CHARM SL & SL3 BETA-LACTAM TESTS (Rev. 3/15)

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

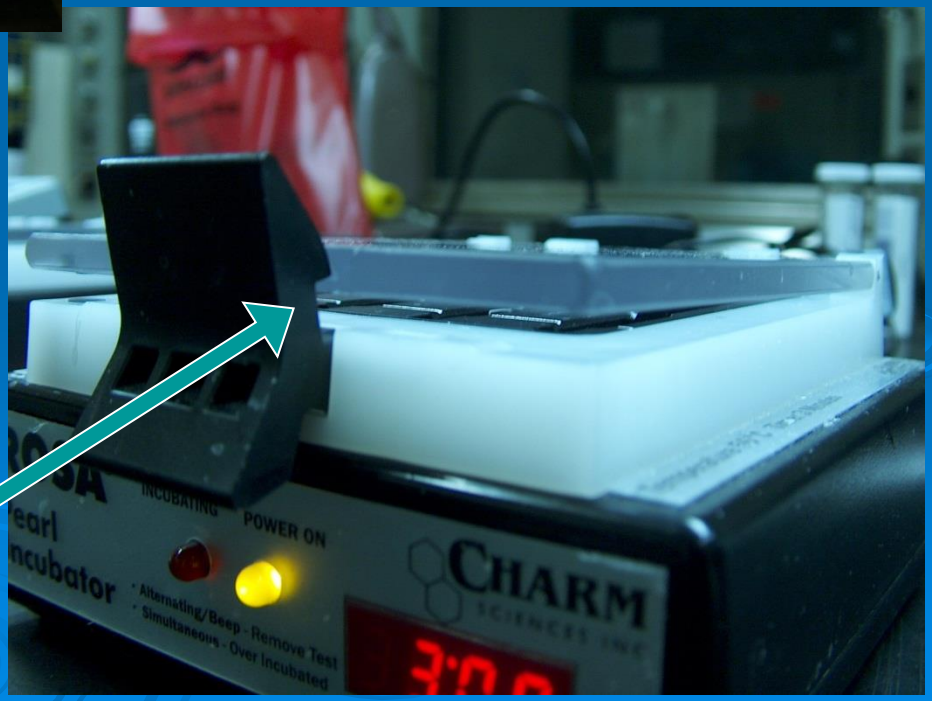
ITEM 3: EQUIPMENT

- Strip Incubator,
  - 56±1°C 8 min timer - SL beta-lactam test;
  - 56±1°C 3 min timer - SL3 beta-lactam test
  - 56±1°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.

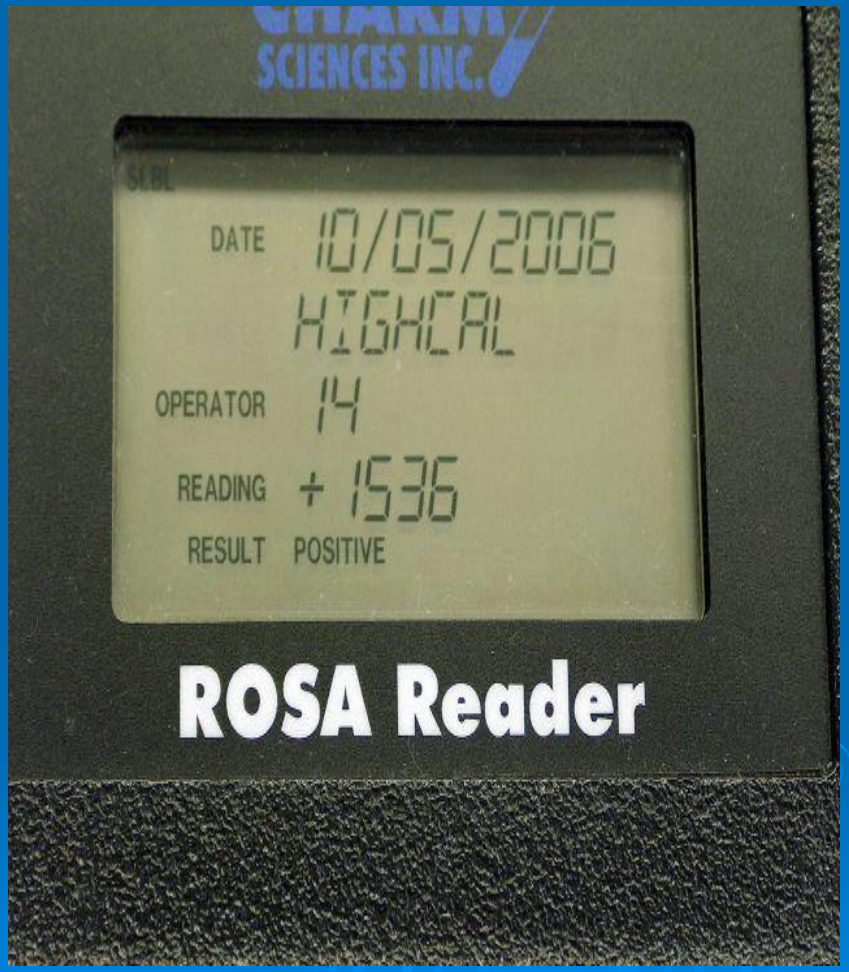


ITEM 3: EQUIPMENT

- ROSA® Reader, ROSA Pearl Reader or Charm EZ ; manual available
  - ROSA Reader V1.03 or higher
    - SL beta-lactam test only
  - ROSA Pearl Reader V3.00 or higher , or Charm EZ
    - SL and SL3 beta-lactam test
  - Calibrators:
    - 2 line for ROSA Reader
    - solid color for ROSA Pearl Reader and Charm EZ

ROSA Reader

ROSA Pearl Reader/ Charm EZ



ITEM 3: EQUIPMENT

- Calibrator serial number must match 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 300µl
- Or single use 300µl poly-pipet with overflow bulb to accurately measure the amount of sample, supplied by the manufacturer (Screening locations only)

Fixed-volume pipettor
J44426
Charm 2 / SL
ave wt. 0.3006g
8/16/13 JR
Labsystems
J44426
4501
Single use poly pipet – supplied by Charm Sciences

ITEM 3: EQUIPMENT

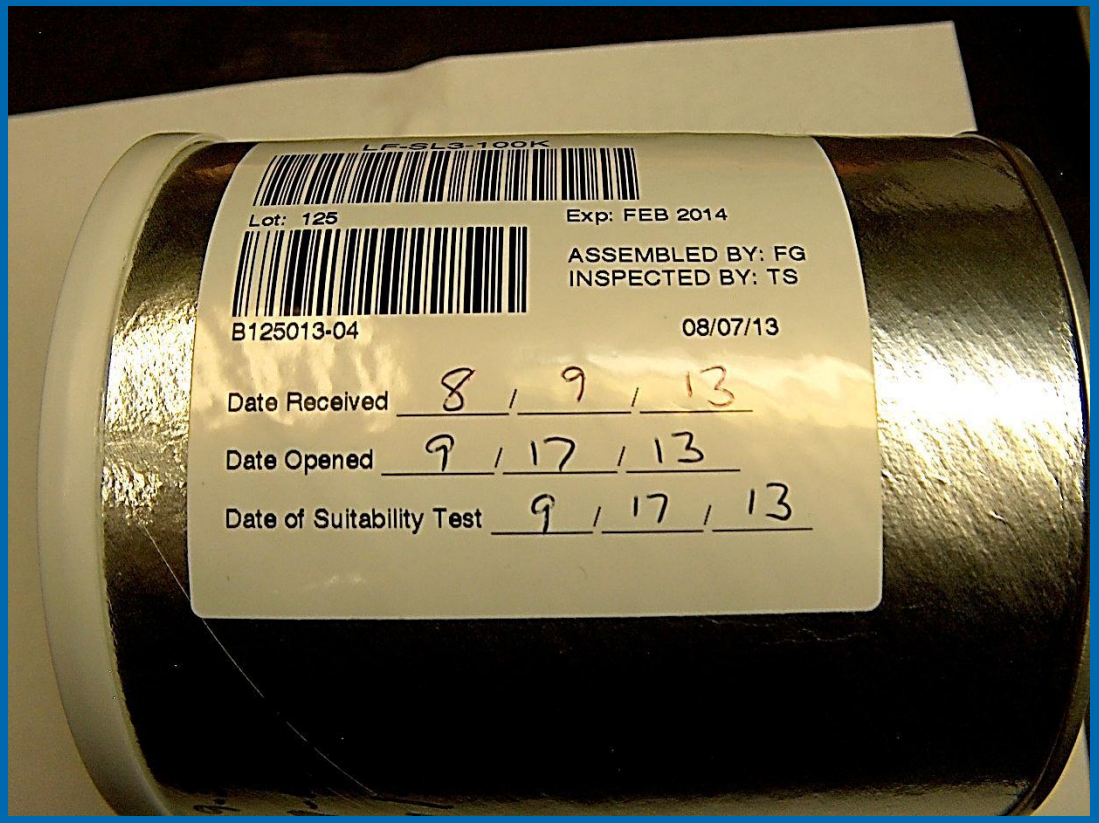
- Optional Timer- required if not built into the Incubator
- Optional Centrifuge-Charm SL only, mini or equivalent (1200-2000 x g) for frozen controls

TEST RUNNING
TEST COMPLETED
CHARM SCIENCES INC.
CHARM SCIENCES
ROSA Incubator

WARNING
MOVING PARTS MAY CAUSE INJURY
DO NOT OPEN LID UNTIL ROTOR STOPS.

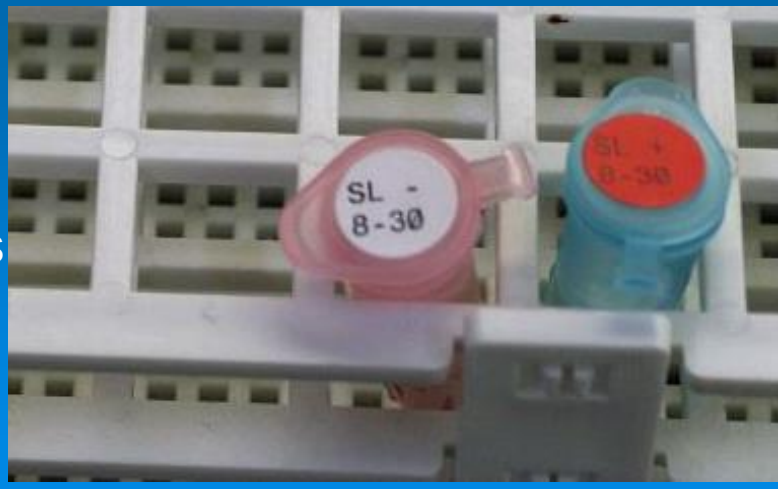
ITEM 4: REAGENTS

- Test strips container must be labeled with date received, date opened, and date of suitability
- Positive Control:
  - 5 ppb Penicillin G
- 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 aliqouts



ITEM 5: REAGENT STABILITY

- SL3 reagents only 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 <u>not</u> acceptable
for use - discard

ITEM 5: REAGENT STABILITY

Positive Control

- Positive Control-manufacturer supplied, dehydrate 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 only, centrifuge thawed control for 3 minutes prior to use and 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 –600 or more negative
  - SL Test: Negative Control can be any of the approved species milk
- Test for suitability each time prepared and/or day of use with records maintained (BFSLS 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 (0-4.5°C) and use within 24 hours. (do not refreeze)
- For SL only, centrifuge thawed control for 3 minutes prior to use and use middle layer

ITEM 6: DAILY PERFORMANCE AND OPERATIONS CHECK

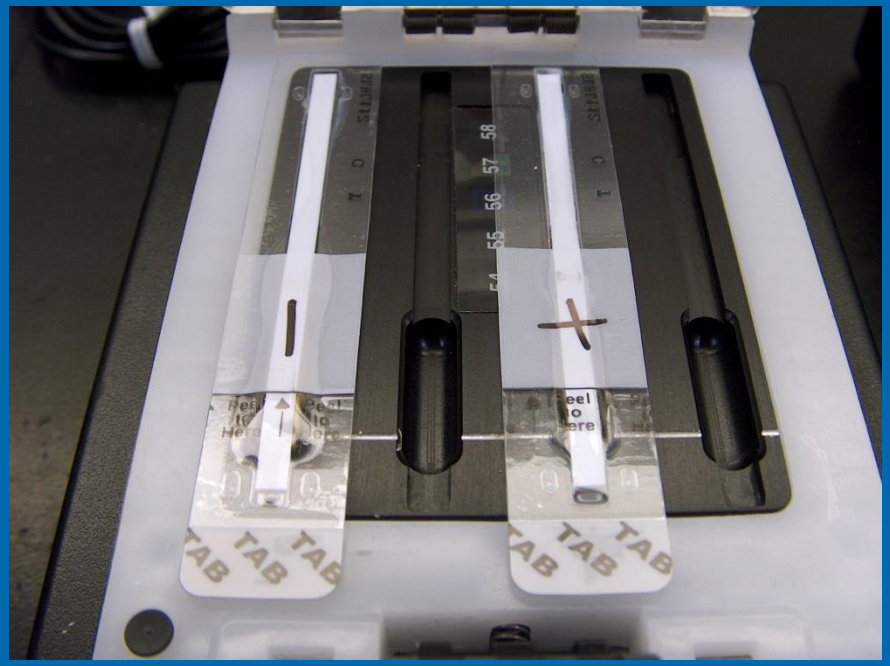
- Reader: Versions 1.05 & higher, use ESC 5 reader function to enter performance monitoring mode
- Check Calibrators, with records maintained (BFSLS 535, Rev. 7/09)
- Controls and calibrators give appropriate readings in performance monitoring mode **prior to any sample analysis**-if out of range contact manufacturer
- **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.
  - Strip(s) may be temporarily placed in incubator for labeling

ITEM 7: TEST PROCEDURE

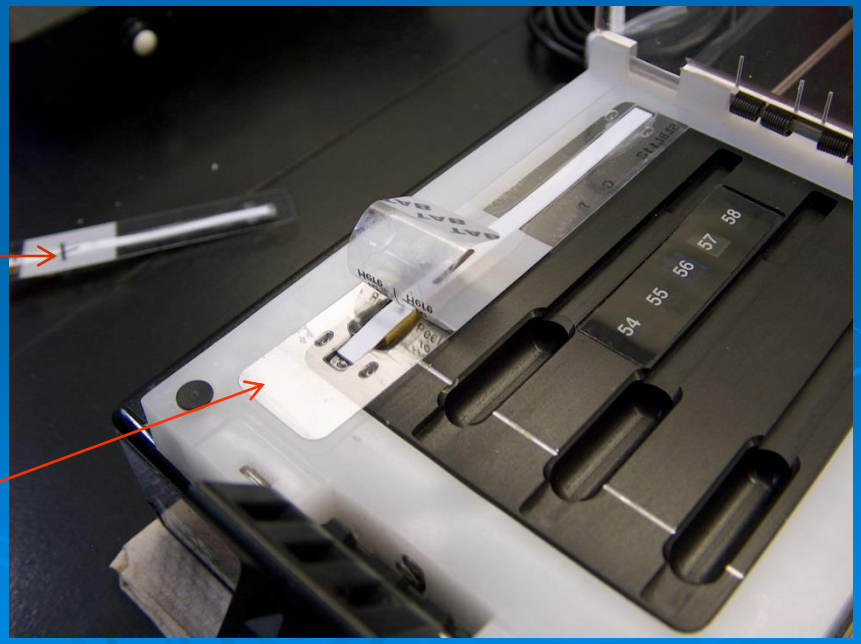
- Shake samples and controls 25 times in 7 seconds with a 1 foot movement or vortex controls for 10 seconds at maximum setting
- Use within 3 minutes
- While holding strip flat in incubator, peel back to line to expose sample pad compartment
- Peel only one strip at a time



Test strips labeled while placed in strip incubator

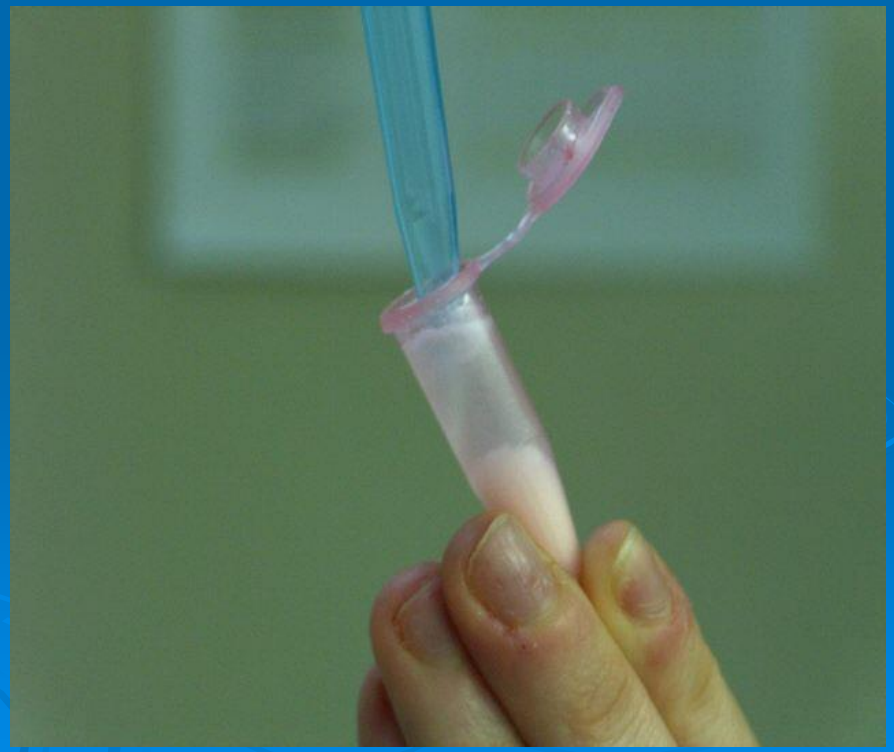
Second strip removed from incubator until ready for sample

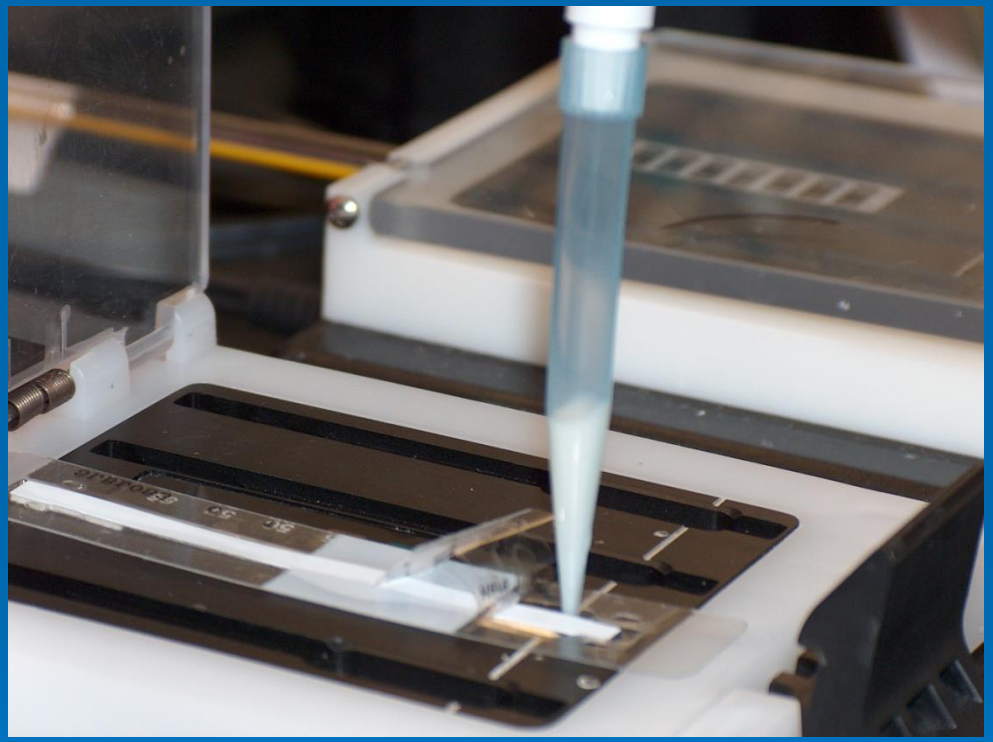
First strip opened to line



ITEM 7: TEST PROCEDURE

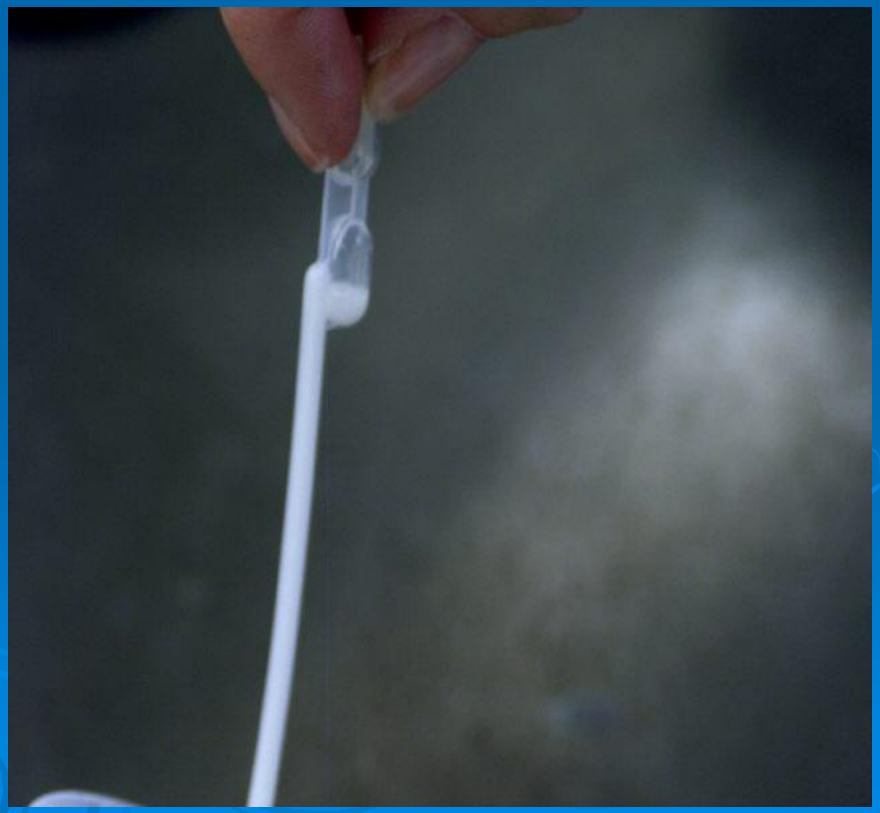
- Draw-up sample avoiding foam or bubbles
- Holding pipette vertically above strip with tip in contact with sample well, slowly pipet sample into test strip





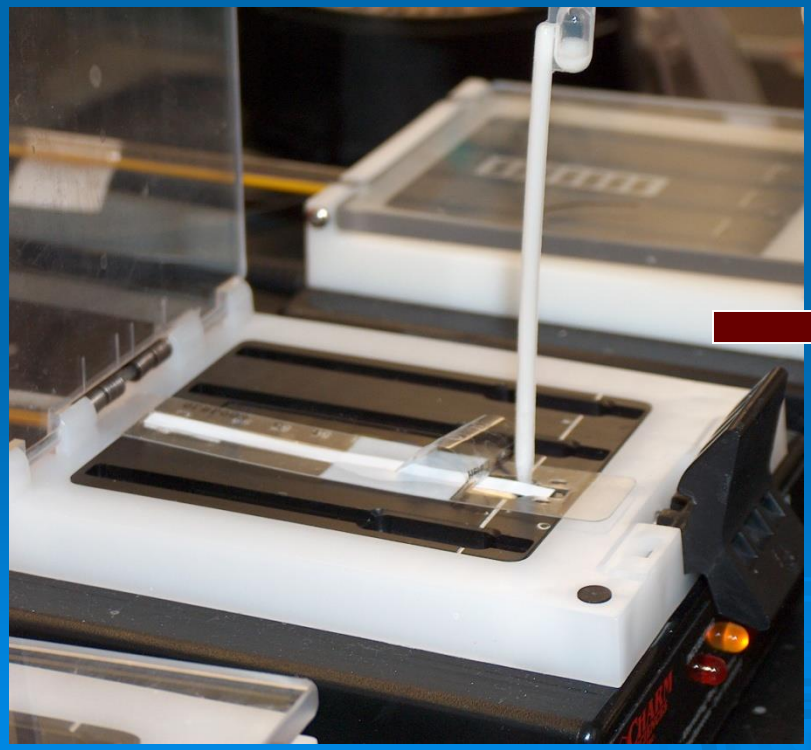
ITEM 7: TEST PROCEDURE

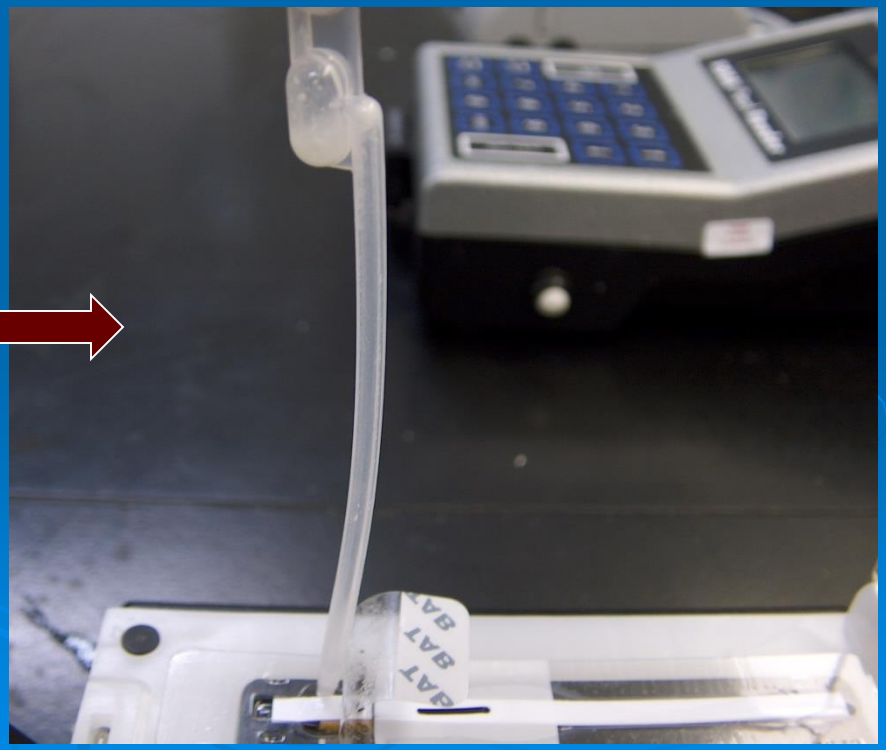
- For Screening only facilities - use the poly pipet provided by the manufacturer
- While holding poly pipet vertically with bulb side pointed down, depress top bulb and insert into sample, below foam
- Release bulb and sample should completely fill pipet shaft and overflow into bottom half of lower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



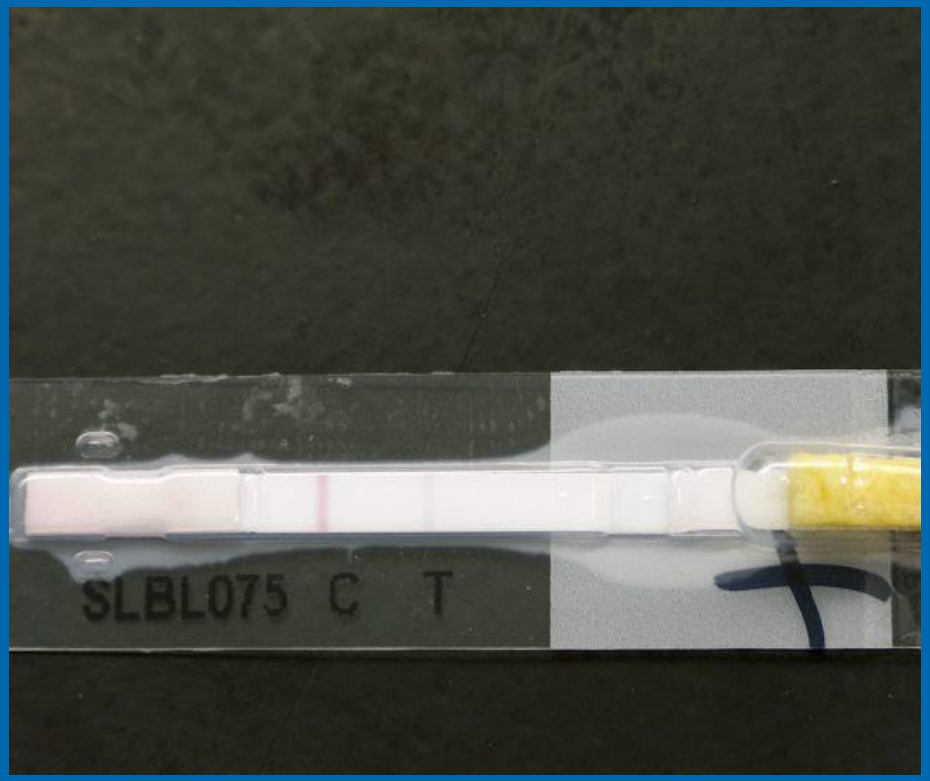


ITEM 7: TEST PROCEDURE

- After pipetting either with the 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 milk into first strip in incubator

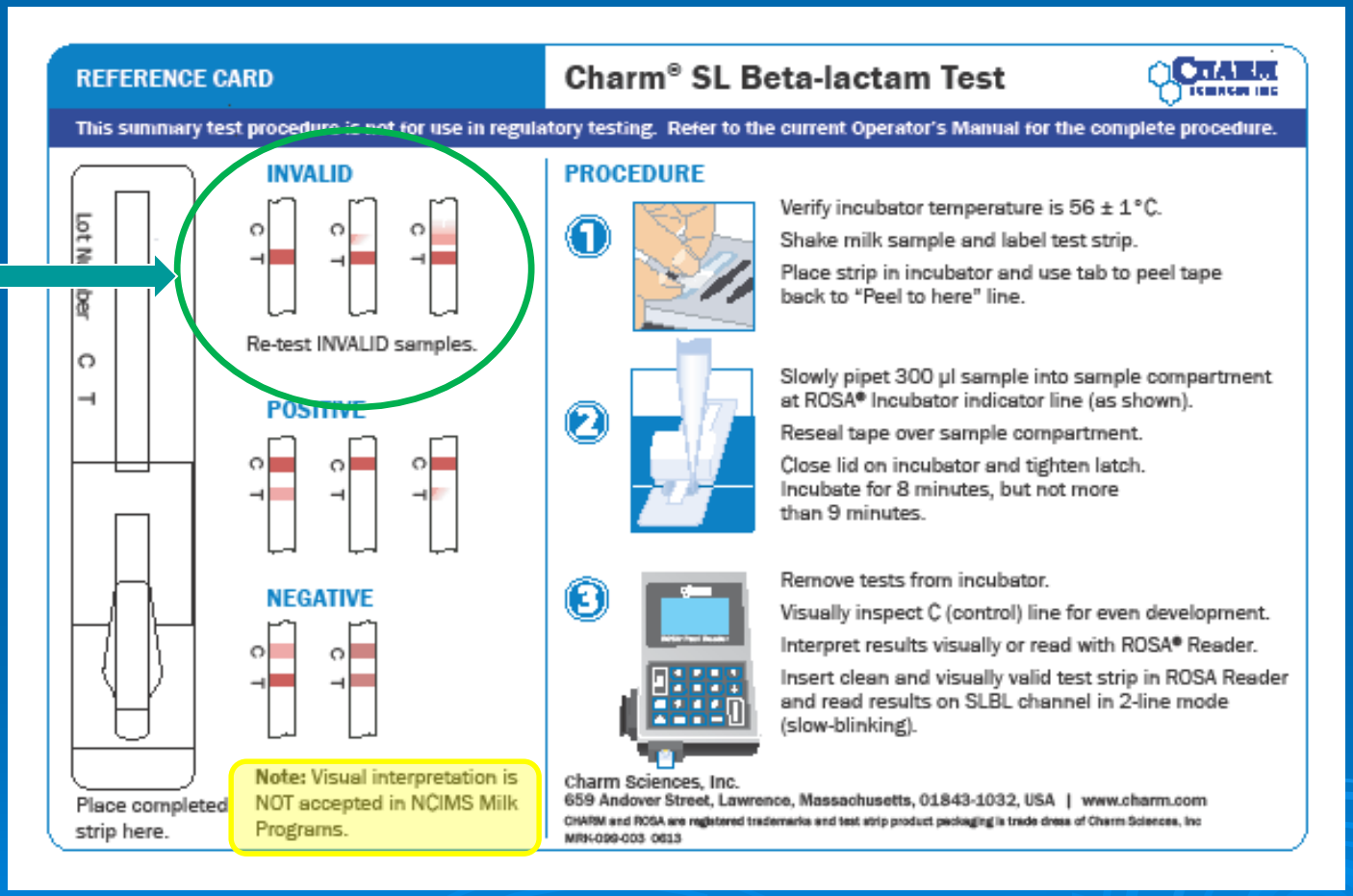
ITEM 7: TEST PROCEDURE

- Close and latch incubator cover, if no automatic timer, set timer for 8 minutes, do not exceed 9 minutes (SL3 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


SLBL075 C T

SLBL075 C T

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

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

Lot Number C T

INVALID

C T C T C T

Re-test INVALID samples.

POSITIVE

C T C T C T

NEGATIVE

C T C T

Place completed strip here.

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

PROCEDURE

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

2. 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.

3. 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).

Charm Sciences, Inc.
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MRH-099-003 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 SL3 beta-lactam test
- Press ENTER
- Reading and interpretation will appear in 5 seconds. Read all strips within 5 minutes (3 minutes for SL3) 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 in accordance with sections 11-13 of FDA 2400 form Appendix N General

ITEM 9: VERIFICATION OF INITIAL POSITIVE

- Initial Positive, Presumptive Positive, Confirmation, and Producer Traceback procedure is addressed in the 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