ELECTRONIC SOMATIC CELL COUNT

Fossomatic[™] 5000/FC/7 (Raw Commingled Cow, Sheep, Goat, Water Buffalo and Camel Milk) IMS #16d

(Unless otherwise stated all tolerances are ±5%)

1.	Lab	orat	ory Requirements (see Cultural Procedures (CP) items 33 & 34)			
	a.	Un-	preserved samples may be run up to 72 hours after initial collection			
	b.	0.0	mples may be tested up to 7 days after initial collection if preserved with 2% 2-bromo-2-nitropropane-1,3-diol (Bronopol TM) or 0.05% potassium hromate ($K_2Cr_2O_7$)			
2.	. Comparative Test with DMSCC [NOT required as a co-requisite for certification of analysts in laboratories purchasing standards from a CERTIFIED provider (item 13.b)]					
	a.	Ana	alyst(s) certified for DMSCC			
	b.		ch analyst seeking certification for the ESCC test shall perform the nparative 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.		quired for laboratories preparing in house standards or using commercially pared standards (items 13.a and c) and for those testing goat or camel milk			
			APPARATUS			
3.	See	CP	items 1-4			
4.	Ele	ctror	nic Somatic Cell Counter			
	a.	Fos	ssomatic FC-7			
	b.	Fos	ssomatic FC			
	c.	Fos	ssomatic 5000			

5.	Wa	ter Bath						
	a.	Circulating and thermosta	tically controlled to 37-42°C					
		REAGENTS						
ô.	Rea	gents						
	a.	Fossomatic Buffer/Buffer	5000, Reagent E					
		Lot #:	Exp. Date:					
	b.	Fossomatic Buffer Small (alternately)					
		Lot #:	Exp. Date:					
	C.	Fossomatic Detergent/Cle	ean 5000, Reagent D					
		Lot #:	Exp. Date:					
	d.	Fossomatic Dye/Dye 5000, Reagent B						
		Lot #:	Exp. Date:					
	e.	Fossomatic Dye Concentr	rate (for Fossomatic 7 with manual mixing option)					
		Lot #:	Exp. Date:					
7.	Oth	er Solutions						
	a.	Fossomatic 7						
		1. Blank Solution: Prep	are Rinse/sheath liquid (item 8.a.1.c or 8.a.2.c)					
	b.	Fossomatic FC and 5000						
		1. Blank solution: Prep Solution or 0.5% S-4	are a 1% (w/v) NaCl solution, MilkoScan Rinse 70 solution					

Pre	para	tion	of Reagents for the Fossomatic 7	
a.	Automatic reagent mixing module [There are two ways (i.e. high and low capacity) to prepare reagents according to the capacity requirements of the respective laboratory]			
	1.	Hig	gh capacity:	
	;	a.	Stock Solution: Heat 500 mL of Fosso 40°C water bath until solution's appea exceed 10 min. Mix 500 mL Fossoma deionized (DI) or MS water; store in a cool location and use within 16 weeks	arance is clear, time not to tic Detergent with 4.5 L of irtight, lightproof container in a
			Lab Prep Date: Lab	ab Exp. Date:
		b.	Buffer/Diluent Solution: Mix 1 L of Sto one bag (354 g) of Fossomatic Buffer to 10 L, heat to 50 - 60°C to speed pro container next to instrument and use	(item 6.a) add DI or MS water ocess; store in buffer/diluent
			Lab Prep Date: Lab	ab Exp. Date:
		C.	Rinse/Sheath Liquid: Mix 250 mL of Swith DI or MS water to make 50 L; sto	,
			Lab Prep Date: Lab	ab Exp. Date:
		d.	Insert Fossomatic Dye bag according	to manufacturer's instructions
	2.	Lov	w-capacity	
		a.	Stock Solution: Heat Fossomatic Determine bath until solution's appearance is cle Mix 125 mL of Fossomatic Detergent water; store in airtight, light proof contuse within 16 weeks	ar, time not to exceed 10 min. with 1125 mL of DI or MS
			Lab Prep Date: Lab	ab Exp. Date:
		b.	Buffer/Diluent Solution: Mix 200 mL or with one bag (70.8 g) of Fossomatic E or MS water to 2 L, heat to 40-60°C to buffer/diluent container next to instrum	Buffer Small (item 6.b) add Dl o speed process; store
			Lab Prep Date: Lab	ab Exp. Date:
		C.	Rinse/Sheath Liquid: Mix 100 mL of Swith Di or MS water to make 20 L; sto	,
			Lab Prep Date: Lab	ab Exp. Date:

8.

		d.	Fossomatic Dye Concentrate	ution: Mix one bottle (200 mL) of (item 6.e) with 400 mL of 3.b.2) and fill up to the 2 L mark with			
			Lab Prep Date:	Lab Exp. Date:			
b.	Man	ual re	eagent mixing module				
	1.	until 125	solution's appearance is clear mL of Fossomatic Detergent w	Detergent (item 6.c) in 40°C water bath t, time not to exceed 10 minutes. Mix with 1125 mL of DI or MS water; store cool location and use within 16 weeks			
		Lab	Prep Date:	Lab Exp. Date:			
	2.	one wate	bag (70.8 g) of Fossomatic Bu	L of Stock Solution (item 8.b.1) with iffer Small (item 6.b), add DI or MS eed process; store buffer/diluent se within 3 weeks			
		Lab	Prep Date:	Lab Exp. Date:			
	3.	Rinse/Sheath Liquid: Mix 100 mL of Stock Solution (item 8.b.1) with DI or MS water to make 20 L; store and use within 3 weeks					
		Lab	Prep Date:	Lab Exp. Date:			
	4.	Fossomatic Dye Working Solution: Mix one bottle (200 mL) of Fossomatic Dye Concentrate (item 6.e) with 400 mL of Buffer/Diluent Solution (item 8.b.2) and fill up to the 2 L mark with Buffer/Diluent Solution					
		Lab	Prep Date:	Lab Exp. Date:			
Prep	arati	ion o	f Reagents for the Fossoma	tic FC			
a.	High	Сар	acity				
	1.	Stoc	k Solution				
		a.	Fossomatic Detergent (item 6 appearance is clear, time not Fossomatic Detergent with 4.3	atic Detergent: Heat 500 mL of i.c) in 40°C water bath until solution's to exceed 10 min. Mix 500 mL 5 L of DI or MS water; store in airtight, location and use within 16 weeks			
			Lab Prep Date:	Lab Exp. Date:			

9.

		b.	Clean 5000, Reagent D (an 5000, Reagent D: Dissolve 500 mL of (item 6.c) in 4.5 L of DI or MS water, heat to ght, lightproof container in a cool location.	
			Lab Prep Date:	Lab Exp. Date:	
	2.	with 10 L	one bag (354 g) of Buffer	L of Stock Solution (item 9.a.1.a. or 9.a.1.b) 5000, Reagent E, add DI or MS water to d process; store in buffer/diluent container thin 6 weeks	
		Lab	Prep Date:	Lab Exp. Date:	
	3.			mL of Stock Solution (item 9.a.1.a. or make 50 L; store and use within 3 weeks	
		Lab	Prep Date:	Lab Exp. Date:	
	4.		ert Dye 5000, Reagent B b ructions	ag (item 6.d) according to manufacturer's	
b.	Low	Сар	acity		
	1.	Sto	ck Solution		
		a.	Detergent (item 6.c) in 40 is clear, time not to exceed Detergent with 1125 mL	somatic Detergent: Heat Fossomatic D°C water bath until solution's appearance ed 10 min. Mix 125 mL of Fossomatic of DI or MS water; store in airtight light location and use within 16 weeks.	
			Lab Prep Date:	Lab Exp. Date:	
		b.	Clean 5000, Reagent D (an 5000/Reagent D: Dissolve 100 mL of (item 6.c) in 900 mL of DI or MS water, in airtight, light proof container in a cool 6 weeks	
			Lab Prep Date:	Lab Exp. Date:	
	2.	9.b. wate	1.b) with one bag (171 g)	5 L of Stock Solution (item 9.b.1.a or of Buffer 5000, Reagent E, add DI or MS to speed process; store in buffer/diluent nd use within 3 weeks	
		Lab	Prep Date:	Lab Exp. Date:	

		3.			•		olution (item 9.b.1.a ond use within 3 weeks	
			Lab	Prep	Date:	_ Lab Exp	. Date:	
		4.		ert Dy ructio		oag (item 6.d) a	ccording to manufacto	urer's
10.	Pre	parat	tion o	of Re	agents for the Foss	somatic 5000		
	a.	[The	ere a	e two	gent mixing module o ways (i.e. high and he capacity requirem			
		1.	Higl	n cap	acity:			
			a.	Sto	ck Solution			
				1.	Fossomatic Deterg solution's appearar 500 mL Fossomatic	ent (item 6.c) ir nce is clear, tim c Detergent witl	Detergent: Heat 500 m n 40°C water bath unti e not to exceed 10 mi h 4.5 L of DI or MS wa er in a cool location an	l n. Mix ater;
					Lab Prep Date:		Lab Exp. Date:	
				2.	of Clean 5000, Rea	agent D (item 6 ; store in airtigh	Reagent D: Dissolve to commend to the commend of th	S water,
					Lab Prep Date:		Lab Exp. Date:	
			b.	or 1 add	0.a.1.a.2) with one b DI or MS water to 1 e in buffer/diluent co	oag (354 g) of F 0 L, heat to 50	k Solution (item 10.a.1 ossomatic Buffer (iten - 60°C to speed proce instrument and use w	n 6.a) ·ss;
				Lab	Prep Date:	Lab	Exp. Date:	
			C.	or 1	•		ock Solution (item 10.a ake 50 L; store and us	
				Lab	Prep Date:	Lab	Exp. Date:	
			d.		ert Fossomatic Dye b	ag according to	o manufacturer's	

		a.	Stock Solution		
		~ :	 Stock Solution using Foss Detergent (item 6.c) in 40° appearance is clear, time Fossomatic Detergent with 	omatic Detergent: Heat Fossomatic C water bath until solution's not to exceed 10 min. Mix 125 mL of n 1125 mL of DI or MS water; store iner in a cool location and use within	
			Lab Prep Date:	Lab Exp. Date:	
			of Clean 5000, Reagent D	n 5000/Reagent D: Dissolve 100 mL (item 6.c) in 900 mL of DI or MS store in airtight, light proof container within 16 weeks	
			Lab Prep Date:	Lab Exp. Date:	
		b.	Small (item 6.b) add DI or MS v	ne bag (70.8 g) of Fossomatic buffer	
			Lab Prep Date:	Lab Exp. Date:	
		C.		nL of Stock Solution (item 10.a.2.a.1 ter to make 20 L; store and use	
			Lab Prep Date:	Lab Exp. Date:	
		d.	Fossomatic Dye Working Solut Fossomatic Dye Concentrate (i Buffer/Diluent Solution (item 10 with Buffer/Diluent Solution	,	
			Lab Prep Date:	Lab Exp. Date:	
b.	Mar	nual r	eagent mixing module		
	1.	Sto	ck Solution:		
		a.	Stock Solution using Fossomatic Detergent: Heat Fossomatic Detergent (item 6.c) in 40°C water bath until solution's appearance is clear, time not to exceed 10 min. Mix 125 mL of Fossomatic Detergent with 1125 mL of DI or MS water; store in airtight lightproof container in a cool location and use within 16 weeks		
			Lab Prep Date:	Lab Exp. Date:	

Low-capacity

2.

			Cle he	ean 5000, Reagent I	Clean 5000/Reagent D: Dissolve 100 mL of D (item 6.c) in 900 mL of DI or MS water, ore in airtight, light proof container in a cool 16 weeks	
			La	b Prep Date:	Lab Exp. Date:	
		2.	10.b.1.b add DI	o) with one bag (70.8 or MS water to 2 L, h	200 mL of Stock Solution (item 10.b.1.a or 3 g) of Fossomatic Buffer Small (item 6.b) neat to 40-60°C to speed process; store to instrument and use within 3 weeks	
			Lab Pre	p Date:	Lab Exp. Date:	
		3.		•	00 mL of Stock Solution (item 10.b.1.a or er to make 20 L; store and use within 3	
			Lab Pre	p Date:	Lab Exp. Date:	
		4.	Fossom	atic Dye Concentrat (item 10.b.2) and fi	olution: Mix one bottle (200 mL) of te (item 6.e) with 400 mL of Buffer/Diluent Il up to the 2 L mark with Buffer/Diluent	
			Lab Pre	p Date:	Lab Exp. Date:	
11.	Alls	soluti	ions lab	eled with date prep	ared and expiration date	
					START UP	
12.	Cell	Cou	nter			
	a.				heath liquid, dye and buffer solutions in the the number of samples to be tested	
	b.	Solu	utions not	used beyond expira	ation date(s)	
	C.	Turr	n power o	on and place instrum	nent in standby mode	
	d.				blank solution (item 7.a or 7.b). The mean nd individual measurements <5,000 cells/mL	
	e.			VE PARAMETERS OCEEDING	ARE OUT OF VARIANCE, CORRECT	
	f.	Mair	ntain rec	ords on all paramete	ers each time instrument is used	

13.	Milk	Ik Standards						
	a.	Cor	mmercially 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.	Cer	rtified provider:	_				
		Lot	:#: Exp. Date:	_				
		Dat	te 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.	Lab	poratory 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 cannot 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.	Hou	urly Control Sample (instrument drift check)	
		1.	Use one of the standards (items 13.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	
14.	Tes	ting	Standards (each time instrument used)	
	a.		at standards to 37-42°C (using a temperature control) and test within 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.		st the standards in triplicate and average the counts for each level; intain records	
	d.		ch standard's average must be within 10% of the DMSCC (item 13) for that el, except within 15% for 100K-200K standard; maintain records	
	e.	of v	peatability – a standard in the 300K to 800K range must have a coefficient variation (CV) of 5% or less on 10 replicates (Refer to Operating Manual); intain records	
	f.	THE	ESE PARAMETERS MUST BE ACHIEVED BEFORE PROCEEDING	
15.	Tes	ting	Samples	
	a.		at samples to 37-42°C (using a temperature control) and test within 30 min eaching temperature	
	b.	Tes	st samples within 10 min after removal from water bath	
	C.	Mix	by inverting at least 2x, test samples within 3 min	
	d.	Rec	cord number of cells counted for each sample	

16.	With	/ith Continuous Operation:					
	a.	Perform a blank check (item 12.d) hourly					
	b.	Test a standard or optionally a control/sample (item 12.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					
17.	Rou	utine Maintenance					
	a.	Maintain records					
		REPORTING					
18.	Con	mputing 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)					
		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 or camel milk is over the regulatory limit, follow confirmation procedure in the PMO					