

**State of California
Office of Administrative Law**

In re:
Department of Public Health

Regulatory Action:

Title 17, California Code of Regulations

Adopt sections: 6500.03, 6500.05, 6500.9,
6500.21, 6500.33, 6500.43,
6500.51, 6500.55, 6500.58,
6500.71, 6500.78
Amend sections: 6500.35, 6500.39, 6500.45,
6500.50, 6501, 6501.5,
6505, 6506, 6506.6, 6506.8,
6506.10
Repeal sections: 6500.65, 6500.67

NOTICE OF FILING AND PRINTING ONLY

Government Code Section 11343.8

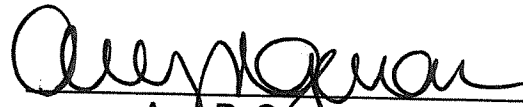
OAL Matter Number: 2017-0406-01

OAL Matter Type: File and Print Only (FP)

On April 4, 2016, the Department of Public Health filed emergency regulations to revise Newborn Screening Program requirements for newborn's physicians, midwives, perinatal health facilities/hospitals, and other out-of-hospital newborn screening providers; update the scope of testing to accommodate the expanded list of disorders for which testing is done; and update definitions, optimal timing, specific details regarding specimen collection, and follow-up requirements to accommodate practice and technology changes in newborn screening. Health and Safety Code section 124977, subdivision (d)(1) provides that the regulations shall become effective immediately upon filing with the Secretary of State; however, the regulations "shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11345.8 and 11346.9 of the Government Code or shall be repealed." This filing contains the Department's Statement of Compliance that it complied with the requirements of section 124977, subdivision (d)(1) of the Health and Safety Code. Additionally, this action amends sections 6500.50, 6501.5, 6505, 6506, 6506.6, 6506.10 to update forms Incorporated By Reference, update timing for testing to align with national standards for newborn screening, and revise permissible delivery service options.

OAL filed this regulation(s) or order(s) of repeal with the Secretary of State, and will publish the regulation(s) or order(s) of repeal in the California Code of Regulations.

Date: April 17, 2017



Amy R. Gowan
Attorney

For: Debra M. Cornez
Director

Original: Dr. Karen Smith
Copy: Linda Cortez

FILE PRINT

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2016-0614-05	REGULATORY ACTION NUMBER 2017-0406-01FP
For use by Office of Administrative Law (OAL) only		
NOTICE		REGULATIONS

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

APR 17 2017

2:57 PM

2017 APR -6 P 3:23
OFFICE OF ADMINISTRATIVE LAW

AGENCY WITH RULEMAKING AUTHORITY
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

AGENCY FILE NUMBER (if any)
DPH-09-010E

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON		TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn		NOTICE REGISTER NUMBER	PUBLICATION DATE	

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) NEWBORN SCREENING PROGRAM	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2016-0323-02EFP
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	ADOPT	
	AMEND	<i>See Attached</i> per agency request ARC 4/17/17
	REPEAL	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	6500.50, 6501.5, 6505, 6506, 6506.6, and 6506.10	
TITLE(S)	17	

3. TYPE OF FILING			
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input checked="" type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input checked="" type="checkbox"/> Other (Specify) Emergency Regulation HSC 124977(d)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
12/26/16 - 1/3/17

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) HSC 124977(d)
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify)		

7. CONTACT PERSON LINDA M. CORTEZ	TELEPHONE NUMBER 916-440-7807	FAX NUMBER (Optional) 916-440-5747	E-MAIL ADDRESS (Optional) linda.cortez@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Karin S. Schwartz</i>	DATE 3/29/17
TYPED NAME AND TITLE OF SIGNATORY Karin S. Schwartz, Deputy Director and Chief Counsel	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

APR 17 2017

Office of Administrative Law

per agency request
ARC 4/17/17

Sections Affected:

Title 17

Adopt:

6500.03, 6500.05, 6500.9, 6500.21, 6500.33, 6500.43, 6500.51, 6500.55, 6500.58, 6500.71, 6500.78

Amend:

6500.35, 6500.39, 6500.45, 6500.50, 6501, 6501.5, 6505, 6506, 6506.6, 6506.8, 6506.10

Repeal:

6500.65, 6500.67

Statement of Compliance with Health and Safety Code Section 124977

The Department has complied with the provisions of Health and Safety Code section 124977(d)(1) by holding a public hearing on July 6, 2016, within 120 days of filing the emergency regulations with the Secretary of State and has complied with Government Code sections 11346.8 and 11346.9. The emergency regulations were filed with the Secretary of State on March 23, 2016.

**TEXT OF REGULATIONS
ARTICLE 1. DEFINITIONS**

(1) Adopt §6500.03 to read:

§6500.03. California Children's Services (CCS).

"California Children's Services (CCS)" means a State and County program providing medically necessary benefits as defined in Title 22, Division 2, Subdivision 7, Chapter 1, §41452 to persons under 21 years of age with physically handicapping conditions who meet medical, financial and residential eligibility requirements for the CCS program.

Note: Authority cited: Sections 20, 100275, 123805, 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 123830, 123835, 123845, 123865, 123870, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(2) Adopt §6500.05 to read:

§6500.05. Confirmatory Test.

"Confirmatory Test" means a laboratory test done to prove or disprove the presence of a specific condition identified by the newborn screening test. This test is performed on a specimen other than the screening specimen.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(3) Adopt §6500.9 to read:

§6500.9. Early Specimen.

"Early Specimen" means a newborn screening specimen collected from a newborn who is less than 12 hours of age.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(4) Adopt §6500.21 to read:

§6500.21. Infant.

“Infant” means a child 29 days through 12 months old.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(5) Adopt §6500.33 to read:

§6500.33. Lost to Follow-Up.

“Lost to Follow-Up” means the inability of the Newborn Screening Area Service Center to locate the newborn or infant for follow-up because:

(a) there is no response to attempts to locate the parents or legal guardian after a minimum of 1 phone call and 1 certified letter using available contact information; and

(b) the Newborn Screening Area Service Center and the Department believe that reasonable attempts have been made to locate the infant.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(6) Amend §6500.35 to read:

§6500.35. Newborn.

“Newborn” means a child less than 29 days old.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(7) Amend §6500.39 to read:

§6500.39. Newborn's Physician.

"Newborn's physician" means the physician caring for the newborn or infant in the perinatal licensed health facility's normal newborn nursery or neonatal intensive care unit or in the outpatient community after discharge.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(8) Adopt §6500.43 to read:

§6500.43. Newborn Screening.

"Newborn Screening" means the testing of infants to identify those at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(9) Amend §6500.45 to read:

§6500.45. Newborn Screening Area Service Center.

"Newborn Screening Area Service Center" means a facility which is contracted with the Department to provide regional newborn screening services.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(10) Adopt §6500.50 to read:

§6500.50. Newborn Screening Specimen.

“Newborn Screening Specimen” means a blood sample taken from an infant that is collected on CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D).

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(11) Adopt §6500.51 to read:

§6500.51. Newborn Screening Test.

“Newborn Screening Test” means a biochemical or other assay of blood spots collected from an infant for the purpose of determining whether the newborn might be at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(12) Adopt §6500.55 to read:

§6500.55. Out-of-Hospital Newborn Screening Providers.

“Out-of-Hospital Newborn Screening Providers” means:

- (a) all healthcare professionals including, but not limited to, licensed midwives (LM), certified nurse midwives (CNM), registered nurses (RN), physician assistants (PA), pediatric nurse practitioners (PNP), physicians/medical doctors (MD), doctors of osteopathy (DO), and naturopathic doctors (ND), who are licensed or certified by the State to provide maternal care and to deliver pregnant women in alternative settings other than perinatal licensed health facilities including, but not limited to, private homes and clinics; and
- (b) staff of health care entities, such as clinics and free-standing independent laboratories that are authorized by the Department to collect newborn screening specimens in alternative settings other than perinatal licensed health facilities.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(13) Adopt §6500.58 to read:

§6500.58. Perinatal Licensed Health Facility Staff.

“Perinatal Licensed Health Facility Staff” means the individuals working in the laboratory, maternal, or nursery departments of perinatal licensed health facilities who collect the newborn screening specimens.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(14) Repeal §6500.65 as follows:

§6500.65. Recall Specimen.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.
Reference: Sections 124980 and 125000, Health and Safety Code.

(15) Repeal §6500.67 as follows:

§6500.67. Recall Test.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.
Reference: Sections 124980 and 125000, Health and Safety Code.

(16) Adopt §6500.71 to read:

§6500.71. Screening Information System (SIS).

“Screening Information System (SIS)”, in this Group, means the Department Newborn Screening Program’s database and associated screens that:

- (a) list the newborn screening specimens that have been received by the Department for testing; and
- (b) provide for reporting of those specimens that are missing.

This system is to be used to verify receipt of specimens and report those that have not been received pursuant to §6506.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(17) Adopt §6500.78 to read:

§6500.78. This Group.

“This Group” means Group 3. Newborn Screening Program in the official California Code of Regulations as follows: Title 17. Public Health, Division 1. State Department of Health Services, Chapter 4. Preventive Medical Service, Subchapter 9. Testing for Heritable Disorders, Group 3. Newborn Screening Program.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

ARTICLE 2. TESTING AND FOLLOW-UP PROGRAM REQUIREMENTS

(18) Amend §6501 to read:

§6501. Scope of Newborn Testing.

Except for provisions in §6501.2 and §6502, each newborn born in California shall be tested for galactosemia, hereditary hemoglobinopathies, phenylketonuria, and primary congenital hypothyroidism and disorders authorized for testing in Health and Safety Codes 124977, 124980 and 125001 in accordance with procedures in this Group.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(19) Adopt §6501.5 to read:

§6501.5. Required Newborn Screening Forms.

The following newborn screening forms from the Department shall be utilized in accordance with provisions in this Group:

(a) For all newborn screening specimen collection pursuant to §6505(a)(1), §6505(a)(2), §6505(b)(1), §6505(b)(2), §6505(c)(1), §6506(a), §6506.6(a), §6506.6(b)(1) and §6506.6(c)(1): CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-126/16)) NBS-I (DE). This form is hereby incorporated by reference.

(b) For parents or legally appointed guardians who object to a newborn screening test pursuant to §6501.2: NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/1406/16) - English version or CDPH 4459(SP) (6/1406/16) - Spanish version. ~~This~~ These forms ~~is~~ are hereby incorporated by reference.

~~(c) For perinatal licensed health facility staff or birth attendants who have not obtained a newborn screening specimen pursuant to §6505(a)(4), §6505(b)(4), §6506(a) or §6506.2: HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS - NO) CDPH 4089 (01/11). This form is hereby incorporated by reference.~~

~~(d)~~ (dc) For county registrars who register infants born outside of a perinatal licensed health facility or who are not attended by a birth attendant pursuant to §6505(d): NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09). This form is hereby incorporated by reference.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(20) Amend §6505 to read:

§6505. Collection of Newborn Screening Specimens.

(a) For each newborn born in a perinatal licensed health facility, the perinatal licensed health facility staff shall:

(1) collect the newborn screening specimen, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - ~~(44-126/16)~~) NBS-I (~~DF~~) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than ~~96~~48 hours of age prior to discharge or transfer of the newborn unless the newborn's condition is life-threatening and the collection cannot be done safely.

Physicians attending critically ill newborns who require special care may postpone collection of a newborn screening specimen until the newborn's emergency condition is stabilized. The receiving perinatal licensed health facility staff shall then collect the newborn screening specimen using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - ~~(6/1644-12)~~) NBS-I (~~FD~~) pursuant to §6501.5(a) and §6504.4(b) as soon as the newborn's condition is stabilized. Any specimen collected on a newborn prior to 12 hours of age is an early specimen and another specimen shall be collected after 12 hours of age pursuant to §6505(a)(2) and §6506.6.

(2) collect a newborn screening specimen prior to red blood cell transfusion when the newborn is stable, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - ~~(6/1644-12)~~) NBS-I (~~FD~~) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the same-day or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to ~~the United States Postal Service~~ another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

~~(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to §6501.5(c), in the event the~~

~~newborn screening specimen is not collected prior to transfer to another perinatal licensed health facility and there is no copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) in the newborn's medical record.~~

(~~5~~4) Collection of a newborn screening specimen under this section shall not apply if the parent or legal guardian has signed a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/1~~6~~4) pursuant to §6501.5(b).

(b) For infants not born in a perinatal licensed health facility, but admitted to a perinatal licensed health facility at any time after birth, the perinatal licensed facility staff shall:

(1) obtain a newborn screening specimen within 48 hours of admission, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (~~11-12~~16)) NBS-I (~~D~~) pursuant to §6501.5(a) and §6504.4(b), unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (~~11-12~~16)) NBS-I (~~D~~), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/1~~6~~4), or a newborn screening result is found in the infant's medical record or the physician has a record of the screening specimen having been collected.

(2) collect a newborn screening specimen prior to red blood cell transfusion, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (~~11-12~~16)) NBS-I (~~D~~) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to ~~the United States Postal Service~~ another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

(~~4~~) ~~complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to 6501.5(c), in the event the newborn screening specimen is not collected.~~

(c) For infants not born in a perinatal licensed health facility and not admitted to a perinatal licensed health facility after birth, out-of-hospital newborn screening providers shall:

(1) collect a newborn screening specimen within 48 hours of the first contact with the infant using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-126/16)) NBS-I (FD) pursuant to §6501.5(a) and §6504.4(b) unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-126/16)) NBS-I (FD) or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/164), or a newborn screening result is found in the infant's medical record.

(2) ensure that specimens are given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to ~~the United States Postal Service~~ another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

(d) For infants born outside of a perinatal licensed health facility and not subsequently admitted to a perinatal licensed health facility, when the birth is being registered at the county registrar's office, the person in the county registrar's office required to register the birth shall notify the Department of the birth the next business day after the birth is registered using the NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09) pursuant to §6501.5(d).

(e) A newborn screening specimen may be collected on a child over 1 year of age with prior authorization from the Department.

(f) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers without identifying the person or persons from whom these results were obtained.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(21) Amend §6506 to read:

§6506. Verification of Receipt of Newborn Screening Specimens by the Department.

(a) Perinatal licensed health facility staff and out-of-hospital newborn screening providers shall check the Department Screening Information System (SIS) within 7 days after the date of birth to verify that the newborn screening specimen has been received by the Department. This applies to all infants for whom perinatal licensed health facilities and out-of-hospital newborn screening providers have responsibility for newborn screening pursuant to §6505(a), (b) and (c). If a specimen has not been received and there is neither a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-1206/16)) NBS-I (FD) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/164) - English version or CDPH 4459 (SP) (6/16) - Spanish version pursuant to §6501.2 and §6501.5(b) present in the newborn's medical record, the staff shall complete a ~~HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS - NO) CDPH 4089 (01/11)~~ pursuant to ~~§6501.5(c)~~. If a specimen has not been received and the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) is present in the newborn's medical record, staff shall enter a missing specimen report into the Screening Information System (SIS), and if the newborn has not been discharged, collect a newborn screening specimen on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/1611-12)) NBS-I (FD) pursuant to §6501.5(a) and §6504.4(b) within 24 hours.

This specimen shall be given to a carrier contracted with the Department or ~~contracted with a newborn screening laboratory or to the United States Postal Service~~ another overnight carrier for transport to the assigned newborn screening laboratory on the same or next business day of the designated carrier.

(b) If a perinatal licensed health facility or a group of perinatal licensed health facilities has an internal computerized system in place to identify specimens received by their designated newborn screening laboratory, and this system has the same criteria to

verify receipt of newborn screening specimens as the Department's Screening Information System (SIS) as described in §6500.71(a) and (b), then their system rather than SIS may be used to verify receipt of their specimens.

Note: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(22) Amend §6506.6 to read:

§6506.6. Follow-Up to Reports of Inadequate and Early Newborn Screening Specimens.

(a) For those specimens identified by the Newborn Screening Area Service Center as early, or where the infant's age at time of specimen collection cannot be determined, the Newborn Screening Area Service Center shall verify with the collecting person or facility the dates and times of birth and specimen collection written on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/1611-12)) NBS-I (FD).

(b) Upon notification by the Newborn Screening Area Service Center that the specimen is verified as an early specimen, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/1611-12)) NBS-I (FD) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by ~~the United States Postal Service~~ another same-day or overnight carrier to the assigned newborn screening laboratory.

(c) When the perinatal licensed health facility staff, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician is notified by the Newborn Screening Area Service Center that a specimen is an inadequate specimen, the perinatal licensed health facility, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/1611-12)) NBS-I (FD) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by ~~the United States Postal Service~~ another same-day or overnight carrier to the assigned newborn screening laboratory.

(d) If a repeat specimen for either an early or an inadequate specimen cannot be obtained, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall notify the Newborn Screening Area Service Center by phone, fax, or e-mail within 48 hours regarding the status of the collection and also again when the specimen has been collected and sent to the Department.

(e) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(23) Amend §6506.8 to read:

§6506.8. Follow-Up to Reports of Positive Results.

(a) When the newborn's physician is notified by a Newborn Screening Area Service Center of a positive test result, the physician shall, within 48 hours of notification:

(1) Consult with a medical specialist from a California Children's Services (CCS) center or a CCS-paneled medical specialist, and upon the specialist's advice, shall refer the infant to a CCS center or a CCS paneled medical specialist for confirmatory testing and/or evaluation, diagnosis, and treatment; and

(2) Instruct the parents about medically necessary recommendations to care for the infant.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(24) Amend Section 6506.10 to read:

§6506.10. Use of Newborn Screening Contracted Laboratories for Repeat and Confirmatory Specimens.

(a) When repeat or confirmatory tests are required, the newborn's physician will ensure that:

- (1) Repeat or confirmatory specimens are collected within 48 hours;
- (2) Specimens are placed in containers appropriate for the specified test; and
- (3) Specimens are transported, on the same or next business day of the designated carrier, by a carrier contracted with the Department or contracted with a newborn screening laboratory or by ~~the United States Postal Service~~ same-day or overnight carrier, to the assigned newborn screening laboratory.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

1. CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF)
(CDPH-4409-(11/12)) NBS-I (D).

Repeal

NBS COPY

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF)
State of California - Health and Human Services Agency
California Department of Public Health

FOR STATE USE ONLY

ADDRESS GRAPH HERE:

Check Digits SN 29 000 001 32

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

BABY'S LAST NAME FIRST NAME STREET ADDRESS CITY STATE ZIP

MOTHER'S INFORMATION LEGAL GUARDIAN INFORMATION

MOTHER'S LAST NAME FIRST NAME MAIDEN NAME MOTHER'S BIRTH DATE MOTHER'S PHONE ALTERNATE/EMERGENCY PHONE

THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION NAME PHONE

NEWBORN'S PHYSICIAN INFORMATION

PHYSICIAN LAST NAME FIRST NAME STREET ADDRESS CITY STATE ZIP PHONE LIC# OR NPA#

RACE/ETHNICITY: FILL ALL THAT APPLY

WHITE CHINESE VIETNAMESE OTHER S.E. ASIAN MIDDLE EASTERN HAWAIIAN SAMOAN HISPANIC JAPANESE CAMBODIAN FILIPINO ASIAN/EAST INDIAN GUAMANIAN NATIVE AMERICAN BLACK KOREAN LAOTIAN (LAOS) OTHER (Specify):

PRIMARY LANGUAGE: (Fill only ONE circle)

ENGLISH SPANISH OTHER (Specify):

FACILITY/SUBMITTER DRAWING SPECIMEN

FACILITY NAME HOSPITAL/SUBMITTER CODE INITIALS OF COLLECTOR

NEWBORN'S BIRTH DATE: MMDDYY HOUR

DATE SPECIMEN COLLECTED: MMDDYY HOUR

BIRTHWEIGHT: GMS

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle)

ONLY HUMAN MILK ONLY FORMULA HUMAN MILK/FORNULA

SEX: MALE FEMALE

REASON FOR TEST: (Fill only ONE circle)

INITIAL SPECIMEN REPEAT OF INADEQUATE OR EARLY (<12 HRS) INITIAL SPECIMEN OTHER REPEAT: (Specify):

AT DELIVERY: WEEKS

NO AT TIME OF COLLECTION? NO YES

IF COLLECTED AT <12 HRS OF AGE, REASON:

TO BE TRANSFUSED OTHER: (Specify):

NURSERY TYPE: NCU REG. NURSERY/CCCR HOME BIRTH OTHER: (Specify)

NEWBORN ON TPN/HYPERAL DRAM/NO ACIDS AT TIME OF COLLECTION? NO YES

RBC TRANSFUSION BEFORE COLLECTION: NO YES - YES, date/time transfusion completed

MEDICAL RECORD# HOSPITAL ORDER #

PLEASE SEE PRIVACY NOTIFICATION WITHIN

To request, request form NBS-TRF from the Genetic Disease Screening Program, Newborn Screening Branch (415) 412-6542 (DDPH - 4400 - (11-12) 4854 (R)

Whatman 903™ LOT 6937812W113 2015-11

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER

APPROVED

NOT APPROVED

SIGNATURE

NAME:

DATE:

EBF

DATE:

SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Part Does Not Print

Part 1 - 2# White CB - 6" x 11 1/4" (±1/16") - Perm Black and Red 185 Inks & Laser Code 3 of 9 Barcode with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

Repeal

Sender's Copy

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF)
State of California - Health and Human Services Agency
California Department of Public Health

FOR STATE USE ONLY

ADDRESSOGRAPH HERE

Check Digits
SN 29 000 001 32

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION

NEWBORN'S PHYSICIAN INFORMATION

RACE/ETHNICITY: FILL ALL THAT APPLY

PRIMARY LANGUAGE: (Fill only ONE circle)

FACILITY/SUBMITTER DRAWING SPECIMEN

NEWBORN'S BIRTH DATE: DATE SPECIMEN COLLECTED:

BIRTH WEIGHT: ALL FEEDINGS SINCE BIRTH: TYPE OF SPECIMEN:

SEX: GMS: (Fill only ONE circle)

GESTATIONAL AGE AT DELIVERY: WEEKS: MED AT TIME OF COLLECTION?

NURSERY TYPE: NEWBORN ON TPNI/HYPERAL OR AMINO ACIDS AT TIME OF COLLECTION?

MEDICAL RECORD #/HOSPITAL ORDER #

HOSPITAL/SUBMITTER CODE INITIALS OF COLLECTOR

REASON FOR TEST: (Fill only ONE circle)

IF COLLECTED AT <12 HRS OF AGE, REASON:

RBC TRANSFUSION BEFORE COLLECTION:

Part 2 - 17# Canary CFB - 6" x 11 1/4" (±1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (199) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER

APPROVED

NOT APPROVED

SIGNATURE

NAME:

DATE:

EBF

DATE:

SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Perf Does Not Print

Repeal

Parent's Copy

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF)
State of California - Health and Human Services Agency
California Department of Public Health

FOR STATE USE ONLY

ADDRESSOGRAPH HERE

Check Digits
SN 29 000 001 32

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION

MOTHER'S BIRTH DATE

ALTERNATE EMERGENCY #

THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION

NEWBORN'S PHYSICIAN INFORMATION

RACE/ETHNICITY: FILL ALL THAT APPLY

PRIMARY LANGUAGE: (Fill only ONE circle)

FACILITY/SUBMITTER DRAWING SPECIMEN

NEWBORN'S BIRTH DATE: DATE SPECIMEN COLLECTED:

BIRTH WEIGHT: ALL FEEDINGS SINCE BIRTH: TYPE OF SPECIMEN:

SEX: ONLY BREAST MILK ONLY FORMULA HUMAN MILK & FORMULA

GESTATIONAL AGE AT DELIVERY: NEWBORN ON TPN/IV/PERAL OR AMINO ACIDS AT TIME OF COLLECTION?

NURSERY TYPE: REASON FOR TEST: (Fill only ONE circle)

MEDICAL RECORD # HOSPITAL ORDER #

PLEASE SEE PRIVACY NOTIFICATION WITHIN

Whatman 903 6937912/W113 2015-11

Part 3 - 20# PINK CF - 6" x 11 1/4" (+/- 1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER

APPROVED

NOT APPROVED

SIGNATURE

NAME:

DATE:

EBF

DATE:

SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Perf Does Not Print

Repeal

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program
Newborn Screening Branch
(Effective August 2008)
Please Review Carefully

This notice describes how personal and medical information about you or your newborn may be used and disclosed and how you can get access to this information.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125030) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result.

If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at

www.cdph.ca.gov/programs/pages/privacyoffice.aspx

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

(continued on next page)

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Perf Does Not Print

Part 3 Back - Prints Black Ink - Spot Glue Indicated in Green Between Parts 3 and 4 Does Not Print

Repeal

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not re-label, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F170, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages
To get a copy of this notice in other languages, Braille, large print, audiotape, or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices
This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights
If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing: Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at: www.cdph.ca.gov/program/pages/privacy/office.aspx

Or
You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

(continued on back)

Paper - 20# Blue Bond - 6" x 11 1/4" (+/-1/16") - Prints Black Ink

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Perf Does Not Print

Repeat

Questions & Answers About the Storage of the Newborn Screening Bloodspots

Why is my baby's blood spot collection card stored by the Genetic Disease Screening Program (GDSP)?

The main reason GDSP stores the used blood spots is to develop new tests to add to the newborn screening testing panel and to provide quality control for testing on an on-going basis. When the Newborn Screening Program began in the early 1980s, we tested for 3 disorders. The stored specimens were used anonymously to develop the new tests, so that we now screen for about 80 disorders. Newborn Screening blood spot cards are not "DNA cards". Your child's DNA is not analyzed for our initial screening tests and his/her "DNA profile" is not stored. There is no personal information on the dried blood spot card, only a unique non-identifying number.

What if I do not want my baby's blood spot collection card used by the Genetic Disease Screening Program? What are my options?

If you decide not to allow the GDSP to use your child's unidentified dried blood spot, you may request that the specimen not be used for research and/or be destroyed by our laboratory. Please realize that if you make this choice, the spot will no longer be available should you or your doctor need it for any further health concerns with your child. Please submit this request in writing to: Chief of the Genetic Disease Screening Program, 855 Marina Bay Parkway, F175, Richmond, CA 94804.

For more information please visit our website at www.cdph.ca.gov/programs/nbs or if you have additional questions you can email us at NBSNews@cdph.ca.gov or call (510) 412-1502.

Attention Parents

- 1) Review the information on the pink copy of your baby's newborn screening test request form. Notify the hospital if your name, address and/or phone or the name, address and phone number of your baby's doctor is not correct.
- 2) Take the pink copy of this form when you go to your baby's first check up. This will help the doctor locate your baby's newborn screening results.

Thank You

For copies of the Notice of Information and Privacy Practices in Spanish and other languages please visit the Newborn Screening Program website at www.cdph.ca.gov/programs/nbs

Para una copia de la NOTIFICACIÓN DE PRÁCTICAS DE INFORMACIÓN Y PRIVACIDAD por favor visite nuestro sitio web del Programa del Análisis de Recién Nacidos en www.cdph.ca.gov/programs/nbs

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Perf Does Not Print

Part 4 Back - Prints Black Ink

Repeat

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NEWBORN SCREENING


LOT 003/12/0113 2015-11 Revision Date: 11/13

CDPH USE ONLY

DO NOT DETACH

INSTRUCTIONS FOR COLLECTING ADEQUATE BLOOD SPECIMENS
Puncture site is indicated by shaded areas on heel. Do not collect from side or back of foot.

***NO COURIER PLASTIC BAGS**



RIGHT ACCEPTABLE
Circle filled and evenly saturated

WRONG UNACCEPTABLE
Layering

Insufficient, multiple applications

Serum rings present

COLLECT SAMPLE FROM SHADED AREA

NOTE:
Do not use capillary tubes for collection of blood spot specimen.
Do not collect blood from antecubital space or dorsal hand vein.
Do not handle blood collection area of specimen collection card prior to, during, or following sampling.

1. Position infant's foot to increase blood flow. Warming of the heel is optional.
2. Clean skin with alcohol and either air-dry or wipe dry with sterile gauze.
3. Puncture heel with sterile disposable lancet, using a firm, quick stab. If using an automated lancet device, place it firmly against the heel prior to device activation.
4. Allow a large drop of blood to accumulate and wipe away with sterile gauze.
5. Allow a second large drop of blood to accumulate. Apply gentle pressure to heel and ease intermittently so blood flows freely.
6. Apply the blood drop to one side of the specimen collection paper until the circle is filled COMPLETELY when viewed from both sides. Do not press collection paper against puncture site. Allow blood to fill circle by natural flow. Do not apply blood to both sides of the paper.
7. Fill the first circle completely before moving on to the next circle. Repeat procedure for each circle.
8. Allow blood spots to air-dry at room temperature for at least three hours. Keep away from direct light (sun or lamp) and heat.
9. Do not close specimen collection form while blood spots are still wet. Do not allow wet specimens to come in contact with each other.
10. DO NOT PUT SPECIMEN IN PLASTIC BAG.

ADDITIONAL INSTRUCTIONS ARE CONTAINED IN "BLOOD COLLECTION ON FILTER PAPER FOR NEWBORN SCREENING PROGRAMS", 5th EDITION (CLSI DOCUMENT LA4-A5)

PRINT ONLY, USE ALL CAPITAL LETTERS, USE BLACK OR BLUE INK ONLY.

Perf Does Not Print

29 000-001-32

29 000-001-32

Part 6 - Whatman 903 Lot W113
6" x 2 1/4" (±1/16")
Prints Bio Black 586 Ink
Green Lines Indicate Gluing
Between Parts 5 & 6 with EBF
Glue #1001 and Do Not Print

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

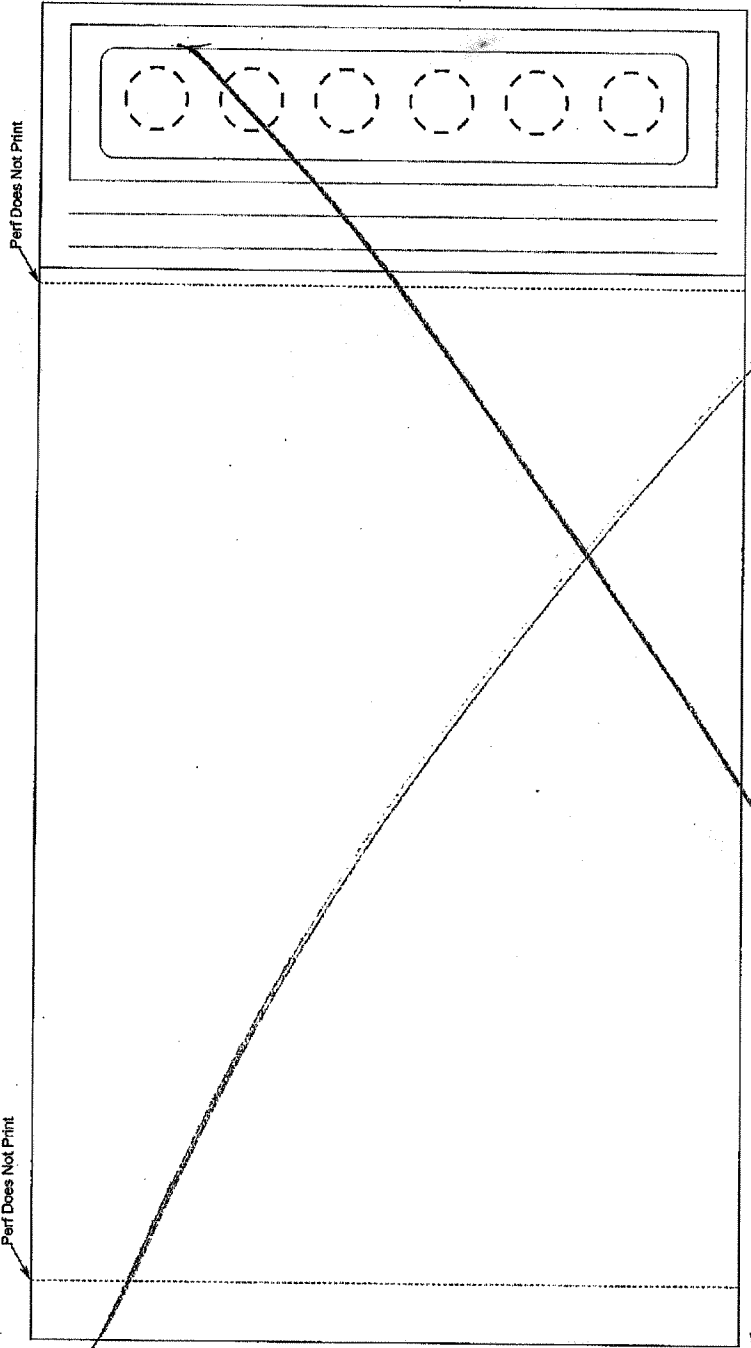
CUSTOMER
APPROVED <input type="checkbox"/>
NOT APPROVED <input type="checkbox"/>
SIGNATURE
NAME:
DATE:
EBF
DATE:
SIGNATURE

Part 5 - 125# White Tag - 6" X 4 1/4" (±1/16") - Prints Black and Red 185 Inks
& 2 Black Serial Numbers with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Perf Does Not Print

Repeat



Part 6 Back
Prints Bio Black 586 Ink
Green Lines Indicate Gluing
Between Parts 6 & 7 with EBF
Gage #1001 and Do Not Print

Part 7 Back - 125# White Tag
6" x 2 1/4" (±1/16")
No Printing on Face or Back

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	EBF
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Repeal



DO NOT WRITE IN THIS AREA
DO NOT HANDLE FILTER PAPER

THIS AREA MAY BE USED TO ADHERE A STICKER
CONTAINING THE INFANT'S FACILITY INFORMATION

Revision Date: 11/12

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH NEWBORN SCREENING

INSTRUCTIONS FOR COMPLETION OF FORM

PLEASE PRINT AND USE BLUE OR BLACK BALL POINT PEN

- NEWBORN'S NAME:** Name as entered on birth certificate, last name first. If multiple birth, indicate A, B, C, etc.
- MOTHER'S INFORMATION:** Name as entered on birth certificate, last name first. Please also include mother's maiden name and last 4 digits of social security number. If mother does not have a social security number, enter 9999.
- THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION:** Answer YES if newborn is a ward of the court and provide contact information for person responsible for baby's care at time of collection.
- NEWBORN'S PHYSICIAN INFORMATION:** Obtain from mother the name of the physician responsible for continuing care of the newborn after discharge.
- NEWBORN'S PHYSICIAN'S LICENSE NUMBER OR NPI NUMBER:** Enter the physician's California license number or national provider identification number.
- RACE/ETHNICITY:** As entered for both parents on birth certificate. These data are required by Government Code 8310.5. Check ALL that apply.
- PRIMARY LANGUAGE:** Please indicate primary language spoken; this helps determine if an interpreter is needed.
- FACILITY DRAWING SPECIMEN:** Name and code number must be entered to ensure correct reporting of results.
- NEWBORN'S BIRTH DATE (AND TIME):** As entered on the birth certificate. All time is to be entered by the 24 hour clock, e.g., 8:30 a.m. is 0830; 9:01 p.m. is 2101.
- BIRTH WEIGHT:** In grams, as entered on birth certificate.
- GESTATIONAL AGE:** Enter gestational age at time of birth in weeks.
- NURSERY TYPE:** Check NICU, Regular Nursery, which includes Family Centered Care (FCC) or Rooming In (RI), Home Birth, or other.
- ALL FEEDING SINCE BIRTH:** Include all feeding from birth to collection. Human milk includes breastfeeding, mother's own expressed milk and banked human milk. If newborn has had neither human milk, nor formula leave this section blank.
- NPO AT TIME OF COLLECTION?:** Answer YES if newborn is NPO (i.e., is taking nothing by mouth) at time of specimen collection.
- NEWBORN ON TPN/HYPERAL or AMINO ACIDS AT TIME OF COLLECTION?:** Answer YES if newborn is being given TPN (total parenteral nutrition, aka hyperalimentation) or amino acids at time of specimen collection.
- DATE SPECIMEN COLLECTED:** Date and hour of specimen collection. This refers to the time the specimen is collected from the newborn.
- TYPE OF SPECIMEN:** Please check only one box. If "OTHER" type of specimen is checked, please specify the type of specimen.
- IF COLLECTED AT <12 HRS OF AGE, REASON?:** If this specimen is being collected prior to the newborn being 12 hours of age, indicate why.
- RBC TRANSFUSION BEFORE COLLECTION:** Please indicate whether the newborn was transfused with RED BLOOD CELLS and the date and time the last transfusion ended prior to specimen collection. DO list intravertine transfusions. DO NOT list fresh frozen plasma, albumin, platelets, or cryoprecipitate as transfusion. DO NOT list transfusions that occurred after the specimen was collected.
- MEDICAL RECORD NUMBER:** Enter number used in medical records department of facility collection specimen.
- INITIALS OF COLLECTOR:** Enter initials of person drawing the specimen.
- DISTRIBUTION:** Original MUST remain attached to specimen. Facility drawing the specimen should retain and file the yellow copy in the newborn's chart. The pink copy should be given to the newborn's parent(s) with instructions to give to the newborn's physician.

PLEASE SEE PRIVACY NOTIFICATION WITHIN

CDPH - 4400 - (11-12)

SN 29 000 001

MSH (2)

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Part 8 Back - 20# White Bond - 6" x 11 1/4" (+/-1/16") - Prints Black and Red Inks

2. NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) – English version or CDPH 4459 (SP) (06/11) – Spanish version.

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program, Newborn Screening Branch
(Effective August 2008) Please Review Carefully

This notice describes how personal and medical information about you or your newborn may be used and disclosed and how you can get access to this information.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result. If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages

To get a copy of this notice in other languages, Braille, large print, audiocassette or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices: This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights

If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at: www.cdph.ca.gov/program/pages/privacyoffice.aspx

Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

10-13-03

NOTIFICACIÓN DE PRÁCTICAS DE INFORMACIÓN Y PRIVACIDAD Departamento de Salud Pública de California
División de Enfermedades Genéticas
Programa de Análisis de Recién Nacidos
(En vigor a partir del 14 de abril de 2003)

Esta notificación describe la manera en que se puede usar y revelar la información personal y médica sobre usted o su recién nacido y cómo usted puede obtener acceso a esta información. Léala con atención.

Obligación legal del Departamento. Leyes federales y estatales restringen el uso, el mantenimiento y la revelación de información personal y médica obtenida por una entidad del estado y requiere ciertas notificaciones a las personas cuya información mantiene. En cumplimiento de estas leyes, se notifica lo siguiente a usted y a los que proporcionan la información:

Autoridad del Departamento y Propósito del Programa de Análisis de Recién Nacidos. El Departamento de Salud Pública obtiene información relativa a los análisis de recién nacidos según lo permiten las Secciones 124980, 125000, 125001, 125025 y 125030 del Código de Salud y Seguridad. Esta información se obtiene electrónicamente e incluye datos como su nombre completo, dirección y la atención médica que obtuvieron usted y su recién nacido. El análisis es requerido por ley (Sección 125000 del Código de Salud y Seguridad) y reglamentaciones (17 CCR 6500 a 6510) y si la información requerida no se proporciona, podría resultar en que los recién nacidos afectados desarrollen incapacidades permanentes o mueran. Si tiene objeciones religiosas al análisis, puede decir "no" al análisis por escrito y firmar un formulario que le indica que el personal (tanto de su hospital, como de su médico y clínica) no son responsables si su bebé tiene problemas porque esas enfermedades no se identificaron y trataron temprano.

Usos y revelación de información sobre la salud. El Departamento de Salud Pública usa la información sobre su salud o la de su recién nacido para hacer el análisis, proporcionar servicios de atención de la salud, obtener pagos por el análisis, para fines administrativos y para evaluar la calidad de la atención que recibe usted o su recién nacido. Parte de esa información se retiene por hasta 21 años. La información no se vende.

La ley también permite que el Departamento use o proporcione la información que tengamos sobre usted o su recién nacido por los siguientes motivos:

- Para estudios de investigación, a menos que usted solicite específicamente por escrito que la información sobre usted no se usa.
- A organizaciones que nos ayuden en nuestras operaciones, por ejemplo para cobranzas.

Aparte de lo que antecede, la información es confidencial y no se entregará sin su autorización por escrito. Si usted firma una autorización para revelar información, puede revocar esa autorización más adelante para parar las revelaciones y los usos futuros, poniéndose en contacto con la persona indicada a continuación.

El Departamento puede cambiar sus normas en cualquier momento, sujeto a las leyes y reglamentaciones aplicables. Si lo desea, puede solicitar una copia de nuestras normas vigentes u obtener más información sobre nuestras prácticas de privacidad, poniéndose en contacto con la persona indicada a continuación o consultando nuestro sitio web, www.dhs.ca.gov/nbs. También puede solicitar una copia impresa de esta notificación.

Derechos individuales y acceso a la información. Usted tiene derecho a ver o a recibir una copia (se le cobrará) de la información sobre su salud o la de su recién nacido y a recibir una lista de las instancias en que hayamos revelado información sobre su salud o la de su recién nacido por motivos aparte de hacer análisis, obtener pagos o para fines administrativos afines. Si le parece que la información en sus datos o en los de su recién nacido es incorrecta o está incompleta, tiene derecho a solicitar correcciones. Tiene derecho a hacernos pedidos razonables de que nos pongamos en contacto con usted únicamente por escrito o en una dirección, casilla postal o número de teléfono diferentes.

Puede solicitar por escrito que restrinjamos la revelación de la información sobre usted o su recién nacido para fines de tratamiento de salud, pagos y fines administrativos. No estamos obligados a acceder a su pedido.

Quejas. Si le parece que no hemos protegido su privacidad o la de su recién nacido o que hemos violado alguno de sus derechos o los de su recién nacido, puede presentar una queja llamando o escribiendo a: **Privacy Officer, CA Department of Public Health, P.O. Box 997413, Sacramento, CA 95899-7413, (916) 445-4646** u **(877) 735-2929 TTY/TDD**. O visite nuestro sitio web: www.dhs.ca.gov/privacyoffice/NPP/default.htm

También puede ponerse en contacto con el secretario del Departamento de Salud y de Servicios Humanos, Oficina de Derechos Civiles, en la siguiente dirección: **Secretary of the Department of Health and Human Services, Office for Civil Rights, 50 United Nations Plaza, Room 322, San Francisco, CA, 94102; teléfono 800-368-1019**. O puede llamar a la Oficina de Derechos Civiles de Estados Unidos, al **866-OCR-PRIV (866-627-7748)** u **866-788-4989 TTY**.

El Departamento no le puede quitar sus beneficios de atención de la salud ni hacer nada que le haga daño de ninguna manera si usted opta por presentar una queja o usar alguno de los derechos de privacidad en esta notificación.

Contacto con el Departamento - La información en este formulario es mantenida por el Departamento de Salud Pública, División de Enfermedades Genéticas. Escribe al Jefe de la División de Enfermedades Genéticas, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

3. HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH 4089 (01/11).

REPEAL

HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO)

PLEASE PRINT USING ALL CAPITAL LETTERS

FOR OFFICE USE ONLY

DATE: MONTH DAY YEAR

FROM: (Give hospital name) _____ HOSPITAL CODE: R

TO: PHYSICIAN'S NAME: LAST FIRST

PHYSICIAN'S ADDRESS: NUMBER STREET SUITE

CITY STATE ZIP CODE

TELEPHONE NUMBER (Indicate area code) EXTENSION

NEWBORN'S NAME: LAST FIRST

SEX: MALE FEMALE MULTIPLE BIRTHS: A B C D

ADDRESS: NUMBER STREET APARTMENT

CITY STATE ZIP CODE

MEDICAL RECORD NUMBER

BIRTH WEIGHT (grams) BIRTH DATE: MONTH DAY YEAR BIRTH HOUR (24 HOUR CLOCK)

MOTHER'S NAME: LAST FIRST MOTHER'S BIRTH DATE: MONTH DAY YEAR

TELEPHONE NUMBER (Indicate area code) OTHER TELEPHONE NUMBER FOR FAMILY

The above newborn was discharged/transferred on (fill one box): MONTH DAY YEAR without a newborn screening specimen taken because

- Newborn Expired
- Parents refused to have specimen collected. Fill out NBS-TR (Screening Test Refusal). Put original in chart and send a copy of the signed test refusal with this form to the California Department of Public Health, Newborn Screening Branch
- Transferred to the following receiving hospital on or before six days of age

HOSPITAL CITY

Other Reason (specify):

<p>INSTRUCTIONS: This form must be completed by the perinatal licensed health facility when it has been determined that an infant was discharged without obtaining a newborn screening specimen. Send copies to:</p> <p>WHITE: California Department of Public Health Newborn Screening Branch 850 Marina Bay Parkway, F175 Mail Stop 8200 Richmond, CA 94804</p> <p>YELLOW: M.D. of record.</p> <p>PINK: Receiving hospital (if transferred)</p> <p>GOLDENROD: Retain for your files</p>	<p>To the Physician: California Code of Regulations, Section 8606.2(b), states: "When the newborn's physician is notified by telephone by the perinatal health facility that a newborn was discharged from the perinatal health facility before a specimen was taken, the newborn's physician shall make every reasonable effort to have a specimen obtained within five days of notification. If the newborn's physician can not obtain the specimen, the area service center shall be notified by the newborn's physician by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the person notified, date, and the information provided." If you have questions, please call your NBS follow-up coordinator (listed on the bottom of every NBS result mailer.)</p>
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PLEASE SEE PRIVACY NOTIFICATION ON REVERSE

To reorder, request form NBS-NO from the Genetic Disease Screening Program, Newborn Screening Branch at (510) 412-1542.

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program, Newborn Screening Branch
(Effective August 2008). Please Review Carefully

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The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

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The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

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You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages

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Notices: This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights

If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at:

www.cdph.ca.gov/program/pages/privacyoffice.aspx

Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-768-4989 TTY

1. CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF)
(CDPH-4409-(6/16)) NBS-I (F)


Adopt

NBS COPY

**CALIFORNIA NEWBORN SCREENING
TEST REQUEST FORM (TRF)
State of California -
Health and Human Services Agency**

FOR STATE USE ONLY

ADDRESSOGRAPH HERE

 **NBS FORM #** 31 000 001 **Check Digits** 54

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS DATE OF BIRTH

BABY'S LAST NAME M M D D Y Y

FIRST NAME BIRTH HOUR BIRTH ORDER IF MULTIPLE

STREET ADDRESS APT. A.#, C.#

CITY ZIP

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION MOTHER'S BIRTH DATE

MOTHER'S LAST NAME M M D D Y Y

FIRST NAME MOTHER'S SSN: LAST 4 DIGITS

MAIDEN NAME MI SSN#

MOM - PH - ONE ALTERNATE/ EMERGENCY # PHO - ONE THIS BABY IS A WARD OF THE COURT

PRIMARY LANGUAGE (Fill only ONE circle):
 ENGLISH SPANISH OTHER (Specify):

FACILITY/SUBMITTER/DRAWING SPECIMEN:

FACILITY NAME HOSPITAL/SUBMITTER CODE INITIALS OF COLLECTOR

INPATIENT/ORDERING PHYSICIAN

LAST NAME FIRST NAME

MEDICAL RECORD/HR # HOSPITAL ORDER #

RACE/ETHNICITY: FILL ALL THAT APPLY

WHITE CHINESE VIETNAMESE OTHER S.E. ASIAN MIDDLE EASTERN HAWAIIAN SAMOAN
 HISPANIC JAPANESE CAMBODIAN FILIPINO ASIAN-EAST INDIAN GUAMANIAN NATIVE AMERICAN
 BLACK KOREAN LAOTIAN (LAOS) OTHER (Specify):

BIRTH WEIGHT: _____ GMS

SPECIMEN NOT OBTAINED (If not collected, specify why):

REFUSED URGENT TRANSFER (Specify receiving hospital in comments)

EXPIRED OTHER (Specify in comments)

SEX: MALE FEMALE

DATE SPECIMEN COLLECTED: M M D D Y Y HOUR

GESTATIONAL AGE AT DELIVERY: _____ WEEKS

TYPE OF SPECIMEN:
 HEELSTICK OTHER (Specify):

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle)

ONLY HUMAN MILK REASON FOR TEST: (Fill only ONE circle):
 INITIAL SPECIMEN
 REPEAT OF INADEQUATE OR EARLY (<12 HRS) INITIAL SPECIMEN
 ONLY FORMULA OTHER REPEAT (Specify in comments)
 HUMAN MILK & FORMULA IF COLLECTED AT <12 HRS OF AGE, REASON:
 TO BE TRANSFUSED
 OTHER (Specify):

NURSERY TYPE:
 NICU / PICU
 REG. NURSERY / FCC / RI
 HOME BIRTH
 OTHER (Specify in comments)

RBC TRANSFUSION BEFORE COLLECTION:
 NO YES - If YES, date/time transfusion completed:
 M M D D Y Y HOUR

NEWBORN'S OUTPATIENT PHYSICIAN INFORMATION (COMMUNITY PRIMARY CARE PROVIDER)

NPI # OR LIC # PHY-PRO-NE

PHYSICIAN LAST NAME

FIRST NAME

STREET ADDRESS SUITE

CITY ZIP

HH Perf Does Not Print

PLEASE SEE PRIVACY NOTIFICATION WITHIN
 To monitor, request form NBS-TRF from the Genetic Disease Screening Program,
 Newborn Screening Branch: (619) 412-1542 (CD/PI) - 4409 - (0119) NBS-1 (F)

903™ **LOT** 7042916 W152 **REF** 10534790 Rev. AB **2019-06**

Part 1 - 21# White CB - 6" x 11 1/4" (±1/16") - Prints Black, Red 185 & Pantone 529U Inks
Laser Barcode 3 of 9 Barcode with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

CUSTOMER

APPROVED

NOT APPROVED

SIGNATURE

NAME:

DATE:

EBF

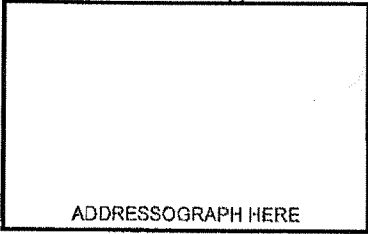
REF: 10534790 REVISION: AB

DATE:

SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will rest in a potential ± 1/16" (1.6mm) tolerance.

Sender's Copy



ADDRESSOGRAPH HERE

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (TRF) State of California - Health and Human Services Agency

FOR STATE USE ONLY

NBS FORM # 31 000 001 54

Check Digits

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS DATE OF BIRTH BIRTH HOUR BIRTH ORDER IF MULTIPLE A, B, C, etc.

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION MOTHER'S BIRTH DATE MOTHER'S SSN- LAST 4 DIGITS THIS BABY IS A WARD OF THE COURT

PRIMARY LANGUAGE (Fill only ONE circle): ENGLISH SPANISH OTHER (Specify): FACILITY/SUBMITTER DRAWING SPECIMEN: HOSPITAL/SUBMITTER CODE INITIALS OF COLLECTOR INPATIENT/ORDERING PHYSICIAN

MEDICAL RECORD/EHR # HOSPITAL ORDER #

RACE/ETHNICITY: FILL ALL THAT APPLY WHITE CHINESE VIETNAMESE OTHER S.E. ASIAN MIDDLE EASTERN HAWAIIAN SAMOAN HISPANIC JAPANESE CAMBODIAN FILIPINO ASIAN-EAST INDIAN GUAMANIAN NATIVE AMERICAN BLACK KOREAN LAOTIAN (LAOS) OTHER (Specify)

BIRTH WEIGHT: GMS SPECIMEN NOT OBTAINED (if not collected, specify why): REFUSED URGENT TRANSFER (Specify receiving hospital in comments) EXPIRED OTHER (Specify in comments) DATE SPECIMEN COLLECTED: SEX MALE FEMALE TYPE OF SPECIMEN: HEELSTICK OTHER (Specify): GESTATIONAL AGE AT DELIVERY: WEEKS

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle) ONLY HUMAN MILK ONLY FORMULA HUMAN MILK & FORMULA REASON FOR TEST: (Fill only ONE circle) INITIAL SPECIMEN REPEAT OF INADEQUATE OR EARLY (<12 HRS) INITIAL SPECIMEN OTHER REPEAT (Specify in comments) IF COLLECTED AT <12 HRS OF AGE, REASON: TO BE TRANSFUSED OTHER (Specify): NURSERY TYPE: NICU / PICU REG. NURSERY / FCC / RI HOME BIRTH OTHER (Specify in comments) RBC TRANSFUSION BEFORE COLLECTION: NO YES - IF YES, date/time transfusion completed:

NEWBORN'S OUTPATIENT PHYSICIAN INFORMATION (COMMUNITY PRIMARY CARE PROVIDER)

CALIFORNIA NBS Card 10534790 Rev. AB Job # 7042916-012 05-16-16 Fourth Proof

CUSTOMER APPROVED NOT APPROVED SIGNATURE NAME: DATE: EBF REF: 10534790 REVISION: AB DATE: SIGNATURE

Note: This PDF form layout is produced to 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will rest in a potential ± 1/16" (1.6mm) tolerance.

Part 2 - 17# Canary CFB - 6" x 11 1/4" (±1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

H Perf Does Not Print

Parent's Copy

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (TRF) State of California - Health and Human Services Agency

FOR STATE USE ONLY

ADDRESSOGRAPH HERE

NBS FORM # 31 000 001 54

Check Digits

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS DATE OF BIRTH BIRTH HOUR ORDER IF MULTIPLE A.M. P.M.

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION MOTHER'S BIRTH DATE MOTHER'S SSN: LAST 4 DIGITS THIS BABY IS A WARD OF THE COURT ALTERNATE/EMERGENCY #

PRIMARY LANGUAGE (Fill only ONE circle): ENGLISH SPANISH OTHER (Specify): FACILITY/SUBMITTER DRAWING SPECIMEN: HOSPITAL/SUBMITTER CODE INITIALS OF COLLECTOR INPATIENT/ORDERING PHYSICIAN MEDICAL RECORD/EHR # HOSPITAL ORDER #

RACE/ETHNICITY, FILL ALL THAT APPLY WHITE CHINESE VIETNAMESE OTHER S.E. ASIAN MIDDLE EASTERN HAWAIIAN SAMOAN HISPANIC JAPANESE CAMBODIAN FILIPINO ASIAN-EAST INDIAN GUAMANIAN NATIVE AMERICAN BLACK KOREAN LAOTIAN (LAOS) OTHER (Specify)

BIRTH WEIGHT: SPECIMEN NOT OBTAINED (if not collected, specify why): REFUSED URGENT TRANSFER (Specify receiving hospital in comments) EXPIRED OTHER (Specify in comments) DATE SPECIMEN COLLECTED: SEX MALE FEMALE GESTATIONAL AGE AT DELIVERY: TYPE OF SPECIMEN: HEELSTICK OTHER (Specify):

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle) ONLY HUMAN MILK ONLY FORMULA HUMAN MILK & FORMULA NURSERY TYPE: NICU/PICU REG. NURSERY/FCC/RI HOME BIRTH OTHER (Specify in comments) REASON FOR TEST: (Fill only ONE circle) INITIAL SPECIMEN REPEAT OF INADEQUATE OR EARLY (<12 HRS) INITIAL SPECIMEN OTHER REPEAT (Specify in comments) IF COLLECTED AT <12 HRS OF AGE, REASON: TO BE TRANSFUSED OTHER (Specify): RBC TRANSFUSION BEFORE COLLECTION: NO YES - If YES, date/time transfusion completed:

NEWBORN'S OUTPATIENT PHYSICIAN INFORMATION (COMMUNITY PRIMARY CARE PROVIDER)

PLEASE SEE PRIVACY NOTIFICATION WITHIN To reorder, request form NBS-TRF from the Genetic Disease Screening Program, Newborn Screening Branch (510) 412-1542 (CDPH - 4409 - (6/16)) NBS-1 (F)

903™ LOT 7042916 W152 REF 10534790 Rev. AB 2019-06

Part 3 - 20# Pink CF - 6" x 11 1/4" (±1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS Card 10534790 Rev. AB Job # 7042916-012 05-16-16 Fourth Proof

CUSTOMER APPROVED [] NOT APPROVED [] SIGNATURE NAME: DATE: EBF REF: 10534790 REVISION: AB DATE: SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Perf Does Not Print

E Perf
Does Not Print

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program (GDSP)
The California Newborn Screening Program
Effective Date: June 2014

THIS NOTICE DESCRIBES HOW PERSONAL AND MEDICAL INFORMATION ABOUT YOU OR YOUR NEWBORN MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained.

State laws include the California Information Practices Act (Civil Code 1798 et seq.), Government Code Section 11015.5 and Health and Safety Code Section 124980. The federal law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 USC 1320d-2(a) (2), and its regulations in Title 45 Code of Federal Regulations Sections 160.100 et seq. In compliance with these laws, you and those providing information are notified of the following.

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The CDPH collects and maintains specimens and information related to newborn screening as permitted in Health and Safety Code Sections 124980, 124977, 124991, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result.

If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out newborn screening specimens and/or general health information about you or your baby, for department-approved studies, such as research related to preventing disease. The material will be provided without any personal identifying information. Researchers can only apply to receive the information if they have been approved by an institutional review board (IRB) and meet all federal and state privacy law requirements.

The Department is authorized by law to charge approved researchers a fee to recover all the expenses related to the research request (including data linkage, retrieval, data processing, data entry, re-inventory, shipping of blood samples, and related data management).

(continued on next page)

Part 3 Back - Prints Black Ink - Straight line gluing indicated in Green Between Parts 3 and 4 Does Not Print

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10534790	REVISION: AB
DATE:	
SIGNATURE	

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The Department reserves the right to change the terms of this notice and to make the new notice provisions effective for all protected health information that it maintains. The most current Privacy Notice can be found at the Newborn Screening Program website: www.cdph.ca.gov/programs/nbs. You may request a copy of the current policies or obtain more information about our privacy practices, by calling the numbers listed below or consulting the Program website. You may also request a paper copy of this Notice. This Privacy Notice can also be found at the website: www.ca.gov/programs/pages/Privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than payment for screening or related administrative purposes.

You have a right to ask that the Newborn Screening Program contact you only in writing, or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information and/or specimen in the ways listed in this notice. However, we may not be able to comply with your request.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect.

Complaints

We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information. If you believe that we have not protected your privacy or have violated any of your rights and wish to file a complaint, please call or write to the: Privacy Officer, CA Department of Public Health, P.O. Box 997377, MS 0506, Sacramento, CA 95899-7377, (916) 440-7671 or (877) 421-9634 TTY/TDD.

You may also contact the United States Department of Health and Human Services, Attention: Regional Manager, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA 94103, telephone (800) 368-1019, or the U.S. Office of Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

The Department cannot take away your health care benefits or any other protected rights in any way if you choose to file a complaint or use any of the privacy rights in this notice.

Department Contact

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Electronic Copies of this Notice: To get a copy of this notice in an electronic format call or write to: Chief, Genetic Disease Screening Program
850 Marina Bay Pkwy, F175, Mail Stop 8200, Richmond, CA 94804
Phone: 510-412-1502 Relay Operator 711/1-800-735-2929

For copies of the Notice of Information and Privacy Practices in Spanish and other languages please visit the Newborn Screening Program website at: www.cdph.ca.gov/programs/nbs

Para una copia de la NOTIFICACIÓN DE PRÁCTICAS DE INFORMACIÓN Y PRIVACIDAD por favor visite nuestro sitio web del Programa del Análisis de Recién Nacidos en www.cdph.ca.gov/programs/nbs

(continued on back)

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE _____	
NAME: _____	
DATE: _____	
EBF	
REF: 10534790	REVISION: AB
DATE: _____	
SIGNATURE _____	

Note: This PDF form layout is produced to 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will rest in a potential ± 1/16" (1.6mm) tolerance.

Part 4 - 20# Blue Bond - 6" x 11 1/4" (±1/16") - Prints Black Ink

E Perf
Does Not Print

E Perf
Does Not Print

Attention Parents

- 1) Review the information on the pink copy of your baby's newborn screening test request form. Notify the hospital if your name, address and/or phone or the name, address and phone number of your baby's doctor is not correct.
- 2) Take the pink copy of this form when you go to your baby's first checkup. This will help the doctor locate your baby's newborn screening results.

Thank you

What Happens To My Baby's Blood Spots After the Newborn Screening Tests Are Done?

California, like many other states, stores leftover newborn screening blood spots. The cards do not have your baby's name or any other personal information on them. The Newborn Screening (NBS) Program does not sequence your baby's entire DNA or store your baby's "DNA profile."

The NBS Program uses leftover blood spots:

- to evaluate and improve the current NBS program
- to develop new tests to add to the panel, such as when cystic fibrosis was added
- for quality control testing to ensure the tests are correct and the lab equipment is working properly

Are the stored blood spots used for anything else?

Yes, California law allows the NBS program to use or provide leftover newborn screening specimens for department-approved studies of diseases in women and children, such as research related to identifying and preventing diseases like birth defects, chronic disease, or exposure to toxins or infections. The blood spots are used without access to any personal identifying information. Because of this, you will not be notified of any study test results for your baby. No extra blood spots or specimens will be collected from your baby for research.

To get a form to request that your child's blood spots be destroyed or not be used for research go to:

www.cdph.ca.gov/programs/GDSP/Pages/ParentForms.aspx.

If you have additional questions about blood spot storage, please visit our website at www.cdph.ca.gov/programs/nbs/NBSDBS-Storage.aspx, email us at CaliforniaBioBank@cdph.ca.gov, or write to us at Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway F175, Richmond, CA 94804.

Para más información sobre el uso y mantenimiento de la muestra de sangre, por favor visite nuestro sitio web del Programa del Análisis de Recién Nacidos en www.cdph.ca.gov/programs/nbs/NBSDBS-Storage.aspx

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

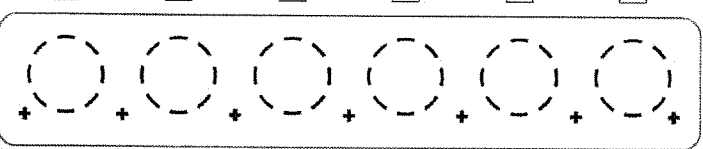
CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10534790	REVISION: AB
DATE:	
SIGNATURE	

Part 4 Back - Prints Black Ink

Note: This PDF form layout is produced to to 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Fold Perf
Does Not Print

31 000 001 54



CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NEWBORN SCREENING

LOT 7042916W152 2018-06 Revision Date 6/15/18

NBS FORM #

CDPH USE ONLY

NBS FORM #

31 000 001 54

Part 6 - 903 Lot W152
6" x 2 1/4" (±1/16")

Prints Bio Black 586 Ink
Green Lines Indicate Gluing
Between Parts 5 & 6 with EBF
Glue #1003 and Do Not Print

DO NOT DETACH

INSTRUCTIONS FOR COLLECTING ADEQUATE BLOOD SPECIMENS

Puncture site is indicated by shaded areas on heel. Do not collect from side or back of foot.

*NO COURIER PLASTIC BAGS



COLLECT SAMPLE FROM
SHADED AREA

- | | |
|--------------|-------------------------------------|
| RIGHT | ACCEPTABLE |
| | Circle filled and evenly saturated |
| WRONG | UNACCEPTABLE |
| | Layering |
| | Insufficient, multiple applications |
| | Serum rings present |

NOTE:
*Do not use capillary tubes for collection of blood spot specimen.
Do not collect blood from antecubital space or dorsal hand vein.
Do not handle blood collection area of specimen collection card prior to, during, or following sampling.*

1. Position infant's foot to increase blood flow. Warming of the heel is optional.
2. Clean skin with alcohol and either air-dry or wipe dry with sterile gauze.
3. Puncture heel with sterile disposable lancet, using a firm, quick stab. If using an automated lancet device, place it firmly against the heel prior to device activation.
4. Allow a large drop of blood to accumulate and wipe away with sterile gauze.
5. Allow a second large drop of blood to accumulate. Apply gentle pressure to heel and ease intermittently so blood flows freely.
6. Apply the blood drop to one side of the specimen collection paper until the circle is filled **COMPLETELY** when viewed from both sides. Do not press collection paper against puncture site. Allow blood to fill circle by natural flow. **Do not apply blood to both sides of the paper.**
7. Fill the first circle completely before moving on to the next circle. Repeat procedure for each circle.
8. Allow blood spots to air-dry at room temperature for at least three hours. Keep away from direct light (sun or lamp) and heat.
9. Do not close specimen collection form while blood spots are still wet. Do not allow wet specimens to come in contact with each other.
10. **DO NOT PUT SPECIMEN IN PLASTIC BAG AT ANY TIME.**

ADDITIONAL INSTRUCTIONS ARE CONTAINED IN "BLOOD COLLECTION ON FILTER PAPER FOR NEWBORN SCREENING PROGRAMS", 5th EDITION (CLSI DOCUMENT LA4-A5)

PRINT ONLY, USE ALL CAPITAL LETTERS, USE BLACK OR BLUE INK ONLY.

VO Perf
Does Not Print

Part 5 - 125# White Tag - 6" X 11 1/4" (±1/16") - Prints Black and Red 185 Inks
& 2 Black Serial Numbers with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10534790	REVISION: AB
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to : 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will rest in a potential ± 1/16" (1.6mm) tolerance.

Fold Perf
Does Not Print

The main form area is a large rectangle with a dashed line at the top and bottom, indicating fold lines. At the top, there is a header section containing six dashed circles arranged horizontally. Below this header, there are several horizontal lines and a large blank area for text or signatures.

VO Perf
Does Not Print

Part 6 Back
Prints Bio Black 586 Ink
Green Lines Indicate Gluing
Between Parts 6 & 7 with EBF
Glue #1003 and Do Not Print

Part 7 Back - 125# White Tag
6" x 2 1/4" (±1/16")
No Printing on Face or Back

CALIFORNIA NBS Card
10534790 Rev. AB
Job # 7042916-012
05-16-16
Fourth Proof

CUSTOMER	
APPROVED	<input type="checkbox"/>
NOT APPROVED	<input type="checkbox"/>
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10534790	REVISION: AB
DATE:	
SIGNATURE	

Part 5 Back - No Printing

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.



DO NOT WRITE IN THIS AREA
DO NOT HANDLE FILTER PAPER

THIS AREA MAY BE USED TO ADHERE A STICKER
 CONTAINING THE INFANT'S FACILITY INFORMATION

Revision Date: 6/16

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NEWBORN SCREENING

INSTRUCTIONS FOR COMPLETION OF FORM

PLEASE PRINT AND USE BLUE OR BLACK BALL POINT PEN

1. **NEWBORN'S NAME:** Name as entered on birth certificate, last name first. If multiple birth, indicate A, B, C, etc.
2. **NEWBORN'S BIRTH DATE (AND TIME):** As entered on the birth certificate. All time is to be entered by the 24 hour clock, e.g., 8:30 a.m. is 0830; 9:01 p.m. is 2101.
3. **MOTHER'S INFORMATION:** Name as entered on birth certificate, last name first. Please also include mother's maiden name and last 4 digits of social security number. If mother does not have a social security number, enter 9999.
4. **THIS BABY IS A WARD OF THE COURT:** Answer Y (Yes) if newborn is a ward of the court and provide contact information for legal guardian responsible for baby's care at time of collection.
5. **PRIMARY LANGUAGE:** Please indicate primary language spoken by mother; this helps determine if an interpreter is needed.
6. **FACILITY DRAWING SPECIMEN:** Name and code number must be entered to ensure correct reporting of results.
7. **INITIALS OF COLLECTOR:** Enter initials of person drawing the specimen.
8. **INPATIENT/ORDERING PHYSICIAN:** Name of physician ordering the test or providing care in the hospital.
9. **MEDICAL RECORD NUMBER:** Enter number used in medical records department of facility collecting specimen.
10. **HOSPITAL ORDER NUMBER:** Use for HL7 messaging only.
11. **RACE/ETHNICITY:** As entered for both parents on birth certificate. These data are required by Government Code 8310.05. Check ALL that apply.
12. **BIRTH WEIGHT:** In grams, as entered on birth certificate.
13. **GESTATIONAL AGE:** Enter gestational age at time of birth in weeks.
14. **ALL FEEDING SINCE BIRTH:** Include all feeding from birth to collection. Human milk includes breastfeeding, mother's own expressed milk and banked human milk. If newborn has had neither human milk, nor formula leave this section blank.
15. **NURSERY TYPE:** Check NICU, Regular Nursery (which includes Family Centered Care (FCC), Rooming In (RI), or Mother Baby Unit), Home Birth, or other.
16. **SPECIMEN NOT OBTAINED:** Check reason a specimen is not obtained. If refused, make sure to complete test refusal form. If baby expired, enter date and reason (if known) in comments. If urgent transfer, specify receiving hospital in comments. For any other reason, check box and specify in comments.
17. **DATE SPECIMEN COLLECTED:** Date and hour of specimen collection. This refers to the time the specimen is collected from the newborn.
18. **TYPE OF SPECIMEN:** Please check only one box. If "OTHER: type of specimen is checked, please specify the type of specimen.
19. **IF COLLECTED AT <12 HRS OF AGE, REASON?:** If this specimen is being collected prior to the newborn being 12 hours of age, indicate why.
20. **RBC TRANSFUSION BEFORE COLLECTION:** Please indicate whether the newborn was transfused with RED BLOOD CELLS and the date and time the last transfusion ended prior to specimen collection. DO list intrauterine transfusions. DO NOT list fresh frozen plasma, albumin, platelets, or cryoprecipitate as transfusion. DO NOT list transfusions that occurred after the specimen was collected.
21. **NEWBORN'S PHYSICIAN'S NPI NUMBER OR LICENSE NUMBER:** Enter the physician's national provider identification number or California license number.
22. **NEWBORN'S PHYSICIAN INFORMATION:** Confirm with mother the name and contact information for the physician who will be responsible for newborn's care after discharge.
23. **DISTRIBUTION:** Original MUST remain attached to specimen. Facility drawing the specimen should retain and file the yellow copy in the newborn's chart. The pink copy should be given to the newborn's parent(s) with instructions to give to the newborn's outpatient physician at first visit.

PLEASE SEE PRIVACY NOTIFICATION WITHIN

(CDPH) - 4409 - (6/16)

NBS
FORM #

31 000 001

NBS-1(F)

Part 8 Back - 20# White Bond - 6" x 11 1/4" (±1/16") - Prints Black and Red 185 Inks

CALIFORNIA NBS Card
 10534790 Rev. AB
 Job # 7042916-012
 05-16-16
 Fourth Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10534790	REVISION: AB
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

2. NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16) – English version or CDPH 4459 (SP) (06/16) – Spanish version



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Genetic Disease Screening Program (GDSP)
The California Newborn Screening Program
Effective Date: June 2014

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Adopt

RECHAZO DE PRUEBAS INICIALES PARA RECIÉN NACIDOS (NBS-TR)

POR FAVOR USA LETRAS DE MOLDE Y TODAS MAYÚSCULAS - NO UTILICE TINTA ROJA

APELLIDO DEL RECIÉN NACIDO _____ PRIMER NOMBRE _____
 FECHA DEL NACIMIENTO: MES [] [] DIA [] [] AÑO [] [] SEXO: VARÓN HEMBRA NUMERO DE TELEFONO [] [] [] [] - [] [] [] []
 DIRECCIÓN: NÚMERO [] [] [] [] CALLE [] [] [] [] [] [] [] [] [] [] [] [] APARTAMENTO [] [] []
 CIUDAD [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] ESTADO [] [] CÓDIGO POSTAL [] [] [] [] [] []
 APELLIDO DE LA MADRE _____ PRIMER NOMBRE _____ FECHA DE NACIMIENTO DE LA MADRE MES [] [] DIA [] [] AÑO [] []
 NACIMIENTO CASERO? SÍ NO NÚMERO DE TRF [] [] [] [] [] [] [] [] NÚMERO DE REGISTRO MÉDICO [] [] [] [] [] [] [] []
 HOSPITAL / ASISTENTE DE PARTO _____ CÓDIGO [] [] [] []

He leído o me han leído y entiendo el material informativo titulado **Información Importante para los Padres sobre el Análisis de Recién Nacido** proporcionado por el Departamento de Salud Pública del Estado de California acerca de las pruebas iniciales en recién nacidos para determinar la presencia de varias enfermedades. He hablado sobre esto con mi proveedor y se han contestado mis preguntas. Estoy consciente de que si mi bebé tiene una de estas enfermedades y no se encuentra y se trata temprano, mi bebé podría tener una seria enfermedad, discapacidad intelectual y hasta morir. Aunque puedo solicitar que estas pruebas se hagan en un momento posterior, demorar el diagnóstico y tratamiento podría resultar en daño permanente a mi bebé.

Estoy consciente de que la ley del estado de California requiere que se haga el análisis a todos los recién nacidos, y que la **única** excepción es cuando está en conflicto con las creencias o prácticas religiosas de los padres. Sabiendo esto, me niego que se le haga esta prueba de recién nacidos a mi hijo y yo acepto toda responsabilidad, personal y jurídica, por las consecuencias. **Entiendo que los posibles daños a mi niño como consecuencia de negar esta prueba pueden incluir discapacidad intelectual, daños neurológicos, y en unos casos, muerte.** Mi decisión fue tomada libremente sin la presión ni la recomendación de nadie.

FIRMA _____ FECHA: MES [] [] DÍA [] [] AÑO [] []

SU NOMBRE: APELLIDO _____ PRIMER NOMBRE _____

RELACIÓN A RECIÉN NACIDO: MADRE PADRE GUARDIAN LEGAL

FIRMA DEL TESTIGO: _____ FECHA: MES [] [] DÍA [] [] AÑO [] []

NOMBRE DEL TESTIGO: APELLIDO _____ PRIMER NOMBRE _____

WHITE - Send to: CA Department of Public Health, Newborn Screening Program, 850 Marina Bay Pkwy, F175, Richmond, CA 94804
 PINK - Give to parent(s) or legal guardian
 YELLOW - File in medical record

POR FAVOR DE LEER LA NOTIFICACIÓN DE PRIVACIDAD AL REVERSO DE ESTE DOCUMENTO

To reorder, request form NBS-TR (Sn) (CDPH 4459) from the Newborn Screening Program (510) 412-1542



Aviso de prácticas de información y privacidad

Depto. de Salud Pública de California (CDPH) – Programa de Detección de Enfermedades Genéticas (GDSP)

Programa de Análisis de Recién Nacidos de California – Vigente a partir de junio de 2014

Este Aviso describe la manera en que se puede usar y revelar información personal y médica sobre usted o su hijo recién nacido, y la manera en que usted puede tener acceso a dicha información. Favor de leer este aviso con atención.

Obligación legal del Departamento

Las leyes federales y estatales restringen el uso, el mantenimiento y la revelación de la información personal y médica que obtienen las entidades estatales y requiere que se entreguen ciertos avisos a las personas sobre las que se mantiene información. Entre las leyes estatales se incluyen la Ley sobre Prácticas de Información de California (sección 1796 y siguientes del Código Civil), sección 11015.5 del Código de Gobierno y sección 124980 del Código de Salud y Seguridad. La ley federal es la Ley de Portabilidad de Seguro Médico y Responsabilidad de 1996 (HIPAA), 42 USC 1320d-2(a)(2), y sus regulaciones del Código de Regulaciones Federales, título 45, secciones 160.100 y siguientes. En cumplimiento de estas leyes, se notifica lo siguiente a usted y a los que proporcionan información:

Autoridad del Departamento y propósito del Programa de Análisis de Recién Nacidos

El CDPH reúne y conserva muestras y datos relacionados con análisis de recién nacidos según lo permiten las secciones 124980, 124977, 124901, 125000, 125001, 125026 y 125030 del Código de Salud y Seguridad. Los datos se reúnen electrónicamente e incluyen información como su nombre, dirección y el cuidado médico que recibieron usted y su hijo recién nacido. El análisis es requerido por ley (sección 125000 del Código de Salud y Seguridad) y por reglamentaciones (17 CCR 6500 a 6510) y si no se proporciona la información requerida, el resultado podría ser que los recién nacidos afectados sufran enfermedades graves o daños permanentes. Si usted tiene objeciones religiosas a este análisis, puede decir "no" por escrito al análisis y firmar un formulario en el que se le informa que el hospital, su médico y el personal de la clínica no serán responsables si su bebé padece problemas por no haber identificado y tratado estas enfermedades en etapa temprana.

Usos y revelación de información sobre la salud

El CDPH usa información sobre su salud o la de su hijo recién nacido para la prueba de detección, para brindar servicios de cuidado de salud, para obtener el pago por la prueba, para fines administrativos y para evaluar la calidad del cuidado que reciben usted o su hijo recién nacido. Parte de esta información se retiene por hasta 21 años. La información no se vende. La ley también permite que el Departamento use o entregue muestras de la prueba de detección y/o información general sobre su salud o la de su hijo recién nacido en estudios aprobados por el departamento, como, por ejemplo, investigaciones para prevenir enfermedades. El material será entregado sin ninguna información de identificación personal. Los investigadores solo podrán solicitar recibir la información si han sido aprobados por una junta de revisión institucional (IRB) y cumplen todos los requisitos sobre privacidad exigidos por las leyes federales y estatales. El Departamento está autorizado por ley a cobrar una cuota a los investigadores aprobados para recuperar los gastos relacionados con la solicitud de investigación (incluido el enlace, la recuperación, el procesamiento, el ingreso y el reinventariado de datos, el envío de muestras de sangre y toda gestión de datos relacionada). El Departamento se reserva el derecho a cambiar los términos de este aviso y a poner en vigencia las disposiciones del nuevo aviso con relación a toda la información protegida sobre salud que mantenga. Puede acceder al aviso de privacidad más reciente en el sitio web del Programa de Análisis de Recién Nacidos en: www.cdph.ca.gov/programs/nbs. Puede solicitar una copia de las políticas actuales u obtener más información sobre nuestras prácticas de privacidad llamando a los números incluidos más abajo o consultando el sitio web del Programa. También puede solicitar una copia de este aviso en papel. Además puede encontrar este aviso de privacidad en el sitio web: www.ca.gov/programs/pages/Privacyoffice.aspx.

Derechos individuales y acceso a la información

El Programa de Análisis de Recién Nacidos tiene que tener su permiso por escrito para usar o entregar información personal o de salud sobre usted por cualquier motivo que no figure en este aviso. Usted puede revocar su autorización en cualquier momento, excepto si el Programa de Análisis de Recién Nacidos ya tomó alguna acción porque contaba con su permiso. Para revocar su autorización, comuníquese con: Chief, Genetic Disease Screening Program, en 850 Marina Bay Parkway, F175, Richmond, CA 94804. Tiene derecho a ver o recibir una copia (le cobrarán) de la información sobre su salud o la de su hijo recién nacido y a recibir una lista de las veces en que revelamos información sobre su salud o la salud de su hijo recién nacido por motivos diferentes al análisis, el pago o propósitos administrativos afines. Tiene derecho a pedir que el Programa de Análisis de Recién Nacidos se comunique con usted solo por escrito o en una dirección, apartado postal o número de teléfono diferentes. El Programa de Análisis de Recién Nacidos se comunicará con usted de la manera en que lo solicite si es necesario para mantenerla segura. Tiene derecho a pedir al Programa de Análisis de Recién Nacidos que no usen ni compartan los datos y/o las muestras de usted o de su recién nacido de las maneras indicadas en este aviso. Sin embargo, existe la posibilidad de que no podamos cumplir con su pedido. Tiene derecho a que se cambien los datos que figuran en su registro o en el de su hijo si falta información o si le parece que la información no está correcta.

Reclamos: Le avisaremos rápidamente si hay una pérdida de datos que podría poner en riesgo la privacidad o seguridad de su información. Si cree que no hemos protegido su privacidad o que hemos violado alguno de sus derechos y desea presentar un reclamo, escriba a: Privacy Officer, CA Department of Public Health, P.O. Box 997377, MS 0506, Sacramento, CA 95899-7377, o llame al (916) 440-7671 o al (877) 421-9634 TTY/TDD. También puede contactarse con: U.S. Department of Health and Human Services, Attn. Regional Manager, Office for Civil Rights en 90 7th Street, Suite 4-100, San Francisco, CA 94103, tel. (800) 368-1019, o con: U.S. Office of Civil Rights al 866-OCR-PRIV (866-627-7748) o TTY al 866-788-4989. El Departamento no puede retirarle sus beneficios de cuidado de salud ni ningún otro derecho protegido de ninguna manera si usted decide presentar un reclamo o ejercer alguno de sus derechos de privacidad incluidos en este aviso.

Contacto con el Departamento: La información incluida en este formulario es conservada por el Programa de Detección de Enfermedades Genéticas del Departamento de Salud Pública de California. Envíe la correspondencia a: Chief, Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8206, Richmond, California, 94804 (510-412-1502).

3. NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A
LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09)

Adopt

NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH)

THIS FORM IS USED FOR CLINICAL FOLLOW-UP
PLEASE SEND THIS FORM IMMEDIATELY AFTER REGISTERING THE BIRTH (DO NOT BATCH MAIL).

PLEASE PRINT USING ALL CAPITAL LETTERS

TO: LOCAL HEALTH OFFICER AND CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
DATE OF REGISTRATION: MONTH DAY YEAR

FROM: BIRTH REGISTRAR OF COUNTY OR CITY

WE HAVE REGISTERED THE FOLLOWING BIRTH WHICH OCCURRED OUT OF A LICENSE HEALTH FACILITY

NEWBORN'S NAME (as shown on the birth certificate): LAST FIRST SEX MALE FEMALE

MOTHER'S COMPLETE NAME: LAST FIRST MAIDEN

CURRENT ADDRESS: NUMBER STREET APARTMENT

CITY STATE ZIP CODE

BIRTH WEIGHT (grams) BIRTH DATE: MONTH DAY YEAR BIRTH HOUR (24 hour clock)

PARENT'S TELEPHONE NUMBER (indicate area code)

HAS A NEWBORN SCREENING TEST BEEN DONE? YES NO

IF YES, WHERE WAS THE TEST DONE?

DATE OF TEST: MONTH DAY YEAR

NEWBORN'S PRIMARY CARE PROVIDER NAME: LAST FIRST

ADDRESS: NUMBER STREET SUITE

CITY STATE ZIP CODE

TELEPHONE NUMBER:

FILL BOX(es) IF APPROPRIATE: INFANT EXPIRED PARENTS REFUSED NEWBORN SCREENING TEST REFUSAL FORM SIGNED (ATTACH NBS-TR)

Please complete this form and mail immediately to:
WHITE- CA Department of Public Health, Newborn Screening Program, 850 Marina Bay Pkwy, F175, Richmond, CA 94804
YELLOW-Local Health Officer
PINK-Retain for your files

PLEASE SEE PRIVACY NOTIFICATION ON REVERSE

To reorder, request form NBS-OH from the Genetic Disease Screening Program, Newborn Screening Program (510) 412-1542.

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH) Genetic Disease Screening Program
Newborn Screening Branch (Effective August 2008)

Please Review Carefully

This notice describes how personal and medical information about you or your newborn may be used and disclosed and how you can get access to this information.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result.

If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages

To get a copy of this notice in other languages, Braille, large print, audiocassette or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices

This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights

If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing: Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at: www.cdph.ca.gov/program/pages/privacyoffice.aspx.

Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7743) or 866-730-4989 TTY.