

## Appendix 9

### NEWBORN AND PRENATAL SCREENING DATA ENTRY AND FOLLOW-UP ACTIONS

#### I. ACTIONS FOR FOLLOW-UP

##### A. Inadequate Specimens

##### 1. Prenatal Screening Specimens

- a. If any specimen is determined to be inadequate, as defined in Appendix 11, the Contractor must document this by completing the log of inadequate specimens and by entering the data into SIS on the same day; and by recording the reason for inadequacy on the respective TRF or on a separate document which is scanned into SIS with the TRF. On PNS samples that are partially inadequate, notify the Prenatal Screening Branch for resolution of overall adequacy, prior to entering this information into the computer.
- b. If, through error of the Contractor, a specimen is lost or cannot be tested, the Contractor must telephone the PNS coordinator at the earliest time on that day so that an adequate repeat specimen may be obtained as soon as possible. The Contractor shall document this telephone contact as specified in 1.a. above. The Contractor shall reimburse the person collecting such repeat specimen for the costs of blood collection if requested.

##### 2. Newborn Screening Specimens

- a. If any specimen is determined to be inadequate, as defined in Appendix 11, the Contractor must telephone the appropriate GDSP-designated NBS ASC at the earliest time that day so that an adequate repeat specimen may be obtained as soon as possible. The Contractor shall document this telephone contact by completing the NBS Positive/Inadequate Log and entering the NBS Confirmation of Contact (CC) data into GDSP's Screening Information System (SIS) by recording the inadequate on the respective TRF and faxing the TRF to the coordinator. The Contractor shall fax a list of positive and inadequate specimens to the Newborn Screening Clinical Services Branch daily.
- b. If any specimen is determined to be partially adequate in that it consists of only one completely and properly filled circle of blood, the Contractor shall:
  - 1) Test the specimen for MSMS, transferase, Biotinidase & hemoglobin; and
  - 2) Telephone the NBS ASC to report the inadequate specimen
- c. If through error of the Contractor, a specimen is mislabeled,

## Appendix 9

inaccurately tested, or lost or the specimen is lost by the Contractor's courier through no fault of the hospital or the party providing the specimen, the Contractor must telephone the NBS ASC at the earliest time during the normal working day so that an adequate repeat specimen may be obtained as soon as possible. The Contractor shall document this telephone contact as specified in 2.a. above. The Contractor shall reimburse the person collecting such repeat specimen for the costs of blood collection if requested.

- d. When a repeat specimen is received, it shall be tested for the full panel of tests. The Contractor shall not charge for any repeat tests since these costs were considered in the overall contract price per infant for the complete panel of tests.

### B. Initial Positives

#### 1. Prenatal Screening Specimens

There are no "initial positive" results for the laboratory to report for PNS screening. The positive/negative designation is calculated by the CDPH computer (SIS) and reported from the CDPH central site.

#### 2. Newborn Screening Specimens

- a. If a specimen is determined to have an initial positive result for MSMS, etc. as defined by CDPH Genetic Disease Laboratory, the Contractor must at the earliest time during the normal working day telephone the result to the appropriate CDPH-designated NBS Area Service Center (ASC) and fax the TRF to the ASC.

The Contractor shall document the telephone contact by completing the NBS Positive/Inadequate Log and entering NBS-CC Form data the same day into SIS. The Contractor shall fax a list of positive and inadequate specimens to Newborn Screening Clinical Services Branch daily.

- b. If a specimen is determined to have an initial positive result for any screened disorder except those determined by the Genetic Disease Laboratory Branch, the Contractor shall telephone the result to the appropriate CDPH-designated NBS ASC following the procedure specified in 2.a. above.
- c. If a specimen is determined by the transferase test to be absent in transferase activity as defined by CDPH Genetic Disease Laboratory Branch, the Contractor must immediately, at any time 24 hours per day, telephone the result to the appropriate CDPH-designated NBS ASC. The telephone contact shall be documented as provided in 2.a. above.
- d. There are no "initial positive" results for the Laboratory to report for

## Appendix 9

CAH2, CF, SCID or hemoglobinopathies screening. The positive/negative designation is interpreted by the CDPH computer and/or reported from the CDPH central site.

- e. The Contractor shall maintain an up-to-date NBS Positive/Inadequate Log. This log shall be used by the Contractor, according to guidelines provided by the Genetic Disease Laboratory Branch, to ascertain that all the contacts designated in A. and B. above, are completed and attributed to the correct newborns and specimens.

### II. DATA ENTRY

DATA ENTRY FOR THE NEWBORN SCREENING PROGRAM HAS PRIORITY OVER DATA ENTRY FOR THE PRENATAL SCREENING PROGRAM.

#### A. Prenatal Screening Specimens

1. Scan and enter accurately all information on Test Request Forms (TRF). Data enter Medi-Cal numbers when they come as a Xerox attachment of the Medi-Cal card.
2. Enter into SIS all the data for each inadequate specimen. These must be entered on the day the inadequate is identified.
3. The PNS test results are electronically transmitted to SIS.
4. Follow protocols established by the Genetic Disease Screening Program for scanning, entering and auditing TRF data.
5. See Table 1 entitled "Quick Reference Chart for Management of PNS Samples" for summary of determining adequacy.

#### B. Newborn Screening Specimens

1. Enter all information on the NBS test request forms (TRF).
2. Enter into SIS the NBS-CC data for each inadequate phone call and initial positive report made to the NBS ASC. These must be entered on the day the phone call is made.

#### C. Both Prenatal and Newborn Screening Data

1. Demographic data (PNS TRFs and NBS TRFs forms) shall be entered on the day received and test results shall be transmitted on the day the test is completed. All data must be entered before the close of the next day following receipt.
2. In the event the Genetic Disease Screening Program (GDSP) computer

## Appendix 9

system is unavailable for data entry due to any system problems or scheduled down time, that data entry must be current by the time that twice the down time has passed, i.e., if the system is down for one day, data entry must be current before two full working days after the computer system is restored as a priority before other backlogged data.

3. Key entry errors should be kept to a minimum. GDSP has the right to request Contractor to cooperate in making periodic checks of data quality. Contractor agrees that the standard of performance for a key entry operator is three errors or less per 300 key strokes averaged over a 30-day period. Contractor agrees to monitor this standard of performance at least monthly.
4. When entering TRF data using the OCR system, the initial entry and validation shall be done by a different operator than the person doing the double data entry field verification. This reduces data entry errors.
5. A minimum of 10% of TRF records entered should be audited daily. The number of errors per form per employee should be noted in an audit log. Count as an error each keystroke that is incorrect, e.g. if the correct number is 123, an entry of 132 is two errors, an entry of 321 is also two errors and 312 would be three errors.
6. Any day that the 10% audit requirement is not met, the reason should be documented in the audit log.

## Appendix 9

**Table 1. Quick Reference Chart for Management of PNS Samples**

PROBLEM	FAX TRF?	ANALYZE SPECIMEN?	DATA ENTRY ACTION
1. No information on tube or in package.	NO	NO	DO NOT assign an accession number to or data enter this specimen. Discard tube.
2. Specimen arrives with NO TRF (name and BCD on TRF label on tube )	No, create a substitute TRF **	NO	Enter substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
3. TRF form arrives without specimen	No, write reason on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is N for No Blood.
4. Hemolyzed specimen with TRF	NO **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is H for Hemolyzed
5. TRF# on tube does not match form # on TRF, but names match	No, write reason including the TRF# from tube on TRF before scanning. **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
6. TRF# on tube does not match TRF# on form, names do not match	For Specimen #1 - No, create a substitute TRF **  For Specimen #2 - No, write reason on TRF before scanning **	NO	Access as 2 different specimens. Specimen #1 is considered a tube without TRF – Enter substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled. Specimen #2 is considered a TRF without a tube. Enter information from TRF. Specimen is inadequate, Adequacy Code is N for No blood.
7. TRF# is not on tube, name on TRF and tube match,	No, write reason on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled
8. No name on tube, accompanied with TRF or other source of patient or clinical information	No, write reason on TRF before scanning **	NO	Enter information from TRF or substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
9. Name on tube, no name on TRF, TRF# and BCD match	No, write name from tube on TRF before scanning **	NO	Enter information from TRF. Enter last name from tube with the addition "On Tube". Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
10. Different middle initials on tube and TRF	No, write reason onto TRF before scanning **	NO	Enter TRF with middle initial from form. Specimen is adequate if middle initials from a legible signature or from a label on the TRF match the tube. Otherwise, specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.

## Appendix 9

PROBLEM	FAX TRF?	ANALYZE SPECIMEN?	DATA ENTRY ACTION
11. Conflict between name on form and signature or label. If signature is missing or illegible, comparison is not required	No, write reason on TRF before scanning **	YES	Enter information from TRF. Adequacy Code is C for Coordinator Resolution
12. Different first name and different last name on TRF and tube, TRF# matches	No, write name from tube on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
13. Same first name but different last names on TRF and tube, TRF# and BCD match a. TRF name and tube name are different, tube last name matches maiden name b. TRF has no maiden name and tube and TRF last name are different c. Last name on form is hyphenated or is a 2 name last name and name on tube has either last name	a. No  b. No, write reason on TRF before scanning **  c. Yes, write single last name from tube on TRF before FAXing	YES  NO  YES	a. Enter information from TRF. Specimen is adequate  b. Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled  c. Enter information from TRF, Adequacy Code is C for Coordinator Resolution
14. Spelling of name is different on TRF and tube	No, write name from tube on TRF before scanning **	NO	Enter name from TRF. Specimen is adequate if spelling of name from a <u>legible</u> signature or from a label on the TRF match the tube. Otherwise, specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
15. First and last names are transposed, TRF# and BCD matched	No, write reason on TRF before scanning **	YES	Enter TRF. Adequacy Code is C for Coordinator resolution
16. First name is different on TRF and tube due to use of customary nickname or diminutive, e.g., Kim for Kimberly	NO	YES	Enter information from TRF. Specimen is adequate
17. BCD on tube does not match BCD on TRF	No, write BCD from tube onto TRF before scanning **	YES	Enter TRF and do not enter either BCD leaving the field blank. This will become a Headline case for the coordinator and coordinator will determine the correct BCD.

## Appendix 9

PROBLEM	FAX TRF?	ANALYZE SPECIMEN?	DATA ENTRY ACTION
18. BCD is on tube but not on TRF or BCD on TRF but not on tube	No, write BCD from tube or "No BCD on tube" on TRF before scanning **	YES	Enter TRF and do not enter either BCD leaving the field blank. This will become a Headline case for the coordinator and coordinator will determine the correct BCD.
19. Different year for BCD on TRF and tube at beginning of year, but same month and day.	NO	YES	Enter the correct year, common problem early in a new year. Specimen is adequate
20. Clinician calls with additional information on patient that has matching name, TRF#, and BCD	Tell clinician to call coordinator	YES	Enter information from TRF. Based on information from clinician, coordinator will correct any errors on TRF.
21. Clinician writes important information about the patient on the form, specimen has matching name, TRF#, and BCD	Yes, circle clinician's comments before FAXing TRF to coordinator	YES	Enter TRF as it is filled out. DO NOT enter extra information into SIS.
22. Clinician writes different trimester on form, i.e., writes First Trimester clearly on Second Trimester Form or vice versa, specimen has matching name, TRF#, and BCD	NO	YES, access specimen as trimester indicated by the clinician on the form	Enter as trimester written on the form. Enter TRF# if SIS allows. If not, enter all zeroes for form number.
23. TRF has invalid or illegible data, specimen has matching name, TRF#, and BCD	Yes, circle portions of concern before FAXing TRF	YES	Enter TRF as it is filled out; leave illegible fields blank.

\*\* FAX TRF to Coordinator when the accession day is Friday, unless directed otherwise.

**REMINDER:** Always use a fax coversheet when faxing the TRF to GDSP or to a Coordinator.