

Appendix 5A

**NBS Accession and Reporting at the NAPS Lab**  
**Tracking Number: CN 002**  
**Version Number: 9.0**

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**I. TITLE**

NBS Accession and Reporting at the NAPS Laboratories.

**II. PRINCIPLE**

Newborn screening specimens are received daily at the laboratory via post office or courier. The specimen comes in the form of blood spots collected on a special collection card attached to the test request form (TRF) containing identification information of the newborn. Each specimen will be assigned with its own unique accession number which consists of the Julian date, check digits, sequence number, a forward slash (/), test type (N), year and the lab site. An adequate specimen is screened for the following disorders: congenital primary hypothyroidism, congenital adrenal hyperplasia, galactosemia, sickle cell anemia, other hemoglobinopathies, and over 40 amino acid and acylcarnitine.

**III. SPECIMEN AND COLLECTION TYPE**

Blood specimens are collected from the heels of newborns, spotted and dried on the collection cards. Each card must be accompanied with a test request form. Cards and TRF are provided by the NBS program.

**IV. EQUIPMENT AND SUPPLIES**

- A. Sato bar code printer
- B. Bar code labels

**V. REAGENTS**

NA

**VI. CALIBRATION AND QUALITY CONTROL**

NA

**VII. PROCEDURES**

- A. Receipt of Specimens
  1. Remove specimens from envelopes. The filter paper collection card and test request form should be attached to each other.
  2. Verify that the specimens received match the specimens listed on the specimen log. If a specimen listed on the log is not received, follow instructions under Processing Specimens Not Received, Section VII.H. If you identify a specimen on the list as a recall specimen or a specimen that should

not have been sent to your laboratory, follow instructions under Processing Specimens Incorrectly Sent to Your Laboratory, Section VII.I.

## B. Criteria Use to Determine Adequacy of Specimens

### 1. Quality

- a. Blood must completely fill both sides of the circles inscribed on the collection card.
- b. Blood spots must be uniform throughout with no clots seen on the surface of either side, without layered or uneven appearance and without a sandwich appearance, i.e. white center layer.
- c. Collection card must not appear to be dirty or have something spilled on the filter paper.
- d. Blood spots must look normal in color, not pale, dark or greenish in color.
- e. Blood spots must be dried before mailing; therefore, blood should not be seen on adjacent papers.
- f. Specimens must not be collected on Lot C or non-standard state collection cards.
- g. Specimen must be received by the 14<sup>th</sup> day after collection (collection date is day one).
- h. Filter paper collection card should be attached to the TRF.

**NOTE:** Current filter paper, Perkin Elmer Ahlstrom 226 Lot # 0120201, and subsequent lots are designed to have the filter paper collection cards attached to the TRF. If a specimen arrives at your laboratory with the filter paper collection card detached from the TRF, and the TRF has different ID number, call the specimen inadequate. If the detached filter paper collection card has the same ID number as on the TRF, and the TRF has all the required information such as baby's name, birthdate, and collection date, then one can apply the NBS Accession and Reporting at the NAPS Labs Protocol to determine adequacy. If your laboratory receives detached collection cards, with or without name, birthdate, and collection date repeatedly, call the ASC coordinator to have the coordinator stop this practice at the collection site. Our intention is not to have this practice continue or increase.

- i. The blood spots must not have Hgb F Pattern Report as "No Peak", "Low Area" or "High Area" when hemoglobin testing is completed (Hemoglobin Assay Protocol section VII.J.2).

### 2. Quantity

The collection card must have at least three adequate blood spots.

**C. Judging Adequacy of Specimens**

1. Judge each blood spot on the collection card using above criteria.
2. If a specimen is inadequate, write a large "I" with an appropriate inadequacy code number (from section D below) on any empty space of the test request form and the specimen collection card, preferably, near the accession barcode labels on both.

**NOTE:** Follow this procedure regardless of when the sample is determined to be inadequate (i.e. during card punching for analysis or after Hb testing).

**D. Codes for NBS Specimen Inadequacy**

- 01 - Circles are not completely filled.
- 02 - Blood is not soaked through evenly to other side of collection card.
- 03 - Clots appear on the surface of the sample.
- 04 - Blood is spread unevenly or layered (improper collection or drying).
- 05 - Blood or paper appears contaminated by spill or is soiled.
- 06 - Blood is very pale.
- 07 - Blood is very dark as though was heated.
- 08 - Blood is greenish as though old.
- 09 - Specimen is too old (>14 days from collection; collection date is day one.)
- 10 - Specimen was found unprotected in mail.
- 11 - Blood spots are not completely dry.
- 12 - Sample does not elute (determined after elution or testing).
- 13 - Specimen was not collected on acceptable filter paper.
- 14 - NBS form number on TRF does not match number on collection paper.
- 15 - Abnormal pattern of test results.
- 16 - No blood is spotted on collection paper.
- 17 - Hemoglobin concentration is too low (determined after testing).

- 18 - Hemoglobin concentration is too high (determined after testing).
- 19 - TRF entered without form number
- 20 - Specimen inadequate for other reason, e.g., filter paper collection card detached from TRF with missing or mismatched information. (Currently, this code is not present in SIS; use “Specimen inadequate – other reason” option.)

E. Apply Barcode Accession Numbers

Specimens must be accessed and tested **within twenty-two hours** of receipt in the laboratory. Place specimens in the freezer if not tested on the day of receipt. **Do not store specimens at room temperature.**

1. Stack the newborn specimens in the following order, adequate then inadequate specimens.
2. Printing barcode accession number labels.
  - a. Turn on the power on NeoGo PC workstation and bar code printer.  
**Note:** PerkinElmer recommends that power to the unit be shut down once a week to allow the system to initialize.
  - b. Logon to the computer. Double click on the appropriate icon.
  - c. The California Screening Project Barcode Printing Program-Neonatal appears on the screen.  
There are nine icons representing the types of bar code labels. Labels can be printed for: Patient Specimens, Proficiency samples, TQC, Low SQC, Medium SQC, High SQC, Reference samples, Mother trays and Follow-up samples.
  - d. Click on the Patient icon. The icon will be depressed and “Enter start sequence number” box will appear.
  - e. To determine the date on the computer:  
Click on the large gray box area to the left of the “Enter start sequence number”. View the date and make changes as needed. If no changes needed, click Cancel to get out.
  - f. Click on the “Enter start sequence number” box. If this is the first barcode label for the current accession date, enter 001 as your first sequence number. This is the only time that you will be required to enter the starting sequence number of the current date. If there have been

patient barcode labels previously printed for the current date, the next sequence number will appear as soon as you click on the “Start” box.

- g. Click the “Number of labels” box. Enter “999” as the last sequence number you wish to print. This will allow continuous bar coding of specimens as they are received.
- h. Click Start. The first accession number is printed on two labels. Two barcode labels are printed for each accession number.
- i. Attach one of the duplicate barcode labels to the test request form. Remove the bar code label on the right and attach it to the box labeled, LABEL AREA, on the upper right corner of the TRF.

**NOTE** (if applicable): The right label **MUST** be taken off the printer first. There is a sensor under the left label so that when the left label is taken off, the next accession number is printed. Since the labels are sticky, when the next set of labels is printed and the second label of the prior accession number is still on the printer, the two labels will stick together. In the event of a misstep, throw the labels away and use the next set of two labels with identical accession number. The screen will display the patient sequence number being printed.

- j. Remove the left label and attach it on the collection card in the box labeled “CDPH Use Only”. The label **must not** touch the blood spots or hang below the bottom edge of the collection card.
- k. Separate the collection card from the TRF. Separate in a manner such that the collection card does not have frayed edge.
- l. Continue until all specimens and test request forms are barcoded.
- m. Click Stop after the last specimen and test request form are barcoded. The last sequence number will be stored in the memory.
- n. Deliver adequate specimens to the punch station. Keep the inadequate samples in the same accessioned day bag (for specimen bank) behind the adequate samples.
- o. Deliver test request forms to data entry station.

- F. Processing Specimens Without Birth Weight on TRF.
1. Proceed to test and enter the TRF with no entry for the birth weight field.
  2. During review and release, Perkin Elmer system will determine if the result is negative, indeterminate, or definite positive using the cutoff for newborns at 2500 grams or greater, the most conservative cutoff. Entered “missing” into the comment field if the information is missing.
  3. Send specimen to GDLB for second screening using MS/MS if result is indeterminate.
  4. Call the coordinator if the result is a positive.
  5. See Section IX.A.3.d. below for cutoffs by weight for 17OHP and refer to Section VII.A.11 in the NBS Supervisor’s Daily Review and Release Protocol to determine if the result is a negative, an indeterminate or a definite positive.
- G. Processing Inadequate Specimens
1. Use the TRF to enter information for each inadequate specimen on the NBS Inadequate Log the same day of accessioning.
  2. Call to notify the appropriate ASC coordinator as soon as possible on the same day of accessioning.
  3. FAX the TRF to the coordinator.
  4. Enter Confirmation of Contact in SIS.
  5. Follow instructions in the NAPS Laboratory Data entry Manual to enter TRF for these specimens with the appropriate codes.
  6. If a specimen’s status goes from adequate to inadequate, i.e., confirmed low Hb pattern and the TRFs are out of lab control and your laboratory cannot change the status, follow the above procedure to call the coordinator, have the coordinator change the status, have coordinator arrange for a repeat specimen, and your laboratory will enter the Confirmation of Contact.
- H. Processing Specimens Not Received
1. Enter missing specimens on the NBS Inadequate Log.
  2. Telephone the ASC coordinator as soon as possible on the same day of accession. If unable to reach coordinator, leave a detailed message in the ASC’s voice mail.
  3. Circle the missing sample(s) on the specimen transport log.
  4. FAX the log to the ASC coordinator.

5. Record date and time of call, your name and the person receiving the call on the log sheet.
- I. Processing Specimens Incorrectly Sent to Your Laboratory
    1. Accession and test specimens according to protocol.
    2. Follow the reporting of a positive result/inadequate per protocol as needed.
    3. Telephone the ASC coordinator assigned to the facility where the sample was collected and ask to correct this problem.
  - J. Data Entry for Test Request Forms
    1. Enter test request forms on the same day samples are accessed.
    2. Follow instructions in the NAPS Laboratory Data Entry Manual, provided by GDB, for data entry of TRF.
  - K. Storage & Shipping of Specimens, Test Request Forms, NBS Presumptive Positive Logs and NBS Inadequate Logs.
    1. Specimens
      - a. Specimens tested
        - 1) At the end of the day's testing, place all specimens from each tray in a zip lock bag.

**Note:** All bags (mother tray bags and accession day bags) should be sealed completely with two desiccant packages inside each bag.
        - 2) Attach the two remaining "Mother tray" barcode, one on each side of the bag, in a manner that it can be easily read or scanned.
        - 3) Place all the bags of specimens in a zip lock bag. Follow the instructions on the Smart Card titled: "Specimen Bank Laboratory Software". Use the TSH punching station to perform the process.
          - a) Make a "shipping bag" bar code label using the bar code printer software. Attach bar code label in the same manner as described for the tray bags.

**NOTE:** Once "shipping bag" is selected, you **MUST** set **Enter start sequence number** to 1 and **Number of labels** to 1 to print the first "shipping bag". The barcode on the first shipping bag **MUST** have 001 as the ending 3 characters. If you need a second shipping bag based on a high volume of specimens, change **Enter start sequence number** to 2 and keep **Number of labels** at 1. You cannot have a barcode on a shipping bag ending in 002 unless you have a barcode on a shipping bag ending with 001. Barcodes for shipping bags must be in sequence starting with 001. This is critical to GDLB to be able to find a specimen in the specimen bank.
          - b) Double click on the icon "Filing cabinet".

- c) When opening the program you will see “Trays that are not in any bag” window and the Trays Ids available.
  - d) Click once on the bar code button to create a new “Shipping bag”. Read the barcode label of the bag. This bag will then be used to store the individual “Mother tray” storage bags.
  - e) Next, click the “Read in” button. Read in all the “Mother tray” bags and click on “Done”. This is the same button that said “Now” before.
  - f) As you read the “Mother tray” barcodes, they will disappear from the “Trays not in any bag” list.
  - g) At any time a tray can be clicked on to reveal the samples it contains.
  - h) Unwanted trays can be deleted, only trays that are actually going to the specimen bank should be stored in the system.
  - i) On the same day, scan the barcode of the “shipping bag” and click “Send”. This marks the bag ready to be sent with the next file transfer to the GDL bank server.
  - j) Click EXIT when finished.
- 4) Ship samples to GDL follow the shipping conditions specified by the Genetic Disease Laboratory in Specimen Handling Protocol for SCID Project (Tracking number GN 503)
- a) In SIS Biobank, click Barcode Management in the Second Tier Menu to create a shipping barcode
    - i. Under Barcode Type, select “Container” under Container Type, select “Shipping Container”
    - ii. Under Number of Barcodes, enter 1
    - iii. Click Generate
    - iv. Click Print on Label Roll to print a Shipping Barcode to be affixed to the biomailer
  - b) In SIS Biobank, click Shipping in the Second Tier Menu
    - i. Click Add Shipment on the Third Tier Menu
    - ii. Under Shipment Type, select “Internal”
    - iii. Under Target Facility, select “GDL”
    - iv. Under Shipping Container Barcode, Use the barcode created in step 4) a)
    - v. Under Container Type, select “Biomailer”
    - vi. Confirm the date under “Shipment Date” is accurate
    - vii. Confirm your name is correct under “Prepared By Name”
    - viii. Enter the GSO tracking number under “Tracking Number”
    - ix. Confirm “Shipment Status” is “Created”
    - x. Click “Save”

- xv. Click “Print Shipment Summary”
  - c) Place all shipping bags into a large plastic bag that lines the mailer. Fold the plastic bag closed and pack tightly so that all excessive air is expelled. Place the FROZEN icepacks outside the bag next to the wall of the Polyfoam biomailer. Do not place icepacks inside specimen bag!! Enclose a copy of the Shipment Summary before seal the Biomailer with strong tape. Affix the GSO label to the biomailer.
  - d) After the biomailer is picked up by GSO, update Shipment Status to “In Transit”.
- b. Specimens After Repeat Testing**  
After repeat testing is completed, return sample(s) to the **original** zip lock bag in the same sequential order as punched for the first test run. GDL will return specimens to the original bag after completion of CAH 2<sup>nd</sup> tier and SCID testing.
- c. Inadequate specimens**  
Place all specimens in a separate zip lock bag labeled as “inadequate” and then in the same shipping bag that has all the specimens tested for that day.
- 2. Test Request Forms (TRF)**
- a. Retain all test request forms for a minimum of thirty days.
  - b. At the end of the thirty-day period, send test request forms, filed by accession number, to the CDPH/Genetic Disease Screening Program.
- 3. NBS Presumptive Positive/Inadequate Logs**  
Retain these forms for a minimum of three years. After this period, they can be discarded to meet HIPPA requirement

## VIII. CALCULATIONS

NA

**IX. REPORTING RESULTS****A. Presumptive Positive Results**

1. At the completion of review and release, print the presumptive positive report for a list of all presumptive positives for TRA, BIO, TSH, 17OHP, and IRT. The Presumptive Positive List shows a **P** under the column Type for definite positives and a **Q** for Indeterminate for CAH.

2. Also print the presumptive positive report for a list of all presumptive positives for amino acids, succinylacetone, and acylcarnitines at the end of MSMS review and release of each day.

3. Presumptive positive cutoffs are entered into the system and are as follows:

- a. TRA – equal to or less than ( $\leq$ ) 50.00 E(nzyme)U(nits) is presumptive positive for Galactosemia.
- b. BIO – equal to or less than ( $\leq$ ) 10.00 ERU is presumptive positive for Biotinidase Deficiency.
- c. TSH – equal to or greater than ( $\geq$ ) 29.00mIU/L is presumptive positive for Congenital Primary Hypothyroidism.
- d. 17OHP – cutoffs are birth weight dependent and can be an indeterminate positive or a definite positive for Congenital Adrenal Hyperplasia.

Birth Weight	Indeterminate Positive*	Definite Positive**
< 1000 grams	80.00 nmol/L	300.00 nmol/L
1000 – 1499 grams	80.00 nmol/L	200.00 nmol/L
1500 – 2499 grams	55.00 nmol/L	80.00 nmol/L
>2499 grams	50.00 nmol/L	70.00 nmol/L

\* An Indeterminate Positive is a result equal to or greater than the concentration listed but less than the Definite Positive concentration. Send these specimens to GDL for second tier CAH steroid profiling.

\*\* A Definite Positive is a result equal to or greater than the concentration listed and must be called to the coordinator.

- e. IRT – equal to or greater than ( $\geq$ ) 62.00ng/mL is presumptive positive for Cystic Fibrosis. Follow instructions under separate cover on how to handle IRT presumptive positives.
- f. MSMS Amino Acids, Succinylacetone and Acylcarnitines –  
(Please refer to Table I and II for values)

- 1) “Equal to” or “greater than” ( $\geq$ ) concentration determines positive status of a primary analyte when it is equal to or greater than the cutoff value except C0 and C2.
- 2) “Equal to” or “less than” ( $\leq$ ) concentration determines positive status of C0 and C2 when they are equal to or less than the cutoff values.
- 3) Ratio determines the positive status of an analyte when it is “equal to”, “greater than” or “less than” the cutoff value.

#### B. Call the ASC Coordinator

1. Retrieve the TRF form for each presumptive positive result for TRA, BIO, TSH, 17OHP, amino acids and acylcarnitines. **DO NOT** call Indeterminate Positives for CAH. Ship these specimens to GDL by overnight delivery as soon as GDL completed review and release.
2. Identify the ASC by hospital of birth.
3. Use the TRF and enter the ASC Coordinator, result exactly as shown on the Presumptive Positive List, and all other information needed on the NBS Presumptive Positive Log.
4. Have the supervisor or designee verify that the accession number and result entered on the log matched the Presumptive Positive List, verify that the accession number on the TRF matched the accession number on the log, and **sign off** on the log.
5. Have the supervisor or designee calls the coordinator and report the result as entered on the log. If unable to reach coordinator, leave a message in the ASC’s voice mail. Provide the information below.
  - a. Your name and where you are calling from
  - b. Date and time of call
  - c. Name and birth date of newborn
  - d. Accession and I number
  - e. Physician’s name and phone number
  - f. Test and result
  - g. Your telephone number
6. FAX the TRF to the coordinator.
7. Follow instructions in the NAPS Laboratory Data Entry Manual to enter Confirmation of Contact including the result reported.  
**NOTE:** Do not call the coordinator for IRT presumptive positive results. Follow instructions under separate cover on how to handle IRT presumptive positives.

#### C. Confirmed High Results

1. TSH and 17OHP

- a. A confirmed high result for TSH is a presumptive positive. A confirmed high result for 17OHP may or may not be a presumptive positive based on birth weight.
  - b. Report to the coordinator the TSH or 17OHP concentration, that the concentration is >STD, what the concentration of the highest STD is, and any concentration >STD is not a quantitated result.  
**NOTE:** Each kit lot has a different concentration for the Std F, highest standard
  - c. Record on the NBS Presumptive Positive Log and Confirmation of Contact.
2. Amino Acids, Succinylacetone, and Acylcarnitines  
Refer to the Tandem Mass assay, Section VII.J.2.9), for complete details on how to handle results that are greater than the linearity range.
    - a. Report result as greater than the linearity range for that analyte when the result is greater than the linearity range, see Table III. Inform the coordinator that value is above the method analytical limits. Do not report the ratio for that analyte.
    - b. Record on the Presumptive Positive Log and Confirmation of Contact.
- D. High Sample Inadequate for Repeat Testing
1. Telephone the appropriate ASC Coordinator and report the concentration for TSH or 17OHP, that the concentration is >STD, the concentration of the highest STD, and any concentration >STD is not a quantitated result.
  2. Inform the coordinator that this is an unconfirmed result and the result cannot be confirmed due to lack of sample.
  3. Record on the NBS Presumptive Positive Log and Confirmation of Contact.
- E. Correct a reported Incorrect Result (Amended Report)
1. Follow protocol for calling a presumptive positive result if you made a mistake in reporting the result.
  2. Report the correct result.
  3. Explain briefly the reason for the discrepancy.
  4. Record on the NBS Presumptive Positive Log and Confirmation of Contact.
- F. Samples Retested
- After a call for a presumptive positive was made to the coordinator and there is a need to repeat the sample, call the coordinator again with the retest result regardless of whether it is still a presumptive positive with a different concentration or the retest result changed the presumptive positive to a negative.

1. Compare the repeat result with the initial result.
2. Call the coordinator with the retest result unless the repeat result is **identical** to the original result. **This is to ensure that the result on the mailer is identical to the result called to the ASC.**
3. Briefly explain the reason for retesting.
4. Record on the NBS Presumptive Positive Log and Confirmation of Contact.

**X. PROCEDURE NOTES**

**NA**

**XI. METHOD LIMITATIONS**

**NA**

**XII. REFERENCES****Table I****MS/MS Cutoff for Amino acids and Succinylacetone**

<b>Analyte</b>	<b>Type of Analyte</b>	<b>Cutoff</b>	<b>Cutoff Type</b>
Alanine	AA	1000	High
Arginine	AA	50	High
Citrulline	AA	60	High
<b>Citrulline</b>	<b>AA</b>	<b>5</b>	<b>Low</b>
Glycine	AA	...	...
Leucine/Isoleucine	AA	250	High
Methionine	AA	100	High
<b>Methionine</b>	<b>AA</b>	<b>8</b>	<b>Low</b>
Ornithine	AA	800	High
Oxoproline	AA	...	
Phenylalanine	AA	155	High
Proline	AA	1500	High
Tyrosine	AA	850	High
Valine	AA	...	...
Arg/Orn	AA Ratio	1.4	High
Cit/Arg	AA Ratio	6.0	High
Phe/Tyr	AA Ratio	1.5	High
Leu/Ala	AA Ratio	1.3	High
Val/Phe	AA Ratio	3.5	High
Succinylacetone	Ketone	4.5	High

**Table I (Continued)****MS/MS Cutoff for Free and Acylcarnitines**

<b>Analyte</b>	<b>Type of Analyte</b>	<b>Cutoff</b>	<b>Cutoff Type</b>
<b>C0</b>	<b>AC</b>	<b>7.0</b>	<b>Low</b>
C0	AC	125	High
<b>C2</b>	<b>AC</b>	<b>11</b>	<b>Low</b>
C2	AC	80	High
C3	AC	6.3	High
C3DC	AC	0.38	High
C4	AC	1.7	High
C5	AC	1.0	High
C5:1	AC	0.6	High
C5OH	AC	0.9	High
C5DC	AC	0.6	High
C6	AC	0.95	High
C8	AC	0.6	High
C8:1	AC	0.7	High
C10	AC	0.65	High
C10:1	AC	0.45	High
C12	AC	2.0	High
C14	AC	1.2	High
C14:1	AC	0.8	High
C14OH	AC	0.2	High
C16	AC	10	High
C16:1	AC	1.4	High
C16OH	AC	0.10	High
C18	AC	4	High
C18:1	AC	7	High
C18OH	AC	0.10	High
C18:1OH	AC	0.10	High
C3/C2	AC Ratio	0.3	High
C0/(C16+C18:1)	AC Ratio	75	High
C16OH/C16	AC Ratio	0.07	High
C3DC/C10	AC Ratio	4.0	High
C5/C3	AC Ratio	0.45	High
<b>C5DC/C3DC</b>	<b>AC Ratio</b>	<b>0.70</b>	<b>Low</b>

**TABLE II**  
(Interpretation and Disease Patterns)  
**Disorders Detected by MS/MS and their Biochemical Markers**

<b>Disorder</b>	<b>Abbreviation</b>	<b>Primary Analyte Elevation</b>	<b>Secondary Analyte Elevation</b>	<b>Urgent Disorder (Report)</b>
CPT-II, CAT Deficiency	CPT-II	C16	C18, C18:1	
LCHADD, TFP Deficiency	LCHADD	C16OH, C16OH/C16, C18OH and C18:1OH	C14OH, C16	YES
VLCADD	VLCADD	C14:1	C14	YES
MCADD	MCADD	C8	C6,C10,C10:1	YES
IVA, 2MBCDD	IVA	C5 (not C4) and C5/C3		YES
3MCC, MGA, HMG	3MCC	C5OH (not C5:1)		
BKT, 2MO3OHBCDD	BKT	C5OH	C5:1	
GA-I	GA-I	C5DC		YES
GA-II, EE	GA-II	C4, C5	C6, C8, C8:1, C10, C10:1, C12, C12:1, C14, C16, C16:1, C18, C18:1, C18:2	YES
SCADD, IBCDD	SCADD	C4[not C5]		
MCD	MCD	C3 and C3/C2 or C5OH		YES
PA/MMA	PA/MMA	C3 and C3/C2		YES
Malonic Aciduria	MAL	C3DC, C3DC/C10 and C5DC/C3DC (Low cutoff)		YES
Carnitine Transporter Deficiency	CTD	C0 ≤ Low cut off C2 ≤ Low cut off		
CPT1	CPT1	C0/(C16 + C18:1)		

**Table II (Continued)**

<b>Disorder</b>	<b>Abbreviation</b>	<b>Primary Analyte Elevation</b>	<b>Secondary Analyte Elevation</b>	<b>Urgent Disorder (Report)</b>
Maple Syrup Urine Disease	MSUD	Leu , Leu/Ala and Val/Phe		YES
Citrullinemia (I/II) ASL Deficiency	CIT	Cit and Cit/Arg		YES
Argininemia	ARG	Arg and Arg/Orn		
HHH Syndrome Gyrtae atrophy, Hyperornithemia w/ Gyrate atrophy	HHH	Orn	Orn/Cit	
5- Oxoprolinemia	Oxopro	5- Oxopro		
Hyperprolinemia	Hypro	Pro		
Homocystinuria	HCY	Met		
Non-Ketotic Hyperglycinemia	NKH	Gly		
Phenylketonuria	PKU	Phe, Phe/Tyr		YES
Tyrosinemia	TYR	Tyrosine		
Tyrosinemia type I	TYRO I	Succinylacetone (SA)		YES

**TABLE III****Analytical Linearity Range of Amino Acids, Succinylacetone, and Acylcarnitines**

<b>Analyte</b>	<b>Linearity Range (<math>\mu\text{M}</math>)</b>
Alanine	4.5- 4090
Arginine	0.6 - 3721
Citrulline	4.8 - 1683
Glycine	50.4 - 4487
Leucine	1.3 - 2545
Methionine	2.5 - 1185
Ornithine	0.6 - 3771
Phenylalanine	0.3 - 2341
Proline	4.7 - 3659
Succinylacetone	0.24 - 158.1
Tyrosine	1.2 - 2816
Valine	0.6 - 2358
C0	0.2 - 2274
C2	0.2 - 735
C3	0.03 - 88
C4	0.07 - 59.81
C5	0.04 - 59.1
C5DC	0.08 - 28.85
C6	0.08 - 61.54
C8	0.02 - 35.2
C10	0.04 - 28.86
C12	0.04 - 42.74
C14	0.02 - 41.81
C16	0.1 - 107.3
C18	0.04 - 32





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**Procedure Revision Log**

Enter section(s) and the page number(s) where deletion, revision or add-ons are found. Indicate whether this is a deletion, revision or an add-on by entering “X” in the appropriate column.

Procedure: NBS Accession and Reporting at the NAPS Lab, CN002, Version 9.0

Revised By: Trang Bui, CLS

Date: 1/17/2012

<b>Sections</b>	<b>Page #</b>	<b>Deletion</b>	<b>Revision</b>	<b>Addition</b>
Birth Weight Table	10		X	
Table I, Cutoffs for AA, SUAC, AC	14 and 15		X	
Table II, Interp. and Disease Patterns	16 and 17		X	
New version	All		X	



