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 ±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
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 ≤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 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