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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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**HOUSE BILL**

**No. 912**      Session of  
2007

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INTRODUCED BY COHEN, CALTAGIRONE, MUNDY, FRANKEL, CURRY, DALEY,  
DeLUCA, DENLINGER, FABRIZIO, FREEMAN, GEORGE, GIBBONS,  
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McILVAINE SMITH, SOLOBAY, STABACK, STURLA, SURRA, SWANGER,  
WATERS AND WHEATLEY, MARCH 22, 2007

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REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES,  
MARCH 22, 2007

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AN ACT

1 Reenacting and amending the act of September 26, 1951 (P.L.1539,  
2 No.389), entitled, as amended, "An act defining clinical  
3 laboratory; regulating the operation of the same; requiring  
4 such laboratories to obtain permits, and to be operated under  
5 the direct supervision of qualified persons; imposing certain  
6 duties upon the Department of Health; and providing  
7 penalties," further providing for the title and for the short  
8 title; providing for legislative findings; further providing  
9 for definitions; providing for clinical laboratory permits;  
10 further providing for permit applications, for regulations,  
11 for hearings and appeals, for exemptions and for unlawful  
12 conduct; providing for regulations, for forensic DNA  
13 laboratories, for exemptions and for hearings and appeals;  
14 and further providing for penalties.

15 The General Assembly of the Commonwealth of Pennsylvania  
16 hereby enacts as follows:

17 Section 1. The title of the act of September 26, 1951  
18 (P.L.1539, No.389), known as The Clinical Laboratory Act,  
19 amended December 6, 1972 (P.L.1388, No.297), is reenacted and  
20 amended to read:

21 AN ACT

1 Defining clinical laboratory and forensic deoxyribonucleic acid  
2 (DNA) laboratory; regulating the operation of [the same]  
3 clinical laboratories and forensic DNA laboratories;  
4 requiring such laboratories to obtain permits or  
5 accreditation, and to be operated under the direct  
6 supervision of qualified persons; imposing certain duties  
7 upon the Department of Health; and providing penalties.

8 Section 2. The preamble of the act, amended December 6, 1972  
9 (P.L.1388, No.297), is reenacted to read:

10 Whereas, the health and lives of the citizens of this  
11 Commonwealth are endangered by incompetent supervision of  
12 clinical laboratory tests; and

13 Whereas, a due regard for public health and preservation of  
14 human life demands that none but scientists competent and  
15 properly qualified by sufficient training in the fundamental  
16 sciences and experienced in their applications in the clinical  
17 laboratory shall be permitted to supervise the work of such  
18 laboratories.

19 Section 3. The act is amended by adding a chapter heading to  
20 read:

21 CHAPTER 1

22 PRELIMINARY PROVISIONS

23 Section 4. Section 1 of the act, amended December 6, 1972  
24 (P.L.1388, No.297), is reenacted and amended to read:

25 Section [1] 101. Short Title.--This act shall be known and  
26 may be cited as "The Clinical and Forensic DNA Laboratory Act."

27 Section 5. The act is amended by adding a section to read:

28 Section 102. Legislative Findings.--The General Assembly  
29 finds as follows:

30 (1) The health and lives of the citizens of this

1 Commonwealth are endangered by incompetent supervision of  
2 clinical laboratory tests.

3 (2) A due regard for public health and preservation of human  
4 life demands that none but scientists competent and properly  
5 qualified by sufficient training in the fundamental sciences and  
6 experienced in their applications in the clinical laboratory  
7 shall be permitted to supervise the work of such laboratories.

8 (3) In a short period of time deoxyribonucleic acid (DNA)  
9 evidence has become a significant element in many court cases.  
10 In this Commonwealth and across the nation, DNA evidence has  
11 proven to be the deciding factor in determining innocence or  
12 guilt. Because of the increasing demand for this information,  
13 the gathering, processing, handling and tabulating of DNA  
14 materials in court cases and other areas has become an area of  
15 great activity. There is often considerable pressure placed on  
16 the few laboratories that process DNA materials. Processing and  
17 handling DNA materials requires considerable expertise and  
18 unique equipment. As is the case in this Commonwealth, most DNA  
19 casework is carried out by large police departments and State  
20 facilities. There are, however, some private labs conducting  
21 this work. As DNA evidence continues to play an integral part in  
22 determining the innocence or guilt of a person, it is vitally  
23 important that laboratories conducting this type of analysis are  
24 well regulated and accredited.

25 Section 5.1. Section 2 of the act, amended December 6, 1972  
26 (P.L.1388, No.297), is repealed:

27 [Section 2. Definitions.--The term "Clinical Laboratory"  
28 means any place, establishment or institution organized and  
29 operated primarily for the performance of all or any  
30 bacteriological, biochemical, microscopical, serological, or

1 parasitological tests by the practical application of one or  
2 more of the fundamental sciences to material originating from  
3 the human body, by the use of specialized apparatus, equipment  
4 and methods, for the purpose of obtaining scientific data which  
5 may be used as an aid to ascertain the state of health.

6 The term "Department" means the Department of Health.]

7 Section 5.2. The act is amended by adding a section to read:

8 Section 103. Definitions.--The following words and phrases  
9 when used in this act shall have the meanings given to them in  
10 this section unless the context clearly indicates otherwise:

11 "ASCLD-LAB" means the American Society of Crime Laboratory  
12 Directors/Laboratory Accreditation Board.

13 "Blind external proficiency testing" means a test sample that  
14 is presented to a forensic laboratory for forensic  
15 deoxyribonucleic acid (DNA) testing through a second agency, and  
16 which appears to the analysis to involve routine evidence  
17 submitted for forensic DNA testing.

18 "Board" means the Forensic DNA Accreditation Board  
19 established in section 502.

20 "Bureau" means the Bureau of Laboratories in the Department  
21 of Health of the Commonwealth.

22 "Clinical laboratory" means any place, establishment or  
23 institution organized and operated primarily for the performance  
24 of all or any bacteriological, biochemical, microscopical,  
25 serological or parasitological tests by the practical  
26 application of one or more of the fundamental sciences to  
27 material originating from the human body, by the use of  
28 specialized apparatus, equipment and methods, for the purpose of  
29 obtaining scientific data which may be used as an aid to  
30 ascertain the state of health.

1 "Department" means the Department of Health of the  
2 Commonwealth.

3 "DNA" means the deoxyribonucleic acid which is located in the  
4 cells and provides the personal genetic blueprint of each  
5 individual through encoded genetic information that is the basis  
6 of human heredity and forensic identification.

7 "DNA testing methodology" means the methods and procedures  
8 used to extract and analyze deoxyribonucleic acid (DNA)  
9 material, as well as the methods, procedures, assumptions and  
10 studies used to draw statistical inferences from the test  
11 results.

12 "FBI" means the Federal Bureau of Investigation.

13 "Forensic DNA laboratory" means any forensic laboratory  
14 operated in this Commonwealth that performs forensic DNA testing  
15 on crime scenes or for purposes of identification.

16 "Forensic DNA testing" means any test that employs techniques  
17 to examine deoxyribonucleic acid (DNA) derived from the human  
18 body for the purpose of providing information to resolve issues  
19 of identification.

20 "Secretary" means the Secretary of Health of the  
21 Commonwealth.

22 "State DNA identification record system" means the State DNA  
23 Data Base reestablished under 42 Pa.C.S. § 4712 (relating to  
24 State DNA Data Base) and the State DNA Data Bank reestablished  
25 under 42 Pa.C.S. § 4713 (relating to State DNA Data Bank).

26 "Supreme Court" means the Supreme Court of the Commonwealth  
27 of Pennsylvania.

28 Section 6. The act is amended by adding a chapter heading  
29 and a section to read:

30 CHAPTER 3

1 CLINICAL LABORATORIES

2 Section 301. Clinical Laboratory Permits.--The department  
3 shall issue a permit for the operation of any clinical  
4 laboratory which meets the requirements of this chapter and  
5 complies with the regulations promulgated under this chapter.

6 Section 7. Sections 3 and 3.1 of the act, amended December  
7 6, 1972 (P.L.1388, No.297), are reenacted, renumbered and  
8 amended to read:

9 Section [3. Limitations] 302. Supervision.--A clinical  
10 laboratory shall be under the direct and personal supervision  
11 of:

12 [1.] (1) A holder of a doctor of science degree or its  
13 equivalent in the basic sciences, including professional degrees  
14 in public health, medicine, osteopathy, pharmacy, dentistry and  
15 veterinary medicine, from a college or university recognized by  
16 the National Committee of Regional Accrediting Agencies or the  
17 Department of Education, in chemistry, biology or microbiology,  
18 and who has had two years of experience in a laboratory  
19 acceptable to the department.

20 [2.] (2) The holder of a master of science degree or its  
21 equivalent in the basic sciences from a college or university  
22 recognized by the National Committee of Regional Accrediting  
23 Agencies or the Department of Education, in chemistry, biology  
24 or microbiology, and who has had a minimum of four years'  
25 experience in a laboratory acceptable to the department.

26 [3.] (3) The holder of a bachelor of science degree or its  
27 equivalent in the basic sciences from a college or university  
28 recognized by the National Committee of Regional Accrediting  
29 Agencies or the Department of Education, in chemistry, biology  
30 or microbiology, and who has had a minimum of five years'

1 experience in laboratory work in a laboratory acceptable to the  
2 department.

3 [4.] (4) From and after July 1, 1973, no clinical laboratory  
4 shall be under the direction and personal supervision of any  
5 person who does not meet the qualifications set forth in clause  
6 [2] (2) of this section, and from and after July 1, 1974, no  
7 clinical laboratory shall be under the direction and personal  
8 supervision of any person who does not meet the requirements of  
9 clause [1] (1) of this section[: Provided, however, That this].  
10 This clause shall apply only to those laboratories for which an  
11 application for a permit is made on or after the dates herein  
12 specified[: And provided further, That this]. This provision  
13 shall apply only to those clinical laboratories required to have  
14 a permit pursuant to the provisions of this [act] chapter.

15 [5.] (5) The [foregoing] limitations in this section shall  
16 not apply to those persons operating a clinical laboratory prior  
17 to [the effective date of this act] January 1, 1952.

18 Section [3.1. Advisory Committee] 303. Advisory Committee  
19 on Clinical Laboratories.--An advisory committee shall be  
20 established for the purpose of advising the secretary in matters  
21 relating to administration of [the act] this chapter. There  
22 shall be seven members, each of whom is experienced in the  
23 clinical laboratory field. At least one member shall be  
24 qualified in the discipline of anatomic pathology and one in  
25 clinical pathology and licensed to practice medicine in [the]  
26 this Commonwealth or eligible for licensure, one shall be  
27 qualified in the field of clinical chemistry, and one shall be  
28 qualified in the field of clinical microbiology. Members of the  
29 committee shall be appointed by the secretary.

30 Section 8. Sections 4 and 5 of the act are reenacted,

1 renumbered and amended to read:

2 Section [4] 304. Application for Clinical Laboratory  
3 Permit.--All persons now operating or hereafter desiring to  
4 operate an analytical-biochemical-biological laboratory shall  
5 make written application to the department for a permit to  
6 operate, which application shall be accompanied by [a fee of  
7 twenty-five dollars (\$25)] an application fee, payable to the  
8 department, and shall be retained by the department.

9 Section [5] 305. Contents of Application for Clinical  
10 Laboratory Permit.--The application shall contain at least the  
11 following:

12 [(a)] (1) The name and address of the persons owning the  
13 place, establishment or institution in which the analytical-  
14 biochemical-biological laboratory is to be or is operated.

15 [(b)] (2) The name and address of the persons operating or  
16 to operate such laboratory.

17 [(c)] (3) The name and address of the qualified person under  
18 whose direct and personal supervision such laboratory is to be  
19 or is operated.

20 [(d)] (4) The kind and nature of the laboratory work to be  
21 or is being done.

22 [(e)] (5) The description of the building, its location,  
23 facilities, equipment, apparatus and appliances to be furnished  
24 or used in the operation of such laboratory.

25 [(f)] (6) Such additional information as the department may  
26 require by any rule or regulation.

27 The facts as set forth in the application shall be duly sworn to  
28 or affirmed by one of the owners of such laboratory.

29 Section 9. Sections 6 and 7 of the act are reenacted and  
30 renumbered to read:

1 Section [6] 306. Revocation of Permit.--(a) Permits shall  
2 become void upon change of director and also upon the removal of  
3 the laboratory to other quarters. A new permit may be issued  
4 without charge when the department has passed upon the  
5 qualifications of the new director or upon the adequacy of the  
6 new quarters and equipment.

7 (b) A permit may be revoked at any time for failure to  
8 maintain proper standards of accuracy, for unethical practice or  
9 for unethical advertising, or for any other cause deemed  
10 adequate by the department.

11 Section [7] 307. Investigation by Department.--Upon the  
12 filing of any application for a permit or for renewal, the  
13 department shall investigate the facts set forth in the  
14 application.

15 Section 10. Sections 8 and 9 of the act are reenacted,  
16 renumbered and amended to read:

17 Section [8] 308. Issuance of Permit.--If the department  
18 finds the statements contained in the application are true, the  
19 [said] department shall issue a permit.

20 Section [9] 309. Contents and Signing of Permit.--(a) The  
21 permits shall contain at least the following:

22 [(a)] (1) The name and address of the laboratory and of its  
23 owner.

24 [(b)] (2) The name and address of the person charged with  
25 the operation of the laboratory.

26 [(c)] (3) The name of the qualified person under whose  
27 supervision the laboratory is operated.

28 [(d)] (b) All permits shall be signed or counter-signed by  
29 the Secretary of Health.

30 Section 11. Section 10 of the act is reenacted and

1 renumbered to read:

2 Section [10] 310. Statement of Grounds for Denial of  
3 Permits.--If the department does not, within six months after  
4 the filing of the application, issue a permit, it shall state  
5 the grounds and reasons for its refusal, in writing, furnishing  
6 a copy to the applicant.

7 Section 12. Section 11 of the act, amended August 4, 1961  
8 (P.L.920, No.400), is reenacted and renumbered to read:

9 Section [11] 311. Inspection.--The department may at any  
10 time visit, enter, examine and inspect the premises occupied,  
11 maintained and conducted by any laboratory, and may examine all  
12 matters in relation thereto. Periodically the department shall  
13 verify the accuracy of the work of each laboratory using such  
14 means and standards as the department shall specify by rule or  
15 regulation.

16 Section 13. Section 11.1 of the act, added August 4, 1961  
17 (P.L.920, No.400), is repealed:

18 [Section 11.1. Rules and Regulations.--The Department of  
19 Health shall have the power, and its duty shall be, to adopt  
20 rules and regulations for the proper enforcement of this act  
21 with regard to the following:

22 (1) Contents of application;

23 (2) Adequacy of laboratory quarters and equipment;

24 (3) Means and standards of accuracy of laboratory  
25 procedures;

26 (4) Definition of unethical practice and unethical  
27 advertising;

28 (5) Any other matters it may deem advisable for the  
29 protection of the public and for carrying out the provisions and  
30 purposes of this act.]

1 Section 14. Section 12 of the act, repealed in part April  
2 28, 1978 (P.L.202, No. 53), is repealed:

3 [Section 12. Hearings and Appeals.--If an application for a  
4 permit is denied, as provided in section ten hereof, the  
5 applicant may request and be entitled to a hearing before the  
6 Secretary of Health, if such request was made within thirty days  
7 after the permit was denied. A permit issued under the  
8 provisions of this act may be revoked or suspended by the  
9 department for cause: Provided, That the permittee is permitted  
10 to be heard by the department, either personally, by counsel, or  
11 both: And provided further, That a written copy of the causes be  
12 furnished him, by registered mail, ten days in advance of the  
13 date set for hearing. Said notice shall fix the time and place  
14 for said hearing, which shall not be more than thirty days from  
15 the date of the mailing of said notice.

16 Any person who shall be aggrieved by any action of the  
17 department under this act or by any rule or regulation  
18 promulgated by the department shall have the right to file a  
19 complaint with the Secretary of Health and to have a hearing  
20 thereon before the Secretary of Health. Such hearing shall be  
21 conducted and the decision of the Secretary of Health on the  
22 issue involved shall be rendered in accordance with the  
23 provisions of the Administrative Agency Law and its amendments,  
24 approved June fourth, one thousand nine hundred forty-five  
25 (Pamphlet Laws 1388), relating to adjudication procedure.]

26 Section 15. Section 13 of the act is repealed:

27 [Section 13. Exemptions.--This act shall not include nor  
28 apply to any laboratory or laboratories maintained and operated  
29 by the Federal government; nor to any laboratory or laboratories  
30 maintained and operated purely for research or teaching

1 purposes.]

2 Section 16. Section 13.1 of the act, added December 6, 1972  
3 (P.L.1388, No.297), is reenacted and amended to read:

4 Section [13.1] 312. Unlawful Conduct.--It shall be unlawful  
5 for any person to solicit, receive, accept, deliver or transmit,  
6 by mail or otherwise, material originating from the human body  
7 on behalf of any person operating a clinical laboratory not in  
8 possession of a permit under this [act] chapter regardless of  
9 whether such laboratory is located in this Commonwealth. The  
10 provisions of this section shall not apply to transactions with  
11 any person operating a clinical laboratory located in another  
12 state, which laboratory has been issued a license or permit in  
13 conformity with the "Clinical Laboratories Improvement Act of  
14 1967," and related statutes. Neither shall this section apply to  
15 transactions with laboratories operated in this State which are  
16 exempt from the permit requirements of this [act.] chapter.

17 Section 17. Section 13.2 of the act, added November 9, 2006  
18 (P.L.1354, No.144), is reenacted and renumbered to read:

19 Section [13.2] 313. Glomerular Filtration Rate Testing.--The  
20 director of a clinical laboratory licensed in this Commonwealth  
21 shall provide that when the laboratory tests a specimen to  
22 determine the serum creatinine level for a patient age 18 or  
23 older, the laboratory shall also calculate the patient's  
24 estimated glomerular filtration rate at no additional charge.  
25 The laboratory shall include the patient's estimated glomerular  
26 filtration rate with its report to the health care professional.  
27 Clinical laboratories in health care facilities shall report the  
28 estimated glomerular filtration rate based on a protocol  
29 developed by the laboratory in consultation with either or both  
30 its medical staff or clinical departments. A laboratory shall

1 only be required to calculate and report a patient's estimated  
2 glomerular filtration rate if information necessary for the  
3 calculation to be considered medically appropriate and valid for  
4 the patient has been made available to the laboratory by the  
5 health care professional. This section shall not apply to  
6 clinical trials and research. Clinical laboratories that do not  
7 have information systems capable of providing estimated  
8 glomerular filtration rates on an automated basis shall have two  
9 years to comply with this section.

10 Section 18. The act is amended by adding a section to read:

11 Section 314. Rules and Regulations.--The department shall  
12 have the power, and its duty shall be, to adopt rules and  
13 regulations for the proper enforcement of this chapter with  
14 regard to the following:

15 (1) Contents of application;

16 (2) Adequacy of laboratory quarters and equipment;

17 (3) Means and standards of accuracy of laboratory  
18 procedures;

19 (4) Definition of unethical practice and unethical  
20 advertising;

21 (5) Any other matters it may deem advisable for the  
22 protection of the public and for carrying out the provisions and  
23 purposes of this chapter.

24 Section 19. The act is amended by adding chapters to read:

25 CHAPTER 5

26 FORENSIC DNA LABORATORIES

27 Section 501. Accreditation of Forensic DNA Laboratories.--  
28 The department shall accredit, regulate and oversee the  
29 operations of forensic DNA laboratories in this Commonwealth  
30 using the standards and system of accreditation established by

1 the board.

2 Section 502. Forensic DNA Accreditation Board.--(a) The  
3 forensic science DNA accreditation board is established in the  
4 department and shall consist of seven voting members and one ex-  
5 officio member as follows:

6 (1) The Secretary of Health or a designee of the secretary,  
7 who shall be chair of the board.

8 (2) The director of the Bureau of Laboratories or its  
9 successor, who shall serve as an ex-officio member of the board.

10 (3) The Commissioner of the Pennsylvania State Police or a  
11 designee.

12 (4) The Attorney General or a designee.

13 (5) One member to be appointed by the secretary for a term  
14 of six years who shall be a scientist having experience in the  
15 area of laboratory standards or quality assurance regulation and  
16 monitoring.

17 (6) Two members to be appointed by the Governor for terms of  
18 four years, one to be a prosecuting attorney, and one to be a  
19 public defender.

20 (7) One member to be appointed by the Chief Justice of the  
21 Supreme Court for a term of six years who shall be a judge or  
22 attorney with a background in biomedical ethics and privacy  
23 issues.

24 (b) The members of the Forensic DNA Accreditation Board  
25 appointed by the Governor, the Chief Justice of the Supreme  
26 Court and the secretary shall be confirmed by a majority vote of  
27 the Senate.

28 (c) Any vacancy created other than by expiration of a term  
29 shall be filled by the appointing authority for the unexpired  
30 term of the member. Any vacancy shall be filled in the same

1 manner as the original appointment. All members shall serve  
2 until successors are appointed.

3 (d) The accreditation board shall meet at least four times  
4 each year and may establish its own rules and procedures  
5 concerning the conduct of its meetings and other affairs not  
6 inconsistent with law.

7 (e) No member of the board shall be disqualified from  
8 holding any public office or employment, nor shall the member  
9 forfeit any such office or employment, by reason of appointment  
10 to the board. Members of the board shall not be required to take  
11 and file oaths of office before serving on the board.

12 (f) Members of the board shall receive no compensation for  
13 their services but shall be allowed their actual and necessary  
14 expenses incurred in the performance of their functions under  
15 this chapter.

16 Section 503. Powers and Duties of Board.--The board shall  
17 have the following powers and duties:

18 (1) To establish minimum standards for:

19 (i) Qualifications for forensic DNA laboratory directors and  
20 such other personnel as the board may determine to be necessary  
21 and appropriate.

22 (ii) The approval of forensic DNA laboratories for the  
23 performance of specific forensic methodologies.

24 (2) To adopt accreditation standards for forensic DNA  
25 laboratories which, at a minimum, include or require:

26 (i) Standards equivalent to or greater than standards  
27 promulgated by ASCLD-LAB.

28 (ii) Standards that require the applicant to comply with the  
29 standards issued by the FBI for forensic DNA laboratories.

30 (iii) Standards which meet the requirements of the

1 Pennsylvania State Police used for the State DNA Identification  
2 Record System.

3 (3) The adoption and implementation of internal and external  
4 proficiency testing programs, which may include a blind external  
5 proficiency testing program for forensic laboratories performing  
6 forensic DNA testing.

7 (4) The designation of one or more entities for the  
8 performance of proficiency tests required under this chapter.

9 (5) The qualifications for and employment of forensic DNA  
10 laboratory inspectors.

11 (6) To establish, appoint and set terms of members to as  
12 many advisory councils as it deems necessary to provide  
13 specialized expertise to the board with respect to new forensic  
14 DNA technologies including testing methodologies.

15 (7) To designate one or more approved methodologies for the  
16 performance of forensic DNA testing.

17 (8) To review and act upon applications by forensic DNA  
18 laboratories for approval to perform forensic DNA testing.

19 (9) To assess and evaluate all DNA methodologies proposed to  
20 be used for forensic analysis.

21 (10) To require a demonstration by an independent laboratory  
22 of any proposed forensic DNA testing methodology proposed to be  
23 used by a forensic laboratory.

24 (11) To develop an application for forensic DNA laboratory  
25 accreditation.

26 Section 504. Objectives of Standards and Accreditation.--The  
27 minimum standards and program of accreditation shall be designed  
28 to accomplish all of the following objectives:

29 (1) Set minimum requirements for the effectiveness,  
30 efficiency, reliability and accuracy of forensic DNA

1 laboratories.

2 (2) Recommend and assist the implementation of the highest  
3 performance of DNA standards.

4 (3) Promote increased cooperation and coordination among  
5 forensic DNA laboratories and other agencies in the criminal  
6 justice system.

7 (4) Ensure compatibility, to the extent consistent with the  
8 provisions of this chapter and any other applicable provision of  
9 law pertaining to privacy or restricting disclosure or  
10 redisclosure of information, with Federal and other state  
11 forensic DNA laboratories to the extent necessary to share and  
12 exchange information, data and results of forensic DNA analysis  
13 and tests.

14 (5) Set forth minimum requirements for the quality and  
15 maintenance of equipment.

16 Section 505. Requirements for Obtaining Accreditation.--The  
17 program of forensic DNA laboratory accreditation shall include,  
18 at a minimum, all of the following requirements:

19 (1) An initial laboratory inspection, and routine  
20 inspections, as necessary, to ensure compliance with  
21 accreditation requirements.

22 (2) Routine internal and external proficiency testing of all  
23 laboratory personnel involved in forensic DNA analysis,  
24 including blind external proficiency testing if the board  
25 determines such a blind proficiency testing program is  
26 practicable and appropriate, the board shall consider such  
27 factors as accuracy and reliability of laboratory results, cost-  
28 effectiveness, time, allocation of resources and availability.

29 (3) Quality control and quality assurance protocols, a  
30 method validation procedure and a corrective action and remedial

1 program.

2 (4) Annual certification to the department by the forensic  
3 DNA laboratories of their continued compliance with the  
4 requirements of the accreditation program.

5 Section 506. Revocation and Suspension of Accreditation.--  
6 The accreditation of a forensic DNA laboratory may be revoked,  
7 suspended or otherwise limited, upon a determination by the  
8 department that the laboratory or one or more persons in its  
9 employ:

10 (1) Is guilty of misrepresentation in obtaining a forensic  
11 DNA laboratory accreditation.

12 (2) Rendered a report on laboratory work actually performed  
13 in another forensic DNA laboratory without disclosing the fact  
14 that the examination or procedure was performed by such other  
15 forensic DNA laboratory.

16 (3) Showed a pattern of excessive errors in the performance  
17 of forensic DNA laboratory examination procedures.

18 (4) Failed to file any report required to be submitted  
19 pursuant to this act or the rules and regulations promulgated  
20 pursuant thereto.

21 (5) Violated in a material respect any provision of this  
22 chapter or the promulgated rules and regulations.

23 Section 507. Cooperation with Department.--The department  
24 may require and receive from any agency of the Commonwealth or  
25 any political subdivision such assistance and data as may be  
26 necessary to enable the department to administer the provisions  
27 of this chapter. The department may enter into such cooperative  
28 arrangements with the State Crime Laboratory, and any other  
29 Commonwealth agency, each of which is authorized to enter into  
30 such cooperative arrangements as shall be necessary or

1 appropriate. Upon request of the department any Commonwealth  
2 agency may transfer to the department such officers and employes  
3 as the department may deem necessary from time to time to assist  
4 the department in carrying out its functions and duties.  
5 Officers and employes so transferred shall not lose their civil  
6 service status or rights, and shall remain in the negotiating  
7 unit, if any, established prior to such transfer.

8 Section 508. Subcontracting of DNA Testing.--Any  
9 Commonwealth accredited forensic DNA laboratory must require  
10 certification of compliance with the standards issued by the  
11 board when an out-of-state subcontractor performs forensic DNA  
12 analysis for the laboratory. The forensic DNA laboratory will  
13 establish and use appropriate review procedures to verify the  
14 integrity of the data received from the subcontractor.

15 Section 509. Confidentiality.--All records, findings,  
16 reports and results shall not be released to insurance  
17 companies, employers or potential employers, health providers,  
18 employment screening or personnel companies, agencies, or  
19 services, or private investigation services, and may not be  
20 disclosed upon request or order of any agency, authority,  
21 division, office, corporation, partnership or any other private  
22 or public entity or person. Nothing contained in this chapter  
23 shall prohibit disclosure in response to a subpoena.

24 Section 510. Unlawful Conduct.--It shall be unlawful for any  
25 person to intentionally disclose a DNA record, or the results of  
26 a forensic DNA test or analysis, to an individual or agency  
27 other than one authorized to have access to such records  
28 pursuant to this chapter or to intentionally use or receive DNA  
29 records, or the results of a forensic DNA test or analysis, for  
30 purposes other than those authorized pursuant to this chapter.

1 Section 511. Compliance Schedule.--Upon enactment of this  
2 chapter, the board shall have one year to establish and  
3 promulgate minimum standards and a program of accreditation for  
4 all forensic DNA laboratories in this Commonwealth. All DNA  
5 laboratories shall apply for accreditation within six months of  
6 the promulgation of the standards. Four years after the  
7 effective date of this chapter, all forensic DNA labs in this  
8 Commonwealth shall be in full compliance with this chapter. Any  
9 forensic DNA laboratory not in full compliance after this time  
10 shall be subject to penalties adopted by the department.

11 Section 512. Additional Research.--(a) Nothing in this  
12 chapter shall be deemed to preclude forensic DNA laboratories  
13 from performing research and validation studies on new  
14 methodologies and technologies which may not yet be approved by  
15 the board at that time.

16 (b) Regulation pursuant to this chapter shall not include  
17 DNA testing on materials derived from the human body for the  
18 purpose of determining a person's genetic disease or medical  
19 condition.

## 20 CHAPTER 7

### 21 PROVISIONS OF GENERAL APPLICABILITY

22 Section 701. Exemptions.--This act shall not include nor  
23 apply to any clinical or forensic DNA laboratory or laboratories  
24 maintained and operated by the Federal government; nor to any  
25 clinical or forensic DNA laboratory or laboratories maintained  
26 and operated purely for research or teaching purposes.

27 Section 702. Hearings and Appeals.--(a) All adjudications  
28 and final actions of the department under this act or the rules  
29 and regulations promulgated under this act shall be subject to  
30 appeal.

1     (b) All hearings on appeals and all procedures relating to  
2 those hearing shall be conducted under the provisions of 2  
3 Pa.C.S. Chs. 5 Subch. A (relating to practice and procedure of  
4 Commonwealth agencies) and 7 Subch. A (relating to judicial  
5 review of Commonwealth agency action).

6     Section 20. Section 14 of the act, amended December 6, 1972  
7 (P.L.1388, No.297), is reenacted, renumbered and amended to  
8 read:

9     Section [14. Penalty.--] 703. Penalties.--(a) Any person  
10 operating a clinical laboratory without first having obtained a  
11 permit from the [Department of Health] department or violating  
12 the provisions of section [13.1 of the act] 312 shall, upon  
13 conviction thereof, be sentenced to pay a fine not exceeding  
14 [five hundred dollars (\$500)] \$500 or to imprisonment not  
15 exceeding one [(1)] year, or both.

16     (b) (1) Any person operating a forensic DNA laboratory  
17 without obtaining the accreditation required by this act, or  
18 who, with the intent to mislead or deceive, misrepresents a  
19 material fact to the department shall be subject to a civil  
20 penalty not to exceed \$7,500 and such other penalties as are  
21 prescribed by the law.

22     (2) Any person who:

23     (i) intentionally discloses a DNA record, or the results of  
24 a forensic DNA test or analysis, to an individual or agency  
25 other than one authorized to have access to such records  
26 pursuant to this act; or

27     (ii) intentionally uses or receives DNA records, or the  
28 results of a forensic DNA test or analysis, for purposes other  
29 than those authorized pursuant to this act shall be guilty of a  
30 felony, and upon conviction thereof, shall be subject to a fine

1 of not more than \$10,000 and such other penalties as are  
2 prescribed by the law.

3 Section 21. The act is amended by adding a chapter heading  
4 to read:

5 CHAPTER 9

6 MISCELLANEOUS PROVISIONS

7 Section 22. Sections 15 and 16 of the act are reenacted and  
8 renumbered to read:

9 Section [15] 901. Interpretation of Act.--The provisions of  
10 this act are severable and if any of its provisions shall be  
11 held unconstitutional, the decision of the court shall not  
12 affect or impair any of the remaining provisions of this act. It  
13 is hereby declared to be the legislative intent that this act  
14 would have been adopted had such unconstitutional provisions not  
15 been included herein.

16 Section [16] 2102. Effective Date.--This act shall become  
17 effective on the first day of January, one thousand nine hundred  
18 fifty-two.

19 Section 23. This act shall take effect in 120 days.