

ELECTRONIC SOMATIC CELL COUNT

Fossomatic™ 7 DC

NCIMS does **NOT** accept or recognize differential counts (DC)

This Model is only approved for Total Somatic Cell Count

(Raw Commingled Cow Milk)

IMS #16

(Unless otherwise stated all tolerances are $\pm 5\%$)

1. Laboratory Requirements (see Cultural Procedures (CP) items 33 & 34)

- a. Un-preserved samples may be run up to 72 hours after initial collection
- b. Samples may be tested up to 7 days after initial collection if preserved with 0.02% 2-bromo-2-nitropropane- 1,3-diol (Bronopol™)

2. Comparative Test with DMSCC

[NOT required as a co-requisite for certification of analysts in laboratories purchasing standards from a CERTIFIED provider (item 11.b)]

- a. Analyst(s) certified for DMSCC
- b. Each analyst seeking certification for the ESCC test shall perform the comparative test
 - 1. Test 4 samples (100K-200K, 300K-500K, 600K-800K and 900K-1.2M) in triplicate for both DMSCC (three separate smears each) and ESCC
 - 2. Results must be evaluated by the FDA/LPET LEO or LEO and shown to be acceptable prior to official use of test in laboratory
 - 3. Copy of comparison and results in QC record (or easily accessible on file in the laboratory); kept for as long as analyst is certified
- c. Required for laboratories preparing in house standards or using commercially prepared standards (items 10.a and c)

APPARATUS

3. See CP items 1-4

4. Electronic Somatic Cell Counter

- a. Fossomatic 7 DC

5. Water Bath

- a. Circulating and thermostatically controlled to 37-42°C

REAGENTS

6. Reagents

- a. Fossomatic DC Buffer

Lot #: _____ Exp. Date: _____

- b. Fossomatic Detergent

Lot #: _____ Exp. Date: _____

- c. Fossomatic DC Dye

Lot #: _____ Exp. Date: _____

7. Other Solutions

- a. Blank Solution: Prepare Rinse/sheath liquid (item 8.a.3)

8. Preparation of Reagents for the Fossomatic 7 DC

- a. Automatic reagent mixing module

1. Stock Solution: Heat 500 mL of Fossomatic Detergent (item 6.b) in 40°C water bath until solution's appearance is clear, time not to exceed 10 min. Mix 500 mL Fossomatic Detergent with 4.5 L of deionized (DI) or MS water, store in airtight, lightproof container in a cool location and use within 16 weeks

Lab Prep Date: _____ Lab Exp. Date: _____

2. Buffer/Diluent Solution: Dissolve 1 bottle of Fossomatic DC Buffer (98.8 g) (item 6.a) in 1 L of deionized water, add DI or MS water to make 10 L, heat to 40 - 60°C to speed process, store in buffer/diluent container and use within 3 weeks

Lab Prep Date: _____ Lab Exp. Date: _____

3. Rinse/Sheath Liquid: Mix 250 mL of Stock Solution (item 8.a.1) with DI or MS water to make 50 L, store and use within 3 weeks

Lab Prep Date: _____ Lab Exp. Date: _____

4. Insert Fossomatic DC Dye bag according to manufacturer's instructions

9. All solutions labeled with date prepared and expiration date

START UP

10. Cell Counter

- a. Check that the volumes of rinse/sheath liquid, dye and buffer solutions in the supply containers are sufficient for the number of samples to be tested
- b. Solutions not used beyond expiration date(s)
- c. Turn power on and place instrument in standby mode
- d. Perform a blank check: Test the blank solution (item 7.a). The mean count must be $\leq 3,000$ cells/mL and individual measurements $< 5,000$ cells/mL
- e. **IF ANY ABOVE PARAMETERS ARE OUT OF VARIANCE, CORRECT BEFORE PROCEEDING**
- f. Maintain records on all parameters each time instrument is used

11. Milk Standards

- a. Commercially prepared: _____
Lot#: _____ Date Rcd: _____
 - 1. Four standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M
 - 2. Perform DMSCC in triplicate on each standard in set and average counts; maintain records
 - 3. Perform DMSCC check in rotation by all certified analysts
 - 4. Standards used within one weekLab Exp. Date: _____
- b. Certified provider: _____
Lot #: _____ Exp. Date: _____
Date Rcd: _____
 - 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 (0.0-7.5°C) of standards as received

4. Maintain copies of all correspondence regarding problems _____
5. Standards used by manufacturer's expiration date _____
6. Failed standards shall be verified with DMSCC _____
 - a. If no analysts certified for DMSCC then a new set of standards is required _____
 - b. Do not continue with official testing until the new standard(s) test(s) in range _____
- c. Laboratory prepared (weekly) _____
 1. Prepare from raw milk > 18 hours old preserved with 0.02% 2-bromo-2-nitropropane- 1,3-diol (Bronopol™) _____
 2. Standards cannot be preserved with formalin _____
 3. Prepare 4 standards in ranges 100K-200K, 300K-500K, 600K-800K and 900K-1.2M; use within one week _____

Lab Prep Date: _____ Lab Exp. Date: _____

 4. Perform DMSCC in triplicate on each standard and average counts; maintain records _____
 5. Perform DMSCC check in rotation by all certified analysts _____
- d. Hourly Control Sample (instrument drift check) _____
 1. Use one of the standards (items 11.a, b or c) in the 600-800K range, test in triplicate and determine average _____
 2. Optionally, prepare sufficient control/sample 600-800K range, test in triplicate and determine average _____

PROCEDURE

12. Testing Standards (each time instrument used) _____

- a. Heat standards to 37-42°C (using a temperature control) and test within 30 min of reaching temperature, use once and then discard, i.e. do not re-use _____
- b. Mix by inverting at least 2x, test standards within 3 min _____
- c. Test the standards in triplicate and average the counts for each level; maintain records _____
- d. Each standard's average must be within 10% of the DMSCC (item 11) for that level, except within 15% for 100K-200K standard; maintain records _____

- e. Repeatability – a standard in the 300K to 800K range must have a coefficient of variation (CV) of 5% or less on 10 replicates **(Refer to Operating Manual)**; maintain records _____
- f. **THESE PARAMETERS MUST BE ACHIEVED BEFORE PROCEEDING** _____

13. Testing Samples _____

- a. Heat samples to 37-42°C (using a temperature control) and test within 30 min of reaching temperature _____
- b. Test samples within 10 min after removal from water bath _____
- c. Mix by inverting at least 2x, test samples within 3 min _____
- d. Record number of cells counted for each sample _____

14. With Continuous Operation: _____

- a. Perform a blank check (item 10.d) hourly _____
- b. Test a standard or optionally a control/sample (item 11.d) in the 600K to 800K range hourly in triplicate and determine the average, must be within 5% of the original established instrument average value (optionally, within 10% of original DMSCC average) _____
- c. Maintain records _____

15. Routine Maintenance _____

- a. Maintain records _____

REPORTING

16. Computing and Reporting Counts _____

- a. Count obtained x 1000 is the cell count/mL milk
[NCIMS does not accept or recognize differential counts (DC)] _____
- 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) _____

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
