

Tab 9 – Public Health Laboratory Testing

Laboratory Data and Sample Testing

Testing and Sharing

The Kentucky State Public Health Laboratory (KSPHL) is a designated Biosafety Level 3 Confirmatory laboratory with the capability to test environmental samples and referred cultures for the identification of biological agents. The KSPHL is a member of the Center for Disease Control and Prevention (CDC) secure Laboratory Response Network (LRN) and tests samples of suspected bioterrorism according to the established procedures and protocols of the LRN. These procedures and protocols are secure and cannot be shared or distributed. The identification of biological agents not suspected of bioterrorism is tested according to standard microbiological procedures using the gold standard of tube biochemicals.

Chemical testing at the KSPHL is performed only on environmental samples using Gas Chromatographic mass spectrophotometry, Infrared and ion mobility spectrometry, and by photo ionization detection. Clinical samples for chemical testing are collected and sent to the KSPHL and the KSPHL does preliminary testing if possible and depending on the results ships the samples to CDC.

The KSPHL does not perform radiological testing. Triage that includes radiological screening is performed on environmental samples before they are submitted to the lab for testing.

The KSPHL has an established notification plan; “Notification Plan for Potential Public Health Incidents” to notify CDC and Kentucky public health officials for threat agents. This notification plan follows the guidelines from the CDC- LRN “Policy statement on Notification of Officials of Significant Laboratory Results.” The KSPHL can electronically submit test result data to CDC via “LRN Results Messenger”.

Packaging and Shipping

The County Emergency Manager will notify the Hazmat Team for collection and shipment of radiological materials and nonclinical chemical specimens to the appropriate labs for analysis.

To send infectious substances, the shipper (Sentinel Labs and LHDs) must be certified to package and ship infectious substances. BRDHD has limited staff certified to ship infectious substances.

In emergencies, certified shipping regulations may be waved. Regulations for shipping infectious substances may be found at: http://www.gpo.gov/nara/cfr/waisidx_02/49cfr173_02.html

The following guidelines would be followed: Federal and international regulations applicable to the shipment of infectious substances are listed in Appendix 1. The International Air Transport Association (IATA) Dangerous Goods Regulations apply to shipment of infectious substances via international and domestic air transportation. PHS 42 CFR Part 72, DOT 49 Parts 171-180, and United States Postal Service (USPS)

regulations apply to domestic transportation by land, air, sea and rail. Currently, IATA has the most stringent requirements for transportation of infectious substances. Additional requirements for the importation of infectious substances from foreign countries are covered in 42 CFR Part 71.54. It is the responsibility of the shipper to ensure correct identification and classification.

Address to whom the samples are shipped:

Kentucky Public Health Laboratory
100 Sower Blvd., North Loading Dock,
P.O. Box 2020
Frankfort, Kentucky 40602-2020

Phone: 502/564-4446

Fax: 502/564-7019

Laboratory Emergency after-hours number: (502) 330-6235

Packing Instructions for the Multi-Shipper

The enclosed Biological Substance, Category B specimen shipping system has been developed in accordance with the DOT triple packaging requirements found in 49CFR 173.199 and IATA Packing Instruction 650 (2005 Dangerous Goods Regulations).

Ambient Diagnostic Shipping System

Components:

IATA size transport box with markings

Medium 95kPa Canister

Aqui-Pak 6 tube absorbent pouch

Biohazard symbol label

Bubble wrap sheet

Transportation

We would follow DOT, USPS, IATA regulations to ship infectious substances. We may seek outside help from Emergency Management, and Law enforcement agencies including the FBI depending on the circumstances. These agencies may be requested to assist with 24/7/365 transportation of specimens to KSPHL. We will be looking forward for specific guidelines from Department for Public Health on case-by-case basis. Map of lab is found in Appendix – Tab 9.

Access to Reference Labs

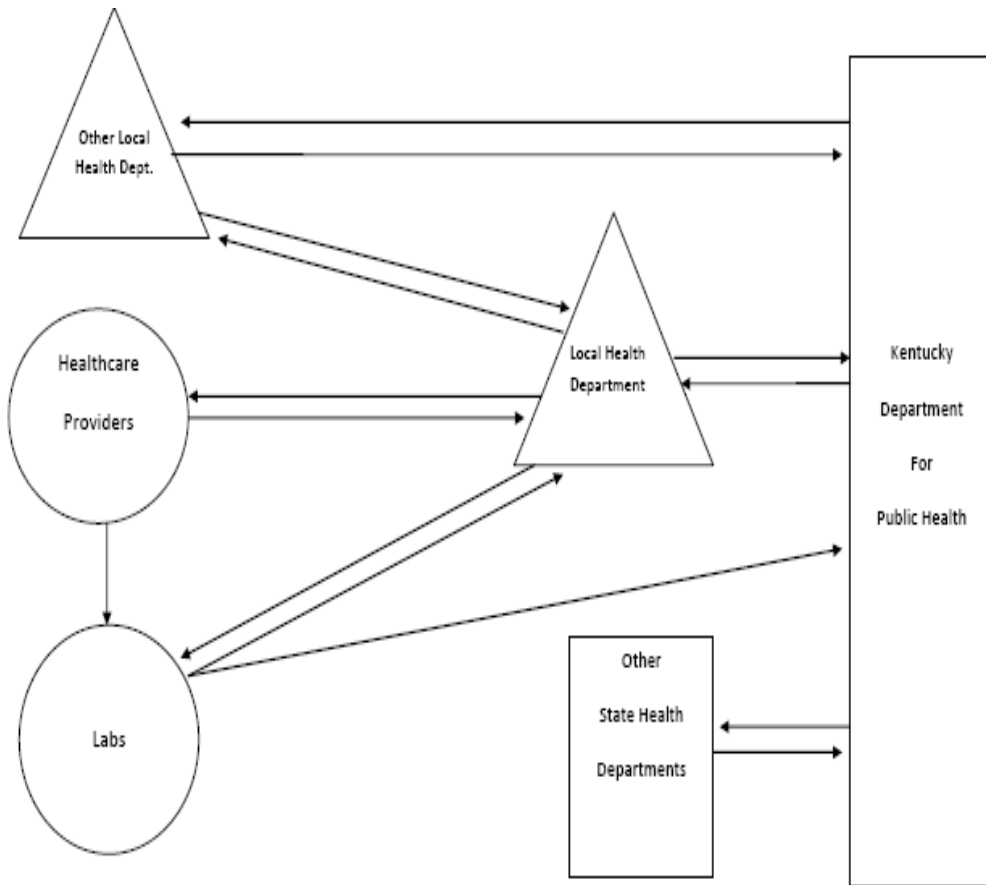
The KSPHL has an on call system in place for after business hours coverage and is available 24/7/365 in the event of bioterrorism or public health incidents and emergencies. For after business hours coverage dial (502) 330-6235, and the KSPHL phone system instructs callers to a number that forwards to the cell number of laboratory personnel performing on call duty. The Security management at the building for the KSPHL and the Kentucky's public health emergency reporting system has all emergency contact information of the laboratory.

Data Management/Flow

Kentucky Laboratory Web Outreach (KY-LWO) allows lab ordering and result access to be accomplished by using the Internet Test Order/ Reporting Interface.

KSPHL laboratory results are sent electronically via the Local Health Network (LHN) to all Local Health Departments and other submitters such as hospitals and reference laboratories. For environmental samples the results are sent by fax to the law enforcement agency or submitter. Results will go by mail or electronically to:

- The submitting law enforcement agency
- The Local Health Department
- Division of Epidemiology and Health Planning, KY Dept. for Public Health



Laboratory test results can be sent to CDC via the secure “LRN Results Messenger.” All data from environmental samples and threat agents are maintained and filed in designated secure restricted access areas. A notification plan is in effect for notifying CDC and Kentucky public health officials of biological threat agents.

Lab Information Flow Chart

KY DPH officials will share laboratory information with other public health officials and partners in neighboring jurisdictions to facilitate the rapid formulations of an

appropriate response via phone, fax, electronically, or through KY-LWO.

Evidence Management

Evidence is submitted to KSPHL with a Chain of Custody form (see Appendix – Tab 9). Security policies and procedures for receiving, processing, and releasing evidence at the KSPHL are established by the criteria of the CDC select agent program and 42 CFR 73.11. These procedures and policies include authorized access and material handling procedures. All evidence is stored in secure restricted access areas.

Laboratory Capacity and Pathogen Identification

Capacity

The KY DPH Division of Laboratory Services will monitor their capacity for laboratory testing. They will activate their MOUs with commercial laboratories when they have reached their maximum capacity for testing. LHD will be notified when maximum capacity has been reached and specimens need to be sent to an alternative laboratory.

KY Laboratory Reference List of Test

A list of all testing available at the state lab can be found at:

<http://chfs.ky.gov/NR/rdonlyres/D1B41D50-E933-421D-87BB-45706429E051/0/referencelistsoftests.pdf>