PASTEURIZED MILK CONTAINERS, CLOSURES AND PACKAGING IMS #22 (PMC)

[Unless otherwise stated all tolerances are ±5%]

1.	Laboratory Requirements						
	a.	Record time and date when samples received					
	b.	Record time and date when samples examined					
		RINSE METHOD APPARATUS					
2.	See	Cultural Procedures (CP) items 1-23					
3.	To /	Add Rinse Solution to Containers					
	a.	Sterile hypodermic syringes (capacity 20 or 100 mL) and needles					
	b.	Or, sterile pipets					
	C.	Or, sterile automatic syringe					
	d.	Or, sterile graduated cylinder					
	e.	Or, pre-dispensed dilution bottles or tubes with rinse solution (see CP item 29.f); volumes checked					
		MATERIALS					
4.	See CP items 24-32						
5.	5. Rinse Solutions						
	a.	Buffered Rinse Solution or Nutrient broth (see CP items 27.m-n) for Standard Plate Count (SPC) and Coliform Plate Count (CPC) agar based media					
	b.	Nutrient broth (see CP item 27.n) for 3M Petrifilm [™] Aerobic Count (PAC), 3M Petrifilm [™] Rapid Aerobic Count (RAC), 3M Petrifilm [™] Coliform Count (PCC) and 3M Petrifilm [™] High Sensitivity Coliform Count (HSCC) plates, Charm [™] Peel Plate [™] Aerobic Count (PPAC), Charm [™] Peel Plate [™] Coliform Count (PPEC) and Charm [™] Peel Plate [™] High Sensitivity Coliform Count (PPECHVS)					
6.	Eth	yl Alcohol, 70%					
7.	Plas	stic Tape					
	PROCEDURE						
8.	lder	ntify Plates (See SPC item 5, Petrifilm item 6 or Peel Plate item 5)					

9.	Con	ntrols (See SPC item 6, Petrifilm item 7 or Peel Plate item 6), in addition;				
a.		Transfer 1 mL of rinse solution to SPC, PAC, RAC or PPAC plate for sterility control				
10.	. Rinse Solution Volumes for Collection of Surface Rinse Samples					
	a.	100	mL (+/- 2mL) for gallons (3784 mL) or larger			
	b.	50 r	mL (+/- 1mL) for ½ gallons (1892 mL)			
	C.	c. 20 mL (+/- 0.4mL) for 100 mL to ½ pints (236 mL), pints (473 mL), and quarts (946 mL)				
	d.	For	containers <100 mL and closures use swab method, see items 18-32			
	e. Irregular shaped containers of <100 mL, use rinse method in item 10.c. Equally distribute the 20 mL among multiple units with the amount per unit n more than 20% of the volume					
11.	. Collection of Surface Rinse Samples					
	a.	Firm walled paper containers, sealed on line				
		1.	Swab top of containers with 70% alcohol at the site of injection			
		2.	Add required amount of rinse solution to each container by injection and seal puncture with plastic tape			
		3.	Vigorously shake container length-wise on flat sides (or quadrants of round containers) 10 times, holding container horizontally			
		4.	Each shake a complete back and forth movement of approximately 20 cm			
		5.	Turn container 90° and repeat horizontal shaking treatment			
		6.	Turn container 90° twice more and repeat horizontal shaking			
		7.	Grasp container and swirl 20 times in a small flat circle while upright (top up)			
		8.	Invert (top down) and repeat swirling of container 20 times			
		9.	Stand upright and allow to drain for 1-3 min			
	b.	Plas	stic capped containers (submitted with caps)			
		1.	Swab top of container with 70% alcohol when appropriate			

	2.	Add required amount of rinse solution by aseptically removing cap, pouring in solution without touching the top and replace cap			
	3.	Complete rinse procedure as described in 11.a.3-9 above			
C.	Flexible-walled containers/bags				
	1.	Add 100 mL aseptically by swabbing an area of tube adjacent to liner with 70% alcohol; introduce rinse by syringe and seal puncture with plastic tape			
	2.	Place container/bag on smooth, clean, firm horizontal surface as flat as its construction permits			
	3.	With hands or roller, move rinse solution back and forth 10 times, contacting all surfaces completely			
	4.	Lift liner and hang with "fill tube" down to permit rinse solution to collect for 1-3 min			
	5.	Transfer rinse solution to sterile container by cutting "fill tube" with sterile scissors			
d.	Irre	gular shaped containers of <100 mL			
	1.	Swab top of container with 70% alcohol when appropriate e.g. at injection site			
	2.	Aseptically add required amount of rinse solution to each container, seal with cap or appropriate sterile closure			
	3.	Complete rinse procedure as described in 11.a.3-9 above			
	4.	Transfer rinse solutions of the multiple containers in sequence by aseptically removing cap or sterile closure, pouring solution into a common sterile container without touching the tops and replacing cap or sterile closure on the sterile container			
San	nple	Measurements			
a.	As described in SPC items 9 & 10, Petrifilm items 10 & 11 or Peel Plate items 9 & 10, except:				
	1.	For Residual Bacterial Count (RBC), pipet 2 mL portion in a single SPC plate or pipet two 1 mL portions on 2 PAC, 2 RAC or 2 PPAC plates			
	2.	For Residual Coliform Count (RCC), pipet 10 mL of remaining rinse solution among 3 CPC plates, or pipet ten 1 mL portions of remaining rinse solution on 10 PCC or PPEC plates or two 5 mL portions on 2 HSCC or PPECHVS plates			

12.

13.	Pouring Agar (See SPC item 13)					
14.	Incubating Plates (See SPC item 14, Petrifilm item 14 or Peel Plate item 13)					
15.	Con	Confirmation Test for CPC (See SPC item 17.c)				
16.	Counting and Recording Colonies (See SPC items 15-17, Petrifilm items 15-17 or Peel Plate items 14-16)					
	a.	Cou	ınt ob	otained from RBC plate(s) recorded as colonies counted		
	b.	If no	colc	onies on RBC plate(s), record as 0		
	c.	Cou	ınt ob	otained from RCC plates recorded as colonies counted		
	d. If no colonies on RCC plates, record as 0					
	e.	Valu	ues a	are recorded as number of colonies per container		
				REPORTS		
17.	7. Reporting Counts				-	
	a.	Rep	ort c	computed bacterial count as RBC/container		
		1.	Cor	ntainers rinsed with 20 mL	-	
			a.	2 mL plated for RBC, multiply colony count by 10	-	
		2.	Cor	ntainers rinsed with 50 mL		
			a.	2 mL plated for RBC, multiply colony count by 25		
		3.	Cor	ntainers rinsed with 100 mL		
			a.	2 mL plated for RBC, multiply colony count by 50		
	b.	Rep	ort c	computed coliform count as RCC/container		
		1.	Cor	ntainers rinsed with 20 mL		
			a.	10 mL plated for RCC, multiply colony count by 2		
		2.	Cor	ntainers rinsed with 50 mL	·	
			a.	10 mL plated for RCC, multiply colony count by 5		
		3.	Cor	ntainers rinsed with 100 mL		
			a.	10 mL plated for RCC, multiply colony count by 10		

	C.	If no colonies appear on plate(s), report as less than n/container, substituting for n the number that would be reported if 1 colony had been counted from the volume of rinse solution plated and multiplied by appropriate factor			
		SWAB METHOD			
		APPARATUS			
18.	See	e CP items 1-23			
19.	Scre	rew-capped Containers			
	a.	7 to 10 cm long to contain:			
		1. 5 mL rinse solution for non-soluble swabs (see item 5)			
		2. 4.5 mL rinse solution for alginate swabs (see item 5, SPC & CPC only)			
	b.	Sterile			
20.	Swa	abs			
	a.	Cotton, non-absorbent (firmly twisted to about 5 mm diameter by 2 cm long over one end of applicator stick 12-15 cm long)			
	b.	Or, calcium alginate fibers (SPC & CPC only)			
	C.	Or, polyester or rayon fibers			
	d. Commercial source, sterile, non-toxic in protected containers				
		Supporting documentation from manufacturer			
		2. Maintain records			
		MATERIALS			
21.	See	e Items 4 & 5			
22.	Sodium Hexa-metaphosphate Solution, 10% (if calcium alginate swabs used, SPC & CPC only), sterile				
23.	Sha	aking Machine, optional (See SPC item 8.c or PAC item 9.c)			
		PROCEDURE			
24.	lden	ntify Plates (See SPC item 5, Petrifilm item 6 or Peel Plate item 5)			
25.	Con	ntrols (See SPC item 6, or Petrifilm item 7 or Peel Plate item 6), in addition;			
	a.	Pipet 1 mL of rinse solution to SPC, PAC, RAC or PPAC plate for sterility control			

	D.	solution plus 0.5 mL Na Hexa-metaphosphate solution and continue as described in 27.a.1, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle						
	C.	For all other fibers, break off swab head in container with 5 mL rinse solution and continue as described in item 27.a.2 & 27.b, pipetting 1 mL rinse solution to plate for RBC sterility control of swab and bottle						
26.	Coll	lectic	on of Swab Samples from Product Contact Surfaces					
	a.	250 sq. cm of product contact surface must be swabbed or five 50 sq. cm for a total of 250 sq. cm (calculate or use template – must be sterile if swab will be in contact with template)						
	b.	Ase	eptically remove sterile swab from container					
	c.	Ope	en vial of solution, wet swab and press out excess solution					
	d.	d. Holding swab at 30° angle to surface, rub over 50 sq. cm area three times, reversing direction between successive strokes						
		1.	For snap or screw cap closures, calculate number of closures required for product contact surface area of 50 sq. cm					
		2.	For cup shaped containers, determine 50 sq. cm for the product contact surface					
	e. Rinse swab in solution and press out excess							
	f.	Swab four additional 50 sq. cm areas After fifth area has been swabbed, position swab head in vial and break stick, leaving swab head in vial						
	g.							
27.	Sample Measurement							
	a.	As described in SPC items 9 & 10;						
		1.	For calcium alginate, add 0.5 mL of sterile Na Hexa-metaphosphate solution (see item 22) to 4.5 mL rinse solution in vial and shake until dissolved [Not acceptable for use with Petrifilm and Peel Plate]					
		2. For all other fibers:						
			a. Shake swab container 50 times					
			b. Each shake a complete back and forth movement of approximately 15 cm					

			c. Strike palm of hand at end of each cycle				
			d. Complete shaking in approximately 10 sec				
	b. As described in Petrifilm items 10 & 11 or Peel Plate items 9 & 10;						
	Shake swab container 50 times						
		2.	Each shake a complete back and forth movement of approximately 15 cm				
		3.	Strike palm of hand at end of each cycle				
		4.	Complete shaking in approximately 10 sec				
	c.	For RBC, pipet 1 mL portion to a single SPC, PAC, RAC or PPAC plate					
	d.	For RCC, pipet 3 mL to a single CPC plate or three 1 mL portions on three PCC or PPEC plates					
28.	Pou	ring	Agar (See SPC item 13)				
29.	Incu	ubation (See SPC item 14, Petrifilm item 14 or Peel Plate item 12)					
30.	Con	nfirmation for CPC test (See SPC item 17.c)					
31.	Counting and Recording Colonies (See SPC items 15-17, Petrifilm items 15-17 or Peel Plate items 14-16)						
	a.	Cou	nt obtained from RBC plates, record as colonies counted				
	b.	If no	colonies on RBC plates, record as 0				
	c.	Cou	int obtained from RCC plate(s) record as colonies counted				
	d.	If no	colonies on RCC plate(s), record as 0				
			REPORTS				
32.	Rep	ortin	g Counts				
	a.	Rep	ort the count in 31.a as the RBC/50 sq. cm				
	b.	If no	o colonies on RBC plate, report as < 1/50 sq. cm				
	C.	Rep	ort the count in 31.c as the RCC				
	d.	If no	colonies on RCC plate(s), report as < 1				