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College Park, MD 20740-3835

M-I-18-6

January 30, 2018

TO: Director, Office of State Cooperative Programs  
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Charm Sciences, Inc. CHARM® Rapid One Step Assay (ROSA®)  
Tetracycline SL (Dilution Confirmation) Test

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm Sciences, Inc. CHARM® ROSA® Tetracycline SL (Dilution Confirmation) Test for the detection of tetracyclines in raw, commingled cow milk.

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the CHARM® ROSA® Tetracycline SL (Dilution Confirmation) Test meets the standards established to determine the acceptance of a Test for use in raw, commingled cow milk. The acceptance of the Test for raw, commingled cow milk represents a claim for Chlortetracycline, Oxytetracycline and Tetracycline. The data has been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix N-Drug Residue Testing and Farm Surveillance of the *Grade "A" Pasteurized Milk Ordinance*.

**NOTE:** Any initial positive test results shall be evaluated using the dilution protocol as specified in the kit labeling and FDA/NCIMS 2400 FORM (N-8 Charm® ROSA® Tetracycline-SL, Rev. 10/17, IMS Product Code #9-C17).

The NCIMS Executive Board voted to accept the use of this Test for Tetracyclines when used as labeled on October 12, 2017. Attached is the memorandum of acceptance from FDA's CVM.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers. The electronic version should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional

Organizations, representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to [robert.hennes@fda.hhs.gov](mailto:robert.hennes@fda.hhs.gov).

A handwritten signature in black ink, appearing to read "Robert F. Hennes", is centered on a light gray rectangular background.

Robert F. Hennes, RS, MPH  
CAPT U.S. Public Health Service  
Milk and Milk Products Branch

Attachment: FDA CVM Memorandum of Acceptance of the Charm Sciences, Inc.  
CHARM® ROSA® Tetracycline SL (Dilution Confirmation) Test



## Memorandum

**To: CAPT Robert F. Hennes, RS, MPH  
Milk and Milk Products Branch**

**From: Philip James Kijak, Ph.D**

**Date: January 26, 2018**

**Subject: Charm® ROSA® Tetracycline SL (Dilution Confirmation) Test**

Charm Sciences, Inc. has provided data to FDA supporting the use of the Charm® ROSA® Tetracycline SL (Dilution Confirmation) test for the detection of Chlortetracycline, Oxytetracycline and Tetracycline for raw, commingled cow milk. This data has been evaluated in accordance with the standards established for the acceptance of screening tests for raw, commingled cow milk to monitor milk in accordance to the provisions of Appendix N of the Pasteurized Milk Ordinance (PMO).

The Charm® ROSA® Tetracycline SL (Dilution Confirmation) test uses an initial screen of the milk to demonstrate if any tetracyclines are present in the milk. If an initial positive sample occurs, a dilution confirmation is used to determine if the concentration obtained is likely to be above the established U.S. tolerance. The 90/95 concentrations and drug concentration response are based on data developed using the dilution confirmation.

The 90/95 percent detection levels (ppb) and drug concentration responses are listed below:

<b>DRUG</b>	<b>90/95</b>	<b>Tolerance (ppb)<sup>1</sup></b>
<b>Chlortetracycline</b>	292	300
<b>Oxytetracycline</b>	243	300
<b>Tetracycline</b>	74	300

<sup>1</sup>The tolerance is established as the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline and tetracycline.

The Drug Concentration Response: (Displayed as percent positive based on 30 samples at each concentration.)

DRUG	Chlortetracycline	Oxytetracycline	Tetracycline
Tolerance (ppb)	300 ppb (Chlortetracycline + Oxytetracycline + Tetracycline)		
Drug Concentration (ppb)			
20			0
40			10
60	3	3	70
80			100
120	27	37	
180	23	77	
240	93	90	
290	97		
300	100	100	100

## RECOMMENDATION

Our evaluation of the data presented by Charm Sciences, Inc. indicates that the performance of this test meets the standards established for acceptance of screening tests for monitoring raw, commingled cow milk for tetracyclines in accordance with the provisions of Appendix N of the PMO. We recommend that the appropriate announcement be issued to the Regulatory/Rating Agencies and the milk industry advising of the Agency's concurrence with the use of this test as labeled. A revision of M-a-85 and M-I-96-10 should be issued to reflect the acceptance of this test.



Philip James Kijak, Ph.D.  
 Director, Division of Residue Chemistry  
 CVM Office of Research

Attachment: Product Label Operator's Manual: Charm® ROSA Tetracycline SL (Dilution Confirmation) Test for Raw Commingled Cow Milk with Dilution Confirmation to Meet U.S. Tolerances