**Section 475.20 Submission of Samples or Specimens**

Each sample or specimen submitted to the Laboratory for any analysis shall be delivered or shipped in a container and manner to preserve the sample/specimen from contamination or destruction and to allow it to reach the Laboratory in a condition that permits a reliable laboratory analysis.

a) The person submitting the sample/specimen shall deliver it to the Laboratory or send it in a package approved by the U.S. Postal Service or another commercial carrier for shipping. Any sample/specimen that is submitted in a package that violates the U.S. Postal Service's guidelines (or another commercial carrier's guidelines if an alternative carrier is used), is damaged in transit, is not received within the prescribed time frame for analysis, or is otherwise received in a condition that does not permit a reliable laboratory analysis, will be discarded. When this occurs, the laboratory result will be reported as indeterminate or unsatisfactory, and the submitter will be notified so that another sample/specimen can be collected and submitted for analysis.

b) For those laboratory services offered, the Laboratory will provide, upon request, sample/specimen collection materials or devices and mailing containers that meet the U.S. Postal Service regulations.

c) Prior to delivering or shipping any sample/specimen to the Laboratory, the person submitting the sample/specimen shall confirm with the Laboratory the availability of the desired laboratory service/analysis and identify which Laboratory site or sites (e.g., Chicago, Springfield, Carbondale or a contract laboratory site) will perform the desired service/analysis and any testing authorization procedures that are required. Samples/specimens shall be delivered or sent only to a specific Laboratory site designated as performing the requested laboratory service or to an alternative site agreed to in advance.

d) The person submitting the sample/specimen shall pay for the postage or transport fee of the package unless alternative arrangements are made with the Laboratory in advance of mailing or shipping a sample/specimen to the Laboratory.

e) Clinical specimens received by the Department will be retained for a minimum of one month. If all test results obtained from a specimen are determined to be within normal range, the specimen will be retained for a maximum of four months. If any test result obtained from a specimen is determined to be abnormal (i.e., out of normal range), the specimen may be retained for a maximum of six years. Specimens that the Department retains may be used within the Department for quality control purposes as required under CLIA. Based on the Department's testing capabilities, specimens with an abnormal result may be referred to other clinical laboratories for supplemental testing to further characterize the abnormality. After the maximum time period for retention, the Department will destroy all specimens.

f) Cultures, isolates and extracts of pathogens that are provided to the Department or result from testing samples/specimens that have been provided to the Department may be shared by the Department with other public health entities for quality assurance or method development purposes, provided that any and all patient identifiable information has been removed.

(Source: Amended at 38 Ill. Reg. 21494, effective October 31, 2014)