

APPENDIX N  
QC FORMS

































































Facility/Laboratory Name: Utter's Dairy

Year 2014

**THERMOMETER ACCURACY CHECK LOG**

Date NIST Tested	NIST	Serial /ID Number	Range	Graduation Interval	Calibration points	Ice point result	Correction Factor <sup>7</sup> °C	Analyst
1/6/14	NIST 1	F95-389	-1 to 101C	0.2	0,32,45,64,85	0.0C	0.0	JM
1/8/14	NIST 2	3697	-50 to 10C	0.2	-30, -15, 0	0.0C	0.0	JM
Date Tested	Test thermometer Location of use	Serial Number	Lab ID	Temp range of use °C	Temp of Test Thermometer °C	Temp and ID of NIST Reference Thermometer °C	Correction Factor °C	Analyst
1/6/14	Sampling	J3398	TC1	0.0-4.5	0.2	0.0 NIST 1	-0.2	JM
1/6/14	Sample receiving	J6689	TC2	0.0-4.5	0.0	0.0 NIST 1	0.0	JM
1/6/14	Fridge, top shelf	Ertco 14479	F1	0.0-4.5	0.6	0.0 NIST 1	-0.6	JM
1/6/14	Fridge, bottom shelf	Ertco 1245	F2	0.0-4.5	-0.2	0.0 NIST 1	+0.2	JM
1/7/14	Incubator, top shelf	Ertco 6695	I1	31-33	31.5	32.1 NIST 1	+0.6	JM
1/7/14	Incubator, bottom shelf	Ertco 1176	I2	31-33	31.9	32.1 NIST 1	+0.2	JM
1/7/14	Charm SL heater block	Ertco 5572	HB1	55-57	56.2	56.0 NIST 1	-0.2	JM
1/8/14	Freezer	Fisher F669	FZ1	<-15.0	-18.2	-18.6 NIST 2	-0.4	JM

- To be done before initial use and at least annually thereafter.
- National Institute of Standards and Testing (NIST) Certified thermometer, or equivalent, with a certificate of calibration.
- Range of test thermometers appropriate for designated use.
- Accuracy of test thermometers checked against certified thermometer.
- Accurate to ± 1.0°C when checked at temperature(s) of use.
- Results recorded and thermometers tagged with the following information: Identification, date of check, temperature of check, correction factor(s) and analyst ID.
- If NIST has a correction other than 0.0°C, use form BFSLS 515a.









COMMONWEALTH OF PENNSYLVANIA  
 DEPARTMENT OF AGRICULTURE  
 BUREAU OF FOOD SAFETY AND LABORATORY SERVICES  
 LABORATORY DIVISION

Facility/Laboratory Name: Utter's Dairy

### Annual Appendix N Training Log

Name	PDA Analyst #	Position (CIS or IS or IA)	Date of Initial Training <sup>1</sup>	Date of On-site Review by IS <sup>2</sup>	Date of On-site review by State LEO <sup>3</sup>	Annual Split Sample Participation Date	Results from Split Samples (Pass/Fail)
Alyssa Thomas	03	IA	4/15/12	3/1/13	NA	3/12/13	PASS
Jeff Michaels	02	IA	10/19/13	3/1/13	NA	3/12/13	PASS
Jason Kirk	01	CIS	NA	NA	6/15/13	3/12/13	PASS
Alice Stone	04	CIS	3/3/12	NA	6/15/13	3/12/13	PASS

EXAMPLE

- Notes:
1. Date of the initial training for Industry Analyst (IA) to gain approval for testing.
  2. Date of annual in-house training and observation of the IA by the Supervisor.
  3. Date of audit with state LEO. Audit participation is optional for IA's and mandatory for all Industry Supervisors.
  4. All IA's and Supervisory must have a successful participation in the annual split samples to maintain approval/certification.

COMMONWEALTH OF PENNSYLVANIA  
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LABORATORY DIVISION

**APPENDIX N TRAINING SESSION**  
**APPROVAL REQUEST FOR NEW ANALYST**

The following individuals have participated in training at: (Facility) \_\_\_\_\_ in (Town) \_\_\_\_\_ PA, concerning the Appendix N Testing Program for Drug Residues for (test) \_\_\_\_\_.

This training was held on \_\_\_\_\_, 20\_\_ by \_\_\_\_\_  
Information and materials presented dealt with the review of the (current) Pasteurized Milk Ordinance (PMO) - Appendix N Testing Program for Drug Residues, Industry Analyst, Industry Supervisor and Certified Industry Supervisor responsibilities. FDA 2400 forms and product inserts, along with quality control records, were used to evaluate approved methods for testing for animal drug residues. Each analyst properly demonstrated testing procedure of approved Appendix N method used at this facility.

The undersigned have been trained in the Appendix N requirements. They understand the responsibilities associated with this testing procedure.

DETERMINED BY FACILITY TRAINER			DETERMINED BY LABORATORY EVALUATION OFFICER		
Name of Participant (print)	SIGNATURE of Participant	Date Trained	Classification	Status	PDA #

Classification: IA= Ind. Analyst, IS = Ind. Supervisor, CIS = Certified Ind. Supervisor    Status: F<sup>A</sup>-Fully Approved, C<sup>A</sup> = Conditionally Approved, P<sup>A</sup> = Provisionally Approved

\_\_\_\_\_  
Facility Supervisor Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
State Laboratory Evaluation Officer Signature

\_\_\_\_\_  
Date Approved

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF AGRICULTURE  
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES  
LABORATORY DIVISION

## APPENDIX N TRAINING SESSION APPROVAL REQUEST FOR NEW ANALYST

The following individuals have participated in training at: (Facility) Utter's Dairy in (Town) Hometown PA, concerning the Appendix N Testing Program for Drug Residues for (test) Charm SL.

This training was held on October 19, 20 13 by Jason Kirk, CIS

Information and materials presented dealt with the review of the (current) Pasteurized Milk Ordinance (PMO) - Appendix N Testing Program for Drug Residues, Industry Analyst, Industry Supervisor and Certified Industry Supervisor responsibilities. FDA 2400 forms and product inserts, along with quality control records, were used to evaluate approved methods for testing for animal drug residues. Each analyst properly demonstrated testing procedure of approved Appendix N method used at this facility.

The undersigned have been trained in the Appendix N requirements. They understand the responsibilities associated with this testing procedure.

DETERMINED BY FACILITY TRAINER			DETERMINED BY LABORATORY EVALUATION OFFICER		
Name of Participant (print)	SIGNATURE of Participant	Date Trained	Classification	Status	PDA #
Jeff Michaels		10/19/13	IS	Ca	03

EXAMPLE

Classification: IA= Ind. Analyst, IS = Ind. Supervisor, CIS = Certified Ind. Supervisor Status: F<sup>A</sup>-Fully Approved, C<sup>A</sup> = Conditionally Approved, P<sup>A</sup> = Provisionally Approved

\_\_\_\_\_  
Facility Supervisor Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
State Laboratory Evaluation Officer Signature

\_\_\_\_\_  
Date Approved

COMMONWEALTH OF PENNSYLVANIA  
 DEPARTMENT OF AGRICULTURE  
 BUREAU OF FOOD SAFETY AND LABORATORY SERVICES  
 LABORATORY DIVISION

Facility/Laboratory Name: \_\_\_\_\_

**SNAPSHOT PERFORMANCE CHECK SET**

YEAR: \_\_\_\_\_ MONTH: \_\_\_\_\_

SERIAL # OF PERFORMANCE CHECK SET: \_\_\_\_\_

DAY	DEVICE 1:C/S _____	DEVICE 2:C/S _____	ANALYST ID# OR INITIALS
	-.15 _____ +.15 _____	-.30 _____ +.30 _____	
1			
2			
3			
4			
5			
6			
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31			

1. Performance Check Set needs to be done day of use along with a positive and negative control.

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Facility/Laboratory Name: WIDE CREEK FARMS

**SNAPSHOT PERFORMANCE CHECK SET**

YEAR: 2013

MONTH: December

SERIAL # OF PERFORMANCE CHECK SET: SNAP001347

DAY	DEVICE 1:C/S = <u>0.73</u>	DEVICE 2:C/S = <u>1.55</u>	ANALYST ID# OR INITIALS
	<u>-.15 = .58</u> <u>+.15 = .88</u>	<u>-.30 = 1.25</u> <u>+.30 = 1.85</u>	
1	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
2	<u>.76</u>	<u>1.58</u>	<u>JK, #01</u>
3	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
4	<u>.77</u>	<u>1.59</u>	<u>AT, #03</u>
5	<u>.76</u>	<u>1.58</u>	<u>JM, #02</u>
6	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
7	<u>.77</u>	<u>1.59</u>	<u>JK, #01</u>
8	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
9	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
10	<u>.77</u>	<u>1.58</u>	<u>JM, #02</u>
11	<u>.76</u>	<u>1.58</u>	<u>AT, #03</u>
12	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
13	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
14	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
15	<u>.77</u>	<u>1.58</u>	<u>JM, #02</u>
16	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
17	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
18	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
19	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
20	<u>.77</u>	<u>1.58</u>	<u>JM, #02</u>
21	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
22	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
23	<u>.77</u>	<u>1.59</u>	<u>JK, #01</u>
24	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
25	<u>.79</u>	<u>1.58</u>	<u>AT, #03</u>
26	<u>.77</u>	<u>1.58</u>	<u>JM, #02</u>
27	<u>.77</u>	<u>1.58</u>	<u>AT, #03</u>
28	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
29	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
30	<u>.77</u>	<u>1.58</u>	<u>JK, #01</u>
31	<u>.77</u>	<u>1.58</u>	<u>JM, #02</u>

1. Performance Check Set needs to be done day of use along with a positive and negative control.

Facility/Laboratory Name: \_\_\_\_\_

**CHARM ROSA READER (ROSA Reader, ROSA Pearl Reader or Charm Sciences equivalent)**

**PRIMARY CALIBRATION STRIPS**

YEAR \_\_\_\_\_ MONTH \_\_\_\_\_

SERIAL # OF PRIMARY CALIBRATION STRIPS \_\_\_\_\_

DAY	<u>LOW RANGE:</u>		<u>HIGH RANGE:</u>		ANALYST ID# OR INITIALS
	-20%	+20%	-20%	+20%	
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
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31					

1. Primary Calibration Strips need to be done day of use along with a positive and negative control.
2. Primary Calibration Strips match ROSA serial number. Calibration strips are specific to an individual reader. Do not interchange strips between different readers.



Facility/Laboratory Name: WIDE CREEK FARMS

**CHARM ROSA READER (ROSA Reader, ROSA Pearl Reader or Charm Sciences equivalent)**

**PRIMARY CALIBRATION STRIPS**

YEAR 2013

MONTH December

SERIAL #(S) OF PRIMARY CALIBRATION STRIPS RR0795

DAY	LOW RANGE:		HIGH RANGE:		ANALYST ID# OR INITIALS
	-20%	+20%	-20%	+20%	
1	-1063	-1594	+1297	+1945	JK
2	-1246	-1445	+1391	+1685	JK
3					
4					
5	-1330		+1401		AT
6					
7	-1455		+1555		JM
8	-1501		+1667		JM
9					
10					
11	-1422		+1333		JK
12					
13	-1456		+1455		JK
14	-1099		+1455		JK
15					
16					
17					
18	-1363		+1537		AT
19					
20	-1489		+1372		JM
21					
22					
23	-1125		+1403		AT
24	-1199		+1743		JM
25					
26					
27	-1099		+1899		AT
28					
29					
30					
31	-1426		+1900		JK

**EXAMPLE**

1. Primary Calibration Strips need to be done day of use along with a positive and negative control.
2. Primary Calibration Strips match ROSA serial number. Calibration strips are specific to an individual reader. Do not interchange strips between different readers.

Please email  
**QUESTIONS OR COMMENTS to**  
**mhydock@pa.gov**