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M-I-20-5

April 8, 2020

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

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

SUBJECT: IDEXX Laboratories, Inc. SNAP® Tetracycline Test Kit

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the NCIMS accepted IDEXX Laboratories, Inc. SNAP® Tetracycline Test Kit for the detection of tetracyclines in raw, commingled cow milk.

The FDA evaluation of the data, presented by IDEXX Laboratories, Inc., indicates that the performance of this test meets the standards established to determine the acceptance of a test for use to detect drug residues in raw commingled cow milk. The acceptance of this test for raw, commingled cow milk represent a claim of detectability for Oxytetracycline and Tetracycline. The data has been evaluated in accordance with the standards established for the acceptance of 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*.

The NCIMS Executive Board accepted the use of this test for Tetracyclines when used as labeled on March 29, 2019. Attached is the letter of acceptance from FDA's CVM.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, State Laboratory Evaluation Officers and Milk Sanitation Rating Officers. This electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also 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 Monica.Metz@fda.hhs.gov.



Monica Metz, Chief
Milk and Milk Products Branch

Attachment: FDA CVM Memorandum of the Acceptance of the IDEXX SNAP* Test Kit



Memorandum

**To: Monica Metz, Chief
Milk and Milk Products Branch**

From: Philip James Kijak, Ph.D.

Date: April 01, 2020

Subject: IDEXX Laboratories, Inc. IDEXX SNAP[®] Tetracycline Test

IDEXX Laboratories, Inc. has provided data to FDA supporting the use of the IDEXX SNAP[®] Tetracycline test for the detection of Oxytetracycline and Tetracycline in 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 IDEXX SNAP[®] Tetracycline test is a ten-minute raw, commingled milk screening test for the detection of tetracyclines. The test validation data package contained all the test results required by the FDA protocol for validation of tests for tetracyclines and the results met the requirements for use as an approved test. For the tetracycline-class of drugs, manufacturers are required to include data from three drugs, Chlortetracycline, Oxytetracycline and Tetracycline. IDEXX Laboratories, Inc. has provided the required data.

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

Drug	90/95	Tolerance (ppb)¹
Chlortetracycline	<600 ²	300
Oxytetracycline	180	300
Tetracycline	292	300

¹The tolerance is established for the sum of residues of the tetracyclines including Chlortetracycline, Oxytetracycline, and Tetracycline.

²A Tetracycline test must have a 90/95 below 300 ppb for Oxytetracycline and for one of remaining two tetracycline-class drugs. The 90/95 for the third drug must be less than 600 ppb.

Table 2: 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			
100		42	18
150		89	53
200		99	80
250		100	94
300	49	100	98
600	99		

RECOMMENDATION

Our evaluation of the data presented by IDEXX Laboratories, 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. 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