
- Use negative control within 72 hours when maintained at 0-4.5°C

ITEM 5: REAGENT STABILITY

Negative Control

- If frozen (within 24 hours of preparation), stored in non-frost-free freezer or in a insulated foam container in a frost-free freezer, for no more than 2 months at -15°C or below
- Thaw, mix, cool ($0.0-4.5^{\circ}\text{C}$) and use within 24 hours. (do not refreeze)
- For SL-5 only, centrifuge thawed control for 3 minutes. Use middle layer.

ITEM 6: DAILY PERFORMANCE AND OPERATIONS CHECK

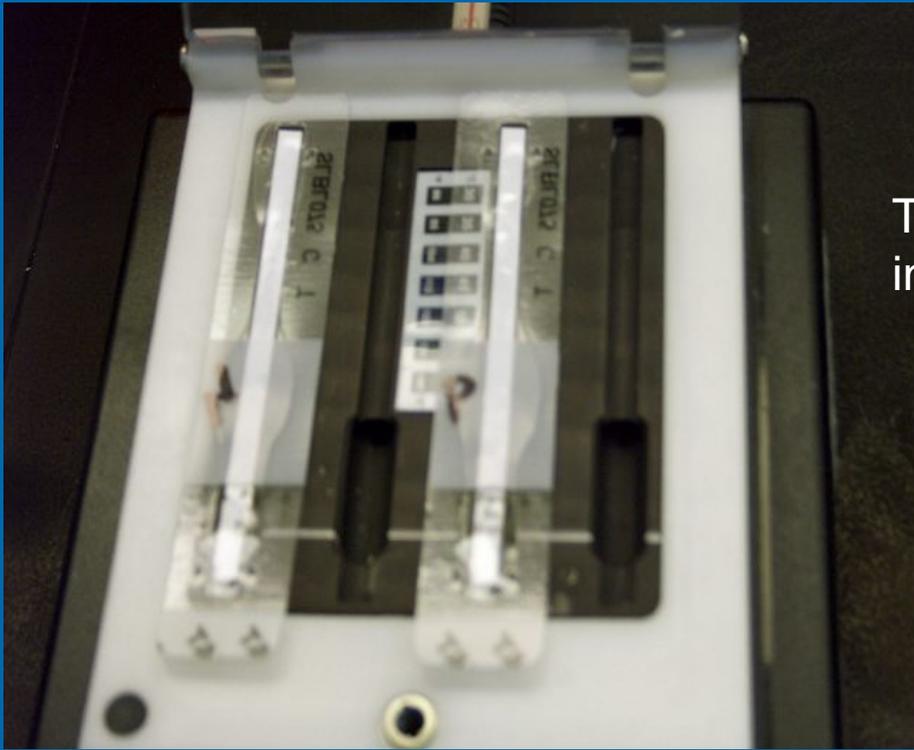
- Reader Versions 1.05 & higher, use ESC 5 reader function to enter performance monitoring mode of Rosa Reader
- Check Calibrators, with records maintained (BFSLS 535, Rev. 7/09)
- Controls give appropriate readings in performance monitoring mode prior to any sample analysis-if out of range contact manufacturer at 1-800-343-2170
- **DO NOT PROCEED IF OUT OF RANGE**

ITEM 7: TEST PROCEDURE

- Set out required number of test strips and place them in a dry labeled container at room temperature, or take out strips as needed
- Discard unused test strips at the end of the day
- Label control strips, one for each sample & control.
- Avoid crushing sample compartment. Check sample well before preceding.

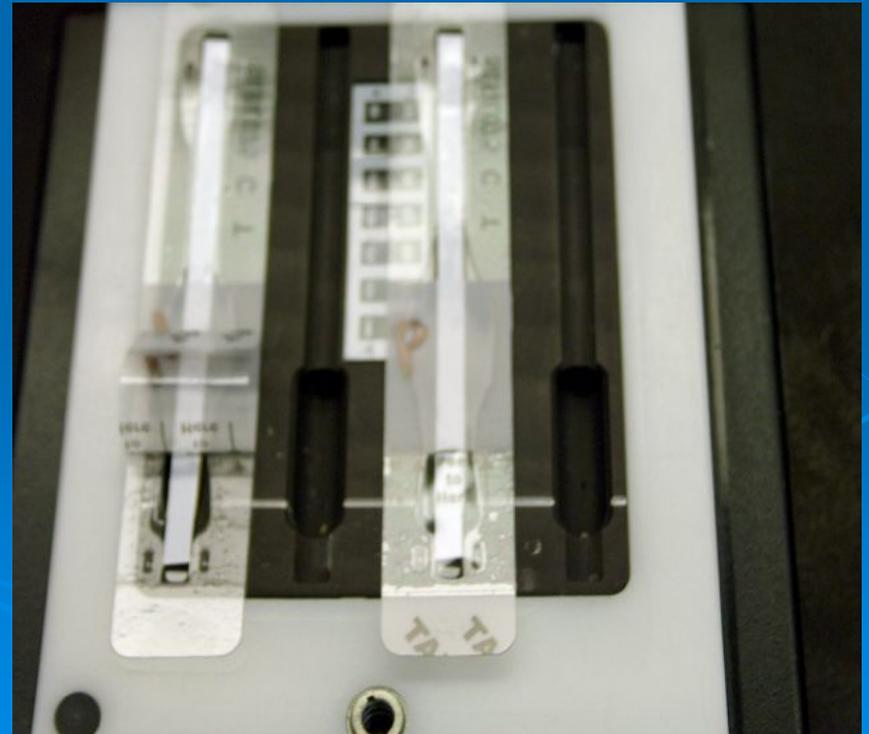
ITEM 7: TEST PROCEDURE

- Shake samples and controls 25 times in 7 seconds with a 1 foot movement or vortex controls for 10 seconds at maximum setting
- Use within 3 minutes
- While holding strip flat in incubator, peel back to line to expose sample pad compartment
- Peel only one strip at a time



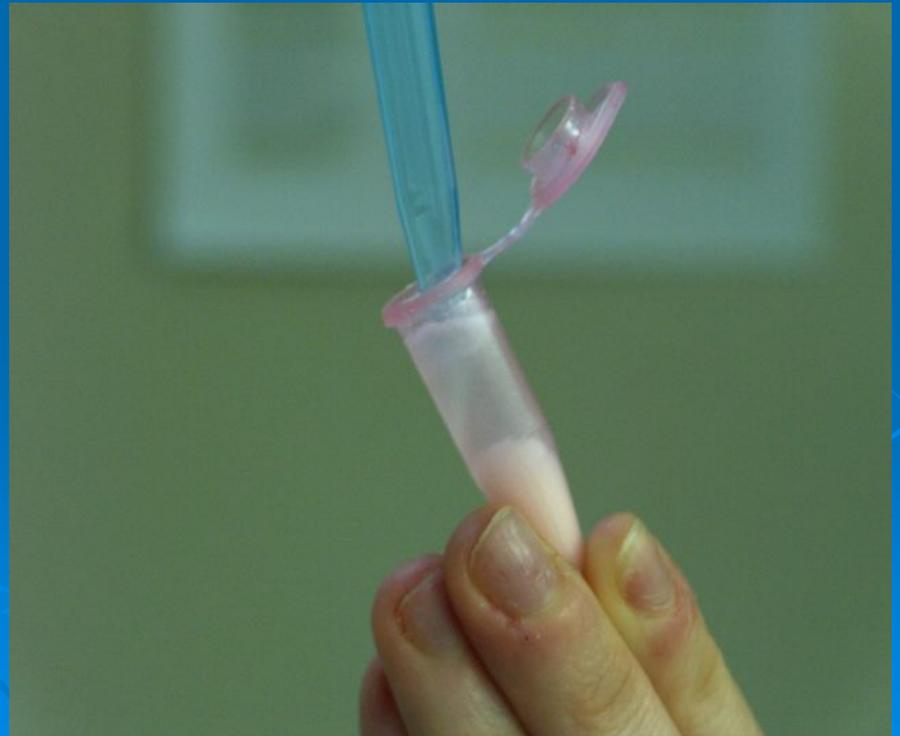
Test strips labeled and placed in strip incubator

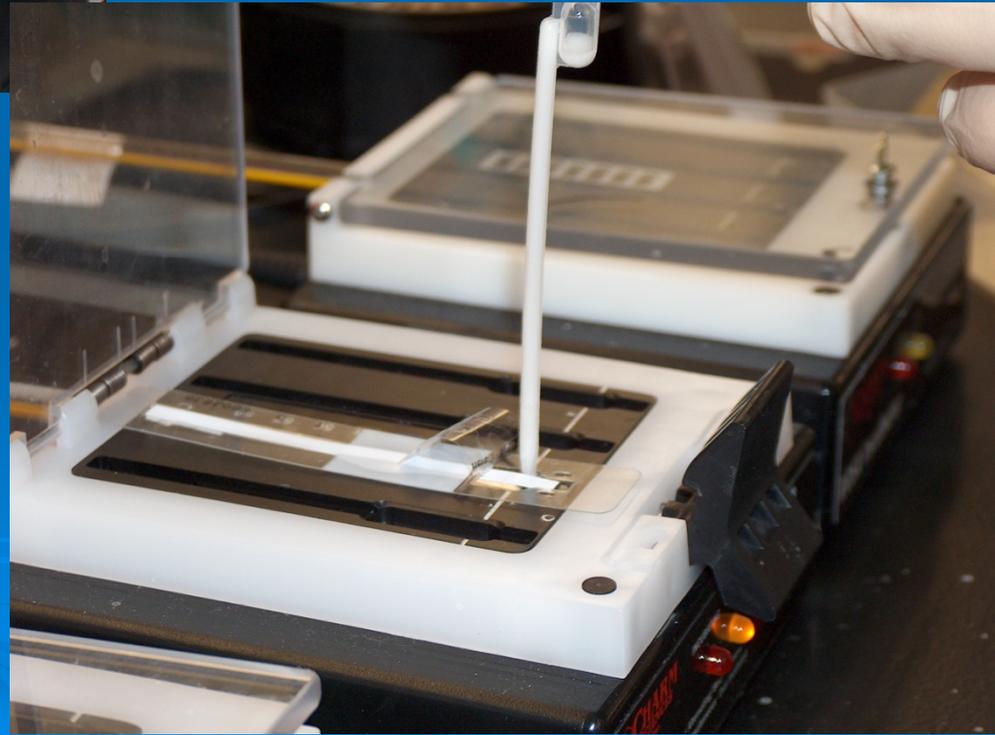
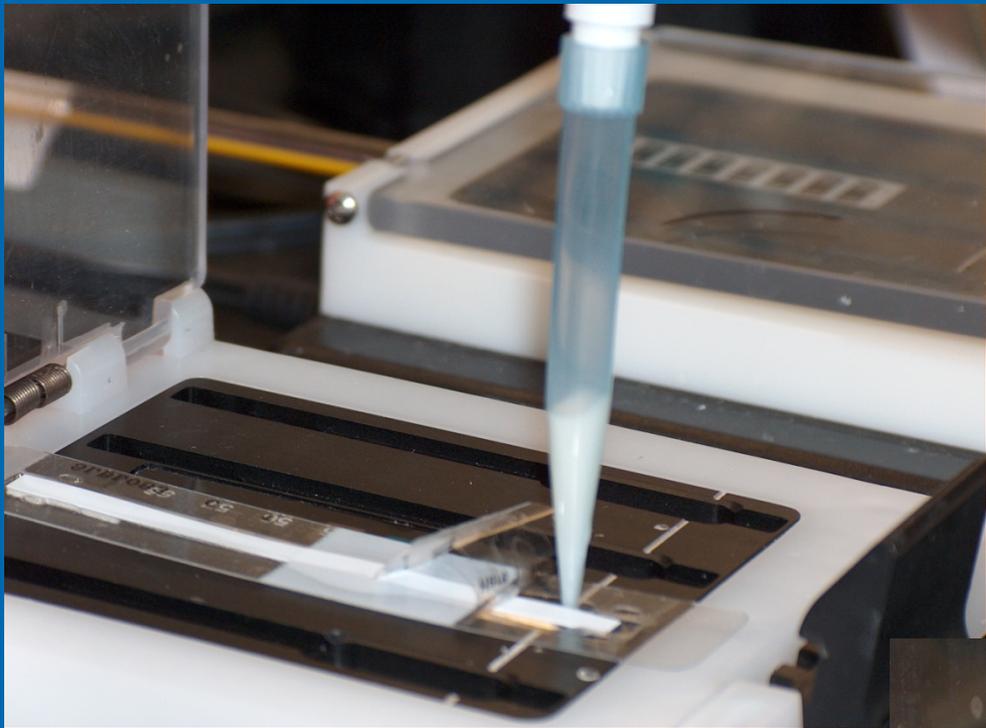
First strip opened to line



ITEM 7: TEST PROCEDURE

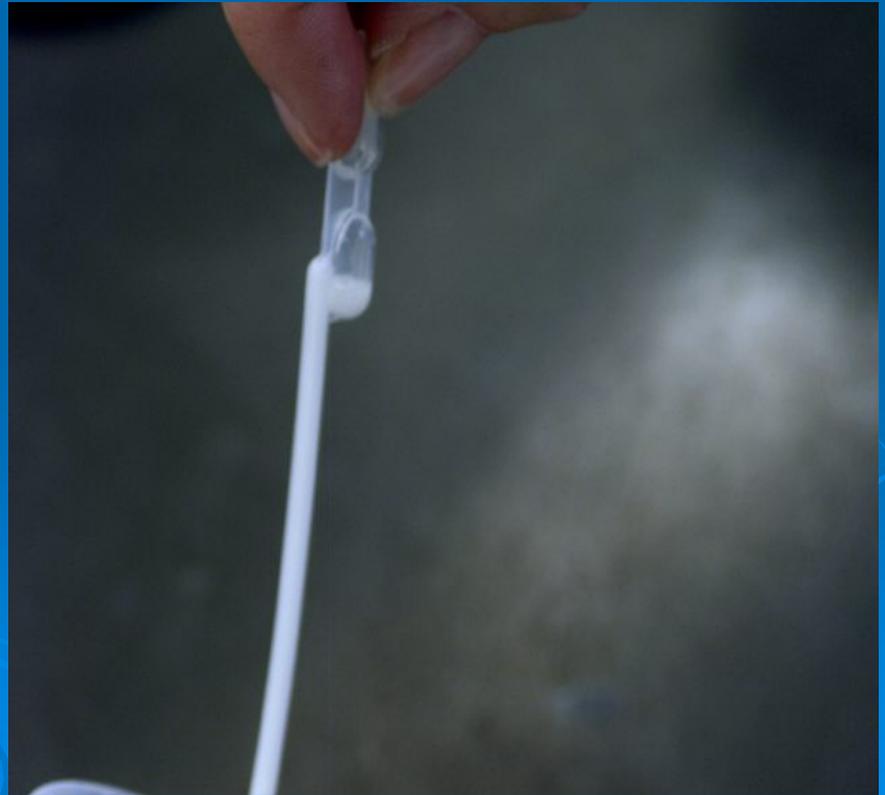
- Draw-up sample avoiding foam and bubbles
- Holding pipette vertically above strip with tip in contact with sample well, slowly pipet sample into test strip





ITEM 7: TEST PROCEDURE

- For Screening only facilities - use the poly pipet provided by the manufacturer
- While holding poly pipet vertically with bulb side pointed down, depress top bulb and insert into sample, below foam
- Release bulb and sample should completely fill pipet shaft and overflow into bottom half of lower bulb

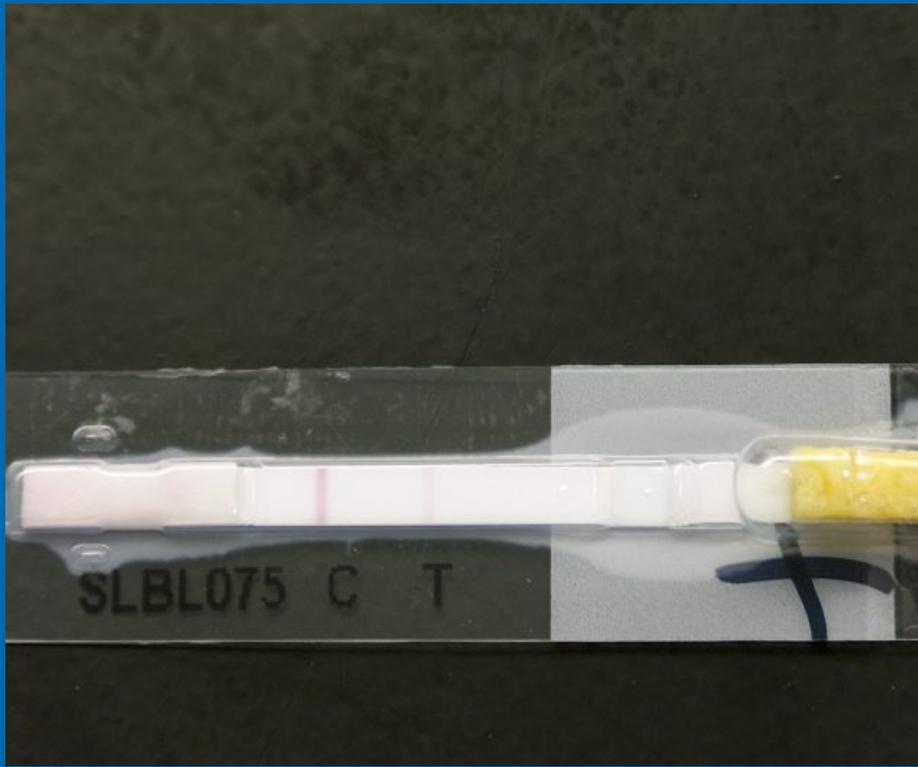


ITEM 7: TEST PROCEDURE

- Pipet sample in pipet shaft into test strip by depressing top bulb only while leaving excess sample in overflow bulb
- After pipetting either with the calibrated pipettor or poly pipet, re-seal plastic firmly around sample pad compartment
- Repeat steps for each control/sample test strip in incubator
- Complete all samples within 2 min (1 min 15 sec for SL3 test) of placing first strip in incubator

ITEM 7: TEST PROCEDURE

- Close and latch incubator cover, if no automatic timer, set timer for 8 minutes, do not exceed 9 minutes (SL-3 set timer for 3 minutes, not to exceed 3 minutes and 30 seconds)
- At the end of incubation, visually inspect C (control line). An absent, partial, or indistinct C line indicates an invalid test and sample must be re-tested



Do not use card for visual interpretation of test strip.
Used only to verify valid vs. invalid test strips.

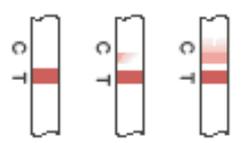
REFERENCE CARD

Charm® SL Beta-lactam Test

CHARM TECHNOLOGY INC.

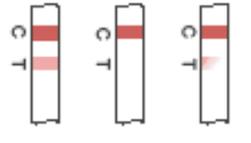
This summary test procedure is not for use in regulatory testing. Refer to the current Operator's Manual for the complete procedure.

INVALID



Re-test INVALID samples.

POSITIVE



NEGATIVE



Place completed strip here.

PROCEDURE

- 

Verify incubator temperature is $56 \pm 1^\circ\text{C}$.
Shake milk sample and label test strip.
Place strip in incubator and use tab to peel tape back to "Peel to here" line.
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Slowly pipet 300 μl sample into sample compartment at ROSA® Incubator indicator line (as shown).
Reseal tape over sample compartment.
Close lid on incubator and tighten latch.
Incubate for 8 minutes, but not more than 9 minutes.
- 

Remove tests from incubator.
Visually inspect C (control) line for even development.
Interpret results visually or read with ROSA® Reader.
Insert clean and visually valid test strip in ROSA Reader and read results on SLBL channel in 2-line mode (slow-blinking).

Note: Visual interpretation is NOT accepted in NCIMS Milk Programs.

Charm Sciences, Inc.
659 Andover Street, Lawrence, Massachusetts, 01843-1032, USA | www.charm.com
CHARM and ROSA are registered trademarks and test strip product packaging is trade dress of Charm Sciences, Inc.
MRN-090-003 0613

ITEM 7: TEST PROCEDURE

- Insert valid strip into reader (set to appropriate channel)
 - SLBL slow blink for SL beta-lactam test
 - SLBL solid (no blink) for SL-3 beta-lactam test
- Press ENTER
- Reading and interpretation will appear in 5 seconds. Read all strips within 5 minutes (3 minutes for SL-3) of completion of incubation.
- Strips may be held vertically, sample compartment down, while waiting to read

ITEM 8: INTERPRETATION WITH ROSA READER

- If there is a negative or zero reading on the reader, the sample is Negative, interpreted as Not Found.
- If there is a positive reading on the reader, sample is an Initial Positive and must be tested again in duplicate with valid positive and negative controls.

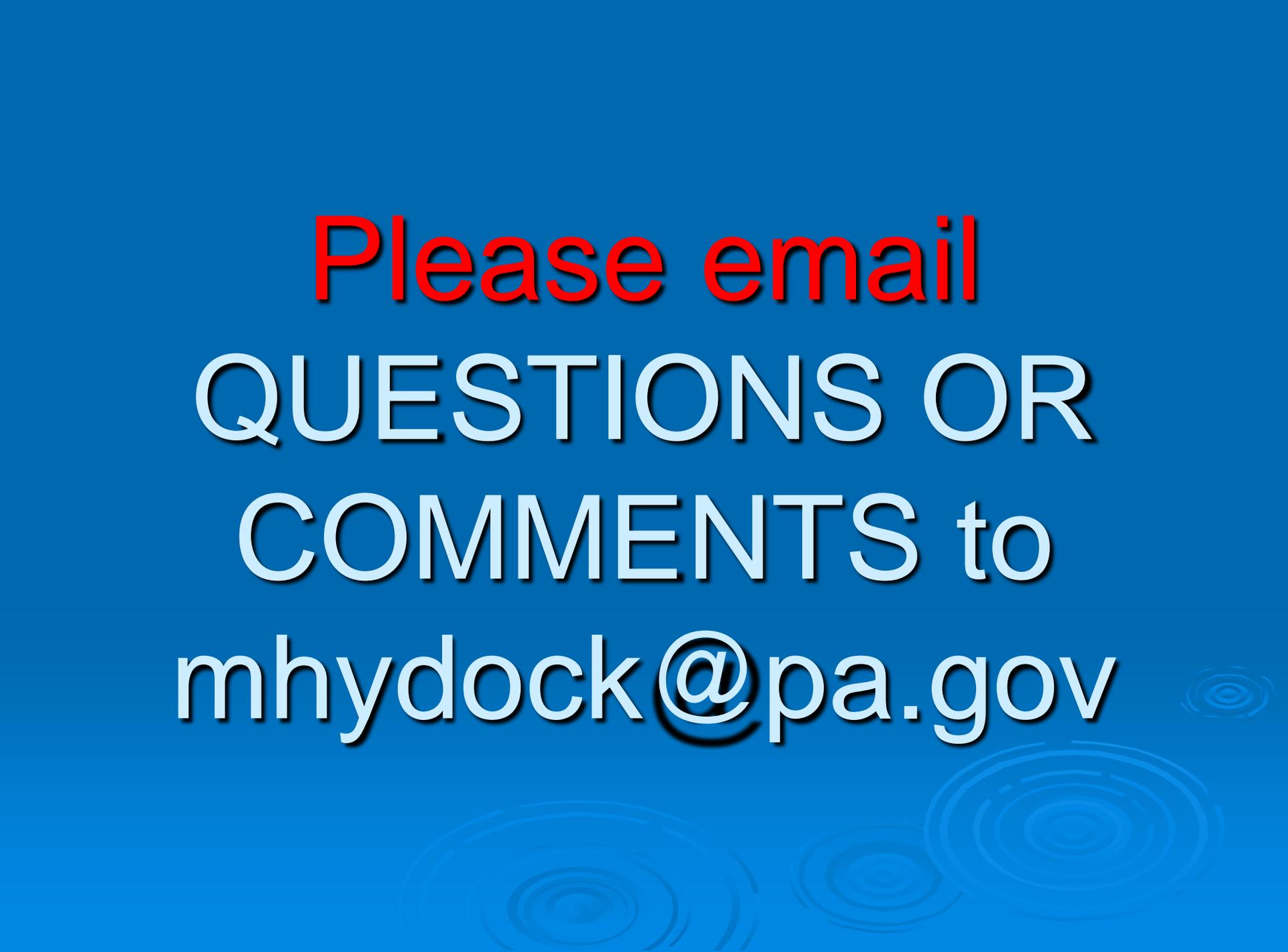
ITEM 9: VERIFICATION OF INITIAL POSITIVE

- Initial Positive, Presumptive Positive, Confirmation, and Producer Traceback procedure will be addressed in the upcoming Appendix N Flow Chart Presentation

ITEM 10: REPORTING

- Reader tapes or computer printouts must be maintained for minimum of 2 years

Please email
QUESTIONS OR
COMMENTS to
mhydock@pa.gov

The background is a solid blue color with several faint, concentric circular patterns scattered across the lower half, resembling ripples in water.