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College Park, MD 20740-3835

M-I-96-10 (Revision #8)

March 22, 2012

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 #7), Issued January 4, 2010). Revision #7 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 as reflected in M-a-85 (Revision #14), Issued March 22, 2012. It modifies the Tables to reflect the acceptance of the following Tests:

- Neogen Corporation BetaStar® Plus Beta Lactam Test;
- Charm Sciences, Inc. Charm® 3 SL3 Beta Lactam Test; and
- Charm Sciences, Inc. Charm® FLUSLBL Flunixin and Beta Lactam Test.

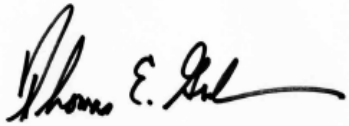
The following Tests have been removed as they are no longer available:

- Neogen Corporation BetaStar® US Beta Lactam Test; and
- Charm® SL3 Beta Lactam 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 milk tank truck 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 milk tank truck 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 milk tank truck.

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



Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Dairy and Egg Branch

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
|--|---|
| BetaStar® Plus Beta Lactam Test | BetaStar® Plus 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® 3 SL3 Beta Lactam Test |
| Charm® <i>B. stearothermophilus</i> Tablet Disk Assay Not a Beta lactam Specific Test. Refer to Footnote ¹ . | BetaStar® Plus Beta Lactam Test 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap® Beta Lactam Test |
| Charm® II Tablet Beta Lactam Test (Competitive Assay) | BetaStar® Plus 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test |
| Charm® II Tablet Beta Lactam Test (Sequential Assay) | BetaStar® Plus 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test |

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
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| Charm® II Tablet Beta Lactam Test (Quantitative Assay) | BetaStar® Plus 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® 3 SL3 Beta Lactam Test |
| Charm® SL Beta Lactam Test | BetaStar® Plus 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test |
| Charm® SL6 Beta Lactam Test | BetaStar® Plus 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® 3 SL3 Beta Lactam Test |
| Charm® 3 SL3 Beta Lactam Test | BetaStar® Plus 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® 3 SL3 Beta Lactam Test |
| Charm® FLUSLBL Flunixin and Beta Lactam Test | Charm® FLUSLBL Flunixin and Beta Lactam Test |
| Charm® II Chloramphenicol Test | Charm® II Chloramphenicol Test |
| Charm® II Sulfa Drug Test (Competitive Assay) | Charm® II Sulfa Drug Test (Competitive Assay) |
| Charm® II Tetracycline Drug Test (Competitive Assay) | Charm® II Tetracycline Drug Test (Competitive Assay) |

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
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| <p>Delvotest P 5 Pack (Reader and Visual)</p> <p>Not a Beta lactam Specific Test. Refer to Footnote¹.</p> | <p>BetaStar® Plus Beta Lactam Test 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap® Beta Lactam Test</p> |
| <p>Delvotest P/Delvotest P Mini</p> <p>Not a Beta lactam Specific Test. Refer to Footnote¹.</p> | <p>BetaStar® Plus Beta Lactam Test 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap® Beta Lactam Test</p> |
| <p>Delvotest SP/Delvotest SP Mini</p> <p>Not a Beta lactam Specific Test. Refer to Footnote¹.</p> | <p>BetaStar® Plus Beta Lactam Test 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test Delvotest P 5 Pack (Reader and Visual) Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini New Snap® Beta Lactam Test</p> |

| PRESUMPTIVE POSITIVE TEST | SCREENING TEST POSITIVE (CONFIRMATION TEST) OPTIONS |
|----------------------------------|--|
| New Snap® Beta Lactam Test | BetaStar® Plus 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® 3 SL3 Beta Lactam Test Charm® FLUSLBL Flunixin and Beta Lactam Test New Snap® Beta Lactam Test |

¹These Tests are not specific for Beta lactams. While they are not validated to NCIMS standards for any drugs other than Beta lactams, a non-Beta lactam drug residue can cause a positive test. A negative or not found (NF) test result using one of the Beta lactam specific Tests to follow-up or confirm a positive result with this test kit will require re-testing the sample using the Charm® *B. stearothermophilus* Tablet Disk Assay, Delvotest P 5 Pack, Delvotest P/Delvotest P Mini or Delvotest SP/Delvotest SP Mini. Any of the listed confirmation test options, other than the four (4) identified in the Tables, are Beta lactam specific Tests.