

Questions and Answers Received re: Newborn Screening testing and Reporting RFP

January 14, 2019

RFP Section	Page	Question and answer
2.2 Scope of Services	4	<p>Will the Mississippi Department of Health kindly provide Appendix A referenced in this section?</p> <p>A: Please see attached appendices.</p>
2.2.1.1 (2)- Detailed Minimum Specifications	5	<p>The DBS card is referenced in Attachment C. However, Attachment C does not have an image of the card. Will the Mississippi Department of Health kindly provide Attachment C that contains an image of the card?</p> <p>A: Please see attached appendices.</p>
2.2.1.1 (4) - Detailed Minimum Specifications	6	<p>Pompe was not included in the list of conditions. Will the Mississippi Department of Health kindly confirm that is the intent and the complete list of conditions is included in this section? Otherwise, please provide a detailed list of all conditions desired.</p> <p>A: Yes, Pompe is included in the list of conditions for Mississippi Newborn Screening. The Mississippi Newborn Genetic Screening Panel consist of: Propionic acidemia, Methylmalonic acidemia (methylmalonyl-CoA mutase), Methylmalonic acidemia (cobalamin disorders), Isovaleric acidemia, 3-Methylcrotonyl-CoA carboxylase deficiency, 3-Hydroxy-3-methylglutaric aciduria, Holocarboxylase synthase deficiency, β-Ketothiolase deficiency, Glutaric acidemia type I, Carnitine uptake defect/carnitine transport defect, Medium-chain acyl-CoA dehydrogenase deficiency, Very long-chain acyl-CoA dehydrogenase deficiency, Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency, Trifunctional protein deficiency, Argininosuccinic aciduria, Citrullinemia, type I, Maple syrup urine disease, Homocystinuria, Classic phenylketonuria, Tyrosinemia, type I, Primary congenital hypothyroidism, Congenital adrenal hyperplasia, S,S disease (Sickle cell anemia), S, β-thalassemia,S,C disease, Biotinidase deficiency, Cystic fibrosis, Classic galactosemia, Severe Combined Immunodeficiencies, Pompe Disease, Methylmalonic acidemia with homocystinuria, Malonic acidemia, Isobutyrylglycinuria, 2-Methylbutyrylglycinuria,3-Methylglutaconic aciduria, 2-Methyl-3-hydroxybutyric aciduria, Short-chain acyl-CoA dehydrogenase deficiency, Medium/short-chain L-3-hydroxyacl-CoA dehydrogenase deficiency, Glutaric acidemia type II, Medium-chain ketoacyl-CoA thiolase deficiency, 2,4 Dienoyl-CoA reductase deficiency, Carnitine palmitoyltransferase type I deficiency, Carnitine palmitoyltransferase type II deficiency, Carnitine acylcarnitine translocase deficiency, Argininemia, Citrullinemia, type II, Hypermethioninemia, Benign hyperphenylalaninemia, Biopterin defect in cofactor biosynthesis, Biopterin defect in cofactor regeneration ,Tyrosinemia, type II, Tyrosinemia, type III,Various other hemoglobinopathies, Galactoepimerase deficiency ,Galactokinase deficiency, T-cell related lymphocyte deficiencies, Mucopolysaccharidosis I (MPS1), Spinal Muscular Atrophy (SMA), andCritical Congenital Heart Disease (CCHD).</p>

2.2.1.1 (5) - Detailed Minimum Specifications	7	Will the Mississippi Department of Health kindly provide Appendix D referenced in this section? A: Please see attached appendices.
2.2.1.3 - Minimum Requirements Part III – Deliverables; Section B	12	Will the Mississippi Department of Health kindly provide more details related to Function 6 referenced in the second paragraph? A: These statistical reports are described in section A .

Appendix A

Title 15: Mississippi Department of Health

Part 4: Office of Health Services Subpart

1: Division of Genetics

Chapter 1. NEWBORN SCREENING AND BIRTH DEFECTS REGISTRY

Subchapter 1. AUTHORITY

Rule 1.1.1. Statutory Authority

1. Sections 41-21-201 and 41-21-203 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health to adopt rules and regulations to carry out the Newborn Screening and Follow-up Program for hypothyroidism, phenylketonuria (PKU), hemoglobinopathy, congenital adrenal hyperplasia (CAH), galactosemia, and other such conditions as specified by the State Board of Health as stated herein below in section Rule 1.1.2.
2. Section 41-24-1 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health to adopt rules and regulations to establish a program of testing to determine the presence of sickle cell trait or sickle cell anemia.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.1.2. Legal Requirements

1. Under the statutory authority, the physician attending a newborn child, or the persons attending a newborn child who was not attended by a physician, is held responsible for ensuring that the child is tested for the newborn screening tests as described in these rules and regulations. State law exempts from these tests any child whose parents object thereto on the grounds that such tests conflict with their religious practices or tenets.
2. Under the statutory authority, screening for congenital hypothyroidism (TSH), phenylketonuria (PKU), hemoglobinopathies (Hgb), congenital adrenal hyperplasia (CAH), and galactosemia (GAL) will be conducted statewide. Screening for the following conditions, as determined and specified by the State Board of Health, will also be conducted:
 - a. Argininemia
 - b. Argininosuccinic Aciduria (ASA Lyase Deficiency)
 - c. Biotinidase Deficiency

- x. 3-Methylglutaconyl-CoA Hydratase Deficiency
- y. Methylmalonic Acidemia (MMA)
- z. Mitochondrial Acetoacetyl-CoA Thiolase Deficiency
- aa. Multiple Acyl-CoA Dehydrogenase Deficiency (MADD or GA II)
- bb. Multiple CoA Carboxylase Deficiency
- cc. 5-Oxoprolinuria (Pyroglutamic aciduria)
- dd. Pompe
- ee. Propionic Acidemia (PPA)
- ff. Severe Combined Immunodeficiency (SCID)
- gg. Short-Chain Acyl-CoA Dehydrogenase Deficiency (SCAD)
- hh. Short-Chain Hydroxy Acyl-CoA Dehydrogenase Deficiency (SCHAD)
- ii. Trifunctional Protein Deficiency (TFP Deficiency)
- jj. Tyrosinemia Type I (TYR I)
- kk. Tyrosinemia Type II (TYR II)
- ll. Very Long-Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD)

SOURCE: Miss. Code Ann. §41-21-201

specimens that have been collected too early or improperly.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.3.2. If the newborn screening tests have to be repeated due to lack of information on the lab slip, the hospital will be charged with finding the newborn and repeating the newborn screening tests.

SOURCE: Miss. Code Ann. §41-21-201

Subchapter 4. LABORATORY REQUIREMENTS

Rule 1.4.1. Compliance with Standards

1. Any laboratory which offers this testing must meet the standards outlined in this section and, if requested, provide the agency with a written statement that they will comply with these standards. All specimens must be tested in an approved laboratory located in the United States.
2. The results of hemoglobinopathies, galactosemia, and congenital adrenal hyperplasia screening are not always clear cut and this type of screening requires extensive input from a recognized reference laboratory. Screening by tandem mass spectrometry requires extensive expertise and experience in this testing methodology.
3. A single control laboratory is required for screening. The laboratory should be proficient in all required testing methodologies.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.4.2. **Specimen Requirements:** Specimen acceptable for analysis includes only dried blood spots for newborn screening, and whole blood or serum for confirmatory testing.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.4.3. Method for Specimen Analysis

1. **Argininemia** : Method: fluorometric assay or by tandem mass spectrometry analysis
2. **Biotinidase Deficiency** : Method: continuous flow enzyme assay
3. **Congenital Hypothyroidism** : Method: Enzyme Immunoassay (EIA)
4. **Cystic Fibrosis (CF)** : Method: Immunoreactive Trypsinogen (IRT)
5. **Congenital Adrenal Hyperplasia (CAH)** : Method: Enzyme Immunoassay (EIA)

- a. Control(s) containing AFSC and FAS must be included in each assay.
- b. All samples that are not normal (not FA or AF) must be sent to a recognized reference laboratory as liquid blood unless a diagnosis has been determined by DNA analysis or other valid means.
- c. If transfused, a repeat blood spot specimen or a liquid blood sample will be collected and tested between two and twelve weeks post last transfusion.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.4.5. Disorders being Screened by Biochemical and Other Technologies

1. **BIOTINIDASE DEFICIENCY:** Biotinidase Deficiency is caused by the complete or partial lack of the enzyme biotinidase. This condition can lead to seizures, developmental delay, eczema, and hearing loss.
2. **CONGENITAL ADRENAL HYPERPLASIA:** Congenital Adrenal Hyperplasia (CAH) is a genetic endocrine disorder caused primarily by a deficiency of enzymes needed for the adrenal glands to make the hormones cortisol and aldosterone. It can result in masculinization of female genitalia as well as adrenal crisis and early infant death.
3. **CYSTIC FIBROSIS:** Cystic Fibrosis (CF) is an inherited condition that affects the glands that produce mucus, tears, sweat, saliva, and digestive juices. It causes severe lung damage and nutritional deficiencies. Respiratory failure is the most dangerous consequence.
4. **CONGENITAL HYPOTHYROIDISM:** Hypothyroidism is a disorder in which there is a decrease in the production of thyroid hormone, possibly resulting in brain damage and mental retardation in the absence of prompt treatment.
5. **GALACTOSEMIA:** Galactosemia is an inborn error of metabolism, inherited as an autosomal-recessive trait, in which the hepatic enzyme galactose-1-phosphate uridyl transferase is absent, preventing the conversion of the milk sugar galactose to glucose. If untreated death can occur in the first month of life.
6. **HEMOGLOBINOPATHIES:** Hemoglobinopathy, which includes sickle cell diseases, thalassemia, and other variants are blood disorders resulting from change in the structure of hemoglobin. Sickle Cell Disease, the most common hemoglobinopathy in Mississippi, is an inherited disease found primarily in African-Americans and people of Mediterranean descent. Although there is no cure for sickle cell disease, early detection is

Subchapter 1. Authority

Rule 2.1.1. Statutory Authority: Section 41-21-205 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health (the department) to adopt rules and regulations to govern the operation of the Birth Defects Registry.

SOURCE: Miss. Code Ann. §41-21-205

Rule 2.1.2. Legal Requirements Under the statutory authority, the Board of Health (the board) shall:

1. establish in the department a birth defects surveillance program to:
 - a. identify and investigate birth defects, and
 - b. maintain a central registry of cases of birth defects
2. design a birth defects data system that will:
 - a. identify and investigate birth defects, and
 - b. provide information on other possible causes of birth defects,
 - c. provide for the development of strategies to prevent birth defects,
 - d. provide for interview studies about the causes of birth defects, and
 - e. provide for the collection of birth defect information
3. adopt rules, regulations and procedures to govern the operation of the registry program and to carry out the intent of this action
4. specify the types of information to be provided to the birth defects registry and the persons and entities who are required to provide such information to the birth defects registry
5. prescribe the manner in which records and other information are made available to the department
6. obtain records and/or test results of individuals with birth defects not previously reported or observed for inclusion in the central registry.
7. collect, analyze and place data in the central registry to facilitate epidemiological studies/ reviews and to maintain security
8. use the registry to:
 - a. investigate the causes of birth defects and other health conditions as authorized by statute,

Genetic Disorders Skin
Congenital Tumors Central Nervous System

3. Persons and Entities Required to Provide Information to the Registry

- a. The physician must report every birth defect case the first time the patient is seen, for individuals born on or after January 1, 2000. A reporting form (See Attachment B) or its equivalent as determined by the Mississippi Department of Health is required when reporting a suspected or diagnosed birth defect. If the patient is seen for another birth defect on another occasion, that defect shall also be reported.
- b. Appropriate birth certificate data will be reported.
- c. Appropriate data from other department registries such as the Cancer Registry, Newborn Hearing Registry will be reported.
- d. The state (s) tertiary care center and other hospitals will report data through newborn discharge summaries or by completing and submitting individual reporting forms.
- e. Appropriate data on specified disorders detected through newborn screening will be reported.

4. Criteria for Inclusion as a Case

- a. The infant/fetus must have a reportable structural defect, newborn screening disorder, functional or metabolic disorder, genetically determined or a defect resulting from an environmental influence during embryonic or fetal life.
- b. The defect optimally should be diagnosed or its signs and symptoms recognized within the first year of life, but defects can be recognized and included up to twenty-one years of age.
- c. An infant must have been born alive or a fetus must have gestational age of at least 20 weeks or a birth weight of at least 350 grams to be included in the Birth Defects Registry.

5. Process for Making Records and Other Information Available to The Birth Defects Registry

- a. Hospitals, physicians, and other health care professionals may submit records and birth defect information electronically or by completing and submitting individual reporting forms.

- b. **Misuse of the Registry Data:** Any person or entity who misuses the information provided to the registry shall be subject to a civil penalty of Five Hundred Dollars (\$500.00) for each such failure or misuse. Such penalty shall be assessed and levied by the board after a hearing, and all such penalties collected shall be deposited into the State General Fund.
7. **Policies and Procedures** The department will maintain written policies and procedures to guide the operations of the Birth Defects Registry.

SOURCE: Miss. Code Ann. §41-21-205

Appendix B

**Format for Electronic Data Submission
To
The Mississippi State Department of Health (MSDH)
Genetic Services Bureau Newborn Screening Program**

The format for electronic data submission must be identical to that currently utilized by the MSDH Genetics Services Bureau (see the attachment Required Database Elements table and Test Results table) for receiving demographic information and test results for forty plus genetic conditions. The program and the laboratory will derive jointly the field names, types, and codes for test results.

Any form of electronic data transfer shall meet the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Questions regarding electronic data submission should be addressed to Avery Polk at the Mississippi State Department of Health Genetics Services Bureau, 570 E. Woodrow Wilson Blvd. O-200, Jackson, MS 39215 or by telephone at (601)576-7619.

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
CountyID	Long Integer	4
CountyName	Short Text	50
DistrictID	Integer	2

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
ctbl_County\$CountyId	1
Fields:	
CountyID	Ascending
ctbl_County\$ctbl_Districtsctbl_County	1
Fields:	
DistrictID	Ascending
ctbl_County\$districtID	1
Fields:	
DistrictID	Ascending
ctbl_County\$PrimaryKey	1
Fields:	
CountyID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
DisorderGroupID	Long Integer	4
DisorderGroup	Short Text	50
DisorderGroupDesc	Long Text	-
SSMA_TimeStamp	Binary	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
ctbl_DisorderGroups\$DisorderGroupID	1
Fields:	
DisorderGroupID	Ascending
ctbl_DisorderGroups\$PrimaryKey	1
Fields:	
DisorderGroupID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
DisorderID	Long Integer	4
Disorder	Short Text	15
DnLoadName	Short Text	10
DisorderGroupID	Long Integer	4
DisorderDesc	Short Text	100

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
ctbl_DisorderList\$Disorder	1
Fields:	
Disorder	Ascending
ctbl_DisorderList\$disorder_group_ndx	1
Fields:	
DisorderGroupID	Ascending
ctbl_DisorderList\$PrimaryKey	1
Fields:	
DisorderID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
DistrictID	Integer	2
District	Short Text	13
DistrictName	Short Text	50

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
ctbl_Districts\$PrimaryKey	1
Fields:	
DistrictID	Ascending

Columns

Name	Type	Size
mnemonicID	Long Integer	4
mnemonic	Short Text	30
mnemonic_desc	Long Text	-
OutcomeID	Long Integer	4
contactID	Long Integer	4
MnemonicLetterSetID	Long Integer	4
CuruptedSpecimen	Yes/No	1
SSMA_TimeStamp	Binary	8

Table Indexes

Name	Number of Fields
ctbl_Mnemonic\$contact_ndx	1
Fields:	
contactID	Ascending
ctbl_Mnemonic\$mnemonic	1
Fields:	
mnemonic	Ascending
ctbl_Mnemonic\$MnemonicID	1
Fields:	
mnemonicID	Ascending
ctbl_Mnemonic\$MnemonicLetterID	1
Fields:	
MnemonicLetterSetID	Ascending
ctbl_Mnemonic\$OutcomeID	1
Fields:	
OutcomeID	Ascending
ctbl_Mnemonic\$PrimaryKey	1
Fields:	
mnemonicID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
ResultIntCode	Short Text	25
ResultCodeDescription	Short Text	100

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
_uniqueindex	1
Fields:	
ResultIntCode	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
EmployeesID	Long Integer	4
EmployeesName	Short Text	25
Inactive	Yes/No	1
SSMA_TimeStamp	Binary	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
dtbl_Employee\$EmployeesID	1
Fields:	
EmployeesID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
AbnormalType	Long Integer	4
AbnormalDesc	Short Text	50

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_AbnormalType\$PrimaryKey	1
Fields:	
AbnormalType	Ascending

Columns

Name	Type	Size
ChildID	Long Integer	4
NewbornID	Long Integer	4
MedicalRecord	Short Text	255
LastName	Short Text	50
FirstName	Short Text	50
BirthDay	Date With Time	8
BirthTime	Short Text	50
BirthPlace	Short Text	10
SexID	Long Integer	4
RaceID	Long Integer	4
EthnicityID	Long Integer	4
Twin	Long Integer	4
PregTerm	Long Integer	4
MotherID	Long Integer	4
PhyID	Long Integer	4
HemoglobinTraitCounselingDt	Date With Time	8
HemoglobinTraitCounselingDtEnt	Date With Time	8
SCTraitCounselingDt	Date With Time	8
SCTraitCounselingDtEnt	Date With Time	8

Table Indexes

Name	Number of Fields
tbl_Child\$birth_day	1
Fields:	
BirthDay	Ascending
tbl_Child\$ethnicityID	1
Fields:	
EthnicityID	Ascending
tbl_Child\$first_name	1
Fields:	
FirstName	Ascending
tbl_Child\$last_name	1
Fields:	
LastName	Ascending
tbl_Child\$motherID	1
Fields:	
MotherID	Ascending
tbl_Child\$NewbornID	1
Fields:	
NewbornID	Ascending
tbl_Child\$PrimaryKey	1
Fields:	
ChildID	Ascending
tbl_Child\$raceID	1
Fields:	
RaceID	Ascending

tbl_Child\$sexID	1
Fields:	
SexID	Ascending
tbl_Child\$tbl_ChildphyID	1
Fields:	
PhyID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
ClosedID	Long Integer	4
ClosedDesc	Short Text	50
PrintDesc	Short Text	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_Close_File_Code\$ClosedID	1
Fields:	
ClosedID	Ascending
tbl_Close_File_Code\$PrimaryKey	1
Fields:	
ClosedID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
ConfirmedCodeID	Long Integer	4
ConfirmedCode	Short Text	20
ConfirmedCodeDesc	Short Text	50
PrintDesc	Short Text	15

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_Confirmed_Code\$Confirmed_Code	1
Fields:	
ConfirmedCode	Ascending
tbl_Confirmed_Code\$PrimaryKey	1
Fields:	
ConfirmedCodeID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
ContactHistoryID	Long Integer	4
SpecimenID	Long Integer	4
ContactDate	Date With Time	8
contactID	Long Integer	4
LetterTypeID	Long Integer	4
Confirmed	Yes/No	1
ConfirmedDate	Date With Time	8
Note	Short Text	255
SSMA_TimeStamp	Binary	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_ContactHistory\$contactID	1
Fields:	
contactID	Ascending
tbl_ContactHistory\$LetterTypeID	1
Fields:	
LetterTypeID	Ascending
tbl_ContactHistory\$PrimaryKey	1
Fields:	
ContactHistoryID	Ascending
tbl_ContactHistory\$SpecimenID	1
Fields:	
SpecimenID	Ascending
tbl_ContactHistory\$TestResultsID	1
Fields:	
ContactHistoryID	Ascending

Columns

Name	Type	Size
MotherID	Long Integer	4
SSN	Short Text	13
Medicaid	Short Text	255
LastName	Short Text	30
FirstName	Short Text	30
Address	Short Text	50
City	Short Text	30
State	Short Text	30
Zipcode	Short Text	50
CountyID	Long Integer	4
Phone	Short Text	15
MotherDOB	Date With Time	8
MotherAge	Short Text	50
AddressCheck	Yes/No	1
SSMA_TimeStamp	Binary	8

Table Indexes

Name	Number of Fields
missing_index_159_158_tbl_Mothers	2
Fields:	
LastName	Ascending
FirstName	Ascending
tbl_Mothers\$countyID	1
Fields:	
CountyID	Ascending
tbl_Mothers\$last_name	1
Fields:	
LastName	Ascending
tbl_Mothers\$medicaid	1
Fields:	
Medicaid	Ascending
tbl_Mothers\$MotherID	1
Fields:	
MotherID	Ascending
tbl_Mothers\$PrimaryKey	1
Fields:	
MotherID	Ascending
tbl_Mothers\$SSN	1
Fields:	
SSN	Ascending
tbl_Mothers\$zipcode	1
Fields:	
Zipcode	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
NewbornID	Long Integer	4
NewbornNum	Short Text	50
MotherID	Long Integer	4
ClosedID	Long Integer	4
Closed_Date	Date With Time	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_NewbornID\$ClosedID	1
Fields:	
ClosedID	Ascending
tbl_NewbornID\$MotherID	1
Fields:	
MotherID	Ascending
tbl_NewbornID\$NewbornID	1
Fields:	
NewbornID	Ascending
tbl_NewbornID\$NewbornNum	1
Fields:	
NewbornNum	Ascending
tbl_NewbornID\$PrimaryKey	1
Fields:	
NewbornID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
PhyID	Long Integer	4
PhysName	Short Text	75
xxx	Short Text	50

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_Physicians\$phyID	1
Fields:	
PhyID	Ascending
tbl_Physicians\$PhysName	1
Fields:	
PhysName	Ascending
tbl_Physicians\$PrimaryKey	1
Fields:	
PhyID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
ReportID	Long Integer	4
AbnormalType	Long Integer	4
GeneratedDate	Date With Time	8
NewbornID	Short Text	25
SpecimenID	Short Text	25
Note	Short Text	255

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_ReportAbnormal\$NewbornID	1
Fields:	
NewbornID	Ascending
tbl_ReportAbnormal\$PrimaryKey	1
Fields:	
ReportID	Ascending
tbl_ReportAbnormal\$ReportID	1
Fields:	
ReportID	Ascending
tbl_ReportAbnormal\$SpecimenID	1
Fields:	
SpecimenID	Ascending

Columns

Name	Type	Size
SpecimenID	Long Integer	4
NewbornID	Long Integer	4
SpecimenNum	Short Text	12
Visit	Short Text	1
AllWnl	Yes/No	1
FeedID	Long Integer	4
LabComment	Long Text	-
hospID	Long Integer	4
DateRecv	Date With Time	8
DateCollected	Date With Time	8
DateTranfused	Date With Time	8
DnLoadDate	Date With Time	8
TreatmentDate	Date With Time	8
PhyID	Long Integer	4
CurrentWeight	Long Integer	4
Ammended	Yes/No	1
PhISpecimen	Yes/No	1
HomeBirth	Short Text	1
SCDiseaseTraitCounseling	Yes/No	1
Archive	Yes/No	1
Billed	Yes/No	1
SSMA_TimeStamp	Binary	8

Table Indexes

Name	Number of Fields
tbl_SpecimenID\$feedID	1
Fields:	
FeedID	Ascending
tbl_SpecimenID\$NewbornID	1
Fields:	
NewbornID	Ascending
tbl_SpecimenID\$PhyID	1
Fields:	
PhyID	Ascending
tbl_SpecimenID\$Specimen_num	1
Fields:	
SpecimenNum	Ascending
tbl_SpecimenID\$SpecimenID	1
Fields:	
SpecimenID	Ascending
tbl_SpecimenID\$tbl_SpecimenIDhospID	1
Fields:	
hospID	Ascending

Columns

<u>Name</u>	<u>Type</u>	<u>Size</u>
TestResultsID	Long Integer	4
SpecimenID	Long Integer	4
mnemonicID	Long Integer	4
disorderID	Long Integer	4
AddedToContactLog	Yes/No	1
ConfirmedCodeID	Long Integer	4
SCDiseaseTraitCounseling	Yes/No	1
SCDiseaseTraitCounselingDt	Date With Time	8
SSMA_TimeStamp	Binary	8

Table Indexes

<u>Name</u>	<u>Number of Fields</u>
tbl_TestResults\$Confirmed_CodeID	1
Fields:	
ConfirmedCodeID	Ascending
tbl_TestResults\$disorderID	1
Fields:	
disorderID	Ascending
tbl_TestResults\$PrimaryKey	1
Fields:	
TestResultsID	Ascending
tbl_TestResults\$SpecimenID	1
Fields:	
SpecimenID	Ascending
tbl_TestResults\$TestResultsID	1
Fields:	
TestResultsID	Ascending

Appendix C

ALL INFORMATION MUST BE PRINTED

903™
 2020-05-31
 US34549
 Rep AD
 [LOT] W162
 [VLD]

NEWBORN SCREENING

TO AVOID RECOLLECTION- Accurately complete the entire form

() First Specimen All tests () Home Birth () Repeat Specimen Reason: <24 hr. Unsatisfactory Abnormal Transfused Inconclusive

Infant's Last Name: _____ First: _____ Previous Last Name: _____
 Birth Date: ____/____/____ Time of Birth: _____
 Date Collected: ____/____/____ Time Collected: _____
 Hospital of Birth Use Code: _____ Hospital or H.D. Use Code: _____ Medical Record Number: _____
 Transferred: () Yes () No

SEX: () 1. Male () 2. Female
 RACE: () 1. White () 2. Black () 3. Asian () 4. Am. Ind. () 5. Other
 ETHNICITY: () 1. Hispanic () 2. Non-Hispanic

Transfused: () Yes () No
 If yes, Date and Time of Last Transfusion: ____/____/____
 Gestation: _____ Weeks Infant's Age: _____
 Birth Weight: _____ Grams
 Feeding: () 1. Breast () 2. Soy () 3. I.V. () 4. Lactose () 5. TPN
 Meconium Stool: () Yes () No

MOTHER'S INFORMATION

Mother's Current Last Name: _____ First: _____ Maiden: _____
 Address: _____ Mother's DOB: _____
 City: _____ State: _____ Zip: _____
 Phone: _____ Medicaid Number: _____
 Mother's Social Security No.: _____ Country of Birth: _____

Physician's Name: _____ Physician's Phone: _____
 Additional Information: _____
 Subscriber's Name and Address: _____

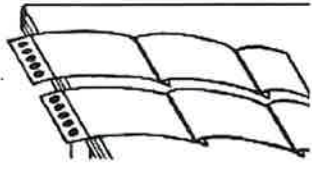
HEARING SCREEN: _____
 R. Ear: _____ L. Ear: _____
 Pass: _____ Refer: _____

PerkinElmer Genetics, Inc. 90 Emerson Lane Bridgeville, PA 15017 (412) 220-2300
 PRO-MEN CLINICAL NUMBER SN 7393686
Critical Congenital Heart Disease Screening Final Q2 Screen: _____
 If not performed, reason: Refused Expired On Q2 Transferred Other
 W/N N/C Final Result: Passed Failed
 Echocardiogram performed? Yes No

Results are based on the assumption that the infant has not been transfused

INSTRUCTIONS

- Hold infant's limb in a dependent position to increase blood flow
- Clean heel thoroughly. Wipe with alcohol and dry before puncturing
- Puncture heel with sterile lancet deep enough to assure free flow of blood.
- Wipe away first drop and discard.
- Allow a large drop of blood to form on infant's heel. Apply the back side of the filter paper directly to the puncture site where the drop of blood has formed. **The drop of blood should be large enough to approximately fill one circle.**
DO NOT: a) Apply more than one drop of blood per circle.
DO NOT: b) Apply blood to both front and back of filter paper.
- Apply blood to all circles.
- Allow blood spots to completely dry in a horizontal position at room temperature for a minimum of 4 hours (see diagram). Do not stack specimens while specimen is exposed. After drying, rewrap this cover sheet to its original position to protect specimen.
- Send by Pre-Paid Overnight Courier within 24 hours of collection to:
- If you have questions please call:



Mississippi State Department of Health Genetic Screening Program at: (601) 576-7619

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Appendix D

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Any lab reports that indicate inconclusive or presumptive positive results for the following categories are to be reported both electronically and via fax to the Central Office for immediate short term follow up.

- Organic Acid Conditions
- Fatty Acids Oxidation Disorders
- Amino Acids Disorders
- Galactosemia
- Congenital Adrenal Hyperplasia