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M-I-96-10 (Revision #5)

March 10, 2004

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Drug Residue Test Methods for Confirmation of Presumptive Positive Results
and Initial Producer Traceback

This coded memorandum replaces and rescinds the previous revisions of this memorandum (M-I-96-10, Revision #4).

This revision is based on the phasing out and addition of several tests. It modifies the Tables to reflect the removal of the Delvo-X-Press and Charm I/Cowside II; the addition of the Charm SL6™; and the transition from the Snap to the New Snap Beta lactam milk screening kits as these tests have either been phased out by the manufacturer, approved for use, or transitioning to a new test, respectively. For information regarding these tests please refer to M-I-96-10 (Revision #4) to see how these tests may be substituted for another equivalent test.

The following Tables have been developed by FDA's Center for Veterinary Medicine (CVM) to demonstrate those screening tests that have been accepted under the requirements of Appendix N of the Grade "A" Pasteurized Milk Ordinance (PMO) to determine whether presumptive positive tanker results are screening positive (load confirmation). These Tables may also be used to determine an appropriate initial producer traceback test to identify the positive producer(s) who contributed the milk containing drug(s) on a positive load.

NOTE: Producers found presumptive positive by one (1) of these tests must be tested for confirmation using the same test that was used to determine the presumptive result for the producer. (See M-a-86, Revision #3)

These Tables do not include any additional requirements for testing and are a reference for which tests are appropriate to test samples from a producer(s), which has contributed milk containing drug(s) to a positive bulk milk pickup tanker.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum should be widely distributed to representatives of the dairy industry, State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations and other interested parties and will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to Robert.Hennes@cfsan.fda.gov.

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**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam/New SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Charm II Tablet Beta lactam Test (Competitive Assay)</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test SNAP Beta lactam/New SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Charm II Tablet Beta lactam Test (Sequential Assay)</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test SNAP Beta lactam/New SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>

<p>Charm II Tablet Beta lactam Test (Quantitative Assay)</p>	<p>Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Tablet Beta lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay)) Charm SL6™ Beta lactam Test Parallux Beta lactam Assay Charm SL Beta lactam Test + Charm II Test for Cloxacillin in Milk (Competitive Assay) SNAP Beta lactam /New SNAP Beta lactam Test Kit + Charm II Test for Cloxacillin in Milk (Competitive Assay)</p>
<p>Charm SL Beta lactam Test</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test SNAP Beta lactam /New SNAP Beta lactam Test Kit Parallux Beta lactam Assay</p>
<p>Charm SL6™ Beta lactam Test</p>	<p>Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Tablet Beta lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm SL6™ Beta lactam Test Parallux Beta lactam Assay Charm SL Beta lactam Test + Charm II Test for Cloxacillin in Milk (Competitive Assay) SNAP Beta lactam /New SNAP Beta lactam Test Kit + Charm II Test for Cloxacillin in Milk (Competitive Assay)</p>
<p>Charm II Test for Cloxacillin in Milk (Competitive Assay)</p>	<p>Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Test for Cloxacillin in Milk Charm SL6™ Beta lactam Test Parallux Beta lactam Assay</p>
<p>Charm II Tetracycline Drug Test</p>	<p>Charm II Tetracycline Drug Test</p>

Charm II Sulfa Drug Test	Charm II Sulfa Drug Test
Delvotest P 5 Pack	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay</p> <p>Charm II Tablet Beta lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta lactam Test (Sequential Assay)</p> <p>Charm II Tablet Beta lactam Test (Quantitative Assay)</p> <p>Charm SL Beta lactam Test</p> <p>Charm SL6™ Beta lactam Test</p> <p>Delvotest P 5 Pack</p> <p>Delvotest P/Delvotest P Mini</p> <p>Delvotest SP/Delvotest SP Mini</p> <p>Penzyme III Test Procedure</p> <p>Penzyme Milk Test</p> <p>SNAP Beta lactam/New SNAP Beta lactam Test Kit</p> <p>Parallux Beta lactam Assay</p>
Delvotest P/ Delvotest P Mini	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay</p> <p>Charm II Tablet Beta lactam Test Competitive Assay)</p> <p>Charm II Tablet Beta lactam Test (Sequential Assay)</p> <p>Charm II Tablet Beta lactam Test (Quantitative Assay)</p> <p>Charm SL Beta lactam Test</p> <p>Charm SL6™ Beta lactam Test</p> <p>Delvotest P 5 Pack</p> <p>Delvotest P/Delvotest P Mini</p> <p>Delvotest SP/Delvotest SP Mini</p> <p>Penzyme III Test Procedure</p> <p>Penzyme Milk Test</p> <p>SNAP Beta lactam/New SNAP Beta lactam Test Kit</p> <p>Parallux Beta lactam Assay</p>

<p>Delvotest SP/ Delvotest SP Mini</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam/New SNAP Beta lactam Test Kit Parallux Beta lactam Assay</p>
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Penzyme Milk Test (continued)	Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam/New SNAP Beta lactam Test Parallax Beta lactam Assay
SNAP Beta Lactam/New SNAP Beta Lactam Test Kit	Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Charm SL6™ Beta lactam Test SNAP Beta lactam/New SNAP Beta lactam Test Kit Parallax Beta lactam Assay
Parallax Beta lactam Assay	Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Tablet Beta lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm SL6™ Beta lactam Test Parallax Beta lactam Assay Charm SL Beta lactam Test + Charm II Test for Cloxacillin in Milk (Competitive Assay) SNAP Beta lactam /New SNAP Beta lactam Test Kit + Charm II Test for Cloxacillin in Milk (Competitive Assay)