**Section 450.5 Scope and Applicability**

a) This Part provides regulatory oversight of all entities certified pursuant to 42 CFR 493, that perform analysis of human specimens for health assessment or to diagnose, prevent or treat disease.

b) All certified CLIA laboratories will be regulated as set forth in 42 CFR 493 and described in the State Operations Manual (Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services), issued by the Department of Health and Human Services.

c) Licensed Laboratory

1) As set forth in this Part, a "licensed" laboratory is a laboratory licensed by the Department under the standards set forth in CLIA laws and regulations (CLIA Law) to accept and test clinical human specimens from a person, in accordance with Article VII of the Act.

2) The licensed laboratory shall maintain certification status in good standing as required by CLIA Law.

d) Physicians, corporations, individuals, local health authorities, and others that intend to conduct clinical tests on human specimens for health assessments or to diagnose, prevent or treat disease shall obtain certification status by the Department in accordance with CLIA Law. Health screening activities under Section 2-120 of the Act may be conducted by a licensed laboratory at the laboratory location listed on the CLIA certificate; however, health screening events shall be conducted in accordance with Sections 450.1300, 450.1310, and 450.1330.

(Source: Amended at 44 Ill. Reg. 20004, effective December 9, 2020)