

DRAFT

Appendix N Modification LEO Responsibilities

For New Tetracycline Test Kits

As a result of Proposal 211 at the 2015 NCIMS Conference in Portland, OR, a pilot program has been established for testing the tetracycline class of drugs in Grade “A” raw cow milk. Manufacturers are working to get approval for rapid test kits to detect oxytetracycline, tetracycline and chlortetracycline in commingled raw cow milk. The pilot program is expected to start in 2017 and is contingent on laboratories being able to use these new test kits. The use of the kits will be specified in the Tetracycline Pilot Program forms specifically produced for the Tetracycline Pilot Program. In order for laboratories to be able to use these new rapid test kits, the testing locations and LEOs will have the following responsibilities:

1. The LEO must be aware:
 - a. That the location will be participating. (*Refer to “Pilot 211 Q&A Document current version,” 1. Participation*)
 - b. Which personnel will or will not be involved in testing (see 2 below).
 - c. That the testing location has a copy of the appropriate Tetracycline Pilot Program form.
 - d. That the testing location has all the equipment and supplies necessary to carry out the testing (Tetracycline Pilot Program form, also see 2 below).
 - e. That the CIS, IS and IA understand the Tetracycline Pilot Program screening presumptive positive determination, confirmation of positive, producer trace-back and producer reinstatement procedures. (**Refer to flow chart “Flow Diagram for Testing Protocol”**)
 - f. That the CIS or IS specifically understands how to conduct dilutions of initial positives to complete the presumptive testing process, and where necessary, dilution of presumptive positive samples to complete the confirmation testing process and carry out producer trace back and producer reinstatement testing.
 - g. That the CIS (i.e., administrative supervisor) or IS have instructed and trained all other CISs, ISs, and IAs, and test specific training records indicate this for these individuals.
2. LEOs will assure that the testing locations are currently approved or accredited for the beta-lactam platform for which new tetracycline test methods have been approved for the Tetracycline Pilot Program.
 - a. Charm SL: The LEO will verify that the testing location is approved/accredited AND personnel are currently approved/certified to run this test for the detection of beta-lactams. If so, an on-site laboratory survey **WILL NOT BE NECESSARY** for a testing location to participate in the Tetracycline Pilot Program to test for tetracyclines.

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- b. Charm SL3: The LEO will verify that the testing location is approved/accredited AND personnel are currently approved/certified to run this test for the detection of beta-lactams. If so, an on-site laboratory survey **WILL NOT BE NECESSARY** for a testing location to participate in the Tetracycline Pilot Program to test for tetracyclines. HOWEVER, the testing location must indicate (subject to verification) that it has a 56 ± 1 °C heater block with an 8 minute timer (already has one or has obtained one). Alternately, the testing location MAY use their current 56 ± 1 °C heater block with a built-in 3 minute timer, but must use a lab timer to measure the 8 minute incubation period.
 - c. IDEXX SNAP NBL: The LEO will verify that the testing location is approved/accredited AND personnel are currently approved/certified to run this test for the detection of beta-lactams. If so, an on-site laboratory survey **WILL NOT BE NECESSARY** for a testing location to participate in the Tetracycline Pilot Program to test for tetracyclines.
 - d. Neogen BetaStar: The LEO will verify that the testing location is approved/accredited AND personnel are currently approved/certified to run this test for the detection of beta-lactams. If so, an on-site laboratory survey **WILL NOT BE NECESSARY** for a testing location to participate in the Tetracycline Pilot Program to test for tetracyclines.
 - e. If the testing location chooses to use analysts that are NOT certified for the current beta-lactam test, then LEOs will have to conduct a performance evaluation either by an on-site laboratory survey or by providing split samples as required by the EML. IAs may be approved as currently allowed for beta-lactam testing (see item 1.g above) or by the manner used by the state to assure capability.
 - f. If the testing location chooses to switch to a different reader for the Tetracycline Pilot Program and use tetracycline tests of the same type and manufacturer as their current beta-lactam test, they just need to inform the LEO and be able to demonstrate that the reader functions correctly (performance testing, subject to verification) and analysts have been trained and know how to use the new reader if different from the one used for beta-lactam testing. If so, an on-site laboratory survey **WILL NOT BE NECESSARY** for a testing location to participate in the Tetracycline Pilot Program to test for tetracyclines.
3. If the testing location chooses to use a platform for which they are not currently approved/accredited and analysts are NOT approved/certified, then LEOs will have to conduct an on-site laboratory survey as specified in the EML.
 4. After the Tetracycline Pilot Program has been initiated and tetracycline testing has started, the LEO will incorporate tetracycline (concentrates available from LPET) in their NEXT scheduled set of split samples or ensure their laboratories testing for tetracyclines participate in a split sample program that includes tetracyclines.