

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-96-10 (Revision #7)

January 4, 2010

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Drug Residue Test Methods For Confirmation Of Presumptive Positive
Results And Initial Producer Trace Back

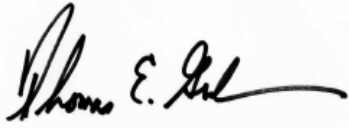
This coded memorandum replaces and rescinds the previous revision of this coded memorandum (M-I-96-10, Revision #6, dated October 1, 2007). Revision #6 will be identified in the next Index of Memoranda of Information (M-I) as "INACTIVE."

This revision is based on the phasing out and addition of several tests. It modifies the Tables to reflect the acceptance of the Neogen Corporation BetaStar® US Beta lactam test and the removal of the Neogen Corporation Penzyme Milk Test and Penzyme III Test as Neogen no longer supports the use of these tests for NCIMS testing.

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 trace back test to identify the positive producer(s) who contributed the milk containing drug(s) on a positive load. 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.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.



Thomas Graham, PhD, Team Leader
Laboratory Proficiency & Evaluation Team



CAPT Robert F. Hennes, RS, MPH
Milk Safety Team

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
|---|--|
| BetaStar® US | BetaStar® US 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 |
| Charm <i>B. stearothermophilus</i> Tablet Disk Assay | BetaStar® US 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 Charm SL3™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap Beta lactam Test |
| Charm II Tablet Beta lactam Test (Competitive 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 Charm SL3™ Beta lactam Test New Snap Beta lactam Test |
| Charm II Tablet Beta lactam Test (Sequential 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 Charm SL3™ Beta lactam Test New Snap Beta lactam Test |
| Charm II Tablet Beta lactam Test (Quantitative 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 |

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
|--|--|
| Charm SL Beta lactam Test | 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 Charm SL3™ Beta lactam Test New Snap Beta lactam Test |
| Charm SL6™ Beta lactam Test | 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 |
| Charm SL3™ Beta lactam Test | 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 Charm SL3™ Beta lactam Test New Snap Beta lactam Test |
| Charm II Sulfa Drug Test | Charm II Sulfa Drug Test |
| Charm II Tetracycline Drug Test | Charm II Tetracycline Drug Test |
| Delvotest P 5 Pack (Reader and Visual) | BetaStar® US 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 Charm SL3™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap Beta lactam Test |

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
|----------------------------------|--|
| Delvotest P/Delvotest P Mini | BetaStar® US 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 Charm SL3™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap Beta lactam Test |
| Delvotest SP/Delvotest SP Mini | BetaStar® US 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 Charm SL3™ Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap Beta lactam Test |
| New Snap Beta lactam Test | 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 Charm SL3™ Beta lactam Test New Snap Beta lactam Test |