

[(iii)] (2) [Criteria that] SET THE STANDARDS AND REQUIREMENTS THAT a proficiency testing program must meet before it can be designated as an approved program.

[(2) The Department or an organization approved by the Secretary shall conduct the proficiency testing program.

(3) All cytology proficiency tests conducted under the proficiency testing program shall be handcarried on site and under the supervision of an official of the Laboratories Administration of the Department of Health and Mental Hygiene, or an organization approved by the Secretary.]

[17-213.] 17-212.

[(a) Except as otherwise provided in this subtitle, a person may not operate a medical laboratory in this State unless the person holds a permit issued by the Secretary.

(b) A permit holder may not offer or perform any service of a medical laboratory that is not authorized by the permit.]

UNLESS A PERSON HOLDS A LICENSE ISSUED BY THE SECRETARY THE PERSON MAY NOT:

(1) OFFER OR PERFORM MEDICAL LABORATORY TESTS OR EXAMINATIONS IN THIS STATE;

(2) REPRESENT OR SERVICE IN THIS STATE A MEDICAL LABORATORY REGARDLESS OF THE LABORATORY'S LOCATION; OR

(3) OFFER OR PERFORM MEDICAL LABORATORY TESTS OR EXAMINATIONS ON SPECIMENS ACQUIRED FROM HEALTH CARE PROVIDERS IN THIS STATE AT A MEDICAL LABORATORY LOCATED OUTSIDE THIS STATE.

[17-214.] 17-213.

[(a) A person may not represent or service any medical laboratory, regardless of location, unless the] UNLESS A medical laboratory [and its director meet the standards and qualifications that the Secretary adopts under this subtitle,] HAS A VALID LICENSE, NO OTHER PERSON ON THE LABORATORY'S BEHALF MAY:

(1) OFFER OR PERFORM MEDICAL LABORATORY TESTS OR EXAMINATIONS IN THIS STATE;

(2) OFFER OR PERFORM MEDICAL LABORATORY TESTS OR EXAMINATIONS ON SPECIMENS ACQUIRED FROM HEALTH CARE PROVIDERS IN THIS STATE AT THE MEDICAL LABORATORY LOCATED OUTSIDE THIS STATE; OR

(3) REPRESENT OR SERVICE IN THIS STATE THE MEDICAL LABORATORY REGARDLESS OF THE LABORATORY'S LOCATION.

[(b) A person may not represent or service in this State any medical laboratory that is not in this State unless the person holds a permit to represent or service the medical laboratory.]