(b) Laboratory supervisors shall report to the State Department of Health and Senior Services, within 48 hours of the completion of the analysis, the results of laboratory examinations for hazardous substances in blood and urine, as follows:

1. Lead:

i. All blood lead test results;

ii. Urine lead levels equal to or greater than 80 μg/dL in individuals greater than 16 years of age.

2. Mercury:

i. Blood mercury levels equal to or greater than 2.8 μg/dL;

ii. Urine mercury levels equal to or greater than 20 μg/L.

3. Arsenic:

i. Blood arsenic levels equal to or greater than .07 μg/ml;

ii. Urine arsenic levels equal to or greater than 100 μg/L.

4. Cadmium:

i. Blood cadmium levels equal to or greater than five μg/L of whole blood;

ii. Urine cadmium levels equal to or greater than three μg/gram creatinine.

(c) The reports required by (b) above shall contain the result of the laboratory examination, including units; the type of specimen tested; the sample number and date the sample was collected and analyzed; the name, address, telephone number, sex, and date of birth or age of the patient; if the patient is over 16 years old, the name, address, and telephone number of the employer; the patient's occupation; the name, address, telephone number, and name of the medical facility of the requesting physician; and the name, address, telephone number of testing laboratory.

Amended by R.1985 d.518, effective October 21, 1985.
See: 17 N.J.R. 1831(a), 17 N.J.R. 2554(b).
(d) added.
Amended by R.1994 d.36, effective January 18, 1994.
See: 25 N.J.R. 3751(a), 26 N.J.R. 362(a).
Amended by R.1994 d.275, effective June 6, 1994.
See: 26 N.J.R. 294(b), 26 N.J.R. 1190(a), 26 N.J.R. 2270(a).
Amended by R.1998 d.175, effective April 6, 1998.
See: 29 N.J.R. 4227(a), 30 N.J.R. 1310(c).
In (b), rewrote the introductory paragraph and 1.

8:44–2.12 Inspection and registration concerning handling of live microorganisms or viruses pathogenic for humans, or birds

(a) Laboratories or other places where live microorganisms or viruses pathogenic for humans, animals, or birds are handled, cultivated or kept shall be subject to inspection and reinspection at any time by authorized representatives of the Department of Health.

(b) The director of a laboratory or person in charge of any other place where live microorganisms or viruses pathogenic for humans, animals, or birds are handled, cultivated or kept shall, on forms provided by the Department of Health, register such laboratory or place with the Department between the dates of March 1, 1954 and April 1, 1954. Such laboratories or other places established on or after April 1, 1954 shall register with the Department prior to handling, cultivating, keeping, selling, transporting or otherwise disposing of live microorganisms or viruses covered by this Section.

1. Laboratories or other places required to be registered under the provisions of this Chapter shall promptly forward all information requested by the Department.

(c) Registration requirements do not apply to laboratories maintained by official governmental agencies, voluntary general hospitals, those physicians licensed to practice medicine and surgery in this State, those veterinarians licensed to practice veterinary medicine in this State, manufacturers of biologics licensed by the United States government.

8:44–2.13 Sale, transportation or other disposal of live microorganisms or viruses pathogenic for humans, animals, or birds

Live microorganisms or viruses pathogenic for humans or birds shall not be sold, knowingly transported or otherwise disposed of in viable form without written permission of the Department of Health, excepting:

(a) Such products manufactured and clearly identified, as required by law, by manufacturers of biologics licensed by the United States government and in compliance with Federal postal and other regulations; or

(b) Diseased tissue, exudate, or other specimens which are enroute to laboratories for the sole purpose of laboratory examination as an aid in diagnosis or control of disease and which are transported in compliance with Federal postal regulations or under conditions as may be prescribed by the Department and sent by physicians licensed to practice medicine and surgery in this State, by veterinarians licensed to practice veterinary medicine in this State or by licensed health officers of this State in the performance of their official duties.

SUBCHAPTER 3. LIMITED PURPOSE LABORATORY

Authority

N.J.S.A. 26:1A–7 and 45:9–42.34.

Source and Effective Date

R.2004 d.219, effective May 19, 2004 (to expire July 18, 2004).
See: 36 N.J.R. 2926(a).

Subchapter Historical Note

Subchapter 3, Limited Purpose Laboratory, was adopted as Emergency New Rules by R.2004 d.219, effective May 19, 2004 (to expire July 18, 2004). See: Source and Effective Date.

8:44–3.1 Limited purpose laboratory; definition and minimum protocols

(a) "Limited purpose laboratory" means a facility operated by a not-for-profit organization receiving grant funds from the Department of Health and Senior Services, hereinafter known as the Department, to operate a counseling and testing site to conduct rapid FDA licensed point-of-care tests for Human Immunodeficiency Virus (HIV).

(b) A limited purpose laboratory shall establish the following protocols at a minimum:

1. Follow-up protocols to ensure that Food and Drug Administration (FDA) approved confirmatory testing is performed;

2. A protocol for the review of test results by the laboratory director and general supervisor;

3. Protocols to ensure that individuals with abnormal results are referred to an appropriate source of medical care and prevention services; and

4. Personnel policies, practices and procedures that adequately support sound rapid FDA licensed point-of-care testing practices.

8:44–3.2 Applicability of subchapter

(a) The subchapter applies to limited purpose laboratories as defined in N.J.A.C. 8:44–3.1(a).

(b) If a limited purpose laboratory is operated at more than one site, each site shall require a separate license.

8:44–3.3 Director

(a) A limited purpose laboratory shall be under the direction of a laboratory director as specified in N.J.A.C. 8:44–2.3(b)2, 3, 4, and 5, and 2.3(c).

(b) The laboratory director can direct multiple limited purpose laboratories which share a quality assurance program and laboratory policies and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44–2.3(b)1. The laboratory director can direct no more than five limited purpose laboratories whose quality assurance program and laboratory policies are not identical and these shall count as one clinical laboratory for the purpose of N.J.A.C. 8:44–2.3(b)1.

(c) The laboratory director shall, at a minimum, serve the limited purpose laboratory on a regular part-time basis to ensure that the provisions of this subchapter are met.

(d) The laboratory director shall be readily available for personal or telephone consultation with staff.

(e) The laboratory director shall be responsible for the proper performance of all testing procedures and for ensuring the competency of all persons performing point of care testing.

(f) The laboratory director shall arrange for a qualified substitute director, prior to the director's absence.

8:44–3.4 Supervision

(a) A limited purpose laboratory shall be supervised by a person, designated as the general supervisor, who can be, but is not limited to being, a physician, professional registered nurse, counseling and testing site coordinator, or health educator, approved by the laboratory director, who, under the general direction of the laboratory director, supervises testing personnel and the report of findings, and in the absence of the laboratory director, is responsible for the proper performance of all laboratory procedures.

1. Limited purpose laboratory records including, but not limited to, patient accession, testing, test results, quality control and temperature monitoring, shall be reviewed at least monthly by the laboratory director, general supervisor, or qualified designee of the laboratory director.

(b) The rapid FDA licensed point-of-care test for Human Immunodeficiency Virus (HIV) shall be performed by personnel, such as professional registered nurses, technicians or non-professionals, who have been trained in accordance with the provisions of the Centers for Disease Control and Prevention (CDC) Quality Assurance Guidelines for Testing using the OraQuick Rapid HIV–1 Antibody Test, hereinafter known as the CDC Quality Assurance Guidelines, which are incorporated herein by reference, as amended and supplemented, and available at http://www.cdc.gov/hiv/rapidtesting/materials/QA–Guide.htm. The laboratory director shall develop testing and operational protocols, which meet or exceed those issued by the CDC.

(c) The laboratory director shall revise quality assurance, testing, and operational protocols and provide training of testing personnel and supervisors, for any new additional point of care rapid HIV test authorized by the Department for use in limited purpose laboratories subsequent to the adoption of these regulations.

8:44–3.5 Screening tests performed

(a) A limited purpose laboratory shall perform only those tests and procedures that are expressly approved by the Department pursuant to N.J.A.C. 8:44–3.1(a).