



Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back for the 2015 NCIMS Proposal 211 Pilot Program for Tetracycline Testing

June 22, 2017

The information below is for use in the 2015 NCIMS Proposal 211 Pilot Program for Tetracycline testing only.

Table 1 has been developed by FDA's Center for Veterinary Medicine (CVM) to demonstrate those screening Tests that have been accepted for use in the 2015 NCIMS Proposal 211 Pilot Program for Tetracycline testing to determine whether presumptive positive milk tank trucks and/or raw milk supplies that have not been transported in a milk tank truck are screening positive (load or raw milk supplies that have not been transported in a bulk milk pickup tanker confirmation). This Table may also be used for producer trace back testing to identify the positive producer(s) who contributed the milk containing tetracyclines on a positive milk tank truck load. Table 1 is a reference for which test(s) are appropriate to test samples from a producer(s), which has contributed milk containing tetracyclines to a positive milk tank truck.

The Charm[®] II Tetracycline Drug Test (Competitive Assay) is an M-a-85 listed test. The manufacturers of all other tests have submitted data to the FDA supporting the suitability of the test for the detection of tetracycline drug residues at or below the tolerance of 300 ppb established for the sum of residues of the tetracyclines, including chlortetracycline, oxytetracycline, and tetracycline, in milk. The validation results have been reviewed by the NCIMS Appendix N Modification Committee and the tests accepted for use in the 2015 NCIMS Proposal 211 Pilot Program for Tetracycline Testing.

Note that data has been submitted demonstrating that several of these tests meet the criteria for listing as an M-a-85 test. The approval status of these tests as of this date is pending. If and when a final approval for any of these tests is granted for listing under M-a-85, an M-I will be issued, M-a-85 updated and M-I-96-10 updated. Table 1 will be updated accordingly.



Table 1. Raw, Commingled Cow Milk

PRESUMPTIVE POSITIVE TEST	SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS
Charm® II Tetracycline Drug Test (Competitive Assay) M-a-85 test	Charm® II Tetracycline Drug Test (Competitive Assay) M-a-85 test
Neogen BetaStar® Advanced for Tetracyclines	Charm® II Tetracycline Drug Test (Competitive Assay) M-a-85 test Neogen BetaStar® Advanced for Tetracyclines Charm® ROSA Tetracycline-SL Test (Dilution Confirmation)
Charm® ROSA Tetracycline-SL Test (Dilution Confirmation)	Charm® II Tetracycline Drug Test (Competitive Assay) M-a-85 test Neogen BetaStar® Advanced for Tetracyclines Charm® ROSA Tetracycline-SL Test (Dilution Confirmation)
IDEXX – SNAP® Tetracycline Test (Dilution Confirmation)	Charm® II Tetracycline Drug Test (Competitive Assay) M-a-85 test Neogen BetaStar® Advanced for Tetracyclines Charm® ROSA Tetracycline-SL Test (Dilution Confirmation) IDEXX – SNAP® Tetracycline Test (Dilution Confirmation)