Ohio Administrative Code

Rule 3701-55-07 Required further screening or diagnostic testing if specimen abnormal.

Effective: July 1, 2023

This rule prescribes the procedures that apply if,upon screening of a specimen, the bureau of public health laboratory determinesthat the result indicates potential risk for one or more of the screeneddisorders.

(A) The director will communicate the results to the following person, as applicable:

(1) If a child was born in a hospital or freestanding birthing center, the director will communicate the results to the child's attending physician, child's primary medical provider, pediatrician, certified nurse midwife, certified nurse practitioner or clinical nurse specialist. If the director is unable to contact the attending physician, child's primary medical provider, pediatrician, certified nurse midwife, certified nurse practitioner or clinical nurse specialist, the director will communicate the results to the newborn screening coordinator at the facility where the child was born.

(2) If the child was not born in a hospital or freestanding birthing center, the director will communicate the results to the person designated in paragraph (A)(2) or (A)(3) of rule 3701-55-05 of the Administrative Code, as applicable.

(B) The person notified of the results by the director under paragraph (A) of this rule will communicate the results to the child's parent, legal guardian, or legal custodian and will obtain and submit a repeat blood specimen for screening or diagnostic testing in accordance with the following procedures:

(1) When the result indicates potential risk for a disorder listed in paragraph (A) of rule 3701-55-02 of the Administrative Code, a screening or diagnostic test will be obtained in accordance with paragraph (B)(3) of this rule as soon as possible, but no later than ten days after notification by the director.

(2) When the results are abnormal for a hemoglobin disease or hemoglobin trait, a diagnostic test

will be obtained in accordance with paragraph (B)(3) of this rule before the child reaches two months of age.

(3) Diagnostic specimens obtained under paragraphs (B)(1) and (B)(2) of this rule will be submitted for testing to a laboratory certified under the current version Clinical Laboratory Improvement Act, 42 USC 263a, that reports results with normal pediatric reference ranges. That laboratory will promptly transmit the results of the diagnostic test to the person who submitted the specimen.

(C) If after ten business days, the person responsible for obtaining and submitting the repeat specimen and/or diagnostic tests under paragraph (B) of this rule is unable to obtain a specimen from a newborn child with an initial screen result of a potential risk despite making a reasonable effort, he or she will notify the health commissioner of the health district in which the mother, legal guardian, or legal custodian resides.

The health commissioner will make a reasonable effort to locate the child and cause a repeat specimen and/or diagnostic tests to be obtained. If the health commissioner is not able to locate that child within thirty days, he or she may close the file.

(D) The health commissioner will submit a report to the director, upon case closure, listing the names and other identifiers of newborns the health commissioner was unable to locate.