ELECTRONIC SOMATIC CELL COUNT

Fossomatic™ Minor
(Raw Cow Milk, Raw Sheep Milk, Raw Goat Milk and Raw Water Buffalo Milk)
IMS #16

(Unless otherwise stated all tolerances ±5%)

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

a. Un-preserved samples may be tested 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™) or 0.05% potassium dichromate ($K_2Cr_2O_7$) _____

PRE-REQUISITE

2. Comparative Test with DMSCC (co-requisite for certification) _____

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 State/Federal 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 _____

APPARATUS

3. See CP items 1-4 _____

4. Water Bath _____

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

REAGENTS

5. Reagents

a. Dye Solution Lot #: _____ Exp. Date: _____ _____

b. Clean 1 Lot #: _____ Exp. Date: _____ _____

c. Clean 2 Lot #: _____ Exp. Date: _____ _____

6. Preparation _____

a. Ready to Use Dye Solution: Pour into a clean glass container designated for the Dye Solution (item 5.a). Use within 4 weeks of dispensing into container _____

Date Dispensed: _____ Exp. Date: _____ _____

b. Clean 1 Solution: In a clean glass container, mix one unit (20 mL) Clean 1 (item 5.b) with deionized (DI) or Microbiologically Suitable (MS) water to make 1 liter, store and use within 4 weeks; when stored at 2-8°C, use within 8 weeks _____

Date Prep.: _____ Exp. Date: _____ _____

c. Ready to Use Clean 2 Solution: Pour into a clean glass container designated for the Clean 2 Solution (item 5.c). Use within 4 weeks of dispensing into container _____

Date Dispensed: _____ Exp. Date: _____ _____

7. All solutions labeled with date prepared and expiration date _____

START UP

8. Cell Count _____

a. Check that the volume of Dye, Clean 1 and Clean 2 solutions in the supply containers is sufficient for the number of samples to be tested _____

b. Solutions not used beyond expiration date(s) _____

c. Perform the "Start Up" Job sequence: If the Zero Count is > 6, repeat "Clean Cuvette" and re-check the zero _____

d. **IF ANY ABOVE PARAMETERS ARE OUT OF VARIANCE, CORRECT BEFORE PROCEEDING** _____

e. Maintain records on all parameters each time instrument is used _____

9. 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. Use standards 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 _____

c. Laboratory prepared (weekly) _____

   1. Prepare from raw milk > 18 hours old preserved with 0.05% potassium dichromate ($K_2Cr_2O_7$) _____

   2. Or, preserved with 0.02% 2-bromo-2-nitropropane-1,3-diol (Bronopol™) _____

   3. Standards <u>cannot</u> be preserved with formalin _____

   4. 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: _____ _____

   5. Perform DMSCC in triplicate on each standard and average counts; maintain records _____

   6. Perform DMSCC check in rotation by all certified analysts _____

d. Hourly Control Sample (instrument drift check) _____

   1. Use one of the standards (items 9.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

10. 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 10x, 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 9) 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 (C_V) of 5% or less on 10 replicates **(Refer to Operating Manual)**; maintain records _____

f. Alternatively, set and run standard check as a “Custom Job”, enter DMSCC values (item 9) into Excel™ macro, starting the job will enable 10.c through 10.e to be run and calculated automatically _____

g. **THESE PARAMETERS MUST BE ACHIEVED BEFORE PROCEEDING** _____

11. 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 10x, test samples within 3 min _____

d. Record number of cells counted for each sample _____

12. With Continuous Operation: _____

a. Perform a zero check (item 8.d) hourly _____

b. Test a standard or optionally a control/sample (item 9) 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 _____

13. Routine maintenance _____

a. 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) _____

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 _____