APPENDIX N
GENERAL REQUIREMENTS
(REV. 10/13)
ITEM 1: WORK AREA

- Ample working space and utilities
- Clean and well ventilated, test kits used in temperature range specified by manufacturer
- Adequate lighting: meaning greater than 50 foot candles at working surface, but preferably 100 foot candles
- Eating and drinking not permitted in immediate testing area
ITEM 2: STORAGE SPACE

- Cabinets, drawers, shelves adequate
- Areas neat, clean, and orderly
ITEM 3: THERMOMETERS

- Thermometers traceable to NIST certified thermometer. Certified thermometer must have current valid certificate available.
- NIST thermometer checked at ice point, annually, preferably just before checking test thermometers
- Range of thermometers appropriate for designated use
- Graduation not greater than 1.0°C for Screening Only facilities; Milk Industry and CIS facilities 0.5°C
Mercury in glass NIST certified thermometer

Digital NIST certified thermometer
NIST thermometer tagged with results of ice point check
ITEM 3: THERMOMETERS

- Accuracy of test thermometers checked against certified NIST thermometer before initial use and **annually**, with a correction factor not to exceed ±1.0°C
- Results recorded on BFSLS 515 (Rev 1/14) Thermometer Accuracy Check Log
- If certified NIST thermometer has a correction factor at ice point, use form BFSLS 515a and record raw and corrected NIST thermometer temperatures
ITEM 3: THERMOMETERS

- Accuracy check records must be current and acceptable whether checked onsite or at another location
- Thermometer tagged with date, identification/location, temperature checked, analyst doing check and any applicable correction factor (0.0°C, if none)
ITEM 3: THERMOMETERS

- Dial thermometers are not permitted in the testing area / laboratory!
- Automatic temperature recording instruments, if used, are to be compared weekly against an accurate thermometer with results recorded.
ITEM 4: REFRIGERATION

- Size adequate for workload
- Must maintain samples at 0-4.5°C; if not, take corrective action and document correction and rechecked temperature
- Reagents must be stored according to manufacturer’s instructions
- Not to be used to store food or drink for consumption
ITEM 4: REFRIGERATION

- Record temperatures twice daily (AM and PM) using two thermometers with bulbs submerged in liquid, placed on upper and lower shelves of the refrigerator.
- Screening only labs have the option of recording temperature once daily.
- Temperatures are to be read and recorded to the nearest 0.1°C.
ITEM 5: FREEZER

- Size adequate for workload
- Maintain temperature –15.0°C or below; if not, take corrective action and document correction and rechecked temperature.
- Reagents must be stored according to manufacturer’s instructions
- Not to be used to store food or drink for consumption
ITEM 5: FREEZER

- Record temperatures twice daily (AM and PM) using thermometer(s) with bulbs submerged anti-freeze liquid
- Screening only labs have the option of recording temperature once daily
- Temperatures are to be read and recorded to the nearest 0.1°C
ITEM 6: BALANCE

- Weight capability appropriate for intended use
- Appropriate sensitivity for accuracy check of pipetting devices within a tolerance of ±5%
- Balance checked monthly with Class S or S1, or equivalent ASTM 1, 2, 3 weights with results recorded on BFSLS 497, rev. 1/14
- Weights have a valid certificate or other verification of authenticity
- Balance checked annually by a qualified service representative with records maintained
ITEM 7: PIPETTORS

- Checked for accuracy every 6 months with ten (10) consecutive measurements by weight using a separate tip for each measurement or, by volume using a Class A graduate for pipettors of >1.0 ml
- Average of all ten measurements must be ±5% of the specified delivery volume
ITEM 7: PIPETTORS

- Pipettors must be etched with identification; Imprinted serial numbers are acceptable.
- Pipettors are tagged with the date and analyst of accuracy check.
- Accuracy check records must be current and acceptable whether checked onsite or at another location.
- Records maintained on BFSLS 503, rev. 1/14.
Pipettor with imprinted serial number
Pipettors tagged with date & results of accuracy check and analyst
PREVENT CONTAMINATION WITH DISINFECTANTS FROM HANDS OR OTHER SOURCES

Pipet tips, disposable pipets, and/or test kits must be decontaminated before discarding, i.e. soaking in a sanitizing solution overnight or autoclaving (sanitizer used in plant should be sufficient, ex. 200ppm chlorine or 25ppm iodine)
Waste bag for use in autoclave

Container with 200ppm bleach solution and appropriate test kit
ITEM 9: SAMPLE REQUIREMENTS

- Ascertain temperature of bulk milk tanker
- A TC (temperature control) sample must be taken, transported, and maintained with the tanker sample until it is tested
- Secure a representative sample for drug residue testing and transport promptly to testing location on ice to maintain temperature
- Record date, time and temperature of sampling
Ice water bath for samples with Temperature Control (TC) sample

TC temperature determined using digital thermometer
DO NOT USE DIAL THERMOMETERS!
ITEM 9: SAMPLE REQUIREMENTS

- Tanker samples tested promptly upon arriving at the testing location, measure TC provided.
- If test kit indicates a positive result, confirmation must be completed within 72 hours of initial collection (time of truck sampling).
ITEM 9: SAMPLE REQUIREMENTS

- Record date, time, and temperature of samples as tested
- Determine sample temperature by inserting a digital thermometer or pre-cooled glass into TC (temperature control)
- If no TC, aliquot samples for testing and measure temperature using one of the producer samples (avoid as routine practice)
Glass TC thermometer kept in alcohol solution. Kept in the fridge when not in use (pre-cooled).
ITEM 9: SAMPLE REQUIREMENTS

- DO NOT accept samples that:
  - are over-filled (more than \( \frac{3}{4} \) full)
  - are leaking
  - have the tops of samples (seals) in direct contact with ice (should be using ‘floater’ racks)
  - are unprotected and submerged in water and/or ice or slush
If raw milk samples exceed 4.5°C on receipt, DO NOT TEST.

However, samples may be received >4.5 °C but < 7°C if time of receipt is ≤ 3 hours from collection and arrival temperature is equal to or less than the temperature of collection.

- Document temperature violation
- Avoid as routine practice
ITEM 10: PERFORMANCE TESTING

- Run a positive and negative control on each new lot of kits before use. Controls must give appropriate results, with records maintained (BFSL5 513 Rev. 1/14).

- Run a negative and positive control DAILY (on days of testing) and when first prepared. Controls must give appropriate results, with records maintained (BFSL5 513a Rev 7/11, BFSL5 513b Rev 7/11).
ITEM 10: PERFORMANCE TESTING

- If controls do not give appropriate results, re-run controls (may be necessary to make new controls).
- If problem persists, **discontinue testing**, contact one of the Laboratory Evaluation Officers and seek technical assistance from the manufacturer.
ITEM 10: PERFORMANCE TESTING

- If available from manufacturer, check instrument calibration with check devices DAILY (on days of testing), with records maintained (BFSL5 534 SNAP Rev 7/09, BFSL5 534a SNAPShot Rev 5/15 & BFSL5 535 Rosa Reader Rev 7/09).

- Devices must give appropriate results. If not, **discontinue testing** and seek technical assistance from the manufacturer.
IDEXX check devices

Charm ROSA
Reader check devices
ITEM 10: PERFORMANCE TESTING

- If more than one analyst performs analysis, have a different analyst run performance checks on rotational basis.
ITEMS: 11-13 INITIAL, PRESUMPTIVE, CONFIRMATION, & PRODUCER TRACEBACK OF SAMPLES

- This is addressed in the Appendix N Flow Chart Presentation
ITEM 14: REPORTING & RECORDS

- Report Positive results as ‘Positive (+) for Beta-Lactam’
- Report Negative results as ‘Not Found (NF)’
- Report tests performed, interpretation of unknowns (samples) and controls (BFSL500 rev. 1/14 or BFSL500a rev. 1/14)
ITEM 14: REPORTING & RECORDS

- Records, including all printouts, must be maintained for 2 years and be available for the LEO to review during the biennial evaluation.
ITEM 15: MISCELLANEOUS

- Current Safety Data Sheets (SDS) accessible to analysts
- Current, applicable survey forms (2400 forms) available in the laboratory
- Positive Report Forms available with instructions
Personnel adequately trained

If an analyst does not have a PA analyst number (PA#) assigned then no training documentation has been approved by PDA.

If no training documentation has been approved by PDA, the analyst in question cannot conduct testing.

All IA’s (Industry Analysts) are to receive re-training annually from an IS or CIS. (BFSLSS 528 rev 1/14)
• Required split sample participation annually if receiving more than 200,000 pounds of milk a week (March Splits)

• Facilities receiving less than 200,000 pounds of milk a week will be required to test check samples brought by the LEO to each on-site evaluation
Please email QUESTIONS OR COMMENTS to mhydock@pa.gov