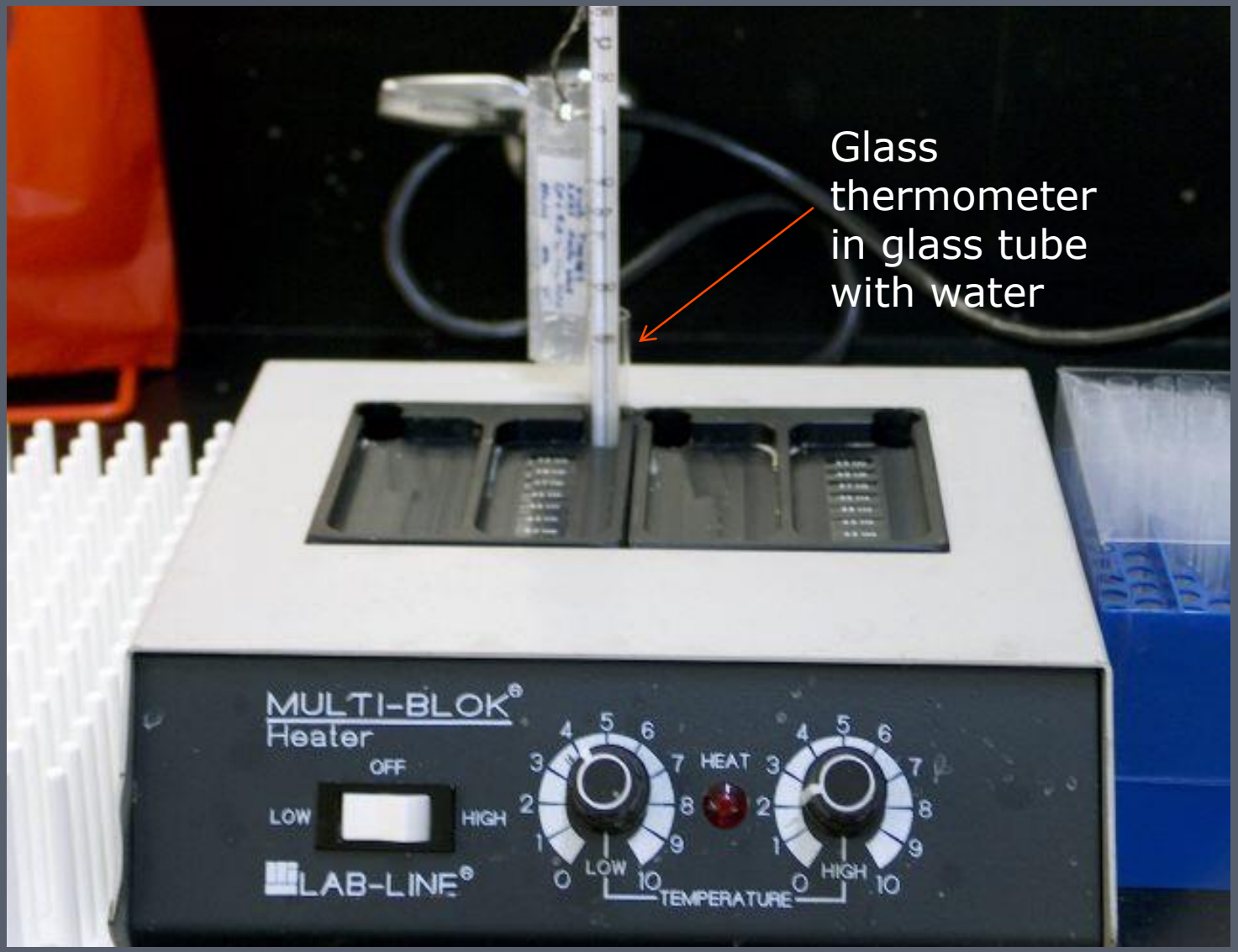
IDEXX NEW SNAP BETA LACTAM TEST

(REV. 3/14)

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

ITEM 3: EQUIPMENT

- Heater block with SNAP inset thermostatically controlled at 45±5°C
- Temperature of heater block is checked by placing standardized thermometer in tube containing liquid (bulb submersed) in heating unit, with records maintained
- Or use a 6 inch partial immersion thermometer placed directly into a well in middle of heating unit, with records maintained

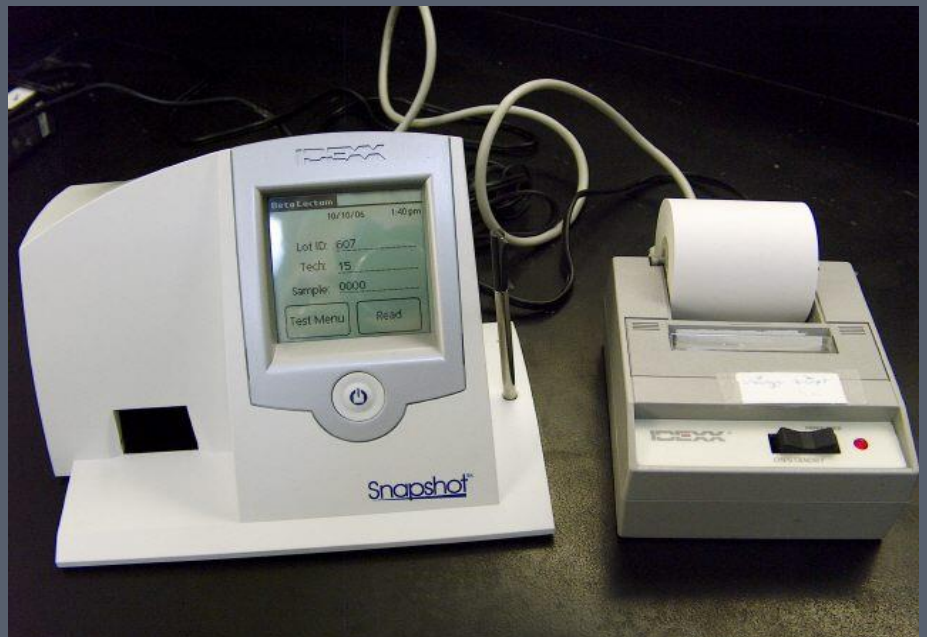

Glass thermometer in glass tube with water
MULTI-BLOK®
Heater
OFF
LOW
HIGH
LAB-LINE®
HEAT
LOW
HIGH
TEMPERATURE

ITEM 3: EQUIPMENT

- IDEXX Readers for SNAP devices, with printer or data download capability
  - SNAPshot® Reader
    - Check Set, Part Number 87-05856-01 (black skirt)
  - SNAPshot® DSR Reader
    - Check Set, Part Number 87-14761-00 (blue skirt)
- Fixed-volume pipettor set to dispense 450 µL with disposable tips, or
- Single use 450 µL± 50 µL pipet with indicator line to measure amount of sample, supplied by the manufacturer (for screening only locations)
- Timer

Fixed Volume pipettors

Single use poly pipet –
Supplied by IDEXX

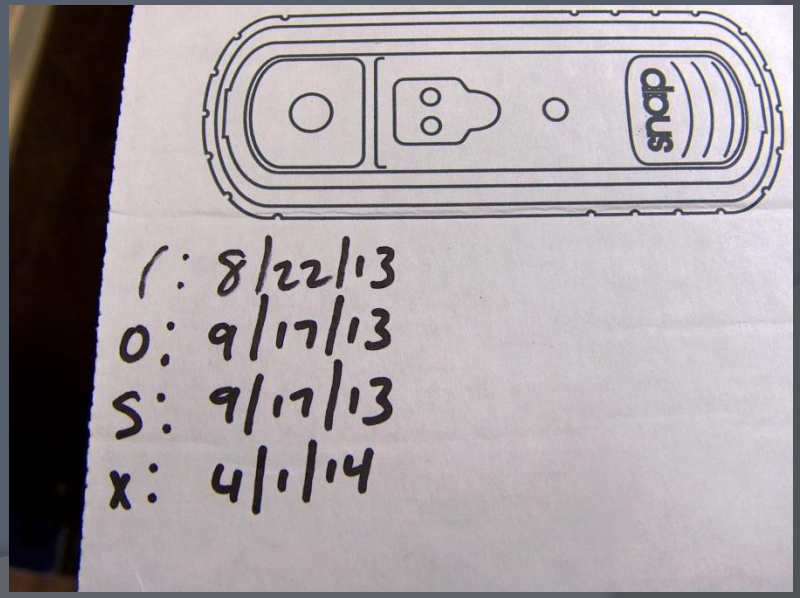


SNAPshot
Reader
with printer

ITEM 4: REAGENTS

- SNAP kit marked with date received, date opened, and date of suitability

Test kit box labeled with date received, date opened, suitability check date



ITEM 4: REAGENTS

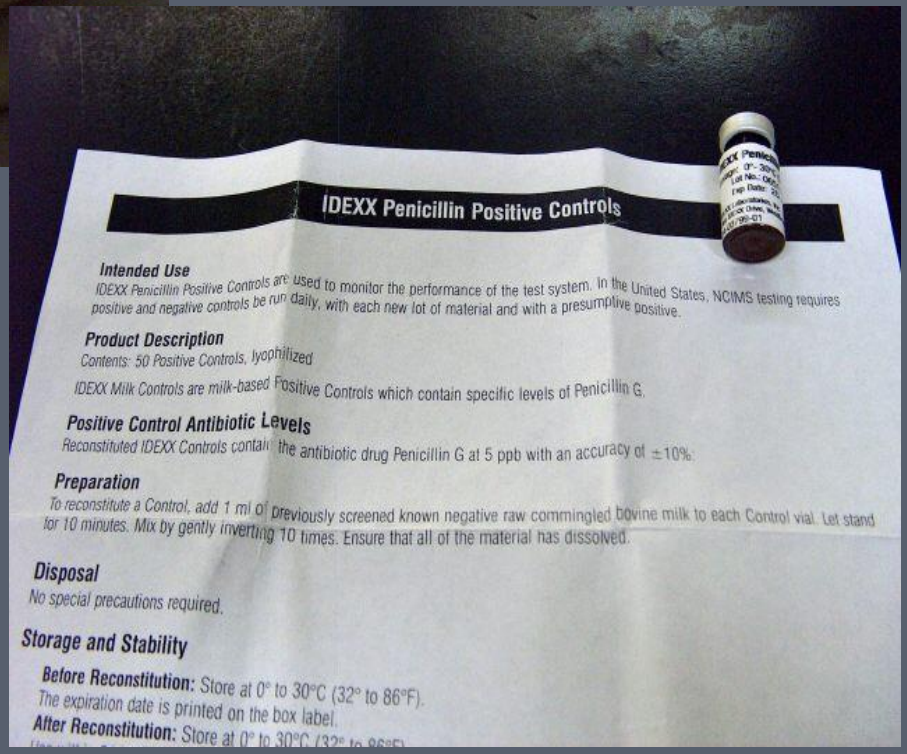
- Positive control
  - IDEXX Penicillin Positive control
- Negative control
  - Previously tested negative raw milk

ITEM 5: REAGENT STABILITY

- Kits must be received within 72 hours if shipped non-refrigerated; over 72 hours must be shipped refrigerated
- Store kits at 0-7.0°C, maintain no longer than manufacturer's expiration date

ITEM 5: REAGENT STABILITY

- Positive Control - Manufacturer supplied, maintain no longer than manufacturer's expiration date
- Store according to label instructions
- Reconstitute as per manufacturer's instructions with fresh or frozen previously screened beta-lactam negative raw milk
- Positive control must produce greater than 1.2 on the IDEXX reader; maintain records(BFSLS 513A rev 7/11)
- Store reconstituted positive control at 0.0-4.5°C for no more than 24 hours



IDEXX Penicillin Positive Controls

Intended Use

IDEXX Penicillin Positive Controls are used to monitor the performance of the test system. In the United States, NCIMS testing requires positive and negative controls be run daily, with each new lot of material and with a presumptive positive.

Product Description

Contents: 50 Positive Controls, lyophilized

IDEXX Milk Controls are milk-based Positive Controls which contain specific levels of Penicillin G.

Positive Control Antibiotic Levels

Reconstituted IDEXX Controls contain the antibiotic drug Penicillin G at 5 ppb with an accuracy of ±10%.

Preparation

To reconstitute a Control, add 1 ml of previously screened known negative raw commingled bovine milk to each Control vial. Let stand for 10 minutes. Mix by gently inverting 10 times. Ensure that all of the material has dissolved.

Disposal

No special precautions required.

Storage and Stability

Before Reconstitution: Store at 0° to 30°C (32° to 86°F).
The expiration date is printed on the box label.
After Reconstitution: Store at 0° to 30°C (32° to 86°F)

ITEM 5: REAGENT STABILITY

- Negative Control - beta-lactam negative raw milk (fresh or frozen)
- Negative control must produce less than 0.95 on the IDEXX reader; maintain records (BFSLS 513B, rev 7/11)
- SNAP Test Negative Control can be any of the approved species milk
- Store fresh negative control milk at 0.0-4.5°C for no more than 72 hours

ITEM 5: REAGENT STABILITY

- Negative control milk can be frozen for later use
- Aliquot within 24 hours and freeze at –15.0°C or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months
- Thaw frozen milk at 0.0-4.5°C
- Once thawed mix thoroughly, **Do Not** use if noticeable protein precipitation is present after thawing
- Thawed negative control milk held at 0.0-4.5°C and used within 24 hours
- Milk controls may not be refrozen

ITEM 6: DAILY PERFORMANCE

- Read Performance Check Set (Device #1 as Negative and Device #2 as Positive)
- Record results on BFSLS 534 (rev 7/09) for older readers or BFSLS 534a (rev 5/15) for newer SNAPShot Readers
- Both devices must read within the limits as indicated on the storage box label of the check set devices
- If check sets fail, Discontinue testing, call IDEXX before proceeding

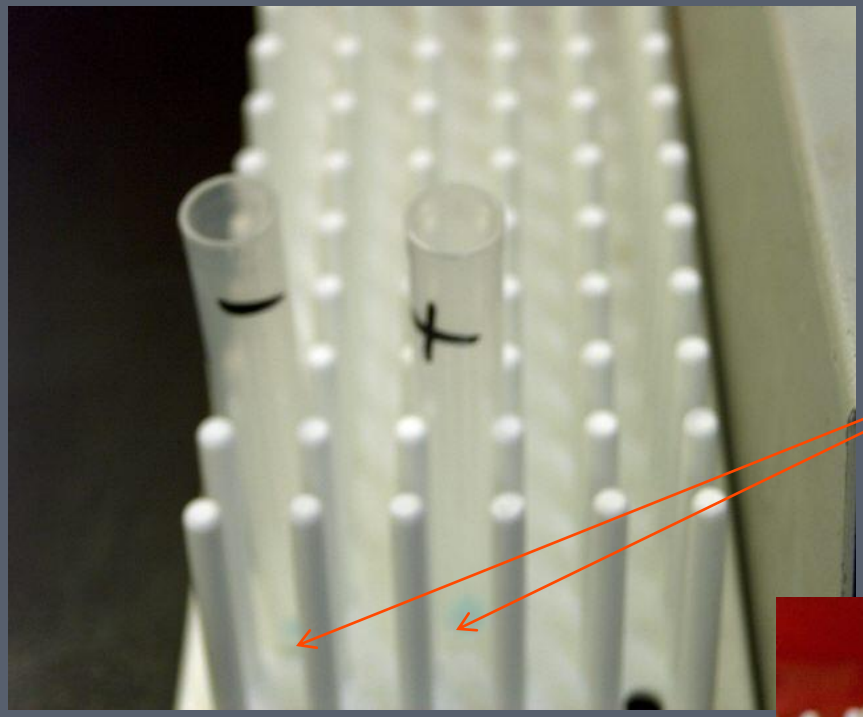

2
1
snap
snap
SNAP00347
12-22-05
MJBennett

ITEM 7: TEST PROCEDURE

- Set out required number of SNAP devices, sample tubes and pipets for the samples to be tested
  - Discard any unused, un-refrigerated devices at the end of the day
- Pre-warm heater block(s) to 45±5C, hold at temperature for at least 5 minutes
- Check initial pre-heating with appropriate thermometer, records maintained

ITEM 7: TEST PROCEDURE

- Continuous use block heaters, check temperature daily(each day of use) with appropriate thermometer, records maintained
- Label each device AND sample tube
- Place only the devices on incubator block, NOT tube(s)
- Verify blue reagent pellet in bottom of tube, if not there, tap to bring pellet down
- Remove and discard sample tube caps



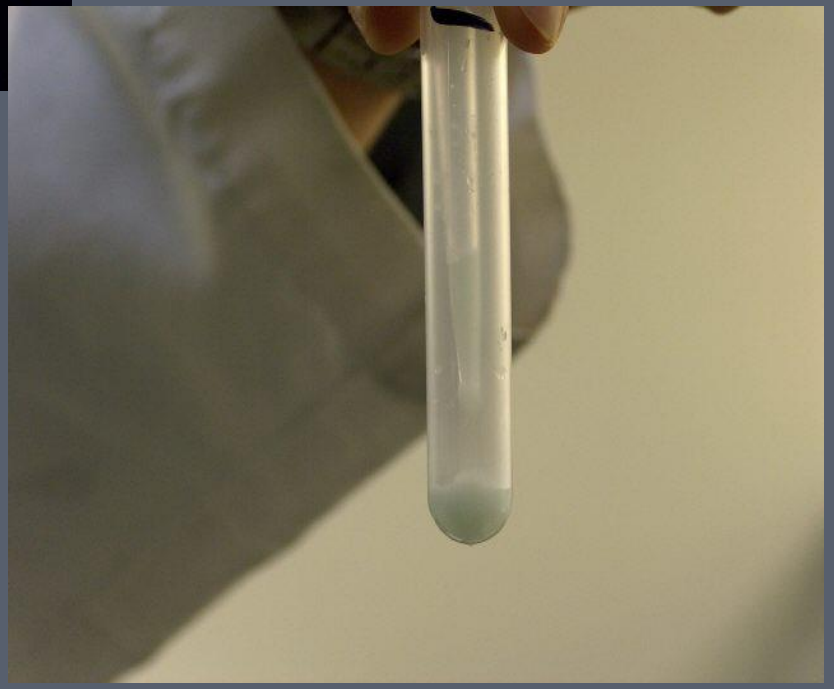
Samples Tubes labeled but not in heater block

Blue reagent pellet in bottom of each tube

Devices labeled and placed on heater block

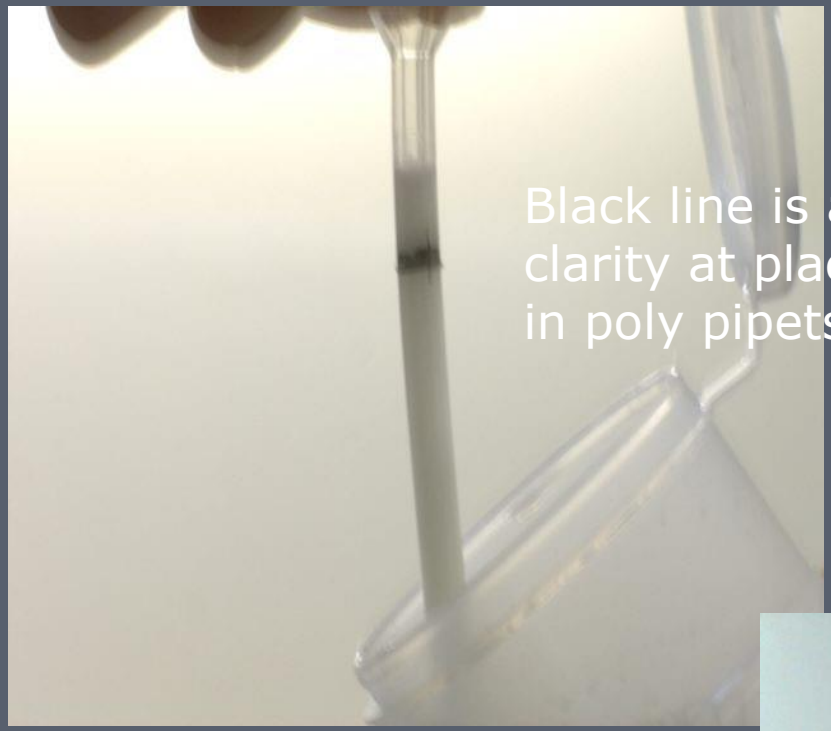
ITEM 7: TEST PROCEDURE

- Mix controls/samples 25 times in 7 seconds through a 1 foot arc, or vortex for 10 seconds at maximum setting, use within 3 minutes
- Add 450 uL of mixed sample/control to corresponding tube(s)
  - Using pipettor with a new tip for each sample/control draw up 450 µL avoiding foam and bubbles
  - Remove tip from liquid
  - While holding the pipettor vertically, expel test portion to sample tube

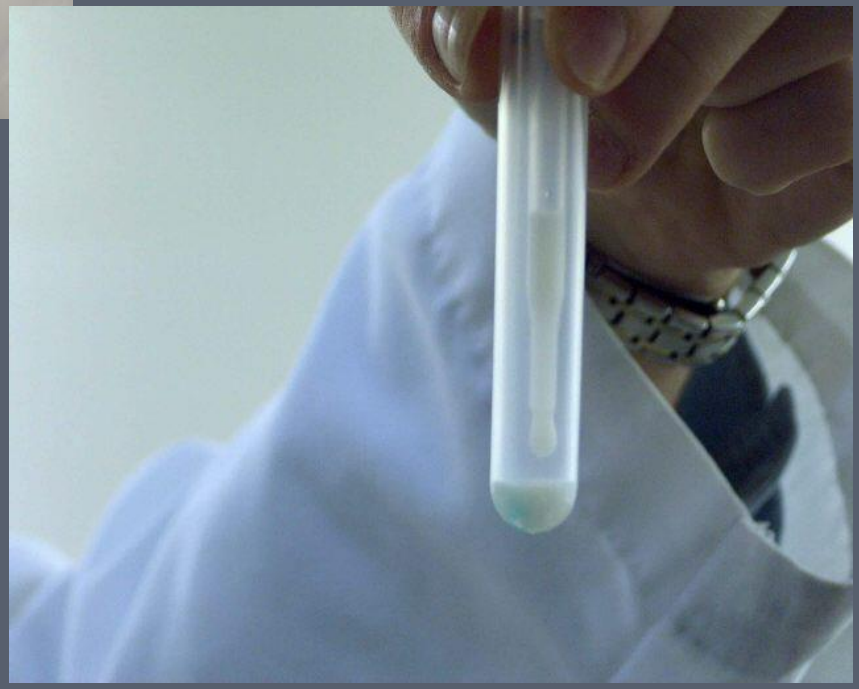


ITEM 7: TEST PROCEDURE

- Screening labs only
- Using a new manufacturer provided single-use 450 µL poly-pipet for each sample/control
  - Draw up 450 uL of sample to indicator line, avoiding foam and bubbles
  - Remove tip from liquid
  - While holding poly-pipet vertically, expel test portion to sample tube



Black line is added for visual clarity at placement of etched line in poly pipets



ITEM 7: TEST PROCEDURE

- Agitate sample tube to dissolve reagent pellet
- Incubate tube(s) in heater block next to device with the corresponding ID for 5 minutes (use timer) at 45±5°C

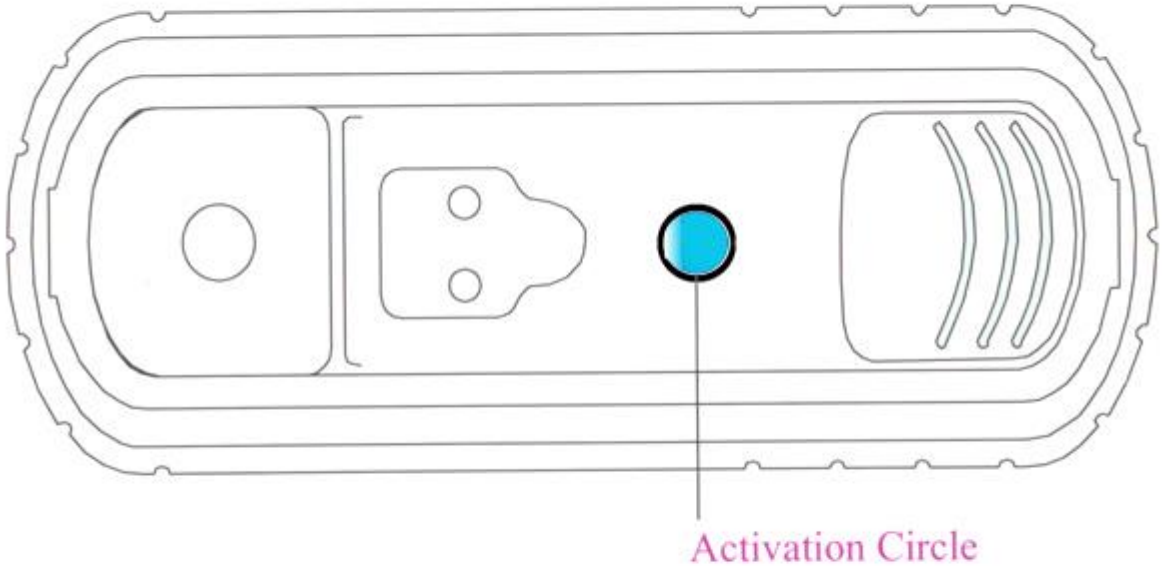

4.2 108
4.1 106
4.9 120
4.8 118
4.7 116
4.5 114
4.4 112
4.3 110
4.2 108
4.1 106

ITEM 7: TEST PROCEDURE

- After incubation, pour contents of each tube into sample well of corresponding device
- Watch blue activation circle as it BEGINS to become white push the Activator firmly until it “snaps” flush with the body of the SNAP device (device remains in heater block)

BFSLS 552 (Rev 5/06)

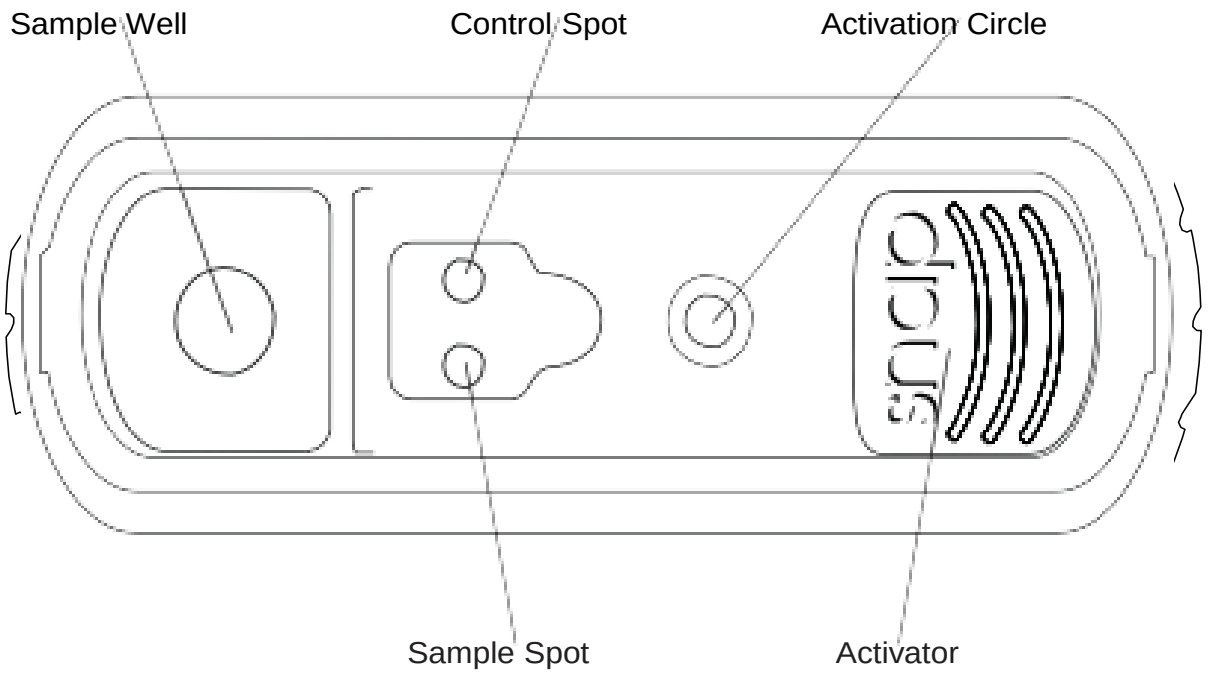
When to SNAP!



Snap the device just as the Activation Circle starts to turn from blue to white.

ITEM 7: TEST PROCEDURE

- Incubate device for 4 minutes (use timer) at 45±5°C
- At the end of incubation, visually inspect the control and test spots
- The Control Spot is on the top and the Test Spot is on the bottom of the Results Window (when activator button to the right and sample well to left)


Sample Well
Control Spot
Activation Circle
Sample Spot
Activator

ITEM 7: TEST PROCEDURE

- The test is invalid and the same sample should be retested with a new SNAP device if:
  - The control spot fails to develop color
  - Blue streaking occurs in the background or the background is the same color as the sample or control spots
  - The sample or control spots are not uniform in color or exhibit poor spot quality

ITEM 7: TEST PROCEDURE

- Insert valid tests IMMEDIATELY (no longer than 30 seconds after incubation) into IDEXX SNAPshot®Reader

ITEM 8: INTERPRETATION

- IDEXX Reader for SNAP devices automatically prints result as Positive or Negative (NF)

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

- Report as Positive results as ‘Positive for Beta Lactam’
- Report Negative results as ‘Not Found(NF)’
- Record test performed, interpretation of unknowns (samples) and controls on BFSLS 500 Rev 1/14 or BFSLS 500a Rev 1/14
- Records and printouts must be maintained for 2 years

Please email QUESTIONS OR COMMENTS to mhydock@pa.gov