**Section 475.10 Definitions**

"Clinical Laboratory Improvement Amendments" or "CLIA" means federal regulations (Centers for Medicare and Medicaid Services, United States Department of Health and Human Services) (Laboratory Requirements; 42 CFR 493) (10/1/13) providing standards applicable to all facilities or sites in the United States that test human specimens for health assessment or to diagnose, prevent or treat disease.

"Department" means the Department of Public Health.

"Director" means the Director of the Department of Public Health.

"Laboratory" means the Division of Laboratories of the Illinois Department of Public Health, including its Chicago, Springfield and Carbondale Laboratories, and any other site designated by contract to perform Department Laboratory services.

"Person" means:

a medical provider;

the State, its agencies and departments, and its officers and employees;

any local health department and its officers and employees;

any grantee or contractor of the Department that agrees to provide services to the Department, or on behalf of the Department, and officers and employees of a grantee or contractor.

"Quality Control" means a procedure or set of procedures to assure the accuracy of results reported by the Laboratory.

"Supplemental Test" means any test approved by the United States Food and Drug Administration or validated under a laboratory's CLIA certification that is used to further characterize a specimen that had received a positive result when initially screened by the Laboratory.

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