

**ATTACHMENT D**  
**Newborn Screening Laboratory**  
**Specific Products and Services**

*Function 1: Filter Paper Kits*

Overview

The selected respondent will create, print and distribute filter paper kits for collection of newborn screening blood specimens. Universal Newborn Hearing Screening (UNHS) test results should be included as part of the information collected from birthing facilities. Pulse oximetry screening results are currently being discussed for addition on the filter paper kits; if added, pulse oximetry screening results should be included as part of the information collected from birthing facilities.

- 101 The Indiana State Department of Health's (ISDH) Genomics and Newborn Screening Program (ISDH/Genomics and NBS) will have the final right of approval on the design, content and quality of all forms created to conduct newborn screening operations. The manufacturer must comply with the Food & Drug Administration's "Good Manufacturing Practices" regulations. Selected respondent will ensure that filter paper kits exceeding the expiration date will not be used for specimen collection.
- 102 The selected respondent will furnish a maximum of 180,000 filter paper kits annually. Manufacturer and lot number for the filter paper must be included on the filter paper section of the kit in accordance with the standard(s) approved by the Clinical Laboratory Standards Institute (CLSI). Sequential system control numbers for each collection kit must be printed on each information section of the collection card and on the filter paper section if that section is detachable.
- 103 The selected respondent must supply approved filter paper kits to ISDH/Genomics and NBS, Indiana birthing facilities (hospitals, midwiferies, etc.) and/or other collection sources within 120 days after the contract commitment. The selected respondent will, at the discretion of the ISDH/Genomics and NBS, distribute the filter paper kits directly to the NBS collection sources.
- 104 The selected respondent will provide filter paper kits, without additional cost, to local health departments, MCH/CSHCS clinics or other outside organizations/individuals as designated by ISDH/Genomics and NBS for the collection of newborn screening specimens. The majority of these kits will be used to collect required repeat screens.
- 105 The selected respondent will collect, store and enter data of all the newborn screening and UNHS test results (and possibly pulse oximetry screening results) from the filter paper kits. The selected respondent will assist ISDH/Genomics and NBS in developing appropriate protocol(s) for proper storage of blood spot cards and release of blood spot cards for use in research. The selected respondent will store blood spot cards in compliance with ISDH/Genomics and NBS policies.
- 106 Changes on the design of the filter paper kits should be discussed with and approved by ISDH/Genomics and NBS.

## Function 2: Newborn Screening Data Collection

### Overview

The selected respondent will receive and process filter paper kits as submitted by birthing facilities, midwives, physicians, clinics and local health officials for newborn screening blood specimens, Universal Newborn Hearing Screening (UNHS) test results and pulse oximetry screening results (if added to the filter paper kits). The required processing includes entering and maintaining demographic data and screening data from the submitted filter paper kits.

- 201 The selected respondent will record into the selected respondent's data files the demographic data, hearing screening data and pulse oximetry screening data (if added to the filter paper kits) from each filter paper kit submitted. Data files will be maintained according to individual infants screened. These data files will be maintained on an automated system. Electronic reporting systems should be available for submitting statistical reports as requested.
- 202 The selected respondent must edit the demographic information according to the criteria in the *Information Required On Filter Paper Kit* section of this Attachment.
- 203 When demographic data is absent or incorrect in initial processing, the selected respondent will attempt, to the extent practicable, to contact the birthing facility/collection source, physician, midwife, MCH/CSHCS clinic or local health official by telephone to obtain the corrected or missing information.
- 204 The selected respondent will add, delete or change demographic data edits as ISDH/Genomics and NBS requires.
- 205 The selected respondent will maintain an accurate count of specimen kits sent to and received from the various collection sources.
- 206 The selected respondent will provide data on kits received by the number of specimens received for a particular infant (e.g., initial screen, repeat test, confirmatory test, initial UNHS test UNHS status of passing/not passing/passing with risk factors/not screened) as requested by ISDH/Genomics and NBS. If pulse oximetry screening information is added to the filter paper kits, the selected respondent will provide data on kits received as specified by ISDH/Genomics and NBS.
- 207 The selected respondent will collect data on kits to compile reports requested by ISDH/Genomics and NBS for heelstick and hearing screening (Function 6). If pulse oximetry screening information is added to the filter paper kits, the selected respondent will collect data & compile reports on kits received as specified by ISDH/Genomics and NBS.
- 208 The selected respondent will collect data and make electronic data reporting accessible to ISDH/Genomics and NBS (Function 6).
- 209 The selected respondent will coordinate with Indiana birthing facilities (including hospitals and midwiferies) to ensure that specimens are obtained and delivered to the selected respondent's facility with minimum delay.

- 210 Respondent will describe the type of pickup services they intend to maintain for Indiana birthing facilities/collection sources (including hospitals and midwiferies). Service must be established for facilities having one or more births per day to allow for pick-up of screening specimens at the birthing facility at least every 24 hours during weekdays and once every 48 hours on weekends. For birthing facilities with less than one (1) birth per day, pick-up will occur when the institution has (a) specimen kit(s) available for analysis.
- 211 Respondents must provide estimates of how often pick-up services will be established for each Indiana birthing facility. For planning purposes, a list of current Indiana birthing facilities is provided in the *Locations* section of this Attachment.

### *Function 3: Performance of Laboratory Testing on Blood Specimens*

#### Overview

The selected respondent will process, analyze, and report results of filter paper kits for newborn screening blood specimens and UNHS test results. The conditions for which the selected respondent must screen include:

#### **Endocrine Disorders**

1. Congenital adrenal hyperplasia (also called CAH)
2. Hypothyroidism

#### **Hemoglobinopathies**

3. Sickle cell anemia (includes testing for S/C anemia & beta-thalassemia)

#### **Metabolic conditions**

##### Amino Acid (AA) Disorders (includes urea cycle disorders)

4. Arginase deficiency (also called argininemia)
5. Argininosuccinic aciduria
6. Bipterin cofactor defects
7. Citrullinemia (also called CIT type I)
8. Citrin deficiency (also called CIT type II)
9. Homocystinuria (also called HCY)
10. Hypermethioninemia
11. Hyperphenylalaninemia
12. Maple syrup urine disease (also called MSUD)
13. Phenylketonuria (also called PKU)
14. Tyrosinemia type I
15. Tyrosinemia type II
16. Tyrosinemia type III

##### Fatty Acid Oxidation (FAO) Disorders

17. 2,4-dienoyl-CoA reductase deficiency
18. Carnitine-acylcarnitine translocase deficiency (also called CACT)
19. Carnitine palmitoyltransferase deficiency I (also called CPT IA)
20. Carnitine palmitoyltransferase deficiency II (also called CPT II)
21. Carnitine uptake defect (also called CUD)
22. Glutaric acidemia type II (also called GA type II, electron transfer flavoprotein deficiency, ETF deficiency, multiple acyl-CoA dehydrogenase deficiency, or electron transferLong chain hydroxyacyl-CoA dehydrogenase deficiency (also called LCHAD))
23. Long chain hydroxyacyl-CoA dehydrogenase deficiency (also called LCHAD)
24. Medium chain acyl-CoA dehydrogenase deficiency (also called MCAD)
25. Short chain acyl-CoA dehydrogenase deficiency (SCAD)

26. Short chain hydroxyacyl-CoA dehydrogenase deficiency (SCHAD)
27. Trifunctional enzyme deficiency
28. Very long chain acyl-CoA dehydrogenase deficiency (VLCAD)

#### Organic Acidemias (OA)

29. 2-Methylbutyrylglycinuria (also called 2-MBG)
30. 3-Hydroxy-3-methyl glutaric aciduria (also called HMG)
31. 3-Methylcrotonyl-CoA carboxylase deficiency (also called 3-MCC deficiency)
32. 3-Methylglutaconic acidemia (also called 3-MGA)
33. Beta-ketothiolase deficiency
34. Glutaric acidemia, type I (also called GA type I)
35. Isobutyrylglycinuria (also called IBG)
36. Isovaleric acidemia (also called IVA)
37. Malonic aciduria (also called MAL)
38. Methylmalonic acidemia (also called MUT or methylmalonyl-CoA mutase)
39. Methylmalonic acidemia with cobalamin disorders (CblA & CblB)
40. Methylmalonic acidemia with homocystinuria (CblC & CblD)
41. Multiple-CoA carboxylase deficiency
42. Propionic acidemia

#### Other

43. Biotinidase deficiency
44. Cystic fibrosis
45. Galactosemia (also called classic galactosemia or G/G) - includes testing for galactosemia D/G variant & other galactosemia variants

The selected respondent will monitor any applicable state and federal statutes and regulations and revise its procedures promptly in order to remain in total compliance with statutes and regulations.

The selected respondent will maintain records of the results of all screening and follow-up testing of infants for these conditions in accordance with Indiana requirements for medical records management.

- 301 The respondent must provide a flow chart showing the steps involved in performing the analysis of a screening specimen from the receipt of the filter paper kit to the sending of the final laboratory analysis report to the collection source.

#### *A. Tracking*

- 302 The selected respondent's system will track and accurately reflect the status of the receipt and analysis of each infant's specimen.
- 303 The selected respondent will provide data on kits received by the number of specimens received for a particular infant as requested by ISDH/Genomics and NBS and in the timeframe and format specified by ISDH/Genomics and NBS.

- 304 The selected respondent will provide data on kits received by the number and status of the UNHS test results as requested by the ISDH Early Hearing Detection and Intervention (EHDI) Program, a sub-program of ISDH/Genomics and NBS, in the timeframe and format specified by ISDH/Genomics and NBS. If pulse oximetry screening information is added to the filter paper kits, the selected respondent will provide data on kits received as in the timeframe and format specified by ISDH/Genomics and NBS.
- 305 Irrespective of any missing demographic information, the selected respondent must perform the analysis of any specimens received. Analysis of blood spots must not be delayed while corrected demographic data is being collected.
- 306 When a filter paper kit does not contain sufficient blood for analysis, or when the kit is not suitable for analysis, the selected respondent will notify the collection source by telephone of the need for a repeat specimen and then follow up with written notice stating the reason why a repeat specimen is necessary and the appropriate time frame for obtaining the specimen. The respondent must describe how it would deal with the issue of insufficient blood quantity for all tests (assign a priority to tests, no analysis, etc.). In the event that a priority is assigned to tests, the respondent should provide a list of the order in which tests would be performed. ISDH/Genomics and NBS reserves the right to stipulate the selected respondent's procedures in this regard.
- 307 Despite the condition of the blood specimen, the selected respondent must enter the demographic information from the filter paper kit into its data system, along with an identifying flag or indicator to facilitate follow-up of required retesting as described in Function 5.
- 308 The selected respondent must also enter Universal Newborn Hearing Screening (UNHS) status as reported on the filter paper kit into its data system.
- 309 Pulse oximetry screening data is currently being discussed as an addition to the filter paper kit. In the event that pulse oximetry screening data is added to the filter paper kit, the selected respondent must also enter pulse oximetry status as reported on the filter paper kit into its data system.
- 310 The selected respondent will electronically report all the data collected from kits and laboratory results, including UNHS hospital screening data (Function 5 and 6) and possibly pulse oximetry screening data, to ISDH/Genomics and NBS as needed. Reports should be submitted in the time frame & format specified by ISDH/Genomics and NBS.

*B. Analysis Report (also see Function 5)*

- 311 After the NBS blood specimens from the filter paper kits have been analyzed by the selected respondent, the results of the various tests on each infant must be entered into the selected respondent's data system. The results will include statements on whether the laboratory considers the results normal, abnormal, presumptive positive or confirmed positive for disorders. The analysis will also indicate whether the specimen met all requirements for a valid screening test and will detail any requirements for further specimen submissions (including, but not limited to, the specific type of specimen required and the time/age at which the specimen should be collected).

- 312 Each day, the selected respondent will make available to ISDH/Genomics and NBS a listing of all infants for whom filter paper kits were received for analysis, the laboratory results of the analysis, the demographic data and other screening status information obtained from each specimen and the current status of any action(s) being taken with regard to the specimen. The selected respondent will provide this analysis via electronic media, in the format required by ISDH/Genomics and NBS. ISDH/Genomics and NBS will provide the selected respondent with the necessary procedures and transmission schedules. The selected respondent must have available, at no charge to ISDH/Genomics and NBS, a computer capable of electronic data transmission that will allow ISDH/Genomics and NBS and the selected respondent to receive and transmit data.
- 313 The selected respondent will maintain electronic and hard copy of records of the results of all screening and follow-up testing of infants in accordance with Indiana requirements for medical records management.

### *C. Turnaround Time*

- 314 The selected respondent will initiate the approved tests within 24 hours of receipt of the specimen and complete the analysis within 72 hours. The selected respondent must provide sufficient personnel to accomplish this maximum acceptable turnaround time, even during peak processing periods.
- 315 The selected respondent will generate a copy of each laboratory report on each infant and deliver it by common carrier to the birthing facility or other collection source within 7 days of receipt of the specimen. A copy for the responsible physician will be included for distribution by the hospital. The selected respondent will maintain a tracking system to document the notification time achieved per specimen. Electronic availability of NBS results is currently being assessed. If alternative availability is implemented, the selected respondent will work with ISDH/Genomics and NBS to ensure that up-to-date information will be available to hospitals and physicians.
- 316 If a birthing facility or other collection source determines that a specimen has been obtained but that no results are available within the newborn's medical records within 10 days of discharge, the birthing facility or other collection source will obtain the results from the selected respondent by telephone and request that another written copy be sent. The selected respondent will provide a copy of the test results at no charge to the collection source.

## Function 4: Screening of Indigent Population

### Overview

The selected respondent must be prepared to analyze, without reimbursement, the specimens and results of newborn screens on a certain number of infants from indigent families. The actual screening of these infants and analysis of blood specimens will be in accordance with the ISDH/Genomics and NBS Program's regulations and policies.

The collection of the blood specimen may be administered by Public Health Nurses in the home or in a clinic situation rather than in a hospital, midwifery or other birthing facility. As such, billing to the birthing facility may not be appropriate. The selected respondent will be prepared to absorb the costs associated with the analysis of these newborn screens. ***Such screens performed without payment should not be included for the state surcharge. For the purposes of this RFP, the selected respondent should assume approximately 100 - 150 of these cases per year.***

- 401 The selected respondent will provide filter paper kits, without additional cost, to local health departments, MCH clinics or other outside organizations/individuals as designated by ISDH/Genomics and NBS for the collection of newborn screening specimens. The majority of these kits will be used to collect required repeat screens.
- 402 In those cases where an original screen was not drawn as required by a birthing facility, the selected respondent must attempt to assess that birthing facility for the cost. If the blood specimen is submitted by a Public Health Nurse, the selected respondent must assume the cost of the screen.
- 403 Costs for initial screens where payment is not received will be listed separately and grouped by collection source on the reports submitted to ISDH/Genomics and NBS.



## *Function 5: Laboratory Follow-Up Procedures/Requests for NBS Results or Data*

### Overview

When a live birth occurs in a hospital, the responsible physician will have a specimen of the infant's blood taken through heel puncture prior to the infant's discharge from the hospital. If the infant is discharged prior to 48 hours after birth or before the infant has been on protein feeding for 24 hours, a blood specimen will be collected; however, collection will not meet the requirements for a valid screening test and must be repeated after 48 hours of age, but no later than 120 hours, after birth.

The selected respondent will report and follow up on the results of the newborn screening blood specimens. The selected respondent will provide a copy of the laboratory results for the responsible physician in the report forwarded to the birthing facility or other collection source (Function 3). This report of the test results is to become part of the patient's clinical record.

Electronic availability of results is currently being assessed. This may change the requirements for notifying the birthing facilities and primary care physicians. The selected respondent will work with ISDH/Genomics and NBS to implement the appropriate changes, regardless of cost.

The selected respondent must create, print and utilize follow-up correspondence notifying collection sources of the status of test results, the need for additional screens, etc. The selected respondent is free to suggest any additional types of follow-up letters that the respondent feels may be beneficial.

The selected respondent will coordinate with the collection source to have all required repeat newborn screening specimens submitted and will provide ISDH/Genomics and NBS with information regarding repeat newborn screens that are not submitted in a timely manner (Function 5).

Specific reporting/follow-up requirements vary based on whether the analysis indicates whether the specimen met all requirements for a valid screening test and whether the screening results were normal, invalid, abnormal, presumptive positive or confirmed positive.

### **Definitions**

**Abnormal screening results:** Values of screen are outside the range of normal values, but do not fit an accepted pattern for disease status of a newborn screening condition

**Confirmatory positive screening results:** Additional testing has been done to confirm the presence of a newborn screening condition

**Invalid specimen:** A specimen that is collected prior to 48 hours after birth or prior to 24 hours of protein feeding, is collected inappropriately, is submitted to the state-designated NBS Laboratory greater than 24 hours after collection, or is otherwise unsatisfactory

**Normal screening results:** Values of screen are within range of normal values

**Presumptive positive screening results:** Values of screen are outside the range of normal values and fit an accepted pattern for a newborn disease condition, but have not yet been confirmed

Valid specimen: A specimen that is collected after 48 hours after birth and after 24 hours of protein feeding; this specimen is collected on the appropriate heel-stick card (according to collection guidelines) and submitted to the state-designated NBS Laboratory within 24 hours of collection.

- 501 In all cases, the selected respondent will include a copy of the laboratory results for the responsible physician in the report forwarded to the hospital/collection source in accordance with Function 3.

*A. Normal Screening Results; Specimen Meets all Requirements for a Valid Screen*

- 502 The selected respondent will report negative laboratory results to ISDH/Genomics and NBS on a mutually agreed-upon basis, as described in Function 3. No additional tests or follow-up actions are required.

*B. Normal Screening Results, but Specimen does not meet Requirements for a Valid Screen*

- 503 Initial notification of the responsible physician is provided by the selected respondent as part of the standard report of laboratory results that is forwarded to the birthing facility/collection source. In most cases, the birthing facility/collection source is already aware that a repeat screen (re-screen) is necessary and has made appropriate coordination with the parent(s)/guardian(s) prior to discharge. The selected respondent will also report these laboratory results to ISDH/Genomics and NBS on a mutually agreed-upon basis as described in Function 3.

- 504 If, five (5) business days after receipt of the initial specimen, the required re-screen has not been received by the selected respondent, then the selected respondent will provide the birthing facility/collection source and responsible physician with written notification of the requirement for a repeat screen as detailed under C below. The selected respondent will also provide a copy of this notification to ISDH/Genomics and NBS on a mutually agreed-upon basis for further follow-up as required. If the required re-screen has not been received by the selected respondent five (5) business days after the written notification was sent, the selected respondent will send a reminder letter regarding the re-screen to the primary care physician and submitting birthing hospital/collection source.

- 505 If the required re-screen has not been received within seven (7) to ten (10) business days of sending the reminder letter, the selected respondent will notify ISDH/Genomics and NBS so that PHN assistance can be obtained.

*C. Invalid Specimen*

- 506 Telephone Notification: In the case of an invalid specimen, the selected respondent will immediately notify the birthing facility/collection source by telephone of the requirement to collect a re-screen within two (2) business days after the birthing facility/collection source has received telephone notification from the selected respondent. This notification will include an explanation of the reason for the specimen's rejection and any available information that would facilitate obtaining a re-screen. In the event the birthing facility/collection source who submitted the specimen is no longer the primary health care provider, the birthing facility/collection source will be responsible for notifying the current health care provider.

507 Written Notification: If a re-screen of an invalid specimen has not been received within five (5) business days after telephone notification, the selected respondent will then forward a written notice of the failure to obtain a screening specimen to the birthing facility and responsible physician or other health provider and forward a copy to ISDH/Genomics and NBS. This written notification must contain, at least, the following information:

- Infant's name\* and hospital identification number
- Infant's date of birth
- Date of specimen collection
- Reason specimen was invalid/Reason repeat is required
- Birthing facility/collection source's name and ID number
- Name/ID # of collection source, if different from hospital
- Responsible physician's name or license number
- Physician's office address, if available
- Physician's office telephone number, if available
- Name of local health official contacted, if applicable
- Mother's name\*
- Father's name, if available\*
- Mother's home address, if available\*
- Father's home address, if different and available\*
- Mother's/father's home telephone number, if available\*
- Date specimen received at laboratory
- Date of specimen rejection report
- Date telephone notification was provided, and the name and telephone number of the hospital's contact person,
- Date that re-screen is required
- Name and telephone number of selected respondent's contact

*\* - Infant name and mother/father information utilized in correspondence from the selected respondent should reflect what is listed on the infant's current legal birth certificate. Correspondence for infants who are in the process of being adopted should utilize the birth mother/birth father information as listed on the original birth certificate until the new, adoptive birth certificate has been issued and recorded with Indiana's Vital Records Registry.*

508 If the required re-screen has not been received by the selected respondent within five (5) business days after the initial written notification was sent, the selected respondent will send a reminder letter regarding the re-screen to the birthing facility/collection source and the responsible physician or other health care provider.

509 If the required re-screen has not been received within seven (7) to ten (10) business days of sending the reminder letter, the selected respondent will notify ISDH/Genomics and NBS so that PHN assistance can be obtained.

#### *D. Special Cases:*

- 510 Whenever the selected respondent determines that a discharged newborn has not received the mandated tests (this will include, but not be limited to, unscreened infants, transfused infants, preterm infants, infants transferring between hospitals, etc.), the selected respondent will forward written notice to the responsible physician through the birthing facility/collection source and send a copy of this notice to ISDH/Genomics and NBS.
- 511 If the required screening specimen has not been received within five (5) days of the required date, the selected respondent will then forward a written notice of the failure to obtain a screening specimen to the birthing facility/collection source and responsible physician or other health care provider and forward a copy to ISDH/Genomics and NBS. The required dates for screening submission for typical “special cases” are as follows:
- Preterm infants must have a screen on the day of discharge or on the sixth day after birth if nursery stay is prolonged past that date.
  - Infants who have a total transfusion prior to a valid screening specimen being obtained must have a screening specimen collected prior to the transfusion. Post-transfusion samples must be collected as outlined by routine re-testing guidelines (1<sup>st</sup> specimen prior to 6 days of life; 2<sup>nd</sup> specimen at 14 days of life; 3<sup>rd</sup> specimen at 30 days of life; specimens collected monthly thereafter until discharge), with the final specimen collected 2 – 4 months after last transfusion.

#### *E. Initial Abnormal Screening Results (Not for Screened Conditions)*

- 512 Initial notification of the responsible physician is provided by the selected respondent as part of the standard report of laboratory results that is forwarded to the birthing facility/collection source. The selected respondent will also report these laboratory results to ISDH/Genomics and NBS on a mutually agreed-upon basis as described in Function 3.
- 513 The selected respondent will contact the birthing facility/collection source and infant’s primary care provider by telephone (see follow-up protocol procedures for details).
- 514 If, five (5) business days after receipt of the initial specimen, the required re-screen has not been received by the selected respondent, then the selected respondent will provide the birthing facility/collection source and responsible physician with written notification. The selected respondent will also provide a copy of this notification to ISDH/Genomics and NBS on a mutually agreed-upon basis for further follow-up as required. If the required re-screen has not been received by the selected respondent five (5) business days after the initial written notification was sent, the selected respondent will send a reminder letter regarding the re-screen to the physician and birthing facility/collection source.
- 515 If the required re-screen has not been received within seven (7) to ten (10) business days of sending the reminder letter, the selected respondent will notify ISDH/Genomics and NBS so that PHN assistance can be obtained.

#### *F. Confirmed Abnormal Screen Results (Not for Screened Conditions)*

- 516 Written notification to the responsible physician is provided by the selected respondent as part of the standard laboratory result report that is forwarded to the birthing facility/collection source. The selected respondent will provide a copy of this notification to ISDH/Genomics and NBS. It is the responsibility of the primary care provider to notify the parent(s)/guardian(s) and recommend appropriate diagnostic and possible therapeutic procedures and psychosocial support.

The written notice of a confirmed abnormal test result must contain, at least, the following information:

- Infant's name\* and hospital identification number
- Infant's date of birth
- Date of specimen collection
- Time of first protein feeding
- Infant's status at time of specimen collection (premature, transfused, on antibiotics, sick, or normal)
- Birthing facility/collection source's name and ID number
- Name/ID # of collection source, if different from hospital
- Responsible physician's name or license number
- Physician's office address, if available
- Physician's office telephone number, if available
- Name of local health official contacted, if applicable
- Mother's name\*
- Father's name, if available\*
- Mother's home address, if available\*
- Father's home address, if different and available\*
- Mother's/father's home telephone number, if available\*
- Date repeat specimen received at laboratory
- Time of repeat report completion
- Results of repeat newborn screening tests
- Date of specimen analysis report
- Further actions recommended or referrals provided
- Name and telephone number of selected respondent's contact

*\* - Infant name and mother/father information utilized in correspondence from the selected respondent should reflect what is listed on the infant's current legal birth certificate. Correspondence for infants who are in the process of being adopted should utilize the birth mother/birth father information as listed on the original birth certificate until the new, adoptive birth certificate has been issued and recorded with Indiana's Vital Records Registry.*

#### *G. Presumptive Positive Screening Results (Only for Screened Conditions)*

- 517 Telephone notification: Upon analysis, if a laboratory result from the selected respondent indicates presumptive positive status for a newborn screening disorder, the selected respondent will immediately contact the birthing facility/collection source by telephone and request that a

second specimen be collected from the child within 48 hours. This notification will include an explanation of the test results and any available information that would facilitate obtaining a re-screen. If there is no known responsible physician, the selected respondent will notify the local health officer in the county of the mother's residence.

518 Written notification: The selected respondent will provide the birthing facility/collection source and responsible physician with written notification of the requirement for a confirmatory screen within three (3) business days of the telephone notification and will forward a copy of this notification to ISDH/Genomics and NBS. This written verification of a presumptive positive test result must contain, at least, the following information:

- Infant's name\* and hospital identification number
- Infant's date of birth
- Date of specimen collection
- Time of first protein feeding
- Infant's status at time of specimen collection (premature, transfused, on antibiotics, sick or normal)
- Birthing facility/collection source's name and ID number
- Name/ID # of collection source, if different from hospital
- Responsible physician's name or license number
- Physician's office address, if available
- Physician's office telephone number, if available
- Name of local health official contacted, if applicable
- Mother's name\*
- Father's name, if available\*
- Mother's home address, if available\*
- Father's home address, if different and available\*
- Mother's/father's home telephone number, if available\*
- Date repeat specimen received at laboratory
- Time of repeat report completion
- Results of repeat newborn screening tests
- Date of specimen analysis report
- Further actions recommended or referrals provided
- Name and telephone number of selected respondent's contact

*\* - Infant name and mother/father information utilized in correspondence from the selected respondent should reflect what is listed on the infant's current legal birth certificate. Correspondence for infants who are in the process of being adopted should utilize the birth mother/birth father information as listed on the original birth certificate until the new, adoptive birth certificate has been issued and recorded with Indiana's Vital Records Registry.*

519 Presumptive positive cases are followed up more aggressively, with at least one phone call per day for three (3) days. If, after three (3) days, the selected respondent is not able to obtain confirmation that the appropriate follow-up (including confirmatory testing where applicable) was done, the selected respondent will notify ISDH/Genomics and NBS so that PHN assistance can be obtained immediately.

#### *H. Confirmed Positive Screening Results (Only for Screened Conditions)*

410 IAC 3-3-5(b) requires that confirmed positive tests be reported immediately by telephone to the birthing facility/collection source, to the responsible physician and to ISDH/Genomics and NBS. Such notification will be recorded in the laboratory's records, specifying date and time of notification, person notified and information provided as indicated below. The report will be followed by a written report within three (3) business days after telephone notification. The report of the test result will become part of the patient's clinical record. If there is no known responsible physician, the local health officer in the county of the mother's residence will be notified.

520 Telephone notification: Upon completing a laboratory analysis that confirms a diagnosis of one of the listed disorders, the selected respondent must immediately notify the birthing facility/collection source, responsible physician and ISDH/Genomics and NBS. The selected respondent will keep a log of this telephone notification, specifying the following:

- Name of infant\* and ID number
- Infant's date of birth
- Mother's name\*
- Mother's/father's home telephone number, if available\*
- Birthing facility/collection source's name or ID number
- Name of collection source's contact person
- Physician's name or license number
- Physician's office telephone number, if available
- Name of local health official contacted, if applicable
- Date of specimen analysis report
- Results of newborn screening tests
- Selected respondent's guidance as to future test requirements or further actions
- Recommended/referrals provided
- Name of ISDH/Genomics and NBS contact person
- Time and date of contact for each telephone notification

*\* - Infant name and mother/father information utilized in correspondence from the selected respondent should reflect what is listed on the infant's current legal birth certificate. Correspondence for infants who are in the process of being adopted should utilize the birth mother/birth father information as listed on the original birth certificate until the new, adoptive birth certificate has been issued and recorded with Indiana's Vital Records Registry.*

521 Written notification: Following the telephone notification, and within three (3) business days of the laboratory result supporting a confirmed positive screen result, the selected respondent will forward written notice to the birthing facility/collection source, responsible physician, ISDH/Genomics and NBS and, if applicable, the local health official in the mother's county of residence.

It is the responsibility of the attending physician or, if no responsible physician is identified, the local health officer in the mother's county of residence to immediately notify the parent(s) of all confirmed positive results and recommend appropriate diagnostic and possible therapeutic procedures and psychosocial support.

(1) In the case of a metabolic condition (galactosemia, biotinidase deficiency and disorders screened by MS/MS), the selected respondent will also provide notification to the designated Metabolic Genetics clinic in order to facilitate the coordination of diagnostic and treatment services with primary care physicians and parents.

(2) In the case of congenital hypothyroidism or congenital adrenal hyperplasia, the selected respondent will also provide a copy of the notification to the attending physician at the designated Pediatric Endocrinology clinic to facilitate coordination of diagnostic and treatment services.

(3) In the case of sickle cell disease or disease status of another hemoglobinopathy, the selected respondent will also provide a copy of the notification to the attending physician and to the designated sickle cell disease follow-up provider in order to facilitate coordination of diagnostic and treatment services.

The written notice of a confirmed positive test result must contain, at least, the following information:

- Infant's name\* and hospital identification number
- Infant's date of birth
- Date of specimen collection
- Time of first protein feeding
- Infant's status at time of specimen collection (premature, transfused, on antibiotics, sick or normal)
- Birthing facility/collection source's name and ID number
- Responsible physician's name or license number
- Physician's office address, if available
- Physician's office telephone number, if available
- Name of local health official contacted, if applicable
- \*Mother's name
- \*Father's name, if available
- \*Mother's home address, if available
- \*Father's home address, if different and available
- \*Mother's/father's home telephone number, if available
- Date confirmatory specimen received at laboratory
- Time of confirmatory report completion
- Results of confirmatory newborn screening tests
- Date of specimen analysis report
- Date telephone notification was provided
- Name and telephone number of the contact person for the birthing facility/collection source, physician and ISDH/Genomics and NBS
- Date of each specimen collection
- Copies of the laboratory report for each specimen collection
- Indication, if applicable, of when treatment began
- Further actions recommended or referrals provided
- Name and telephone number of selected respondent's contact



*\* - Infant name and mother/father information utilized in correspondence from the selected respondent should reflect what is listed on the infant's current legal birth certificate. Correspondence for infants who are in the process of being adopted should utilize the birth mother/birth father information as listed on the original birth certificate until the new, adoptive birth certificate has been issued and recorded with Indiana's Vital Records Registry.*

*I. Response to Requests from Birthing Facilities/Collection Sources/Physicians/State Departments of Health*

- 522 If a birthing facility/collection source or physician determines that a specimen has been obtained but that there are no results available in the newborn's medical records within ten (10) days after discharge, the birthing facility/collection source or physician will obtain verbal confirmation of the results from the selected respondent by telephone and request that another written copy be sent. The selected respondent will provide a copy of the test results as requested, without charge, in accordance with Function 3.
- 523 Requests for newborn screening results submitted by birthing facilities/collection sources, physicians or other health care providers or state departments of health will be reviewed by the selected respondent. These requests should include, at a minimum, the infant's name, infant's date of birth, infant's birth mother's name and the name of the infant's birthing facility/collection source. If the requestor includes all of the above information and the requestor's right to access can be verified, the selected respondent may release a copy of the newborn screening results to the requestor. If the requestor's right to access cannot be verified, the selected respondent will be responsible for either obtaining completed information or denying the request.
- 524 Requests for newborn screening results submitted by parent(s)/legal guardian(s) of infants or any other entity (including, but not limited to, researchers and other individuals who do not represent a birthing facility, physician's office or state department of health) must be immediately referred to ISDH/Genomics and NBS. The selected respondent cannot verify or release any information about these requests.
- 525 Requests for any other type of newborn screening data or information (including, but not limited to, requests for de-identified aggregate data and requests that are submitted by researchers, members of the general public, media sources and legislative representatives) must be immediately referred to ISDH/Genomics and NBS. The selected respondent cannot verify or release any information about these requests.

## Function 6: Laboratory Reports

### Overview

410 IAC 3-3-4 and 3-3-5 require laboratories performing newborn screening to provide at least monthly reports of its screening activities to ISDH/Genomics and NBS. The selected respondent will provide reports to ISDH/Genomics and NBS pertaining to its operations in support of the newborn screening programs as indicated below.

All reports will identify the period being reported, will be submitted electronically, and are to be submitted in the timeframe and format requested by ISDH/Genomics and NBS.

Section A below lists the reports that the selected respondent will be required to submit to ISDH/Genomics and NBS as noted (weekly, monthly, quarterly, etc.). Section B below lists the reports that ISDH/Genomics and NBS may request of the selected respondent, but that will not be required on a regular basis. For reports in section B below, the selected respondent is expected, as part of its internal quality assurance program, to maintain an electronic database that contains all of the information required for each report and to regularly evaluate these reports. ISDH/Genomics and NBS reserves the right to request additional reports or remove reports from these lists at any time.

#### A. **Required** Newborn Screening Reports

##### 601 ***Weekly Newborn Screening Follow-up Status Report***

This report should be submitted to ISDH/Genomics and NBS electronically and will include the following information:

- Number of follow-up letters sent and phone contacts conducted (for reminder letters)
- Date and time each of the above follow-ups were conducted
- Indication of additional follow-ups needed on specific cases, including name of infant, date of birth (DOB), birthing facility/collection source, hospital ID #, name of mother, phone and address of mother, phone and address of physician, follow-up status, and other information as requested by ISDH/Genomics and NBS.

##### 602 ***Monthly NBS Statistics Report***

This report will include the following information:

- Time period covered by the report
- Number of initial screens conducted, listed by collection source
- Number of repeat screens conducted, listed by collection source
- Number of invalid specimens, listed by collection source
- Number of confirmed abnormal results, listed by collection source
- Number of presumptive positive results, listed by collection source
- Number of confirmed positive results, listed by collection source

##### 603 ***Monthly Invalid Specimens—Patient Detail Report***

This report will include the following information for all invalid screens:

- Time period covered by the report
- Infant's name
- Infant's ID number

- Name of collection source and ID number
- Date unacceptable specimen drawn
- Name of mother
- Address of mother
- Date of repeat sample or indication of no follow-up screen
- Subtotal of unacceptable screens by collection source
- Total number of unacceptable specimens

604 ***Monthly Presumptive Positive Results – Patient Detail Report***

This report will include the following information for all presumptive positive screening results:

- Time period covered by the report
- Type of disorder identified as presumptive positive
- Infant’s name
- Infant’s ID number
- Name of collection source and ID number
- Data regarding the nature of the presumptive positive identification, indicating specific status such as classical, carrier, or variant status (e.g., classic PKU, Hgb FAS, Hgb FS, galactosemia variant)
- Subtotals of presumptive positive results, listed by disorder
- Subtotals of presumptive positive results, listed by collection source
- Total number of all presumptive positive results

605 ***Monthly Confirmed Positive Results – Patient Detail Report***

This report will include the following information for all confirmed positive screening results:

- Time period covered by the report
- Type of confirmed disorder
- Infant’s name
- Infant’s ID number
- Name of collection source and ID number
- Data as to the type of disorder identified, indicating the specific status such as classical, carrier, or variant status (e.g., classic PKU, Hgb FAS, Hgb FS, galactosemia variant)
- Subtotals of confirmed positive results, listed by disorder
- Subtotals of confirmed positive results, listed by collection source
- Total number of all confirmed positive results

606 ***Not-Screened Cases—Patient Detail Report (to be submitted weekly)***

This report should be submitted electronically and will include the following information:

- Infant’s name
- Infant’s ID number
- Name of collection source and ID number
- Name of mother
- Phone and address of mother
- Mother’s county of residence
- Name of physician
- Phone and address of physician

607 ***Not-Passed Cases – Patient Detail Report (to be submitted weekly)***

This report should be submitted electronically and will include the following information:

- Infant’s name
- Infant’s ID number
- Name of collection source and ID number
- Name of mother
- Phone and address of mother
- Mother’s county of residence
- Name of physician
- Phone and address of physician
- Screening status (e.g., ear passed/not passed)

608 ***Monthly UNHS Statistics Report***

This report will include the following information:

- Number of hearing screens conducted, listed by collection source
- Number of repeat screens conducted, listed by collection source
- Number of infants passed screens, listed by collection source
- Number of infants who did not pass screens, listed by collection source
- Number of infants not screened, listed by collection source

609 ***Quarterly Newborn Screening Fee Summary Report***

This report should be submitted to ISDH/Genomics and NBS electronically and will include the following information:

- Time period covered by the report
- Number of initial screens conducted, listed by DOB
- Number of repeat screens conducted
- Total number of all screens conducted
- Number of initial screens for indigents, listed separately by collection source
- NBS fees collected and transferred to ISDH. Total amount owed ISDH is \$30 for each initial screen conducted.
- Photocopies of the invoices/check stubs submitted to ISDH (to be submitted via fax to 317-234-2995, ATTN: Director of Genomics & NBS)

*B. Other Newborn Screening Reports*

610 ***Monthly Elapsed Time Processing Summary Report***

This report will list the number of hours of elapsed time from receipt to completion of analysis for each specimen received by the selected respondent within the given time period.

611 ***Monthly Notification Summary Report***

This report will list the number of hours of elapsed time from completion of specimen analysis to the mailing of the reports to collection sources for each specimen received by the selected respondent within the given time period. The name of the infant will also be provided for all instances in which notification was sent more than 24 hours after laboratory analysis was completed.

612 ***Monthly Transit Turnaround Time Report***

This report will list the number of screening specimens, by collection source, that were received by the selected respondent more than five (5) days after being collected by the collection source within the given time period.

613 ***Monthly Transit Turnaround Time – Patient Detail Report***

This report will include the following information for all screening specimens that were received by the selected respondent more than five (5) days after being collected by the collection source within the given time period.

- Time period covered by the report
- Name of collection source and ID number
- Infant's name
- Date of birth
- Date specimen was drawn
- Date specimen was received by the selected respondent
- Was the specimen quality/quantity acceptable (Yes or No)?
- Were the screen results normal (Yes or No)?

614 ***Monthly Comprehensive Turnaround Time Report***

This report will list the number of initial screening specimens, by collection source, whose laboratory reports are generated by the selected respondent more than ten (10) days after the infant's birth. This report will also list which of these specimens were received by the selected respondent more than five days after being collected by the collection source.

615 ***Monthly Comprehensive Turnaround Time—Patient Detail Report***

This report will include the following information for all initial screening specimens whose laboratory reports are generated by the selected respondent more than ten (10) days after the infant's birth.

- Name of collection source and ID number
- Infant's name
- Date of birth
- Date specimen was drawn
- Date specimen was received by the selected respondent
- Date Specimen Laboratory Report was generated
- Were the screen results normal (Yes or No)?

616 The selected respondent must be capable of providing analytical reports pertaining to the various disorders tested. The State will review proposals with consideration given to the respondent showing strong analytical capabilities.

***C. Other Data Submissions***

617 The selected respondent will submit all data collected from paper kits, laboratory test results and other statistics electronically and in a format compatible with ISDH format (Function 2). All data submissions should be completed by the selected respondent within the timeframe specified by ISDH.

## *Function 7: Statistical Compilations/Annual Report*

### Overview

The selected respondent, as part of its internal quality assurance program, is expected to maintain statistics on its own laboratory operations, as well as on the NBS activities of the birthing facilities/collection sources that submit newborn screening specimens.

In order to support ISDH's ability to completely assess the statewide NBS program, the selected respondent will submit to ISDH/Genomics and NBS the following annual statistics on each collection source and on overall program performance. These statistical reports are in addition to those reports required to be submitted by the selected respondent as described in Function 6.

### *A. Annual NBS Statistical Report*

- 701 The selected respondent will submit these reports to ISDH/Genomics and NBS no later than March 1, each year (covering the period of the preceding January through December). This report will also include cumulative statistics for the entire calendar year.
- 702 All reports will identify the time period being reported. These reports will include information pertaining to the operation of the newborn screening program for each collection source and overall program performance for at least the following areas:
- Number of initial screens conducted
  - Number of repeat screens conducted
  - Total number of all screens conducted
  - Average age of infants when initial specimen collected
  - Percentage of infants who did not require any repeat screens
- Of those infants requiring a repeat screen to ensure a valid test, the respondent will report:
- Percentage receiving repeat screen before two weeks of age
  - Percentage receiving repeat screens after two weeks of age, but before three weeks
  - Percentage receiving repeat screens after three weeks of age
  - Percentage not receiving required repeat screen
  - Number of required confirmatory screens not conducted
  - Number of screening specimens that were received by the selected respondent more than five (5) days after being collected by the birthing facility/collection source
  - Number of initial screens for which payment is not received
  - Number of invalid specimens
  - Number of confirmed abnormal results
  - Number of presumptive positive results, listed by disorder
  - Number of confirmed positive results, listed by disorder
- 703 In addition to those items listed in element 702 above, the selected respondent will provide the following information based on its own laboratory operations:
- Average number of hours of elapsed time from receipt to completion of analysis for a specimen received by the selected respondent

- Average number of hours of elapsed time from completion of specimen analysis to mailing of the report to hospitals/physicians
- Total number of instances in which notification was sent more than 24 hours after laboratory analysis was completed

704 The respondent will provide ISDH/Genomics and NBS with a breakdown of the accuracy of demographic data completion on the filter paper kits. This will include a summary of errors committed by collection sources, as well as data entry/clerical errors committed by the selected respondent's staff.

*B. Recommended Additional NBS Statistical Reports*

705 In addition to the statistical compilation listed above, respondents are encouraged to submit additional statistical indices that they feel would contribute to an assessment of the Genomics and NBS Program.

706 The selected respondent will assist ISDH/Genomics and NBS to complete national surveys and statistical reports upon request.

*Function 8: Newborn Screening Fund Collection/Processing/Reporting*

Overview

The Indiana State Department of Health Newborn Screening Program is funded by the collection of a \$30 newborn screening surcharge for each initial newborn screen performed. The selected respondent will assess and collect the fees from birthing facilities/collection sources, physicians and midwives. The accumulated collections from the newborn screening fees will be submitted on a monthly basis by the selected respondent to the Division of Finance at the ISDH. Payment will be postmarked no later than five (5) days after the close of the preceding month. The selected respondent will also submit a monthly report on the number of newborns screened as described in Function 6. Revenues submitted by the selected respondent to ISDH will correspond with the number of newborns screened.

- 801 The amount to be paid to ISDH each month for the Newborn Screening Fund is determined as follows: determine the total number of screens performed during the month, then subtract from this figure the number of repeat screens performed during that month. The difference between the total number of screens performed and total number of repeat screens performed represents total number of initial screens drawn. The total amount owed ISDH is this number of initial screens multiplied by \$30. This amount must equal the amount of the monthly check submitted to ISDH.
- 802 Payment of the newborn screening fee owed to ISDH, as identified on the laboratory's Monthly Summary Newborn Screening Fee Report, will be postmarked no later than five (5) days after the close of the preceding month.
- 803 The selected respondent's invoice/check stub submitted with the payment must read "Newborn Screening Program Terms." The selected respondent will forward the check for the monthly fees, together with a copy of the monthly Newborn Screening Fee Report, to:  
Indiana State Department of Health  
ATTN: Cashier's Office  
2 North Meridian Street  
Suite 200  
Indianapolis, IN 46204
- 804 A photocopy of each submitted invoice/check stub will be submitted on a monthly basis to:  
Indiana State Department of Health  
ATTN: Genomics and Newborn Screening Program  
2 North Meridian Street, Section 7F  
Indianapolis, IN 46204



## *Function 9: NBS Laboratory In-Service and Educational Requirements*

### Overview

Upon the award of the contract for newborn screening laboratory services, the selected respondent must be prepared to provide information and in-service presentations to birthing facilities/collection sources, physicians, midwives, local public health officials or other health care providers who may utilize its services. The selected respondent must also be prepared to provide information regarding newborn screening to the public.

901 ISDH will have the final right of approval on the content and design of all educational materials regarding the conduct of newborn screening.

902 *In-Service and Educational Activities for Health Care Providers*

Approximately 24 presentations must be performed each year in coordination with ISDH/Genomics and NBS. General in-service presentations must include the following information:

- Discussion of rules and regulations pertaining to the Newborn Screening Program in Indiana.
- Discussion of how to complete the filter paper kit, with emphasis on specific items/data elements which the selected respondent has regularly noted to be inaccurate or incomplete.
- Discussion of particular blood collection techniques appropriate to the newborn screening heel stick and the application of blood to the filter paper kit. This will include a reminder that use of capillary tubes for NBS collection is not recommended, instruction on drying and transportation procedures for the specimens and detailed information related to the time frame requirements for the specimen to be received by the selected respondent.
- General discussion of newborn screening laboratory philosophy and operating experience.
- Discussion of the laboratory testing procedures and laboratory quality control procedures, with emphasis on critical elements in obtaining an accurate result.
- Discussion of the various follow-up requirements, forms and procedures utilized by the selected respondent.
- Discussion of the laboratory result reports that are provided to the collection sources by the selected respondent.
- Discussion of fees assessed and reports issued to the collection sources.

903 *NBS Guidance Booklet for Newborn Screening Collection Sources*

In addition to the in-service training presentations, the selected respondent must prepare, publish and distribute an informational booklet to all collection sources explaining the steps and processes required to meet its responsibilities under the Newborn Screening Program. This guidance booklet will include at least the following information:

- General program information
  - Rules and regulations pertaining to screening newborns
  - General discussion of NBS laboratory philosophy and operating experience
- Summary of screening criteria
  - Explanation of parents'/legal guardians' right of informed refusal based on religious objections
- Collection schedule

- How to collect and submit blood specimens
  - Explanation of how to complete and submit the collection kit, with emphasis on specific items/data elements which the selected respondent has regularly noted to be inaccurate or incomplete. This will include instruction on procedures for blood spot collection.
  - Notification that use of capillary tubes in newborn screening specimen collection is not recommended in Indiana
- Transportation of specimens
  - This will include instruction on storage and transportation procedures for the specimens, as well as detailing the time requirements for the specimen to be received by the selected respondent.
- Explanation of the laboratory testing procedures and laboratory quality control procedures, with emphasis on critical elements in obtaining an accurate result.
- Laboratory result reports
  - Explanation of the laboratory result reports that are provided to the collection sources by the selected respondent.
- Explanation of follow-up forms and procedures utilized by the selected respondent.
- Notification that the collection source is responsible for reporting and providing follow-up for screening results and providing information to the NBS Laboratory.
- Discussion of potential follow-up responsibility by physicians/birthing facilities in situations involving positive screening results.
- Discussion of monthly reporting requirements to ISDH/Genomics and NBS by responsible physicians/birthing facilities.
- Explanation of administrative reports issued to the collection sources.

ISDH/Genomics and NBS will have the final right of approval on the design, content and quality of all materials created for distribution to collection sources.

904 *Coordination of Corrective Action with Collection Sources*

The selected respondent will monitor specimens received from collection sources to ensure compliance with Indiana NBS statutes, regulations and policies, as well as with the selected respondent's procedures and operating guidelines.

The selected respondent will be prepared to identify recurring difficulties or problems stemming from certain collection sources and will initiate/participate in discussions with birthing facilities, physicians, midwives, etc. in order to resolve these problems. Types of problems can include, but are not limited to, improper completion of demographic data, higher than normal incidence of invalid specimens and early discharges without a blood draw. Any continued violation of ISDH/Genomics and NBS's or the selected respondent's NBS program requirements must be reported to ISDH/Genomics and NBS for further action.

905 *Newborn Screening General Education and Information Pamphlet*

The selected respondent must prepare, publish and distribute an informational pamphlet explaining Indiana's Newborn Screening Program in general terms. The selected respondent will provide a supply of this pamphlet to all NBS collection sources, as well as to other health care providers. This guidance booklet is intended to be handed out to expectant mothers and other members of the lay public, and will include at least the following information:

- General program information
- List of disorders included in Indiana's NBS
- Explanation of the importance of newborn screening for the infant's health
- Explanation of notification procedures for test results

ISDH/Genomics and NBS will have the final right of approval on the design, content and quality of all materials created for distribution to collection sources and health care providers.

906 *Newborn Screening Site Visits and Informational Seminars*

The selected respondent will be prepared to participate with ISDH/Genomics and NBS in any educational or informational seminars (limited to a maximum of four per year) that may be held to discuss newborn screening or genetics. The selected respondent will be responsible for all transportation, salaries and reimbursable travel expenses incurred by its staff while participating in these seminars or while supporting the in-service training as listed above.

## *Function 10: Price*

### Overview

The information requested in this Functional area is required to maintain service levels currently provided to the Indiana public. Costs for this contract performance are paid through individual patient fees collected by birthing facilities/collection sources. Although the State is not paying for this contract directly, by designating a single laboratory that hospitals must use to process newborn screening blood specimens, the State has assumed a fiduciary responsibility to birthing facilities/collection sources and patients concerning the cost of the program. In this view, the individual patient's cost for the laboratory screening procedure is more pertinent than the total annual cost.

- 1001 The unit price per initial screening (entire battery) that the selected respondent will charge Indiana birthing facilities/collection sources for laboratory services will remain in force throughout the term of the contract unless ISDH authorizes, in writing, a change in the fee charged.
- 1002 The selected respondent will be required to perform repeat tests as required by ISDH rules or regulations. The selected respondent will not invoice any patient, birthing facility/collection source, physician, clinic, local health official or midwife any charge for repeat test analyses and/or reporting. The selected respondent must anticipate that repeat testing will not exceed 30,000 neonates annually.
- 1003 Revenues generated by the selected respondent in performance of this contract must remain with the project and not be utilized by the selected respondent for any purpose unrelated to improving the Indiana Newborn Screening Program.
- 1004 The selected respondent will collect the ISDH screening surcharge for all infants receiving an initial screen as detailed in Function 8. No surcharge will be assessed, collected or reported for infants receiving repeat screens.
- 1005 The selected respondent will designate at least one (1) individual in its organization to serve as the primary point of contact between the selected respondent and ISDH/Genomics and NBS. ISDH reserves the right to approve the respondent's contact individual. ISDH also reserves the right to request that the selected respondent change the contact individual, if ISDH so desires. The selected respondent will then assign another individual to serve as the primary contact. ISDH will also have the right to approve or disapprove any replacements named by the selected respondent.
- 1006 In order to meet and interact with the selected respondent's staff and to conduct oversight and monitoring responsibilities, the selected respondent will, upon request of ISDH, pay quarterly the round trip cost of transportation for two employees of ISDH to the selected respondent's facility. The mode of transportation will be determined by ISDH. In addition, the selected respondent will assume the costs of two nights' lodging, meals and transportation for the ISDH employees while conducting business at the selected respondent's facility. This provision will apply only in the circumstance that the selected respondent's facility is beyond normal commuting distance (50 miles) from the ISDH/Genomics and NBS office location.

- 1007 In order to improve communication between the designated laboratory and Indiana physicians, birthing facilities, midwives and local health officials, the selected respondent will, for at least five (5) working days each month, maintain a staff person in Indiana to meet with individuals involved with the Indiana Newborn Screening Program. The selected respondent will be responsible for all transportation, salaries and reimbursable travel expenses incurred by its staff while conducting business in Indiana.

Each respondent must provide the following additional information:

- 1008 Each respondent must indicate the unit price per initial screening (entire battery) that it will charge Indiana birthing facilities/collection sources and midwives for laboratory services utilized in detecting biotinidase deficiency, congenital adrenal hyperplasia, congenital hypothyroidism, cystic fibrosis (IRT and DNA), galactosemia, hemoglobinopathies, homocystinuria, maple syrup urine disease, phenylketonuria and other conditions screened by tandem mass spectrometry described in the review of Function 3, per patient specimen. Do not include the current ISDH screening surcharge (\$30) in this indicated price.
- 1009 Each respondent must provide a breakdown of the laboratory analysis charges, indicating the portion of the total charges that are related to each specific condition included in Indiana's newborn screen, to each individual test conducted and any other identifiable factors.
- 1010 Each respondent must provide a complete budget of overall operating expenses associated with administering the Indiana NBS laboratory services program. This will include the number, duties, qualifications and salary of staff members assigned to this program, operating costs and an estimate of the profit margin expected from the program.
- 1011 Each respondent will submit a conversion plan outlining the proposed steps and time frames involved in transferring all newborn screening testing from the current laboratory to its facility.
- 1012 Each respondent should have a disaster plan in place to ensure the continued operation of newborn screening laboratory services in the event of extraordinary circumstances, including, but not limited to, natural disasters, arson, fire, criminal activity, vandalism, financial insolvency, pandemic flu, bioterrorism and failure to meet statutory or regulatory requirements. This plan should address how, if necessary, laboratory screening activities will be transferred to new management or facilities and how and where data will be backed up in the event of a disaster. **Each respondent will submit a copy of this disaster plan with the contract proposal.**

## *Function 11: Quality Assurance (QA)*

### Overview

Provision of a Quality Assurance (QA) program for newborn screening is required under the provision of Indiana Code 16-41-17 and 410 Indiana Administrative Code 3-3-4.

Laboratory screening of selected newborn genetic disorders plays an important role in identification of affected infants. Although these disorders are extremely rare, false negative reporting that results in “missed cases” can have a catastrophic effect on the affected newborns, the screening laboratory and the state regulatory agency.

In order to avoid these catastrophic consequences, the test procedures must be performed in a laboratory capable of producing reliable test results with no false negatives. An effective Quality Assurance program is essential in order to accomplish this goal.

#### *A. Documents the selected respondent will be routinely required to provide to ISDH*

- 1101 The selected respondent will provide to ISDH/Genomics and NBS the following:
- Copies of the current QA plan and any revisions as generated.
  - Copies of the current NBS laboratory Standard Operating Procedures (SOPs) and any revisions as generated.
  - Copies of all internal QA reports as generated.
  - Copies of the results of any CLIA inspections, CAP inspections/proficiency testing and any NRC inspections concerning the laboratory’s operations, as they are received.

#### *B. ISDH may choose to implement a Proficiency Testing (PT) Program*

- 1102 As part of the total QA program, ISDH may choose to implement a proficiency testing (PT) program wherein ISDH will prepare and validate PT materials. The decision regarding whether a PT program is beneficial will be made in consultation with the selected respondent. If such a program is implemented, the selected respondent will test the PT materials by routine screening tests and report the results to ISDH.
- 1103 ISDH may conduct site visits to the selected respondent’s laboratory as considered advisable by ISDH after coordination with selected respondent’s personnel.

Each respondent must provide the following additional information for paragraphs C through N below:

#### *C. Standard Operating Procedures*

- 1104 Provide a copy of the Standard Operating Procedure (SOP) to be used to conduct the newborn screening. At a minimum, this SOP must include the following provisions:
- Procedures for the review/update of the SOP at least annually. This updated procedure will include the requirement for the SOP to be signed off by the technical supervisor and is subject to review by ISDH.
  - Flow charts of the testing procedures for each test used.
  - A description of the basis of selection of negative, borderline, and positive controls.

- A description of the criteria for rejection of a specimen.
- A description of the criteria for requiring a repeat specimen.
- Procedures to report normal, valid test results.
- Procedures to report test results when control values are outside acceptable ranges.
- Procedures to report/follow-up presumptive positive test results.
- Confirmatory tests to be used and procedures to report confirmatory test results.

#### *D. Quality Assurance*

- 1105 Provide a copy of the (proposed) newborn screening Quality Assurance plan.
- 1106 Provide a copy of the latest results the selected respondent has received from CLIA inspections, CAP inspections/proficiency testing and any NRC inspections that may have been conducted concerning the laboratory's operations.

#### *E. Safety Guidelines*

- 1107 Provide a copy of laboratory safety guidelines for blood and body fluids, including protective techniques and procedures to clean up blood or serum spills.

#### *F. Personnel Quality Assurance*

- 1108 Describe criteria for selection of the laboratory personnel.
- 1109 Describe training of personnel when new tests are adopted.
- 1110 Describe the continuing education program for laboratory personnel.
- 1111 Describe the proficiency testing program to be used for PKU, HCU, MSUD, galactosemia, hypothyroidism, hemoglobinopathies, biotinidase deficiency, CAH, CF (IRT and DNA) and other conditions screened by tandem mass spectrometry as described in the review of Function 3.

#### *G. Quality Control (QC)*

- 1112 Describe what documentation of QC performance will be available for review/inspection by ISDH upon request.
- 1113 Describe how documentation of QC performance is maintained for situations that may require such proof. This documentation will be available for review/inspection by ISDH upon request.
- 1114 Describe how information/data will be obtained and maintained to document comparability of the contract laboratory to other newborn screening laboratories nationally. This documentation will be available for review by ISDH upon request.
- 1115 Describe usage of control charts.
- 1116 Describe intra-laboratory proficiency testing program.

- 1117 Describe procedures used for routine monitoring to ensure controls are in range.
- 1118 Describe QC specifications for the media and reagents.
- 1119 Describe how laboratory reports are checked for transcription/clerical errors.

#### *H. Testing for galactosemia*

- 1120 Describe the principle of testing for galactosemia.
- 1121 Describe the test method for galactose and galactose-1-phosphate currently used for initial and for confirmatory testing, if different.
- 1122 Describe the test procedure for galactosemia, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1123 Provide references for the galactosemia test.

#### *I. Testing for biotinidase deficiency*

- 1124 Describe the principle of testing for biotinidase deficiency.
- 1125 Describe the test method for biotinidase deficiency currently used for initial and for confirmatory testing, if different.
- 1126 Describe the test procedure for biotinidase deficiency, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1127 Provide references for the biotinidase deficiency test.

#### *J. Testing for congenital adrenal hyperplasia (CAH)*

- 1128 Describe the principle of testing for congenital adrenal hyperplasia.
- 1129 Describe the test method for CAH currently used for initial and for confirmatory testing, if different.
- 1130 Describe the test procedure for CAH, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1131 Provide references for the CAH test.

#### *K. Testing for congenital hypothyroidism (CH)*

- 1132 Describe the principle of testing for CH.



- 1133 Describe the test method for CH currently used for initial and for confirmatory testing, if different.
- 1134 Describe the test procedure for CH, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1135 Provide references for the CH test.
- 1136 Describe how results of the CH test are used to determine a clinical assessment or “congenital hypothyroidism,” “other thyroid results outside normal limits” or “within normal limits.”

*L. Testing for hemoglobinopathies*

- 1137 Describe the principle of testing for hemoglobinopathies.
- 1138 Describe the test method for hemoglobinopathies currently used for initial and for confirmatory testing, if different.
- 1139 Describe the test procedure for hemoglobinopathies, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1140 Provide references for the hemoglobinopathies test.

*M. Testing for cystic fibrosis*

- 1141 Describe the principle of IRT testing for cystic fibrosis.
- 1142 Describe the test method for IRT testing for cystic fibrosis currently used for initial and for confirmatory testing, if different.
- 1143 Describe the test procedure for IRT testing for cystic fibrosis, including QC of reagents, result calculations and criteria for interpretation of test results.
- 1144 Describe the principle of DNA testing for cystic fibrosis.
- 1145 Describe the test method for DNA testing for cystic fibrosis currently used for initial and for confirmatory testing, if different. Include a list of *CFTR* mutations included in DNA panel.
- 1146 Describe the test procedure for DNA testing for cystic fibrosis, including QC of reagents, result calculations and criteria for interpretation of test results.

*N. Testing for conditions screened by MS/MS*

- 1147 Describe the principles of testing of conditions screened by tandem mass spectrometry method.

1148 Describe the test procedure for MS/MS screening.

1149 Describe the method for quality control.

## *Function 12: Additions to NBS Testing Battery*

### Overview

Potential respondents may be required to discuss their ability to implement testing of potential disease cases for severe combined immunodeficiency syndrome (SCID). ISDH/Genomics and NBS and the respondents will arrive at mutually agreed upon definitions of a potential SCID case. The following are points to consider for future discussions:

- 1201 Include the type of test procedure that would be utilized for each condition.
- 1202 Discuss the types of pre-implementation testing that would be undertaken to ensure appropriate results when actual testing began.
- 1203 Discuss procedures, principles, interpretations, values and references that might be utilized in implementing the new test.
- 1204 Discuss time frames that would be required to fully implement the test.
- 1205 Discuss what testing materials and equipment are expected to be utilized. Explain what capital equipment expenses would be required in implementing the test.
- 1206 Provide details about the expected monthly operating expenses associated with the new test for each condition.
- 1207 Provide an estimate of the increase in laboratory analysis fees that would be passed on to hospitals and birthing centers for each condition.
- 1208 Potential respondents must document whether they currently engage in testing for SCID. If so, please expound upon current experiences in the area and lessons learned that must be incorporated in future planning.

*Information Required On Filter Paper Kit*

**Data Elements Required**

**Edits**

1. Infant's Last Name	Mandatory Keying
2. Infant's First Name or Initial	Key If Available
3. Date of Birth	Mandatory Keying
4. Sex	Mandatory Keying
5. Infant's Hospital Identification Number	Mandatory Keying
6. Time of Birth (Military Time)	Mandatory Keying
7. Mother's Name	Mandatory Keying
8. Father's, or Other Relative's Name	Key If Available
9. Mother's Address	Mandatory Keying
10. City	Mandatory Keying
11. State	Mandatory Keying
12. Zip	Mandatory Keying
13. <u>Race:</u>	Key One
a. White	
b. Black or African American	
c. American Indian or Alaska Native	
d. Asian, Hawaiian or Other Pacific Islander	
e. Other/Unknown	
14. <u>Ethnicity:</u>	Key One
a. Hispanic or Latino	
b. Non-Hispanic or Latino	
c. Other/Unknown	
15. Mother's Telephone Number	Mandatory Keying
16. Hospital/Birthing Institution	Mandatory Keying
17. Physician License Number	Mandatory Keying
18. Physician Office Address	Not Keyed
19. Physician City	Not Keyed
20. Physician State	Not Keyed
21. Physician Zip	Not Keyed
22. Physician Office Telephone	Mandatory Keying
23. Date of Screen	Mandatory Keying
24. Time of Screen (Military Time)	Mandatory Keying
25. Date of First Protein Feeding	Mandatory Keying
26. Time of First Protein Feeding	Mandatory Keying
27. Test Code (Initial, Repeat)	Mandatory Keying
28. Birth weight	Mandatory Keying
29. Collection Source ID	Mandatory Keying
30. > 48 Hours	Mandatory Keying
31. > 24 Hours Protein Feeding	Mandatory Keying
32. <u>Status:</u>	Key All Applicable
a. Premature – Indicate gestational age	
b. On Antibiotics	
c. Transfused	
d. Normal	

- |   |                             |
|---|-----------------------------|
| 33. 1st Test < 48 Hours                       | Mandatory Keying            |
| 34. 1st Test > 48 Hours                       | Mandatory Keying            |
| 35. 2nd Test                                  | Mandatory Keying            |
| 36. Previously Abnormal Result                | Key If Applicable           |
| 37. Previously QNS                            | Key If Applicable           |
| 38. <u>Test Results:</u>                      |                             |
| a. Screening Test Normal                      | Key If Applicable           |
| b. Screening Test Presumptive Positive        | Indicate Test               |
| c. Screening Test Confirmed Positive          | Indicate Test               |
| d. Screening Test Abnormal                    | Indicate Test If Applicable |
| 39. Other Tests                               | If Applicable               |
| 40. Previous Test Number                      | Key If Applicable           |
| 41. <u>Feeding Type:</u>                      | Key Type(s)                 |
| a. Lactose Formula                            |                             |
| b. Soy Formula                                |                             |
| c. Breast                                     |                             |
| d. NPO  |                             |
| 42. System Control Number                     | Mandatory Keying            |
| 43. Checked By                                | Key Initials                |
| 44. Specimen Rejected for Reason              | Key Reason                  |
| 45. Filter Paper Circles for Blood Collection | Mandatory                   |
| 46. Mother's Age or Birth Date                | Key If Available            |

Insert sheet for newborn hearing screening information

- 47. Hearing Screening Conduct Time
- 48. Hearing Screening Status: Passed
- 49. Hearing Screening Status: Not Passed
- 50. Hearing Screening Not Passed: Right Ear
- 51. Hearing Screening Not Passed: Left Ear

### Locations of Indiana Birthing Facilities (February 2011)

Hospital	Street Address	City	State	Zip
Adams County Memorial Hospital	1100 Mercer Ave.	Decatur	IN	46733-2324
Auburn Birthing Center				
Believe Midwifery Services	118 W. Main Street	Thorntown	IN	46071
Bluffton Regional Medical Center	303 S. Main St.	Bluffton	IN	46714-3697
Cameron Memorial Community Hospital	416 E. Maumee St. P. O. Box 901	Angola	IN	46703-2015
Clark Memorial Hospital	1220 Missouri Ave. P. O. Box 69	Jeffersonville	IN	47130-0069
Columbus Regional Hospital	2400 E. 17th St.	Columbus	IN	47201-5360
Community Hospital of Anderson	1515 N. Madison Ave. P. O. Box 2680	Anderson	IN	46011-3457
Community Hospital of Bremen	1020 High Road	Bremen	IN	46506-1699
Community Hospital of Indianapolis - East	1500 N. Ritter Ave.	Indianapolis	IN	46219-3095
Community Hospital of Indianapolis - North	7150 Clearvista Dr.	Indianapolis	IN	46256-4699
Community Hospital of Indianapolis - South	1402 E. Co. Line Rd. P. O. Box 4701	Indianapolis	IN	46227-0999
Community Hospital of Munster	901 Mac Arthur Blvd. C/O Reference Lab	Munster	IN	46321-2959
Daviess Community Hospital	1314 E. Walnut P. O. Box 760	Washington	IN	47501-2190
Dearborn County Hospital	600 Wilson Creek Rd.	Lawrenceburg	IN	47025-1199
Decatur County Memorial Hospital	720 N. Lincoln Ave.	Greensburg	IN	47240-1398
DeKalb Memorial Hospital	1316 E. 7th St. P. O. Box 542	Auburn	IN	46706-9212
Dukes Memorial Hospital	275 W. 12th St.	Peru	IN	46970-1698
Dupont Hospital	2520 E. Dupont Rd.	Fort Wayne	IN	46825-1675
Elkhart General Hospital	600 E. Blvd. P. O. Box 1329	Elkhart	IN	46514-1111
Fayette Regional Health System	1941 Virginia Ave.	Connersville	IN	47331-2893
Floyd Memorial Hospital	1850 State St.	New Albany	IN	47150-4997
Franciscan Alliance – St. Anthony Health (Crown Point)	1201 S. Main St.	Crown Point	IN	46307
Franciscan Alliance – St. Anthony Health (Michigan City)	301 W. Homer St.	Michigan City	IN	46360-4358
Franciscan Alliance – St. Elizabeth Health (Lafayette East)	1701 S. Creasy Lane	Lafayette	IN	47905
Franciscan Alliance – St. Francis Health (Indianapolis)	8111 S. Emerson Ave.	Indianapolis	IN	46237
Franciscan Alliance – St. Francis Health ( Mooresville)	1201 Hadley Rd.	Mooresville	IN	46158

Franciscan Alliance – St. Margaret Health (Dyer)	24 Joliet Street		Dyer	IN	46311
Franciscan Alliance – St. Margaret Health (Hammond)	5454 Hohman Ave.		Hammond	IN	46320-1999
Gina Herman D/B/A Southern Indiana Homebirth	8104 Lincoln Ave, Unit B		Evansville	IN	47715
Good Samaritan Hospital	520 S. 7th St.		Vincennes	IN	47591-1068
Goshen Birthing Center	1155 Lighthouse Lane		Goshen	IN	46526
Greene County General Hospital	R R 1 Box 1000	P. O. Box 453	Linton	IN	47441-9457
Hancock Memorial Hospital - Andis Women's Unit	801 N. State St.	P. O. Box 827	Greenfield	IN	46140-1270
Harrison County Hospital	1141 Hospital Drive NW		Corydon	IN	47112-8402
Hendricks Regional Health	1000 E. Main St.	P. O. Box 409	Danville	IN	46122-1991
Henry County Memorial Hospital	1000 N. 16th St.	P. O. Box 490	New Castle	IN	47362-0490
Howard Regional Health System Hospital	3500 S. Lafountain St.	P. O. Box 9011	Kokomo	IN	46904-9011
Indiana University Health Arnett Hospital	5165 McCarty Lane		Lafayette	IN	47905
Indiana University Health Ball Memorial Hospital	2401 University Ave.		Muncie	IN	47303-3499
Indiana University Health Bloomington Hospital	601 W. 2nd St.	P. O. Box 1149	Bloomington	IN	47401-1149
Indiana University Health Goshen General Hospital	200 High Park Ave.	P. O. Box 139	Goshen	IN	46526-0139
Indiana University Health LaPorte Hospital	1007 Lincolnway	P. O. Box 250	Laporte	IN	46371-0250
Indiana University Health Methodist Hospital	1701 N. Senate Blvd.	P. O. Box 1367	Indianapolis	IN	46202-1367
Indiana University Health North Hospital	1170 N. Meridian St.		Carmel	IN	46032
Indiana University Health Paoli Hospital	642 W. Hospital Rd.	P. O. Box 499	Paoli	IN	47454-9672
Indiana University Health University Hospital	550 N. University Blvd.		Indianapolis	IN	46202
Indiana University Health West Hospital	1111 Ronald Reagan Pkwy.		Avon	IN	46123
Indiana University Health White Memorial Hospital	720 S. 6 <sup>th</sup> St.		Monticello	IN	47960
Jasper County Hospital	1104 E. Grace St.		Rensselaer	IN	47978-3296
Jay County Hospital	500 W. Votaw St.	P. O. Box 1069	Portland	IN	47371-1369
Johnson Memorial Hospital	1125 W. Jefferson St.	P. O. Box 549	Franklin	IN	46131-2140
King's Daughters Hospital	1 King's Daughter Dr.	P. O. Box 447	Madison	IN	47250-0447
Kosciusko Community Hospital	2101 E. Dubois Dr.		Warsaw	IN	46580-3210
Lutheran Hospital of Indiana	7950 W. Jefferson Blvd.		Fort Wayne	IN	46804-1677
Major Hospital	150 W. Washington St.		Shelbyville	IN	46176-1245
Margaret Mary Community Hospital	321 Mitchell Ave.	P. O. Box 226	Batesville	IN	47006-0226
Marion General Hospital	441 N. Wabash Ave.		Marion	IN	46952-2690
Memorial Hospital -	1101 Michigan Ave.	P. O. Box 7013	Logansport	IN	46947-7013

Logansport				
Memorial Hospital - South Bend	615 N. Michigan St.		South Bend IN	46601-1087
Memorial Hospital & Health Care - Jasper	800 W. 9th St.		Jasper IN	47546-2516
Methodist Hospital - Northlake Campus - Gary	600 Grant St.		Gary IN	46402-6099
Methodist Hospital - Southlake Campus - Merrillville	8701 Broadway		Merrillville IN	46410-7099
Morgan Hospital & Medical Center	2209 John R. Wooden Dr.		Martinsville IN	46151-1852
New Eden Care Center	7890 W. 100 S.		Topeka IN	46571
Parkview Hospital (Parkview Randallia)	2200 Randallia Dr.		Fort Wayne IN	46805-4699
Parkview Huntington Hospital	2001 Stults Rd.		Huntington IN	46750
Parkview LaGrange Hospital	207 N. Townline Rd.		LaGrange IN	46761-9499
Parkview Noble Hospital	951 E. Hospital Dr. P. O. Box 728		Kendallville IN	46755-0249
Parkview North Hospital	1115 Parkview Plaza Drive		Fort Wayne IN	46845
Parkview Whitley Hospital	353 N. Oak St.		Columbia City IN	46725-1697
Perry County Memorial Hospital	1 Hospital Rd.		Tell City IN	47586-1928
Porter –Valparaiso Memorial Hospital	814 Laporte Ave.		Valparaiso IN	46383-5898
Pulaski Memorial Hospital	616 E. 13th St.		Winamac IN	46996-1117
Putnam County Hospital	1542 S. Bloomington St.		Greencastle IN	46135-2297
Reid Hospital & Health Care Services	1100 Reid Parkway		Richmond IN	47374-9986
Riley Hospital for Children at Indiana University Health	702 Barnhill Dr. RM 3017		Indianapolis IN	46202
Riverview Hospital	395 Westfield Blvd. P. O. Box 220		Noblesville IN	46060-1425
Saint Catherine Hospital of East Chicago	4321 Fir St.		East Chicago IN	46312-3097
Saint John's Health System	2015 Jackson St.		Anderson IN	46016-4339
Saint Joseph Hospital/Health Care Center	1907 W. Sycamore St.		Kokomo IN	46901-4197
Saint Joseph Medical Center - Fort Wayne	700 Broadway		Fort Wayne IN	46802-1493
Saint Joseph Regional Medical Center - Mishawaka	5215 Holy Cross Parkway		Mishawaka IN	46544-1999
Saint Joseph Regional Medical Center - Plymouth	1915 Lake Ave. P. O. Box 670		Plymouth IN	46563-9393
Saint Mary Medical Center - Evansville	3700 Washington Ave.		Evansville IN	47750-5107
Saint Mary Medical Center - Hobart	1500 S. Lake Park Ave.		Hobart IN	46342-6699
Saint Vincent Carmel Hospital	13500 N. Meridian		Carmel IN	46032
Saint Vincent Dunn	1600 23 <sup>rd</sup> Street		Bedford IN	47421
Saint Vincent Frankfort Hospital	1300 S. Jackson St. P. O. Box 669		Frankfort IN	46041-0669



Saint Vincent Randolph Hospital	473 Greenville Ave.	P. O. Box 407	Winchester	IN	47394
Saint Vincent Women's Hospital	8111 Township Line Rd.	P. O. Box 80430	Indianapolis	IN	46260
Schneck Medical Center	411 W. Tipton St.		Seymour	IN	47274
Scott County Memorial Hospital	1451 N. Gardner St.		Scottsburg	IN	47170
Sullivan County Community Hospital	2200 N. Section St.		Sullivan	IN	47441
Terre Haute Regional Hospital	3901 S. 7th St.		Terre Haute	IN	47802-4299
The Women's Hospital (Deaconess)	4199 Gateway Blvd		Newburgh	IN	47630
Union Hospital -Terre Haute	1606 N. 7th St.		Terre Haute	IN	47804-2780
Wishard Memorial Hospital	1001 W. 10th St.	Labor/Delivery F3	Indianapolis	IN	46202-2879
Witham Health Services	2605 N. Lebanon St		Lebanon	IN	46052
Woodlawn Hospital	1400 E. Ninth St.		Rochester	IN	46975-8937