## DSHS Newborn Screening (NBS) Program

**Current as of April 2008**

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### Data Entry

**Abbreviations**
- CI = Check In Group
- DOR = Date of receipt
- N = Newborn specimens
- F = Follow-up specimens
- RR = Requested repeats
- NBS = Newborn Screening
- Demo = Demographic Information
- LIMS = Laboratory Information Management System
- UNSAT = Unsatisfactory specimens

Testing laboratory schedules based on the number of newborn specimens (N) bundles which are taken as priority over follow-up (F) specimens bundles.

### NBS Specimen Receiving Workflow

**Specimen Acquisition Check-In Group**
- Specimen received from submitter and delivered to Check In Group (CI).
- Review acceptability of specimens or review lab disposition of specimens.
- 
  - **ACCEPTABLE**
  - Sort specimens based on type: N, F, or RR
  - Stack N, F specimen types in bundles of 88 and stamp DOR.
  - Gather # of bundles that correspond w/lab testing schedule.

  - **RR**
  - Stack RR specimens for same day processing.
  - Verify RR specimen type. Non-RR's sorted accordingly.

  - **UNSATS**
  - Sort specimens per unsat type: Expired test card or “Other” unsats
  - Stack unsatisfactory specimens and stamp DOR.
  - Verify unsat assignments recorded in LIMS.

- Link DOR to specimen kit serial numbers.
- Assign lab ID to specimens.
- Conduct final review of specimens. Link lab ID to kit serial numbers.
- Separate demo data from specimen filter paper.

**Deliver demo info to Demographic Entry area.**

### Data Entry

- Data Entry receives demo forms
- NBS Demo Data Entry in LIMS

### Symbols:
- Event triggering the process
- Nested Process (calls another process)
- Task
- Output
- Decision Box
- Role
- Meeting
- End of process
- Page connector

### Testing

- **For “Others”, determine specimen disposition & return specimens to CI.**
- **Key:**
  - NBS = Newborn screening
  - CI = Check In Group
  - DOR = Date of receipt
  - N = Newborn specimens
  - F = Follow-up specimens
  - RR = Requested Repeats
  - LIMS = Laboratory Information Management System
Run NBS Disorder Tests

1. Specimen received in lab for testing
   - Punch specimen blood cards to supply samples into analysis plates

CAH
- Start AutoDelfia runs
- Results entered in database
- Review screens
- Pull, punch and run retests
- Evaluate worklist
- Release normals and abnormals

Hypothyroidism
- Start AutoDelfia runs (T4 only)
- Results entered in database
- Review screens
- Pull, punch and run retests including TSH
- Evaluate worklist
- Are all results acceptable?
  - Yes: Release normals and abnormals
  - No: CAH and Hypothyroid run by Endocrine lab area

Biotinidase
- Analyze screens
- Results entered in database
- Review screens
- Pull and punch retests
- Evaluate worklist
- Are all results acceptable?
  - Yes: Release normals and abnormals
  - No: Review screens

MSMS
- Analyze retests
- Review screens
- Pull and punch retests
- Evaluate worklist
- Are all results acceptable?
  - Yes: Release normals and abnormals
  - No: Results entered in LIMS

Hemoglobinopathy
- Analyze retests
- Results entered in database
- Review screens
- Punch retests
- Evaluate worklist
- Are all results acceptable?
  - Yes: Release normals and abnormals
  - No: Run and read retests

Galactosemia
- Analyze screens
- Results entered in database
- Review screens
- Pull and punch retests
- Evaluate worklist
- Are all results acceptable?
  - Yes: Release normals and abnormals
  - No: Results entered in LIMS

Results entered in database
- Are all results acceptable?
  - No: Add elution solution into specimens
  - Yes: Review screens

CAH and Hypothyroid run by Endocrine lab area; Galactosemia and BIOT run by GAL/BIOT lab area

Return to main process
Run NBS Disorder Tests

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CAH and Hypothyroid run by Endocrine lab area; Galactosemia and BIOT run by GAL/BIOT lab area

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Abbreviations

NBS = Newborn Screening
LIMS = Laboratory Information Management System
MSMS = Tandem mass spectroscopy
HPLC = High Pressure Liquid Chromatography
CM = Case Management
BIOT = Biotinidase
CH = Congenital Hypothyroidism
CAH = Congenital Adrenal Hyperplasia
PKU = Phenylketonuria
GAL = Galactosemia
PCR = Polymerase chain reaction
TSH = Thyroid-stimulating hormone
T4 = Thyroxine

If meets PCR criteria, pull specimen and forward to DNA lab
Run DNA test
Results as expected?
Yes
Store specimen in freezer
Prepare and send generated DNA report to submitter
Notify CM
End

If meets PCR criteria, pull specimen and forward to DNA lab
Run DNA test
Results as expected?
Yes
Store specimen in freezer
Prepare and send generated DNA report to CM
Notify CM
End
Receive bundled white copies from receiving (both acceptable and global unsats)

Scan UPC code from form to auto populate submitter, date of receipt and lab identification number.

Data entry personnel enter remaining information on form.

Verify data entry correct and release demographic information.

Stores bundles of white copies

End

Symbols:
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Case Creation: Abnormal result notification received

CM confirms receipt w/lab for very abnormal results.

Initial Notification of Abnormal Result

Possible Actions Needed - (dependent on disorder & screen type)
- Repeat Screen
- Blood work, Diagnostic Testing
- Referral to Specialist

Conduct/Continue follow-up activities until resolution.

Action taken by PCP/Physician?

YES

Patient cleared from Dx or Dx patient referred to specialist?

NO

Document clinical feedback in LIMS to complete short-term follow up.

End

NO

CM confirms receipt w/lab for very abnormal results.

Very abnormal specimens are faxed immediately to CM for immediate action by nurses. An abnormal result creates a case in LIMS.

Abbreviations

NBS = Newborn Screening
Dx = Diagnosis
LIMS = Laboratory Information Management System
CM = Case Management
PCP - Primary Care Physician

Symbols:

- Event triggering the process
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Initial Notification of Abnormal Screen

**Case Management**

- Initial notification of abnormal screen is initiated.

  - Can Dr be contacted?
    - NO
    - Contact hospital facility.
    - Baby still at hospital?
      - NO
      - Contact facility. Request assistance with locating parent.
      - Family contact info viable?
        - NO
        - Research child whereabouts by contacting entities such as regional social workers, local clinics, local health departments and law enforcement.
        - Attempt to contact family, provide results and requested action, obtain doctor information - send certified letter with information as well
        - Found?
          - NO
          - Check Medicaid database, internet and other resources.
    - YES
    - Contact doctor. Provide results & recommend action.

  - YES
    - Doctor/facility/parent contacted. Provide results & recommend action.
    - *If appropriate action not taken by parent & serious risks involved, contact CPS.

**Physician/Facility/Parent**

- Return to CM flow

  - Feedback should be given to Case Management staff.
  - Necessary steps to obtain confirmed diagnosis and administration of proper treatment should be taken.
  - Physician/Patient appointment should be scheduled.

  - Dr agrees to follow up w/parent?
    - YES
    - Agreement to take action w/child?
      - YES
      - Doctor/facility/parent contacted. Provide results & recommend action.
      - NO
      - *If appropriate action not taken by parent & serious risks involved, contact CPS.
    - NO
    - NO
    - NO

**Abbreviations:**

- Dr. - Doctor
- CPS - Child Protective Services
- CM - Case Management
Congenital Adrenal Hyperplasia (CAH)

- Receive abnormal results from lab
- Call hospital to obtain birth weight
- Mail letter to parents
- Call lab with birth weight for result re-evaluation
- Abnormal Birth weight included?
  - Yes
    - Call hospital to obtain birth weight
    - Mail letter to parents
  - No
    - Call lab with birth weight for result re-evaluation

- Initial Notification of Abnormal Result
- Initial Notification of Normal Result
- Mail letter to parents
- Request 2nd specimen
  - No
    - Letter to hospital or doctor
  - Yes
    - Link with previous screen
- Abnormal Results
  - Normal
    - Notify hospital or doctor of results
    - Request 2nd specimen
      - No
        - Letter to hospital or doctor
      - Yes
        - Link with previous screen
        - 2nd specimen received?
          - Yes
            - Letter to hospital or doctor
          - No
            - Link with previous screen
- Notify hospital or doctor of results
- Provide list of endocrinologists and suggest protocols
- Diagnosis by endocrinologist
  - Cleared
    - Enter diagnosis and notify lab as appropriate
    - Follow up regularly per long term protocol with endocrinologist until client is 18 years of age
  - Diagnosed
    - Enter diagnosis and notify lab as appropriate
    - Follow up regularly per long term protocol with endocrinologist until client is 18 years of age

Follow-up

- Timeframes:
  - If very elevated – Call back next working day to verify patient seen and get sodium and potassium levels. Call back the following week for results of serum test.
  - If slightly or moderately elevated – Call back after 2nd specimen tested or 2 weeks, whichever comes first.
Galactosemia (GAL)

Receive abnormal screen from lab

Initial Notification of Abnormal Result

Yes

First screen?

No

Request follow-up screen. Inform physician and provide DNA report (from laboratory) when available.

Follow up test received?

Yes

Normal

Results?

Abnormal

Provide list of metabolic specialists, list of formulas and request child be put on soy formula

Cleared

Enter diagnosis and notify lab if appropriate

Follow up using long term protocol until 4 years of age

Diagnosis

Diagnosed

End

No

Send parent letter

Request 2nd screen

Follow up test received?

Yes

Normal

Results?

Abnormal

Provide list of metabolic specialists

Cleared

Enter diagnosis and notify lab if appropriate

Follow up using long term protocol until 4 years of age

Diagnosis

Diagnosed

End

No

Call physician or hospital for retest

Follow-up Timeframes:

For very elevated – Call back every 24 hours until child is treated
For slightly or moderately elevated – follow up every 2 to 3 days until child is treated

Symbols:

Event triggering the process

Nested Process (calls another process)

Task

Output

Decision Box

Role

Meeting

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Page connector

Request 2nd screen

Inform physician and provide DNA report (from laboratory) when available.

Follow up test received?

Yes

Normal

Results?

Abnormal

Provide list of metabolic specialists, list of formulas and request child be put on soy formula

Cleared

Enter diagnosis and notify lab if appropriate

Follow up using long term protocol until 4 years of age

Diagnosis

Diagnosed

End

No

Send parent letter

Request 2nd screen

Follow up test received?

Yes

Normal

Results?

Abnormal

Provide list of metabolic specialists

Cleared

Enter diagnosis and notify lab if appropriate

Follow up using long term protocol until 4 years of age

Diagnosis

Diagnosed

End

No

Call physician or hospital for retest

Follow-up Timeframes:

For very elevated – Call back every 24 hours until child is treated
For slightly or moderately elevated – follow up every 2 to 3 days until child is treated

Symbols:

Event triggering the process

Nested Process (calls another process)

Task

Output

Decision Box

Role

Meeting

End of process

Page connector
receive abnormal screen from lab

Initial Notification of Abnormal Result

Fax and mail physician letter
Mail parent letter

Request second test from physician

2nd screen received?

Yes

Link to first screen

Fax/mail physician letter
Mail parents letter

DNA confirmation complete?

Yes

Sickling?

Non-Sickling

Mail letter to regional social worker
Fax/mail physician letter
Mail parents letter

Case manager follows up per long term protocol until client is 18 years of age

End

Follow-up Timeframes:
Notify primary care physician within 48 hours.

* Most trait conditions are not referred to case management

Symbols:
- Event triggering the process
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Phenylketonuria (PKU)

Initial Notification of Abnormal Result

Unless on TPN, request second screening and serum test

Child discharged?

Yes → Contact physician and letter to parents

No → On TPN?

Yes → Request 2nd screen

No → Second screen?

Yes → Results

Normal → Contact physician with results

Abnormal → Nurse reviews serum results

Results

Normal → Provide physician with results and list of metabolic specialists

Abnormal → Fax results to metabolic specialist

Diagnosis

Cleared → Close

Diagnosed → Enter diagnosis and notify lab if appropriate

Follow up per long term protocol until 4 years of age

End

Follow-up Timeframes:

For moderately and very elevated – Next working day follow-up

For slightly elevated – Follow-up of no second screen in 2 weeks.

Symbols:

Event triggering the process

Nested Process (calls another process)

Task

Output

Decision Box

Role

Meeting

End of process

Page connector

Abbreviations

TPN = Total parenteral nutrition
Hypothyroidism

Receive abnormal screen from lab

Mail letter to parents

Request serum and 2nd screen if:
- moderately or very elevated
- slightly elevated TSH and both T4/TSH abnormal
- elevated T4
- elevated T4 and TSH
For all other combinations, request 2nd screen

No 2nd screen received?

Results?

Normal

Abnormal

Mail certified letter to parents

Request local thyroid profile

Nurse reviews results

Mail certified letter to parents

Results?

Normal

Abnormal

Birth weight low and T4 low/TSH normal?

Yes

No

Send certified letter to parents

Recommend referral to specialist

Diagnosis Cleared

Diagnosed

Follow up until 4 years of age

End

Symbols:
- Decision Box
- Event triggering process
- Nested Process (calls another process)
- Task
- Output

Follow-up Timeframes:

If very elevated – follow up at 48 hours and every 72 hours after that until diagnosed/treated.

If moderately or slightly elevated – Follow up at 48 hours and every 7 days after that until diagnosed/treated.
NBS Specimen Collection Kit Management Workflow

**Container Prep/Kit Management**

- **Submitter requests NBS kits**
  - KM receives request for NBS kits.
  - **Provider in LIMS?**
    - **NO**
      - **Addresses the same?**
        - **NO**
          - **Addresses Tracked**
            - Report To
            - Bill To
            - Ship To
        - **YES**
          - **Check for duplicate orders.**
    - **YES**
      - **Create/update submitter in LIMS.**
      - **Check submitter status for prepaid order requests.**
        - **Serial numbers on test kits are tied to kit type:**
          - Medicaid/Charity or Pre-Paid.
        - **On hold?**
          - **YES**
            - **Contact Billing for approval to ship kits.**
          - **NO**
            - **Process request in LIMS.**
              - **Process kit requests when billing notifies that submitter is no longer on hold.**
              - **Contact submitter. Notify request on hold until account cleared with billing.**
            - **NO**
              - **Bill submitter for prepaid kits.**
        - **YES**
          - **Process Medicaid/Charity kits for submitter, not prepaid card kits.**
    - **Mail kits**
    - **File order form**

**Billing**

- **Symbols:**
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  - Role
  - Meeting
  - End

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- **End of process**
- **Page connector**

**Abbreviations**

- NBS = Newborn Screening
- KM = Kit Management Staff
- LIMS = Laboratory Information Management System