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 and Goat Milk)
IMS #16g

(Unless otherwise stated all tolerances are ±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 11.a and c) and those testing goat milk _____

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 volume of rinse/sheath liquid, dye and buffer solutions in the supply containers is 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 ≤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 week _____

Lab 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 are 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 _____

e. If goat milk is over the regulatory limit, follow confirmation procedure in PMO _____