

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION MILK LABORATORY EVALUATION FORM	LABORATORY <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:70%;">LOCATION</td> <td>LAB #</td> </tr> </table>	LOCATION	LAB #		
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ELECTRONIC SOMATIC CELL COUNT
Fossomatic 5000
 [Unless otherwise stated all tolerances are ± 5%]

- 1. Laboratory Requirements (see CP, item 33)**
- a. Unpreserved samples may be run up to 72 hours after initial collection
 - b. Samples may be run up to 7 days after initial collection if preserved with 0.02% 2-bromo-2-nitropropane-1,3-diol (Bronopol™) or 0.05% potassium dichromate (K₂Cr₂O₇)
 - c. Comparative test with DMSCC
 - 1. Performed by each analyst performing ESCC test
 - 2. Test 4 samples (100K-200K, 300K-500K, 600K-800K and 900K-1.2M) in triplicate for both DMSCC (three separate smears each) and ESCC (three separate subsamples each, do not read same sample three times)
 - 3. Results must be shown to be acceptable prior to official testing by analyst performing comparison, i.e. analyst is not certified until found acceptable. **(co-requisite for certification)**
 - 4. Copy of comparison and results in QC record (or easily accessible file in laboratory) - d. Analysts certified in DMSCC

APPARATUS

- 2. See Cultural Procedures, items 1-5**
- 3. Water Bath**
- a. Circulating and thermostatically controlled to 37-42C

REAGENTS

- 4. Preparation**
- a. 1 Liter bags
 - 1. Stock Solution: Dissolve 500 mL of Clean 5000 in 4.5 L of deionized water, heat to about 60C, store in airtight, light proof container in a cool location and use within 16 weeks
Date Prep. _____ Exp. Date _____
 - 2. Buffer/diluent Solution: Mix 1 L of stock solution with one bag (354 g) of Buffer 5000, add deionized water to 10 L, heat to 40 - 60C to speed process, store in diluent container next to instrument and use within 3 weeks (enough for about 25,000 samples)
Date Prep. _____ Exp. Date _____
 - 3. Rinse/sheath Liquid: Mix 250 mL of stock solution with deionized water to make 50 L, store and use within 3 weeks (enough for about 5000 samples)
Date Prep. _____ Exp. Date _____
 - 4. Insert Dye 5000 bag according to manufacturer's instructions - b. 0.5 Liter Bags
 - 1. Stock Solution: Dissolve 100 mL of Clean 5000 in 900 mL of deionized water (use syringe), heat to about 60C, store in airtight, light proof container in a cool location and use within 16 weeks

- Date Prep. _____ Exp. Date _____
- 2. Buffer/diluent Solution: Mix 0.5 L of stock solution with one bag (171 g) of Buffer 5000, add deionized water to 5 L, heat to 40 - 60C to speed process, store in diluent container next to instrument and use within 3 weeks (enough for about 10,000 samples)
Date Prep. _____ Exp. Date _____
- 3. Rinse/sheath Liquid: Mix 100 mL of stock solution with deionized water to 20 L, store and use within 3 weeks (enough for about 2000 samples)
Date Prep. _____ Exp. Date _____
- 4. Insert Dye 5000 bag according to manufacturer's instructions
- c. Stock Solutions for 5000 basic

 - 1. Dye/buffer stock solution: Dissolve 3 ethidium bromide tablets in 1 L of deionized water, stir to completely dissolve tablets, store in dark cool location, use within 16 weeks
Date Prep. _____ Exp. Date _____
 - 2. Clean 5000 stock solution: Dilute one bottle of Clean 5000 in 4.5 L of deionized water, heat to about 40 - 60C to speed process, store and use within 16 weeks
Date Prep. _____ Exp. Date _____

- d. Working Solutions for 5000 basic

 - 1. Buffer/diluent solution: Dissolve one bag of Buffer 5000 in about 8 L of deionized water in 10 L container, add 1 L of Clean 5000 stock solution and fill to a total of 10 L with deionized water, store and use within 6 weeks
Date Prep. _____ Exp. Date _____
 - 2. Dye/buffer solution: Mix 1800 mL of Buffer/diluent solution and 200 mL of Dye stock solution in the reagent bottle and place in the instruments according to instructions, use within 6 weeks
Date Prep. _____ Exp. Date _____
 - 3. Rinse/sheath liquid: Fill a 50 L container with about 49 L of deionized water, add 250 mL of Clean 5000 stock solution and fill to 50 L with deionize water, use within 3 weeks
Date Prep. _____ Exp. Date _____

- 5. Storage Periods and Temperatures**

 - a. Storage time for Buffer 5000 and Clean 500 is one year from FE (Foss Electric, i.e., manufacture) date
FE Date _____ Exp. Date _____
 - b. Store Dye 5000 at 2-8C for a maximum of 1 year from FE Date
FE Date _____ Exp. Date _____
 - c. Rinse 5000, used to rinse dye interface when instrument has not been used for more than 7 days, store for 1 year from FE date, if seal is not broken, after seal is broken store at 2-8C for no more than 6 months
FE Date _____ Exp. Date _____

- 6. Other Liquids**

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Fossomantic 5000**

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- a. Blind solution: Prepare a 1% (w/v) NaCl solution _____
 - b. Cleaning solution for milk waste tube: Prepare a 0.5% S-470 solution (5 g per Liter), heat to 50 - 70C, used to clean the milk waste tube at end of day, use within 1 week
Date Prep. _____ Exp. Date _____
 - c. Cleaning solution for flow cell flush: Use 0.5% S-470 solution (see item b above) _____
- 7. All solutions labeled with date prepared and expiration date** _____

START UP

- 8. Cell Counter** _____
- a. Turn power on and place instrument in standby mode _____
 - b. Check that enough rinse/sheath liquid, dye and buffer solutions are available in the external containers _____
 - c. Solutions not used beyond expiration date(s) _____
 - d. Perform a blind check before starting measurement, if mean count is < 3000 cells/mL and individual measurements < 5000, within acceptable limits _____
 - e. **IF ANY ABOVE PARAMETERS ARE WRONG, CORRECT BEFORE PROCEEDING** _____
 - f. Records maintained on all parameters each time instrument is used _____
- 9. Milk Standards** _____
- a. Commercially prepared: _____
Lot # _____ Date Rcvd. _____
 - 1. Four standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M _____
 - 2. Do DMSCC in triplicate on each standard in set and average counts, records maintained _____
 - 3. DMSCC check performed in rotation by all certified analysts _____
 - 4. Standards used within one week _____
 - b. Certified provider: _____
Lot # _____ Exp. Date _____
Date Rcvd. _____
 - 1. Four standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M _____
 - 2. Maintain copies of all provided DMSCC values _____
 - 3. Measure and maintain records of temperature (0 - 7.2C) of standards as received _____
 - 4. Maintain copies of all correspondence regarding problems _____
 - c. Laboratory prepared (weekly) _____
 - 1. Prepare from raw milk > 18 hours old preserved with 0.05% potassium dichromate (K₂Cr₂O₇) _____
 - 2. Or, preserved with 0.02% 2-bromo-2-nitropropane-1,3-diol (Bronopol™) _____
 - 3. Standards *cannot* be preserved with formalin _____
 - 4. Prepare 4 standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M, used within one week _____
Date prep. _____ Exp. Date _____
 - 5. Do DMSCC in triplicate on each standard and average counts, records maintained _____
 - 6. DMSCC check performed in rotation by all certified analysts _____

- d. Hourly Control Sample (instrument drift check) _____
 - 1. Use one of the standards (items 9a or b) in the 500-800K range, run in triplicate and determine average _____
 - 2. Optionally, prepare sufficient control/sample 500-800K range, run in triplicate and determine average _____

PROCEDURE

- 10. Testing Standards (each time instrument used)** _____
- a. Heat standards to 37-42C (using a temperature control) and read within 30 minutes of reaching temperature; use once and then discarded, i.e., do not re-use _____
 - b. Mix by inverting at least 2x, place in rack and put onto automatic track, run within 10 minutes _____
 - c. Run the standards three times and average the counts for each level, records maintained _____
 - d. Each standard's average must be within 10% of the DMSCC (item 9) for that level, except within 15% for 100K-200K standard, records maintained _____
 - e. Repeatability - a standard in the 300K to 800K range must have a coefficient of variation (C_v) of 5% or less on 10 replicates (**Refer to Operating Manual**), records maintained _____
 - f. **THESE PARAMETERS MUST BE ACHIEVED BEFORE PROCEEDING** _____
- 11. Testing Samples** _____
- a. Heat samples to 37-42C (using a temperature control) and read within 30 minutes of reaching temperature; samples *must not* be reused and must be discarded after use _____
 - b. Mix by inverting at least 2x, place in rack and put onto automatic track, run within 10 minutes of reaching the testing temperature _____
- 12. With continuous operation:** _____
- a. Run a standard or optionally a control/sample (item 9d) in the 500K to 800K range hourly, must be within 5% of the original established instrument average value (optionally, within 10% of original DMSCC average) _____
 - b. Run control 3x _____
 - c. Run zero control (item 8d) _____
 - d. Maintain records _____
- 13. Routine maintenance** _____
- a. Perform as described in operating manual _____
 - b. Maintain records _____

REPORTS

- 14. Computing and Reporting Counts** _____
- a. Count obtained x 1000 is the cell count/mL milk _____
 - b. In reporting electronic somatic cell counts (ESCC/mL), record only first two left hand digits, raising second digit to next higher number when third digit is 6 or more _____
 - c. Report the two left hand digits (rounded) _____
 - 1. If the third digit is 5 the second digit is rounded by the following rule _____
 - a. When the second digit is odd round up, raise the second digit by 1 (odd up, 235 to 240) _____

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Fossomantic 5000**

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- b. When the second digit is even round down, delete the 5 and report the second digit as is (even down, 225 to 220)
- d. If count on instrument is < 100 report as < 100,000 ESCC/mL