

**PENNSYLVANIA DEPARTMENT OF HEALTH  
DIVISION OF NEWBORN SCREENING AND GENETICS  
NEWBORN SCREENING AND FOLLOW-UP PROGRAM**

**Initial and Referral Follow-Up Process for the Additional Conditions Listed in the  
Newborn Child Testing Act (ACT 36) Excluding Cystic Fibrosis**

Requirements for the Hard Copy Report of Results

For all abnormal results laboratories will fax a copy of the laboratory report(s) that indicate:

- Results of all conditions listed in the Newborn Child Testing Act (act 36) to the Newborn Screening and Follow-up Program (NSFP).
- That the Department of Health is following up on all conditions listed in the Newborn Child Testing Act.

Reporting Results of Supplemental Conditions to Submitter/Primary Care Provider  
During Business Hours (8:00 a.m.- 4:00 p.m.)

- Laboratory will send a copy of all supplemental results, including within normal limits, to the primary care provider (PCP) listed on the filter paper (unless the PCP is signed up to receive them electronically through PerkinElmer).
- Laboratory will identify all filter papers and results associated with a newborn in order to capture all second inconclusive filter papers. The second inconclusive result is referred to as a presumptive positive result.
- Laboratories will make the first and immediate contacts for reporting all abnormal results.
- For first inconclusive results, laboratory will contact the submitter or primary contact person as designated by each submitter.
- For unacceptable presumptive positive results, laboratory will verbally notify PCP and recommend an immediate consultation with a treatment center.
  - Laboratory will ask PCP to call the treatment center, inform them of the result and request follow-up steps
- Laboratory will call out and report the second inconclusive results the same as a presumptive positive result notification.
- For presumptive positive (including the second inconclusive) results, laboratory will contact the PCP and request that the newborn is immediately referred to treatment center/specialist. The laboratory will:
  - Instruct PCP to contact the family
  - Continue to call PCP until results have been reported to the responsible health care provider
  - Ask the PCP to identify treatment center
  - If PCP does not immediately identify treatment center – lab will assign a treatment center either geographically, or in the case of Philadelphia, on a rotating basis
- PerkinElmer will continue to call the PCP back once the DNA result is available.

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**Initial and Referral Follow-Up Process for the Additional Conditions Listed in the  
Newborn Child Testing Act (ACT 36) Excluding Cystic Fibrosis (cont.)**

Reporting Results of Abnormal Supplemental Conditions to the Newborn Screening and Follow-Up Program During Business Hours (8:00 a.m.- 4:00 p.m.)

- Inconclusive results: Laboratory will fax copy of all inconclusive results to the Department following notification to submitter, and:
  - Will also fax to NSFP a list of all inconclusives the following business day (UMASS will include presumptive positives). List will indicate if the inconclusive is a repeat filter paper
- Presumptive positive results: Laboratory will notify NSFP by phone of a presumptive positive result (including two inconclusives) immediately after notification to the PCP, and:
  - Immediately after phone notification, Laboratory will fax to NSFP:
    - Copy of abnormal result report
    - Copy of laboratory fact sheets
    - Copy of notes that include:
      - The full name of the person they spoke to
      - Phone number to reach that person
      - Name of the referral center
      - (PerkinElmer may make contact notes available electronically).

Laboratory Reporting Results Of Abnormal Supplemental Conditions After Hours And Weekends/Holidays

- For unacceptable presumptive positive results, Laboratory will call the treatment center and will inform them of the results and that they gave a recommendation to the PCP for an immediate consultation with the treatment center.
  - Laboratory will ask PCP to call the treatment center, inform them of the result and request follow-up steps
- For all presumptive positive results, including two inconclusives, laboratory will call the treatment center recommended by the PCP, and:
  - Notify them of the abnormal report and fax a copy if available at the time of the call
  - Give the name and contact information of the notified PCP
- For all abnormal results, the laboratories will fax to NSFP copies of contact notes, the laboratory results report and the laboratory's fact sheets the next business day.

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Newborn Screening and Follow-Up Program Role

***Inconclusive Results***

- PerkinElmer Urgent Repeat Recommendations
  - Send a letter within two days requesting a repeat to mother, submitter and PCP
  - If no repeat in system after 5 days - call submitter
  - If repeat not in system 16 days from receipt at laboratory, urgent notice letter sent to mother, doctor and submitter
  - Final review two weeks later
- Regular Repeat
  - Send a letter within two days requesting a repeat to mother, submitter and PCP
  - If repeat not in system after two weeks will call the submitter and send an urgent notice letter to mother, PCP and submitter
  - Final review two weeks later

***Presumptive Positive Results***

- NSFP will call the treatment center immediately upon receipt of information from Laboratory:
- NSFP will fax to the treatment center:
  - A copy of the abnormal report if they do not have copy of the report
    - Report will include INCOMPLETE REPORT sticker
    - Will request that the treatment center call the laboratory for a complete report
  - The 4 day follow-up sheet
  - Diagnosis Sheet within 3 days
- NSFP will inquire if the treatment center has heard from the PCP; if yes, ask if the treatment center has made contact with the parent.
- If the treatment center has not been contacted by the PCP:
  - NSFP will contact PCP reported by laboratory and reiterate need to immediately contact treatment center and mother
  - Both UMASS and PerkinElmer request both a referral to a treatment center and a repeat specimen
  - If repeat is completed and comes back positive again, no follow up needed by NSFP as long as newborn has been referred
- On the fifth day after faxing the 4 day Follow-up sheet to the treatment centers NSFP will check on the see if the sheet is returned. If the document is not received, NSFP will call the treatment center to obtain the information.
  - If contact has not been made, NSFP will send Urgent Notice to PCP and mother

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Newborn Screening and Follow-Up Program Role

***Presumptive Positive Results (cont.)***

- If newborn not seen at treatment center yet, NSFP will fax additional follow-up sheet
- Treatment center will fax follow-up sheet back to NSFP once appointment has occurred.
- NSFP will follow-up with treatment center until diagnosis is obtained.
- NSFP will enter case data into the National Newborn Screening Information System.

Follow-up after Laboratory Calls on Weekends/Holidays

- NSFP will follow up with treatment center next business day after first notification of pre-pos to check status of appointment and fax 4 day follow-up sheet and Diagnosis sheet when available.