DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION **MILK LABORATORY EVALUATION FORM**	LABORATORY	
	LOCATION	LAB #
	DATE	X = DEVIATION O = NOT USED U = UNDETERMINED NA = NOT APPLICABLE

CULTURAL PROCEDURES – GENERAL REQUIREMENTS
[Unless otherwise stated all tolerances are ±5%]

1. Work Area .....
- a. Level table or bench, ample working space and utilities .....
- b. Clean, well ventilated, temperature 16-27C reasonably free from dust and drafts .....
- c. Well-lighted, > 50 foot-candles at working surface (pref. 100) .....
- d. Microbic density of air ≤ 15 colonies/plate in 15 min exposure, or ≤ 10 colonies/PAC plate in 15 min exposure, if not corrective actions taken .....
- e. Freedom from congestion and traffic, only compatible laboratory functions performed .....
- f. Safe working environment — Refer to OSHA .....
  1. Eating and drinking *not* permitted in laboratory .....
  2. Food and drinks for consumption not stored in laboratory
  3. Analysts wear buttoned/snapped lab coats/uniforms and protective eye-wear, lab coats/uniforms remain on-site ....
  4. Safety equipment available .....
  5. MSDS sheets in laboratory available to analysts .....
  6. Has functioning fume hood with acceptable sash (if necessary, see DMSCC procedure) .....
  7. Flammable solvent areas continuously well ventilated and temperature controlled .....
  8. Proper disposal of potentially hazardous materials .....
     a. Contaminated samples disposed of properly .....
     b. Contaminated glassware or plasticware disposed of or decontaminated properly .....
     c. Hazardous chemical disposed of properly .....
- g. Storage Space .....
  1. Cabinets, drawers, and shelves adequate .....
- h. Areas neat, clean and orderly .....
- i. Floors clean, walls and ceilings in good repair .....
- j. Laboratory free of insects and rodents .....

2. Records .....
- a. All laboratory related records maintained and available for announced surveys .....
  1. Three (3) years for state central labs .....
  2. Two (2) years for other labs, minimum requirement, States may require longer periods .....
- b. Quality control and sample records available to laboratory evaluation officer during survey .....
- c. Records contain written corrective actions when taken .....
- d. Records written in ink or other indelible substance, pencil or erasable ink not allowed .....
- e. Corrections to quality control records, bench sheets and reports follow the requirements below: .....
  1. Make a single line through the incorrect information .....
  2. Write in the correct information next to the incorrect information .....
  3. Person making the correction initials the information .....
  4. If not obvious, include reason for correction .....
- f. Requirements for electronic/computer records .....
  1. Software must be well documented .....
  2. Protocols and policies must be clearly documented .....
  3. Records must be indexed and cross referenced to allow easy review, or must be printed and made available .....
  4. Records must be secure from unauthorized access and changes .....
  5. When corrections are necessary the old information must be retained, the person making the correction must be identified and the reason for the change recorded .....
  6. If records are not available at time of audit, facility will be cited for not having records and will be subject to penalties .....

APPARATUS & MATERIALS

3. Thermometers .....
- a. National Institute of Standards and Testing (NIST) Certified Thermometer, or equivalent, with certificate Serial Number _____ .....
  1. Graduation interval not more than 0.5C (0 - 100C) otherwise not more than 1.0C (< 0 or > 100C) .....
  2. Calibration date on certificate _____ .....
  3. Annually, checked at the ice point Date _____ .....
- b. Range of test thermometers appropriate for designated use .....
  1. Mercury-in-glass, alcohol/spirit or digital in degrees centigrade .....
  2. Plastic lamination recommended for mercury thermometers .....
- c. Graduation interval not more than 0.5C (0 - 100C) otherwise not more than 1.0C (< 0 or > 100C) .....
- d. Accuracy of test thermometers checked against certified thermometer .....
  1. Accurate to ±1C when checked at temperature(s) of use .....
  2. Results recorded and thermometers tagged .....
     a. Tag includes identification/location, date of check, calibration temperature and correction factor(s) (read to within ±0.5C) .....
- e. All test thermometers accuracy checked before initial use and annually, including autoclave maximum registering and hot air oven thermometers .....
- f. Electronic thermometers checked before initial use and annually as described above .....
- g. Automatic temperature recording instruments, if used, compared weekly against accurate thermometers, results recorded .....
- h. Dial thermometers not used in the laboratory .....

4. Refrigeration (Sample _____) .....
(Reagent _____) .....

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CULTURAL PROCEDURES – GENERAL REQUIREMENTS

[Unless otherwise stated all tolerances are ±5%]

a. Size adequate for workload ..... _____
b. Maintains samples at 0-4.4C; if temperature out of range, record samples as not analyzed ..... _____
c. Used for storage of milk or milk products, media and reagents only ..... _____
1. Not to be used to store food or drink for consumption ..... _____
d. Record temperature (corrected) daily, in AM and PM, from two thermometers with bulbs immersed in liquid (in sealed containers) ..... _____
e. Thermometers located on upper and lower shelves of use ..... _____

5. Freezer (_____) ..... _____
a. Size adequate for workload ..... _____
b. Maintains −15C or below ..... _____
c. Used for storage of frozen milk products, controls, media and reagents only ..... _____
1. Not to be used to store food or drink for consumption ..... _____
d. Record temperature (corrected) daily, in AM and PM, thermometer with bulb immersed in antifreeze liquid (in sealed containers) ..... _____

6. Pipets (Glass _____ Plastic _____ Pipettor _____) ..... _____
a. Appropriate capacity ..... _____
b. Must conform to APHA specifications ..... _____
c. Graduations distinctly marked with contrasting color ..... _____
d. Discard those with broken tips, scratches or other defects ..... _____
e. Pipettors, calibrated, fixed volume type only ..... _____
1. Calibrate with ten (10) consecutive weighings quarterly (using separate tip for each weighing), average of all 10 weighings must be ±5% of specified delivery volume (≤1.0 mL by weight, ≥ 1.0 mL by volume using class A graduated cylinder), records maintained .....
2. Etched with identification and tagged with date calibrated ..... _____
3. Sterile tips appropriate to pipettor(s) being used ..... _____

7. Pipet Containers ..... _____
a. Used for sterilization, storage; non-toxic ..... _____

8. Dilution Bottles and Closures, reusable ..... _____
a. Bottles of borosilicate glass _____ or approved plastic _____ with smooth tops ..... _____
b. Capacity 150 mL, indelibly marked at 99±1 mL level ..... _____
c. Closure non-toxic rubber stopper or plastic screw cap with liner ..... _____
d. New Bakelite type plastic caps and closures treated to remove toxic residues, tested using a *B. stearothermophilus* type assay ..... _____
e. Discard bottles and caps with chips, cracks, scratches or other defects ..... _____

9. Petri Dishes (Glass _____ or Plastic _____) ..... _____
a. Bottom at least 80 mm I.D., and 12 mm deep for plate counts ..... _____
Brand _____ ..... _____
b. Bottom 86.1 - 87.0 mm I.D., and 12 mm deep for BsDA ..... _____
Brand _____ ..... _____
c. Bottom flat and free from bubbles, scratches or other defects ..... _____

10. Petri Dish Container ..... _____
a. Used for sterilization, storage; non-toxic ..... _____

11. Hot-Air Sterilizing Oven (_____) ..... _____
a. Sufficient size to prevent crowding of interior in normal usage ..... _____
b. Constructed to provide uniform temperature in chamber ..... _____
c. Thermometer or temperature recorder with adequate range (to 220C) ..... _____
1. Thermometer checked at temperature of use for accuracy before initial use, records maintained ..... _____
2. Thermometer bulb immersed in sand ..... _____
d. Records maintained for each sterilization cycle including date, start-up time, time sterilization temperature reached, and length of time at sterilization temperature ..... _____
e. Temperature indicator used each load ..... _____
f. Performance checked with full load and recorded quarterly (preferably weekly) using spore (*B. subtilus*) strips, include positive control check, results maintained ..... _____
1. Brand: _____ ..... _____
2. Lot #: _____ Exp. Date: _____ ..... _____

12. Sterilization by Dry Heat ..... _____
a. Material in center of load heated to ≥ 170C for ≥ 2 hrs ..... _____
b. Oven not crowded (< 75% of shelf in gravity type, 90% in forced air type) ..... _____

13. Autoclave (Media _____) ..... _____
(Waste _____) ..... _____
a. Sufficient size to prevent crowding of chamber ..... _____
b. Thermometer or temperature recorder-controller properly located to register chamber temperature ..... _____
c. Has pressure gauge and properly adjusted safety valve ..... _____
d. Connected to suitable saturated steam line or steam generator ..... _____
e. Chamber temperature checked at least quarterly (preferably more frequently, ex. weekly with sterility check) with full load with maximum registering thermometer and results recorded ..... _____
f. Cycle timing checked quarterly and found to be accurate, record maintained ..... _____
g. Records maintained for each sterilization cycle including date, start-up time, temperature and time temperature reached, length of time at temperature, time at end of run, time removed and item(s) autoclaved (including waste) ..... _____
1. Strip recorders that provide the above information are acceptable if strips (or copies) are maintained in permanent record, include items autoclaved, time removed and initials ..... _____
2. Circular charts must be interpreted and must have written records to verify the information stated above ..... _____
h. Temperature indicator used each load ..... _____
i. Performance checked with full load and results recorded *weekly* using spore (*B. stearothermophilus*) strips or suspensions, include positive control check, results maintained ..... _____
1. Brand: _____ ..... _____
2. Lot #: _____ Exp. Date: _____ ..... _____
j. Routine maintenance performed and records maintained ..... _____

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CULTURAL PROCEDURES – GENERAL REQUIREMENTS

[Unless otherwise stated all tolerances are ±5%]

14. Sterilization by Moist Heat .....
- a. Media autoclaved at 120±1C .....
  - 1. Dilution buffer blanks for 15 min (30 min optional) .....
  - 2. Media for 15 min (sugar broths as per manufacturer instructions) .....
- b. Media autoclaved within 1 hr of preparation .....
- c. Dilution buffer autoclaved on same day prepared .....
- d. Stoppers or caps slightly loosened to permit passage of steam and air .....
- e. All air expelled from autoclave before pressure allowed to rise .....
- f. Autoclave will reach 120±1C within 15 min (5 min pref) of starting air-exhaust .....
- g. Properly operating and calibrated temperature gauge (not a pressure gauge) relied on to insure sterilization .....
- h. After sterilization, pressure gradually reduced (≥ 15 min) and media removed promptly when atmospheric pressure is reached .....
- i. Total time in autoclave less than 1 hour .....

15. Incubator and/or Incubator Room (SPC, PAC and Coliform)
(#1 _____) .....
(#2 _____) .....
- a. Sufficient size to prevent crowding of interior .....
- b. Shelves placed to assure uniformity at 32C±1C .....
- c. Chamber temperatures measured by not less than two thermometers with bulbs immersed in liquid (in sealed containers) .....
- d. Thermometer located on the top and bottom shelves of use .....
- e. Temperature (corrected) recorded from each thermometer twice daily (AM and PM) .....
- f. Agar (10 - 12 mL) in SPC plates and/or (1 mL) in PAC plates must not lose more than 15% weight after 48 hrs incubation .....
  - 1. Agar weight loss of SPC and/or PAC plates tested quarterly and results recorded .....
    - a. Test minimum of two (2) plates/films per shelf in use, one on each side of shelf, preferably test 10 plates *evenly* distributed throughout the incubator .....
  - 2. Corrective action taken when criteria not met and records of corrective actions maintained .....
    - a. If weight loss is out of compliance take corrective actions (humidify incubator, reduce air flow, etc.) and retest as above and record .....
    - b. Use more agar (15 - 20 mL), if this option used laboratory must document that this amount of agar is routinely used for plating .....

16. Colony Counter .....
- a. Quebec dark-field model or equivalent with satisfactory grid plate .....

17. Hand Tally, accurate .....

18. pH Meter (Milk Lab _____) .....
(Media Prep _____) .....
- a. Electronic only, readable to 0.1 pH units .....
- b. Daily calibration and slope records and maintenance log maintained when in use .....
- c. Record date electrodes (double junction reference pref) put into service (write in QC record and tag probe) .....

19. pH Measurement .....
- a. All measurements made at room temperature .....
- b. Instrument standardized with known buffer solutions .....
  - 1. Three commercially prepared standard solutions used .....
  - 2. Each aliquot used once and discarded .....
  - 3. pH 4, 7 and 10 suggested for linearity and proper function of meter .....
  - 4. Slope determined (95 - 102%) _____ each time meter calibrated, records maintained .....
- c. Medium pH recorded each time measured .....
- d. Final (after sterilization) pH of each batch of medium determined before use, records maintained .....
  - 1. Standard Methods Agar, pH 7.0±0.2 .....
  - 2. Violet Red Bile Agar, pH 7.4±0.2 .....
  - 3. Brilliant Green Bile Broth, pH 7.2±0.2 .....
  - 4. PM Indicator Agar, pH 7.8±0.2 .....
  - 5. Buffered Rinse Solution, 7.2±0.2 .....
  - 6. Nutrient Broth, pH 6.8±0.2 .....
  - 7. Letheen Broth, pH 7.0±0.2 .....
  - 8. Lauryl Tryptose Broth (LST), pH 6.8±0.2 .....
  - 9. M-Endo Agar or Broth, pH 7.2±0.2 .....
  - 10. MMO-MUG Medium, pH 7.4±0.2 .....
  - 11. Stock Phosphate Buffer, pH 7.2±0.2 .....
  - 12. Stock $MgCl_2$ Solution, pH 7.2±0.2 .....
  - 13. Dilution Buffer, pH 7.2±0.2 .....

20. Balance (Milk _____) .....
(Media _____) .....
(Analytical _____) .....
- a. Electronic only, sensitive to ≥ 0.1g for general laboratory purposes and proper sensitivity for calibrations and antibiotics .....
- b. Class S or S1, or equivalent ASTM 1, 2, or 3, weights .....
  - 1. Certificate or other verification of authenticity .....
  - 2. Free from excessive wear, filth and corrosion .....
  - 3. Weights within class tolerance .....
- c. Checked monthly with weights corresponding to normal use of balance (ex. 100, 200, 500, 1000 mg, etc. for analytical balances, and 5, 10, 25, 50, 100, 150g, etc. for other balances), records maintained .....
- d. Checked at least annually, or when weights out of tolerance, by a qualified representative for good working order with proof of check in laboratory .....
  - 1. Date of last check _____ .....

21. Water Baths .....
- a. Thermostatically controlled to appropriate temperature(s) .....
- b. Water circulation capability, baths up to 64C .....
- c. Appropriate size for work loads .....
- d. Suitable water level maintained .....

22. Mechanical Dilution Bottle Shaker .....
- a. Type described in SMEDP, 11th Edition .....
- b. Other acceptable _____ .....

23. Microwave Oven for Melting Media .....
- a. Analysts instructed to take extreme caution as media expands rapidly at the boiling point .....

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CULTURAL PROCEDURES – GENERAL REQUIREMENTS
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24. Microbiologically Suitable (MS) Water ..... _____
- a. Type _____ ..... _____
- b. System used _____ ..... _____
- c. Monthly testing criteria
  1. Standard plate count < 1,000 colonies/mL (< 10,000 colonies/mL if stored) ..... _____
  2. Total chlorine residual negative, recorded as less than the detection limit of test used ..... _____
  3. Resistance exceeds 0.5 megohm/cm or conductance is less than 2.0 umhos/cm (at 25C) ..... _____
     - a. Brand: _____ Std. _____ ..... _____
     - b. Test performed in another lab _____ ..... _____
- d. Tested annually for total metals (Pb, Cd, Cr, Cu, Ni and Zn), not to exceed 0.05 mg/L for each metal and not to exceed 0.1 mg/L total for all metals ..... _____
- e. If criteria not met, corrective action(s) taken and recorded in QC record ..... _____
- f. Records maintained ..... _____

25. Dilution Buffer and Blanks ..... _____
- a. Stock phosphate buffer (Date prepared _____) ..... _____
  1. Prepared in laboratory (34g KH_2PO_4/liter) with MS water ..... _____
  2. Purchased commercially prepared _____ ..... _____
  3. Lot No. _____ Exp. Date _____ ..... _____
     Rcd. Date _____ Date Opened _____ ..... _____
  4. Place in small containers (≤ 100 mL), autoclave and store in refrigerator ..... _____
- b. Stock $MgCl_2$ Solution, Optional (Date prepared _____) . _____
  1. Prepared in laboratory (38g $MgCl_2$/liter or 81.1 g $MgC1_2$. $6H_20$/liter) with MS water pH _____ ..... _____
  2. Purchased commercially prepared _____ ... _____
  3. Lot No. _____ Exp Date _____ ..... _____
     Rcd. Date _____ Date Opened _____ ..... _____
  4. Place in small containers (≤ 100 mL), autoclave and store in refrigerator ..... _____
- c. Prepare dilution buffer with 1.25 mL stock buffer/liter of MS water ..... _____
  1. Optionally, add 5 mL of stock $MgCl_2$/liter of MS water ..... _____
- d. Dilution bottles filled to contain 99±2 mL dilution buffer after sterilization ..... _____
  1. After sterilization and after cool visually observe and discard any blanks with < 97 or > 101 mL ..... _____
  2. Of remaining blanks appearing to have the correct volume, check 1 blank for every 25 that were made using a class A graduate cylinder (or equivalent) ..... _____
  3. Maintain records of volume checks, including batch size ..... _____
  4. If *any* blanks out of tolerance, discard entire lot, record lot as discarded ..... _____
- e. Blanks tested at 6 month intervals for toxic substances ..... _____
  1. Plate milk dilution at 0, 15, 30, 45 min ..... _____
  2. If the 45 min count is 20% less than 0 min count, determine cause and retest after correction made, records maintained ..... _____
- f. Alternatively, commercially prepared dilution buffer blanks used ..... _____
  Lot No. _____ Exp. date _____ ..... _____
  Rcd. Date _____ ..... _____
  1. Volume records maintained as above ..... _____
  2. Toxicity checked as above on *each* new lot received ..... _____
  3. Check pH and record ..... _____
- g. Records maintained ..... _____
- h. Corrective action taken when criteria not met, records maintained ..... _____

26. Reagent Chemicals - of ACS Grade ..... _____

27. Media ..... _____
- a. Use dehydrated medium of correct composition ..... _____
  1. Each bottle dated on receipt (in lab or by central receiving, which ever first) and when first opened for use ..... _____
  2. Stored as specified by manufacturer; after opening, each bottle tightly capped following each use ..... _____
  3. Commercially sealed medium kept no longer than manufacturer's expiration date ..... _____
  4. Opened bottles used until manufacturer's expiration date ... _____
  5. Discarded if any change is noted in appearance or hydration regardless of manufacturer's expiration date .... _____
- b. Plate Count Agar _____ ..... _____
  1. Composition: Pancreatic Digest of Casein ----- 5 g ..... _____
     Yeast Extract ---------- 2.5 g
     Glucose ---------- 1 g
     Agar ---------- 15 g
     MS water to make ---------- 1 L
  2. Lot No. _____ Exp. Date _____
     Rcd. Date _____ Date Opened _____ ..... _____
- c. Petrifilm Aerobic Count (PAC) Plate ..... _____
  1. Lot No. _____ Exp. Date _____
     Rcd. Date _____ Date Opened _____ ..... _____
- d. Violet Red Bile Agar _____ ..... _____
  1. Composition: Yeast Extract ---------- 3 g ..... _____
     Peptone or Gelysate ---------- 7 g
     Bile Salts ---------- 1.5 g
     Lactose ---------- 10 g
     Sodium Chloride ---------- 5 g
     Neutral Red ---------- 0.03 g
     Crystal Violet ---------- 0.002 g
     Agar ---------- 15 g
     MS water to make ---------- 1 L
  2. Boil 2 min, temper and use within 3 hours (do not autoclave) ..... _____
  3. Lot No. _____ Exp. Date _____
     Rcd. Date _____ Date Opened _____ ..... _____
- e. Petrifilm Coliform Count (PCC) Plate ..... _____
  1. Lot No. _____ Exp. Date _____
     Rcd. Date _____ Date Opened _____ ..... _____
- f. Petrifilm High Sensitivity Coliform Count (HSCC) Plate ..... _____
  1. Lot No. _____ Exp. Date _____
     Rcd. Date _____ Date Opened _____ ..... _____
- g. Brilliant Green Lactose Bile Broth _____ ..... _____
  1. Composition: Peptone or Gelysate ---------- 10 g ..... _____
     Lactose ---------- 10 g
     Oxgall ---------- 20 g

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Brilliant Green ---------- 0.0133 g
MS water to make ---------- 1 L

2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

h. PM Indicator Agar _____ ..... _____
1. Composition: Beef Extract ---------- 3 g ..... _____
Peptone ---------- 5 g
Tryptone ---------- 1.7 g
Soytone ---------- 0.3 g
Dextrose ---------- 5.25 g
Sodium Chloride ---------- 0.5 g
Dipotassium Phosphate ------ 0.25 g
Polysorbate 80 ---------- 1 g
Brom Cresol Purple ---------- 0.06 g
Agar ---------- 15 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

i. Buffered Rinse Solution _____ ..... _____
1. Composition Stock Phosphate Buffer ---- 1.25 mL ..... _____
10% Na Thiosulfate Solution -- 5 mL
Azolectin ---------- 4 g
Tween 20 ---------- 10 g
MS water to make ---------- 1 L
2. Weigh hygroscopic Azolectin rapidly and dissolve by heating over boiling water ..... _____
3. Date prepared _____ ..... _____

j. Nutrient Broth (laboratory use only) _____ ..... _____
1. Composition Beef Extract ---------- 3 g
Peptone ---------- 5 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

k. Letheen Broth _____ ..... _____
(For use with Petrifilm, Do not use diluents containing thiosulfate or sodium citrate)
1. Composition Peptamin ---------- 10 g ..... _____
Beef Extract ---------- 5 g
Lecithin ---------- 0.5 g
Sorbitan Monooleate ---------- 5 g
Sodium Chloride ---------- 5 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

l. Lauryl Tryptose Broth (LST) _____ ..... _____
1. Composition Tryptose ---------- 20 g ..... _____
Lactose ---------- 5 g
Dipotassium Phosphate ------ 2.75 g
Monopotassium Phosphate ---------- 2.75 g
Sodium Chloride ---------- 5 g
Sodium Lauryl Sulfate --------- 0.1 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

m. M-Endo Agar _____ ..... _____
1. Composition Yeast Extract ---------- 1.2 g ..... _____
Casitone ---------- 3.7 g
Thiopeptone ---------- 3.7 g
Tryptose ---------- 7.5 g
Lactose ---------- 9.4 g
Dipotasium Phosphate --------- 3.3 g
Monopotasium Phosphate ------ 1 g
Sodium Chloride ---------- 3.7 g
Sodium Desoxycholate --------- 0.1 g
Sodium Lauryl Sulfate ------- 0.05 g
Sodium Sulfite ---------- 1.6 g
Basic Fuchsin ---------- 0.8 g
Agar ---------- 15 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

n. M-Endo Broth _____ ..... _____
1. Composition Yeast Extract ---------- 1.5 g ..... _____
Casitone ---------- 5 g
Thiopeptone ---------- 5 g
Tryptose ---------- 10 g
Lactose ---------- 12.5 g
Dipotasium Phosphate ------ 4.375 g
Monopotasium Phosphate - 1.375 g
Sodium Chloride ---------- 5 g
Sodium Desoxycholate --------- 0.1 g
Sodium Lauryl Sulfate ------- 0.05 g
Sodium Sulfite ---------- 2.1 g
Basic Fuchsin ---------- 1.05 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

o. MMO-MUG Medium _____ ..... _____
1. Commercial or lab prepared media containing MMO-MUG ..... _____
2. Composition Ammonium Sulfate ---------- 5 g ..... _____
Manganese Sulfate -------- 0.0005 g
Zinc Sulfate ---------- 0.0005 g
Magnesium Sulfate ---------- 0.1 g
Sodium Chloride ---------- 10 g
Calcium Chloride ---------- 0.05 g
Sodium Sulfite ---------- 0.04 g
Amphotercin B ---------- 0.001 g
o-nitrophenyl-ß-D-galactopyranoside ---------- 0.5 g
4-methylumbellifery-ß-D-glucuronide ---------- 0.075 g
Solanium ---------- 0.5 g
Hepes Buffer
Sodium Salt ---------- 5.3 g
Organic Acid ---------- 6.9 g
MS water to make ---------- 1 L
2. Lot No. _____ Exp. Date _____
Rcd. Date _____ Date Opened _____ ..... _____

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CULTURAL PROCEDURES – GENERAL REQUIREMENTS
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p. Charm E*Colite ..... _____
1. Lot No. _____ Exp. Date _____
Rcd. Date _____ ..... _____

28. Medium Preparation ..... _____
a. Media-making utensils borosilicate glass, stainless steel or other non-corrosive equipment ..... _____
b. Weigh required amount of dehydrated medium or ingredients ..... _____
c. Combined with required amount MS water, dissolved and mixed in a suitable container ..... _____
d. pH adjusted if necessary ..... _____
e. Heated (covered), not under pressure, if necessary, to complete solution (microwave preparation not allowed) ..... _____
f. Water restored, as necessary, to compensate for loss due to evaporation ..... _____
g. Distributed into suitable containers so that no part of medium is more than 2.5 cm from any surface ..... _____
1. In general, containers filled no more than half of total volume ..... _____
h. Suitable container closures used and autoclaved as necessary ..... _____
i. Pre-dispensed rinse solutions for containers ..... _____
1. Dispense in appropriate volume (20, 50, 100 mL, or other) and sterilize ..... _____
2. Perform quality control checks for volume (100±2 mL) as described in cultural procedures item 25d ..... _____

29. Prepared Media Storage ..... _____
a. Protected from water loss and light ..... _____
b. Only screw-capped containers kept no more than 6 months ..... _____
c. Prepared Charm PMI plates, kept no more than 5 days in sealed container at 0-4.4C (tag with date of preparation) ..... _____
d. BGB broth at room temperature ..... _____
1. Screw capped tubes for 3 months ..... _____
2. Loose (slip) capped tubes for 1 week ..... _____
3. Stored in dark ..... _____
e. Petrifilm plate storage ..... _____
1. Refrigerate unopened packages of Petrifilm plates at or below 8C, if frozen allow 30 min room temperature thaw time before opening packages ..... _____
2. Use before expiration date on package ..... _____
3. After opening, return unused plates to foil pouch, seal pouch by folding and taping/clipping open end shut ..... _____
4. Store re-sealed packages ≤ 21C, ≤ 50% relative humidity. **Do not refrigerate opened packages.** ..... _____
5. Use Petrifilm plates within one month after opening package (tag with date opened) ..... _____

30. Detergent Suitability Test ..... _____
a. Detergent residue test performed if laboratory washes and re-uses glassware (not required if *only* disposable items used) ..... _____
b. Detergent is suitable for laboratory use ..... _____
Brand _____
Brand _____ ..... _____
c. Test each new brand/lot, records maintained ..... _____

31. Cleaning Pipets ..... _____
a. Used pipets discarded in disinfectant ..... _____
b. Rinsed in tap water at 15-30C ..... _____
c. Thoroughly washed with suitable detergent and rinsed ..... _____
d. Cleaned with strong cleaning solution such as acid dairy cleaner as necessary ..... _____
e. Final rinse with MS water ..... _____
f. Several pieces from each batch tested (preferably while still wet) for residual acid or alkali with aqueous 0.04% bromthymol blue. If color reaction not dark green to light blue, re-rinse and test again. Records maintained ..... _____

32. Cleaning Other Glassware and Apparatus ..... _____
a. Heated to 85C or disinfected unless pathogens suspected; then sterilization required prior to washing ..... _____
b. Washed with hot water and suitable detergent and rinsed .... _____
c. Machine washed (_____) ..... _____
d. Hand washed _____ ..... _____
e. Final rinse with MS water ..... _____
f. Several pieces from each batch tested (preferably while still wet) for residual acid or alkali with aqueous 0.04% bromthymol blue. If color reaction not dark green to light blue, re-rinse and test again. Records maintained ..... _____

SAMPLES

33. Laboratory Requirements ..... _____
a. Record time, date, and temperature of samples as received ..... _____
b. Determine sample temperature ..... _____
1. Insert a pre-cooled thermometer into temperature control (pre-cooling of electronic/digital thermometer probes is not necessary) ..... _____
2. Temperature control must be at least half the size of the largest test container ..... _____
3. Performed by trained personnel, not by collector, establish record to indicate training performed ..... _____
c. If temperature control (TC) for each tank truck and each plant or delivery truck group of samples is *missing,* a test sample may be sacrificed and used as the TC ..... _____
d. Do not accept or test samples if sample containers are leaking ..... _____
e. Do not accept or test samples if unprotected samples are submerged in ice/ice water slush ..... _____
f. Do not accept fluid samples, which are frozen, for microbial or somatic cell analysis ..... _____
g. Do not accept raw samples if sample containers have no head space (about ¾ full) ..... _____
h. If milk sample temperature control exceeds 4.4C on receipt, do not test microbiologically (samples may be tested if temperature does not exceed 7C **and** time of receipt is ≤ 3 hours from collection and sample receipt temperature is no greater than that at collection) ..... _____
i. Store fluid samples at 0-4.4C until tested, if storage temperature exceeds 4.4C prior to testing record as LA (see 4.b.) ..... _____
j. Do not proceed with analysis if above criteria have not been met ..... _____
k. Record date, time and temperature of samples when tested ..... _____

LABORATORY	LAB #	LOCATION	DATE

CULTURAL PROCEDURES – GENERAL REQUIREMENTS
[Unless otherwise stated all tolerances are ±5%]

l. Begin testing of samples within 48 hr. of first collection (if time of collection not available use 12:01 am of date of collection) ..... ____

m. If chemical tests are made, remove portions for microbial analyses first ..... ____

34. Sample Bench Sheet Requirements ..... ____

a. Must show date, time and temperature collected, along with name of official sampler ..... ____

b. Must show date, time and temperature when brought to the laboratory, along with whom received the samples ..... ____

c. Must show date and time of analysis, temperature of samples at start of analysis, and names of analyst(s) performing test(s) ..... ____

d. Sample bench sheets or records must contain all results (raw and calculated in their proper format) of tests performed and the results of all controls that apply to each test ..... ____

1. Plate count procedure controls include:

a. Microbic air density ..... ____

b. Dilution buffer ..... ____

c. Pipets ..... ____

d. Agar ..... ____

e. Temperature of agar at plating (45±1C) ..... ____

2. Results of inhibitor test(s) accompany all plate count and coliform results ..... ____

3. Control results recorded for each inhibitor test performed .... ____

4. All above recorded on sample bench sheets ..... ____

MISCELLANEOUS

35. Laboratory Practices ..... ____

a. Personnel adequately trained and/or supervised ..... ____

b. Satisfactory participation in annual split samples ..... ____

c. Copies of current, applicable FDA 2400 series survey forms in laboratory ..... ____

d. Copy of current edition *Standard Methods* in laboratory ..... ____

e. Copy of current *AOAC Manual of Methods* in laboratory if necessary ..... ____

f. Copy of written Quality Assurance Plan, required for state central laboratories ..... ____

g. Laboratory management has signed and returned the agreement to abide by the provisions of the NCIMS and the procedures for the Evaluation of Milk Laboratories ..... ____

h. Laboratory evaluation officer conducted survey unobstructed by laboratory or facility personnel ..... ____