

“Specimen collection form” means the current specimen collection form as provided by the Department of Health and Senior Services.

“Testing laboratory” means the Inborn Errors of Metabolism Laboratory, Division of Public Health and Environmental Laboratories, New Jersey Department of Health and Senior Services, PO Box 371, Trenton, NJ 08625-0371.

“Unsatisfactory specimen” means a specimen which is received by the testing laboratory in a condition unacceptable for testing.

Amended by R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Rewrote “Follow-up Program” and “Responsible physician”; inserted “Home health agency”; and in “Serum specimen”, added “; serum specimens are sent to the Department testing laboratory” at the end.

8:19-2.3 Diseases and conditions tested

(a) The testing required by N.J.S.A. 26:2-111 and this subchapter shall be done by the testing laboratory according to recognized clinical laboratory procedures.

(b) Diseases and conditions to be tested shall include, but not be limited to:

1. Phenylketonuria;
2. Galactosemia;
3. Hypothyroidism;
4. Sickle cell anemia; and
5. Other hemoglobinopathies; as designated by the Commissioner.

8:19-2.4 Responsibilities of the chief executive officer

(a) The chief executive officer shall:

1. Cause the development and implementation of written policies and procedures, to be reviewed by the Department and revised as required, for the early detection and treatment of biochemical disorders, pursuant to N.J.S.A. 26:2-110 and 111;
2. Designate a staff person to coordinate hospital or agency screening practice and function as a contact person with the Follow-up Program;
3. Assure that a satisfactory specimen is submitted to the testing laboratory for each infant born in the hospital, or admitted to the hospital within the first 28 days of life with no satisfactory specimen having been previously collected.
4. Assure that the infant’s parent is informed of the purpose and need for newborn screening and given newborn screening educational materials provided by the Follow-up Program;
5. Assure that specimen collection forms are properly stored upright in a cool and dry environment prior to use;

6. Assure that specimens are taken utilizing correct specimen collection techniques as described on the back of the specimen collection form;

7. Assure that specimens conform to the following criteria for satisfactory specimens:

- i. The specimen collection forms shall be filled in completely, accurately and legibly;
- ii. The sample shall be collected on S & S 903 blotter paper (located on the right side of the collection form);
- iii. The blotter paper shall be attached to the forms; and
- iv. The specimen quantity shall be sufficient to run all assays;

8. Assure that satisfactory specimens are collected according to the following criteria:

- i. The circles on the blotting paper shall be completely and evenly saturated;
- ii. The specimen shall not be contaminated or diluted;
- iii. The blood shall not be clotted or caked; and
- iv. The blotting paper shall not be torn, scratched, or distorted because of faulty or improper collection techniques;

9. Assure that specimens are taken before the infant is 48 hours old. If an infant is transferred or discharged from a facility prior to 48 hours of life, a specimen shall be collected prior to discharge unless there are medical reasons to prevent specimen collection;

10. Assure that the parent shall be instructed directly and in writing of the need to collect a repeat specimen between the third and seventh day of life if the infant has been fed protein for fewer than 24 hours at the time of discharge or is less than 24 hours of age;

11. Assure that every effort is made to obtain a specimen prior to any anticipated blood transfusion;

12. Assure that, in the event of prolonged hospitalization for specialized medical care, a specimen is taken when the infant is 48 hours old. If an infant is on prolonged hyperalimentation and is receiving greater than 2.5 grams of protein/kilogram, a repeat specimen shall be taken. The greater than 24 hours box on the specimen collection form shall be checked and hyperalimentation noted on the form. For those infants not on hyperalimentation, a repeat specimen shall be taken weekly until there have been 24 hours of normal oral feeding on full strength formula;

13. Assure that in the case of inter-hospital transfer of the infant, the transferring hospital shall provide written notification to the receiving hospital indicating whether or

not a specimen has been taken prior to transfer. Following transfer, the chief executive officer of the receiving hospital shall assume responsibility for collection of the specimen in accordance with these regulations;

14. Assure that the date and time of specimen collection are recorded on the infant's permanent health record;

15. Assure that biohazardous specimens are thoroughly dried and then placed in a paper envelope provided by the testing laboratory;

16. Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection by first class mail or its equivalent;

17. Assure that all test results forwarded to the chief executive officer or his designee by the testing laboratory are included in the infant's permanent health record;

18. Transmit or cause to be transmitted a copy of test results to the physician of record;

19. Assure that repeat specimens are collected when requested by the testing laboratory for specimens not satisfactory for testing according to criteria in (a)7 and 8 above, or specimens for which assay results cannot be interpreted because of any of the following conditions:

- i. Transfusion(s) given before specimen collection;
- ii. Antibiotics given before specimen collection (if effects cannot be removed);
- iii. Specimen collected before the infant has received protein feeding for 24 hours;
- iv. Incomplete elution from blotter during assay;
- v. Specimen received 14 days or more after collection date; and
- vi. Specimen collected before infant is 24 hours of age;

20. Assure that written documentation is recorded in the infant's permanent medical record of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report when an initial specimen is not satisfactory for testing and a repeat specimen is not obtained; and

21. Assure that infants weighing 1,500 grams or less have repeat screening specimens taken at seven days, 14 days, 42 days of age or at discharge, whichever comes first.

Amended by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Rewrote (a).

8:19-2.5 Responsibilities of the birth attendant

(a) The birth attendant shall:

1. Submit or cause to be submitted to the testing laboratory an initial blood specimen taken before the infant is 48 hours old from all infants born outside of, and not admitted to, a hospital;

2. Follow the specimen collection and submission procedures specified in N.J.A.C. 8:19-2.4;

3. Collect or cause to be collected a repeat specimen when requested by the testing laboratory, and shall submit or cause such repeat specimen to be submitted to the testing laboratory within 24 hours of collection; and

4. If a repeat specimen is not obtained, place on the infant's medical record written documentation of efforts made to secure or cause to be secured a repeat specimen within 14 days of receipt of the laboratory report.

Amended by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

In (a), changed N.J.A.C. reference in 2, and substituted "place on the infant's medical record" for "submit to the testing laboratory" following "obtained,".

8:19-2.6 Responsibilities of the responsible physician

(a) The responsible physician shall:

1. Interpret all test results;

2. Comply with the specimen collection and submission procedures specified in N.J.A.C. 8:19-2.4;

3. Promptly collect or cause to be collected repeat specimens requested by the testing laboratory and submit the specimens to the testing laboratory;

4. Promptly collect or cause to be collected repeat specimens as recommended by the testing laboratory in the case of abnormal test results;

5. If a repeat specimen is not obtained within the time frame recommended on the test report, assure that written documentation is recorded in the infant's medical record of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report;

6. Include in the infant's health record the test results received from the chief executive officer or from the testing laboratory;

7. In the case of confirmed abnormal test results, arrange for diagnostic evaluation;

8. Provide case information, specimens, hard copy of test results, and other information requested by the Follow-up Program; and

9. Remain responsible for the follow-up until the responsibility is actively accepted by another physician.

Amended by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Rewrote (a).

8:19-2.7 Responsibilities of the home health agency

(a) The home health agency shall:

1. Follow the specimen collection procedures specified in N.J.A.C. 8:19-2.4(a)5 through 8 and 16;
2. Provide notification to the hospital or birth attendant that the specimen has been collected; and
3. Assure that written documentation is recorded in the infant's permanent medical record of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report when an initial specimen is not satisfactory for testing and a repeat specimen is not obtained.

New Rule, R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Former N.J.A.C. 8:19-2.7, Responsibilities of the public health officer, recodified to N.J.A.C. 8:19-2.8.

8:19-2.8 Responsibilities of the public health officer

(a) The public health officer shall:

1. Provide assistance to the Follow-up Program, when requested, in locating families of infants;
2. Collect or cause a repeat specimen to be collected when notified of the need for a repeat specimen by the Follow-up Program. The specimen shall be submitted within 24 hours of collection;
3. Submit written documentation, within 14 days of receipt of the laboratory report to the infant's permanent medical record of efforts made to secure or cause to be secured such repeat specimen if a repeat specimen is not obtained within the time frame recommended by the Follow-up Program; and
4. Provide notification to the hospital or birth attendant that the specimen has been collected.

Recodified from N.J.A.C. 8:19-2.7 and amended by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

In (a), rewrote 3 and added 4. Former N.J.A.C. 8:19-2.8, Responsibilities of the testing laboratory, recodified to N.J.A.C. 8:19-2.9.

8:19-2.9 Responsibilities of the testing laboratory

(a) The testing laboratory shall:

1. Determine if a specimen is satisfactory, according to the criteria listed in N.J.A.C. 8:19-2.4(a) 7, 8, and 19;
2. Request a repeat specimen from the submitter for unsatisfactory specimens;
3. Test satisfactory specimens for disease and conditions, according to recognized clinical laboratory procedures;
4. Issue reports of not clinically significant results to the chief executive officer or to the responsible physician, that is, the submitter of the specimen; and

5. Issue reports of abnormal results to the submitter of the specimen and to the responsible physician.

Recodified from N.J.A.C. 8:19-2.8 by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Former N.J.A.C. 8:19-2.9, Responsibilities of the Follow-up Program, recodified to N.J.A.C. 8:19-2.10.

8:19-2.10 Responsibilities of the Follow-up Program

(a) The Follow-up Program shall:

1. Make every reasonable effort to follow abnormal test results to case disposition as specified in the Follow-up Program Procedures Manual;
2. Assist families of children with abnormal test results to access health care as necessary;
3. Identify and maintain contact with medical consultants (neurologists, endocrinologists, geneticists, hematologists) for each disease tested;
4. Identify treatment resources to families and assure that they are receiving care;
5. Provide educational support for activities carried out under this rule; and
6. In conjunction with the testing laboratory:
 - i. Monitor compliance with this subchapter;
 - ii. Identify problems in compliance and assist in their remediation; and
 - iii. Prepare and distribute an annual report, to include outcome data, descriptive statistics, program evaluation and recommendations.

Recodified from N.J.A.C. 8:19-2.9 by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Former N.J.A.C. 8:19-2.10, Exemption from testing, recodified to N.J.A.C. 8:19-2.12.

8:19-2.11 Responsibility of the Department

The Commissioner shall determine an adequate laboratory fee and appropriate funding for testing, follow-up and treatment services which will enable the Department to carry out the responsibilities pursuant to P.L. 1988, c.24, § 3 (N.J.S.A. 26:2-111). The fee is specified under N.J.A.C. 8:45-2.1.

New Rule, R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

8:19-2.12 Exemption from testing

(a) This subchapter shall not apply in the case of any infant or child whose parent or guardian objects to the testing on the grounds that testing would conflict with his or her religious tenets or practices.

(b) In case of refusal to test pursuant to (a) above, the chief executive officer or responsible physician or birth attendant or home health agency shall assure that documentation of refusal to test becomes part of the infant's permanent medical record.

(c) The chief executive officer or responsible physician or birth attendant or home health agency shall assure that a copy of documentation of refusal to test is forwarded to the testing laboratory.

Recodified from N.J.A.C. 8:19-2.10 and amended by R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

In (b) and (c), inserted references to home health agencies.

8:19-2.13 Confidentiality of reports

The reports made pursuant to this subchapter are to be used only by the Department of Health and Senior Services and other agencies that may be designated by the Commissioner and shall not otherwise be divulged or made public so as to disclose the identity of any person. Such reports shall not be included under materials available to public inspection pursuant to P.L. 1963, c.73 (N.J.S.A. 47:1A-1 et seq.).

New Rule, R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).