

5001 Campus Drive
College Park, MD 20740-3835

M-I-18-4

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® TRIO Test, Beta lactams Only

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm Sciences, Inc. CHARM® TRIO Test for the detection of Beta lactams in raw, commingled cow milk. The CHARM® TRIO Test detects three (3) classes of drugs, Beta lactams, tetracyclines, and sulfonamides. The scope of FDA's evaluation is limited to the Beta lactams class.

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the CHARM® TRIO 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 Ampicillin, Ceftiofur, Cephapirin, Cloxacillin, and Penicillin G. 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* (PMO).

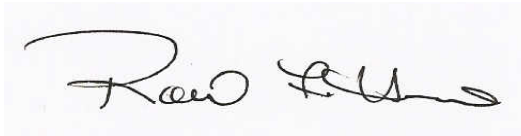
NOTE: The CHARM® TRIO Test detects Amoxicillin below the tolerance of 10 ppb. However, it does not meet the sensitivity requirements of the PMO for Amoxicillin. The calculated 90/95 for Amoxicillin is 3.5 ppb, less than 50% of the tolerance.

The NCIMS Executive Board voted to accept the use of this Test for Beta lactams 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.

A handwritten signature in black ink, appearing to read "Robert F. Hennes". The signature is written in a cursive style with a large initial "R".

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® TRIO Test, Beta lactams Only



Memorandum

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

From: Philip James Kijak, Ph.D.

Date: January 29, 2018

Subject: Charm Sciences, Inc. Charm® TRIO Test, Beta lactams Only

Charm Sciences, Inc. has provided data to FDA supporting the use of the Charm® TRIO test for the detection of Ampicillin, Ceftiofur, Cephapirin, Cloxacillin and Penicillin G 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). Although the Charm® TRIO test detects Amoxicillin below tolerance, it does not meet the sensitivity requirements of the PMO. The calculated 90/95 for Amoxicillin is 3.5 ppb, less than 50% of the tolerance.

The Charm® TRIO test detects three classes of drugs, Beta lactams, Tetracyclines, and Sulfonamides. Charm Sciences, Inc. is seeking approval for use of the Charm® TRIO test for PMO testing of milk. This memorandum addresses the review and acceptance of the data provided by Charm Sciences, Inc. for PMO testing of Beta lactam drugs only. The review of the test for sulfonamides and tetracyclines will be addressed separately.

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

DRUG	90/95	Tolerance/Target Testing Level
Amoxicillin¹	3.5	10
Ampicillin	8.8	10
Ceftiofur²	50	100
Cephapirin	14.5	20
Cloxacillin	8.5	10
Penicillin G	2.0	5

¹The 90/95 for Amoxicillin is less than 50% of the tolerance and does not meet the requirements of the PMO.

²Total parent and desfuroylceftiofur related metabolites.

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

DRUG	Amoxicillin	Ampicillin	Ceftiofur	Cephapirin	Cloxacillin	Penicillin G
Tolerance/Target Level (ppb)	10	10	100 ¹	20	10	5
Drug Concentration (ppb)						
1	3					0
2	60	0			0	93
3	97					100
4	100	3		0	33	100
5						100
6	100	70			80	
8	100	97		30	100	
10	100	100			100	
12				90		
16				100		
20			0	100		
40			27			
50			93			
60			100			
80			100			
100			100			

¹Total parent and desfuroylceftiofur related metabolites.

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 Beta lactams 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.

A handwritten signature in black ink that reads "Philip James Kijak". The signature is written in a cursive style with a large, prominent 'K'.

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

Attachment: Product Label Operator's Manual: Charm® TRIO Test for Beta lactams, Sulfa
Drugs, and Tetracyclines in Raw, Commingled Cow Milk