PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

PART 205
CLINICAL AND OTHER LABORATORIES

333.20501 "Laboratory" defined; principles of construction.

Sec. 20501. (1) As used in this part, "laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2015, Act 104, Eff. Oct. 1, 2015.

Compiler's note: For transfer of powers and duties of the division of health facility licensing and certification in the bureau of health systems, division of federal support services, and the division of emergency medical services, with the exception of the division of managed care and division of health facility development, from the department of public health to the director of the department of commerce, see E.R.O. No. 1996-1, compiled at MCL 330.3101 of the Michigan Compiled Laws.

For transfer of powers and duties of the bureau of health services from the department of consumer and industry services to the director of the department of community health by Type II transfer, see E.R.O. No. 2003-1, compiled at MCL 445.2011.

Popular name: Act 368

333.20507 Laboratories to which MCL 333.20501 to 333.20525 inapplicable.

Sec. 20507. Sections 20501 to 20525 do not apply to any of the following:

(a) A laboratory where examinations are always performed personally by the individual desiring the information.

(b) A laboratory operated by an individual licensed to practice medicine, osteopathic medicine and surgery, dentistry, or podiatry who performs clinical laboratory tests or procedures personally or through his or her employees only as an adjunct to the treatment of the licensee's patients.

(c) A laboratory operated in the manner described in subdivision (b) by a group of not more than 5 individuals licensed to practice medicine, osteopathic medicine and surgery, dentistry, or podiatry.

(d) A laboratory operated by a college, university, or school approved by the department of education that is conducted for the training of its students, if the result of an examination performed in the clinical laboratory is not used in the diagnosis and treatment of disease.

(e) A laboratory operated by the federal government.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20511 Repealed. 2015, Act 104, Eff. Oct. 1, 2015.

Compiler's note: The repealed section pertained to contents, display, and validity of license for clinical laboratory.

333.20515 Repealed. 2015, Act 104, Eff. Oct. 1, 2015.

Compiler's note: The repealed section pertained to staffing and operation of clinical laboratory.

333.20521 Authorization to order laboratory test classified by Food and Drug Administration.

Sec. 20521. Only a physician, dentist, or other person authorized by law can order a laboratory test that has been classified by the Food and Drug Administration as moderate or high complexity. A laboratory test that is classified by the Food and Drug Administration as waived does not require an order.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2015, Act 104, Eff. Oct. 1, 2015.

Popular name: Act 368

333.20525 Repealed. 2015, Act 104, Eff. Oct. 1, 2015.

Compiler's note: The repealed section pertained to denial, limitation, suspension, or revocation of license.

333.20531 Lead analysis; clinical laboratory reporting requirements.

Sec. 20531. Not later than 90 days after the effective date of this section, the department shall mail a notice to each clinical laboratory doing business in this state explaining the reporting requirements of this section. Beginning October 1, 2005, a clinical laboratory that analyzes a blood sample for lead shall report the results of the blood lead analysis to the department electronically in a format as prescribed by the department. The

clinical laboratory shall submit the report to the department as required under this section within 5 days after the analysis is completed.

History: Add. 2004, Act 54, Imd. Eff. Apr. 12, 2004.

Popular name: Act 368

333.20551 Registration of laboratory or other place handling, cultivating, selling, giving away, or shipping pathogenic microorganisms, or doing recombinant deoxyribonucleic acid research; application for and duration of registration number; "handled", "cultivated", and "shipped" defined.

Sec. 20551. (1) A laboratory or other place where live bacteria, fungi, mycoplasma, parasites, viruses, or other microorganisms of a pathogenic nature are handled, cultivated, sold, given away, or shipped from or to or where recombinant deoxyribonucleic acid research is done shall be registered with the department, and a registration number shall be issued to each place registered. An application for a registration number shall be made by the person in charge of the laboratory or other place where the pathogens are handled or where recombinant deoxyribonucleic acid research is done. The registration number is valid for 1 year and may be renewed upon application to the department.

(2) As used in this section and section 20552, "handled", "cultivated", or "shipped" does not include the collection of specimens, the initial inoculation of specimens into transport media or culture media, or the shipment to registered laboratories, but does include any additional work performed on cultivated pathogenic microorganisms or any recombinant deoxyribonucleic acid research is done.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2015, Act 104, Eff. Oct. 1, 2015.

Popular name: Act 368

333.20552 Registration of laboratory, department, or school handling pathogens or doing recombinant deoxyribonucleic acid research; application for and duration of registration number.

Sec. 20552. The department shall register a laboratory or a department of a college, university, or school which is responsible for the handling, cultivating, selling, giving away, or shipping of the microorganisms described in section 20551(1) or is engaged in recombinant deoxyribonucleic acid research. The person in charge of the laboratory or department where the pathogens are handled or where recombinant deoxyribonucleic acid research is done shall apply for a registration number. The registration is valid for 1 year and may be renewed upon application.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.20554 Sale, gift, or other distribution of live pathogenic microorganisms and cultures or recombinant deoxyribonucleic acid materials; contents of label on container; record.

Sec. 20554. Live pathogenic bacteria, fungi, mycoplasma, parasites, viruses, or other microorganisms or cultures of the microorganisms when sold, given away, or shipped by a laboratory or other person, shall bear a label on the container showing the registration number of the laboratory or other person sending the specimens and the name and address of the person to whom sent. A laboratory or person shall not sell or convey a live pathogenic microorganism or recombinant deoxyribonucleic acid materials to any other laboratory or person in this state without permission of the department unless each is registered under section 20551 or 20552. The laboratory or person shall keep a record of each sale, gift, or other distribution of live pathogenic microorganisms and cultures or recombinant deoxyribonucleic acid materials containing the name and laboratory address of the recipient or purchaser. The record shall be at all times open to examination and copying by a representative of the department.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368