

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC**

FSIS NOTICE

43-12

6/26/12

USING THE KIDNEY INHIBITION SWAB (KISTM) TEST TO DETECT ANTIMICROBIAL DRUG RESIDUES IN ALL LIVESTOCK IN SLAUGHTER ESTABLISHMENTS – PHASE IV

I. PURPOSE

This notice informs inspection program personnel (IPP) that on August 19, 2012, the Agency will extend the process of replacing the Fast Antimicrobial Screen Test (FAST) with the Kidney Inhibition Swab (KISTM) test to all livestock slaughter establishments (KISTM test Phase IV), including all swine, sheep, lamb, and goat slaughter establishments that did not implement the KISTM test in Phase I, II, or III.

II. BACKGROUND

Carcasses for sampling and testing by the KISTM test are selected and handled in the same way as carcasses selected for FAST; see [FSIS Directive 10,800.1](#) and [FSIS Directive 10,220.3](#).

III. TRAINING

A. Training materials on the KISTM test are available for Public Health Veterinarians (PHVs) and Consumer Safety Inspectors (CSIs) at livestock slaughter establishments involved in Phase IV and are also available upon request for use by PHVs and CSIs at livestock slaughter establishments that implemented KISTM testing during Phase I, II, or III.

B. In some cases, this phase of the implementation will occur in livestock slaughter establishments that have already started to use the KISTM test for cattle and swine. There should already be IPP in these livestock slaughter establishments trained to perform the KISTM test. Training materials on “Performing the KISTM Test” in both CD-ROM and written formats will be sent from the FSIS Midwestern Laboratory to Inspectors-in Charge (IICs) at livestock slaughter establishments not selected for KISTM test Phase I, II, or III. Training materials will arrive by July 30, 2012. The IICs at the livestock slaughter establishments at which KISTM test Phase IV is to be implemented are to provide the training materials to those IPP (if not already trained) designated by the IIC to conduct the KISTM test. Immediately after reviewing both the “Performing the KISTM Test” CD-ROM and written instructional booklet, the designated IPP are to log onto AgLearn and affirm completion of the KISTM test training. Any IIC at a livestock

DISTRIBUTION: Electronic

NOTICE EXPIRES: 7/1/13

OPI: OPPD

slaughter establishment who has not received training materials by the date above, or who wishes to request additional training materials, should contact CEDL@fsis.usda.gov in a timely manner. The KIS™ test instructional booklet is also available online at http://www.fsis.usda.gov/PDF/KIS_Booklet_0710.pdf.

IV. RECEIPT OF TEST SUPPLIES

A. IICs at livestock slaughter establishments at which KIS™ test Phase IV is to be implemented will receive KIS™ test supplies, including heating blocks, by July 30, 2012. IICs at livestock slaughter establishments where KIS™ test Phase I, II, or III was implemented will receive additional KIS™ test supplies if KIS™ test Phase IV is now to be implemented at such establishments, including heating blocks (if extra heating blocks have been requested). IPP are to begin using the KIS™ test, as appropriate, for all livestock as soon as IPP designated to conduct the test have completed the training, but not before August 19, 2012.

B. In an effort to better direct available Agency resources, IICs at livestock slaughter establishments that recorded on average less than one FAST per week may not receive KIS™ test supplies as outlined above. If that is the case, IPP at these establishments are to discontinue use of the FAST and submit the kidney, liver, and muscle tissue samples from all livestock to be tested directly to the FSIS Midwestern Laboratory for analysis after August 19, 2012.

C. Additional KIS™ test supplies can be obtained from the FSIS Midwestern Laboratory via Outlook at SamplingSupplies-MidwesternLab@fsis.usda.gov. The following is the list of KIS™ test supplies available at the FSIS Midwestern Laboratory:

1. Digital Dry Block Heater (tests up to 20 units);
2. KIS™ (Kidney Inhibition Swab) Tests (in packets of 25 tests);
3. Negative Controls (4 tablets - approximately 1 month, as each reconstituted tablet is good for 5 days when stored at proper temperatures);
4. 15 ml Tube of Deionized or Distilled Water (or equivalent);
5. Timer;
6. Transfer Pipettes (in packs of 25 – approximately 1 month) or equivalent device for delivering 1ml of water; and
7. Test Tube Rack (or equivalent device, to hold KIS™ tests).

D. When requesting supplies, IICs are to include the establishment name and number, establishment mailing address, specific supplies needed, and phone contact information.

V. DISPOSAL OF FAST EQUIPMENT

A. As mentioned above, the KIS™ test is to replace FAST for all livestock. IICs in livestock slaughter establishments that have FAST equipment and supplies are to contact Ina Mendoza-Wilson, Administrative Services Division, via Outlook or phone at 301-504-4269 for instructions on how to properly dispose of all excess FAST equipment and supplies.

B. Some older incubators may still contain mercury thermometers, which can be identified by their silver or metallic-colored indicator material. Mercury is a toxic material subject to many regulations for recycling, disposal, transportation, and shipping. All unbroken mercury thermometers are to be returned to the FSIS Midwestern Laboratory. For instructions on how to return unbroken thermometers, contact the FSIS Midwestern Laboratory by calling 314-263-2680 or contact the Laboratory Safety Officer through LaboratoryInquiryMidwesternLab@fsis.usda.gov.

C. If a mercury thermometer is broken, it is deemed a hazardous waste that requires special handling and for that reason, is not to be shipped to the FSIS Midwestern Laboratory. Instead, IPP are to contact the FSIS Environmental Health and Safety Branch in Beltsville, MD at 301-504-4245 for guidance on how to properly handle and dispose of the broken mercury thermometer.

VI. IN-PLANT PROCEDURE AND DECISION RESPONSIBILITY

A. In-plant PHVs will be responsible for conducting the KIS™ test or supervising a CSI assigned to conduct the KIS™ test. The KIS™ test may be performed by PHVs or CSIs.

B. The PHV or CSI conducting the test is to read the results between 3 and 16 hours after incubation. The results for the KIS™ test are based on a distinct color or color changes. If the KIS™ test results are positive, the PHV or CSI is to submit kidney, liver, and muscle tissue samples to the Midwestern Laboratory for further testing and continue to retain the carcass and parts. The PHV or CSI is to follow the directions provided in [FSIS Public Health Inspection System \(PHIS\) Directive 13,000.2](#) for reporting the results from in-plant residue screening tests.

C. In cases where there is doubt as to the KIS™ test outcome, and there is no in-plant PHV, the CSI performing the test is to take a digital photograph of the test vial and send it electronically to the PHV assigned to cover that establishment to make a final determination. In those Districts or establishments without access to a digital camera, in case of an unclear reading of the KIS™

test, the PHV assigned to cover that establishment is to make the final determination.

D. If the KIS™ test result is negative, the PHV or CSI is to release the carcass and parts, unless in the professional opinion of the PHV there is reason to believe that residues exist that the in-plant rapid screening test will not or did not detect (e.g., flunixin, phenylbutazone). In such cases, the PHV or CSI is to submit kidney, liver, and muscle tissue samples to the Midwestern Laboratory for further testing and continue to retain the carcass and parts.

E. If the carcass and parts have not already been condemned for other pathology, action on the retained carcass and parts is dictated by FSIS laboratory results. Carcass condemnation is the responsibility of the PHV, based on final results from the FSIS laboratory.

VII. DATA ANALYSIS

In order to monitor operational performance, effectiveness of program implementation, and scientific outputs of the drug residue program, a number of Agency offices analyze data from the in-plant KIS™ tests. The Office of Data Integration and Food Protection (ODIFP) evaluates program effectiveness and operational performance on a monthly basis. ODIFP analyzes sample collection and analysis rates nationally and by district and circuit. In addition, ODIFP analyzes the number of confirmed positive KIS™ test results and evaluates the relationship between KIS™ test results and establishment condemnation rates. ODIFP shares its analysis with other FSIS program areas, including the Office of Public Health Science (OPHS) Risk Assessment Division's Chemical Residue Risk Staff and the Office of Field Operations. The OPHS and the Policy Development and Risk and Innovations Management Divisions of the Office of Policy and Program Development (OPPD) consider KIS™ test results in designing the veterinary drugs part of the National Residue Program, in collaboration with the Food and Drug Administration (FDA). OPHS and OPPD also take the KIS™ test results into account in collaborating with FDA on drug residue enforcement matters, including the Residue Violation Information System (RVIS).

Direct all technical questions to the Policy Development Division and all sampling questions to the Risk Innovation and Management Division at 1-800-233-3935 or submit your questions through askFSIS at <http://askfsis.custhelp.com>.



Acting Assistant Administrator
Office of Policy and Program Development