

Appendix 14



Specimen Handling Protocol For SCID Project

Tracking number GN 503

Version Number: 1.1

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Appendix

I. Title

Specimen Handling Protocol for SCID Project

II. Principle

The purpose of this protocol is to ensure that the NBS specimens, shipped from NAPS Laboratories to GDLB for the SCID pilot, are received, logged in, tested, and properly stored in the Specimen Bank in a timely fashion. GDL receives specimens for the SCID pilot on Tuesdays to Fridays from all seven NAPS Area Laboratories for the DNA analyses. Chain of custody procedures are followed to prevent the loss of any specimens during handling. After completion of testing, the specimens are placed in designated boxes to be transported to the Specimen Bank for long term storage.

III. Specimen Collection and Type

Initial specimens, blood spots dried on filter paper, collected for the State's Newborn Screening Program.

IV. Equipment and Supplies

Archive boxes
Biomailers
Chain of Custody Logbook
Freezer, -10 to -20°C
Refrigerator, 4 to 10°C

V. Reagents

Not Applicable

VI. Calibration and Quality Control

Not Applicable

VII. Procedure

A. At the NAPS Laboratories

1. After completion of testing of each day's initial specimens for the newborn screening panel, place the day's specimens into a biomailer and store in the refrigerator.
2. Ship the biomailers with NBS specimens following the schedule provided by GDLB. An example of shipment schedule can be found in the Appendix. NBS specimens are only sent to GDLB only after all tests are done at the NAPS lab. Specimens are usually are shipped on the 7th-8th days after accession.
3. Complete the revised Shipment of Confirmation of Tested Newborn Blood Spot Specimens form, form is attached, for each day bag and place the form in a 13" x 18" zip lock bag in the biomailer box. In order to trace the whereabouts of specimens, it is imperative that the Julian Dates and Sequence Numbers of specimens sent to Stanford Medical and GDLB be listed on the form.
4. Label the biomailer box with GDLB's mailing address, Attn: SCID Project Team, and place a sticker on which your laboratory writes your laboratory number (name) and the julian date of the specimens in the biomailer.
5. Seal the box with masking tape with the mailing address clearly visible. Send the biomailer box (es) to GDLB every Monday to Thursday.

B. At GDLB

1. GDLB receives biomailer boxes for the SCID pilot from NAPS laboratories on Tuesday, Wednesday, Thursday and Friday.
2. The lab assistant receiving the biomailers

- a. Logs the biomailer onto the Shipping and Handling log sheet.
- b. Takes the biomailer boxes to the Accession Lab and logs them to the SCID Daily log sheet
3. The assigned lab assistant opens biomailers and put day bags of specimens to temporary storage boxes according to Julian date. He/she logs each temporary storage boxes and contents to SIS Biobank
4. The assigned lab assistant puts 2nd tier specimens and returned specimens from Stanford Medical as they become available into the original day bags using the list on the Shipment confirmation of Tested Newborn Bloodspot Specimen forms.
5. Lab assistant takes the specimens to the walk-in refrigerator, C228, and places into shelves labeled “SCID Project, To Be Tested” by julian day.
6. When SCID testing is done, analyst returns all boxes and specimens to walk-in refrigerator, C228, and places them to the shelves labeled “SCID Project, Testing Completed”.
7. Return day bags from the “SCID Project, Testing Completed” boxes to the long- term storage facility on a biweekly basis.

VIII. Calculations

Not Applicable

IX. Reporting Results

Not Applicable

X. Procedure Notes

Not Applicable

XI. Limitations of Procedure

Not Applicable

State of California
Department of Public Health
Genetic Disease Laboratory Branch

XII. References

Not Applicable

Appendix

SHIPMENT OF NBS SPECIMENS FOR SCID TESTING (9/17/12 to 10/11/12)

Shipment Date			Julian day			
Monday	17-Sep-12		252	253	254	255
Tuesday	18-Sep-12		256			
Wednesday	19-Sep-12					
Thursday	20-Sep-12		257	258		
Monday	24-Sep-12		259	260	261	262
Tuesday	25-Sep-12		263			
Wednesday	26-Sep-12					
Thursday	27-Sep-12		264	265		
Monday	1-Oct-12		266	267	268	269
Tuesday	2-Oct-12		270			
Wednesday	3-Oct-12					
Thursday	4-Oct-12		271	272		
Monday	8-Oct-12		273	274	275	276
Tuesday	9-Oct-12		277			
Wednesday	10-Oct-12					
Thursday	11-Oct-12		278	279		

State of California
Department of Public Health
Genetic Disease Laboratory Branch

SHIPMENT CONFIRMATION OF TESTED NEWBORN BLOOD SPECIMENS

TO: California Department of Public Health
Genetic Disease Laboratory Branch
850 Marina Bay Parkway #G205
Richmond, CA 94804

Attn: SCID Project Team

FROM: _____

Enclosed are newborn screening blood spot specimens from:
Julian Date (First 3 digits of Accession Number): _____
Month/Year: _____ / _____

Date Shipped to GDL: ____ / ____ / ____
Number of Boxes Shipped: _____
Shipped by (print name): _____

Specimens Sent for Confirmatory Tests (CAH and IRT)
Specimens Sent to GDLB
Julian Date:
Sequence Number(s):
Specimens Sent to Stanford University
Julian Date:
Sequence Number(s):

State of California
Department of Public Health
Genetic Disease Laboratory Branch

Prepared by: _____ Date: _____
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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: Specimen Handling Protocol for SCID Project, Tracking number GN 503, Version 1.1

Revised By: _____ Date: _____

Section	Page #	Deletion	Revision	Add-on
VII	3-4		X	X

