

# NEWBORN SCREENING *News*

Spring 2016

THE CALIFORNIA NEWBORN SCREENING PROGRAM

## 2-Day Transit Time for Newborn Screening Specimens

The goal of Newborn Screening (NBS) is the prompt detection and treatment of newborns diagnosed with a screened disorder in order to prevent or decrease the associated morbidity and mortality. Therefore, it is of vital importance that the testing be done promptly so that the results can be communicated as soon as possible.

In the last few years, there has been a great deal of national interest in transit time for newborn screening specimens. The *Milwaukee Journal Sentinel* published an investigative report in November 2013 describing how delays can have devastating effects on the health of children who have a disorder identified by NBS.

This investigative report sparked a national dialogue on the subject and led to recommendations on collection and transit times of NBS specimens at the federal level.

*The article can be found at <http://www.jsonline.com/watchdog/watchdogreports/Deadly-Delays-Watchdog-Report-Delays-at-hospitals-across-the-country-undermine-newborn-screening-programs-putting-babies-at-risk-of-disability-and-death-228832111.html>*

The federal Advisory Committee on Heritable Disorders in Newborns and Children recommended that all specimens should be received at the laboratory within 24 hours of collection. As a step toward this recommendation, the California NBS Program has set a new goal of 2 days for specimen-to-laboratory delivery.

Overall, California hospitals get specimens to the testing laboratory in a timely manner. Of the over 490,000 NBS specimens received in 2014, 74.8% arrived at the lab within two days of collection, 91.3% arrived by three days, 97.6% arrived by 4 days and 99.3% arrived by 5 days. The median transit time was approximately 1.4 days.

Every quarter, each facility should receive a copy of their Hospital Evaluation Performance Profile (HEPP) report which includes data about transit time. Please use this tool to monitor your facility's individual performance. If your facility has specimens that take three or more days to get to the screening lab, please examine  
*(continued on page 2)*



### Transit Stars

Congratulations to 116 Transit Stars for getting 95% or more of your specimens to the lab within 2 days for Fiscal Year 2014-2015. Our 116 Transit Stars include 50 NICUs, 26 hospitals, 14 outpatient clinics, and 26 midwifery facilities. To see if your facility is a Transit Star, please visit the NBS website at

[www.cdph.ca.gov/programs/nbs/Pages/NBSTransitTimes.aspx](http://www.cdph.ca.gov/programs/nbs/Pages/NBSTransitTimes.aspx)

Contact GDSP or your Area Service Center to learn how you can become a Newborn Screening Transit Star!

Please share this information with **all staff** involved with Newborn Screening (MCH, NICU, and Lab) to help us to ensure timely collection and transit to save babies' lives.

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### NEWS FLASH!

On February 16, 2016, the U.S. Department of Health and Human Services announced the addition of adrenoleukodystrophy (ALD) to the federal Recommended Uniform Screening Panel (RUSP) for newborns. The CDPH Genetic Disease Screening Program continues to work on the implementation of Assembly Bill 1559 (Chapter 565, Statute of 2014), which requires the expansion of the California Newborn Screening (NBS) Program to include ALD when added to the RUSP. GDSP anticipates having all systems in place to screen for ALD by mid-2016. Once the systems are in place, GDSP will be able to retroactively screen all newborn specimens received on or after February 16th, 2016.

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your process and call your Area Service Center staff to find ways to decrease the transit time to two days or less. Delays in specimen transit result in delays to diagnosis and treatment.

Most facilities are now using Golden State Overnight (GSO). GSO pick-up is Monday thru Friday for all facilities. The majority also have Saturday pick-up. Every effort should be made to have specimens collected early enough in the day so that they can be dried and ready for pick-up the same day.

A specimen ready for transit after the daily pick-up has to wait until the next day. Additionally, specimens should never be batched or held.

Specimens that are collected after the daily pick-up or on Sunday should be stored in a cool dry place until Monday or the next business day. They should not be placed near heat to dry them, or in a refrigerator or freezer.

The conscientious and timely transport of the NBS specimens is an integral part of the success of the screening program. We appreciate your efforts in making sure that every baby's NBS specimen gets handled correctly.

For any questions/concerns about transit issues, please contact your Area Service Center, which can be found on page 4 of this newsletter.

To order GSO shipping supplies, please call **(916) 636-5135**.

## Timely Collection AND Timely Transit Saves Babies' Lives

In February 2015, the Advisory Committee for Heritable Disorders in Newborn and Children (ACHDNC) issued recommendations for state newborn screening programs to improve Newborn Screening Specimen Collection and Transit Timeliness.

In early 2015, California and six other states began a Newborn Screening Timeliness Collaborative Improvement and Innovation Network (COIN) project sponsored by the NewSTEPs Program of the Association of Public Health Laboratories (APHL) in collaboration with the Colorado School of Public Health. In alignment with the ACHDNC recommendations, California has two specific 2015 Newborn Screening Collection and Transit Time goals.

### Specimen Collection Time Goal:

By March 2016, the percentage of California initial newborn screening specimens collected between 12-48 hours will increase from the current 90% to 95%.

### Transit Time Goal:

By March 2016, 85% of initial newborn screening specimens collected will be received at the NAPS Lab within 2 calendar days.

Timeliness, while imperative for early detection and early intervention for all disorders, is especially critical for the sixteen disorders designated "Urgent" by the ACHDNC. Disorders such as medium chain acyl-CoA dehydrogenase (MCAD) deficiency, galactosemia, congenital adrenal hyperplasia (CAH), propionic acidemia (PA), and maple syrup urine disease (MSUD) can manifest within the first few days of life. Three key components -- timely collection, prompt shipment, and efficient lab processing -- help our goal to identify disorders by the newborn's 5th day of life.

The Hospital Evaluation Performance Profile (HEPP) Report will now reflect these parameters. Each collection facility should review the HEPP report to ensure they are meeting these goals. Prompt detection and treatment of children diagnosed with a screened disorder can help to achieve the best possible outcomes.

For more information on the ACHDNC Recommendations, please visit [www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/timelinessnbskelmtanksley.pdf](http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2015/sixth/timelinessnbskelmtanksley.pdf)

## How to Check the Expiration Date on the Test Request Form

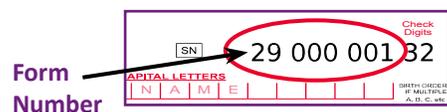
The expiration date is located on the bottom right hand corner of the Test Request Form (TRF) next to the hourglass icon. To prevent the specimen from being deemed inadequate, thereby avoiding the need to re-draw the specimen from the newborn, it is extremely important to check the expiration date on the TRFs. Always use TRFs with the earlier expiration date first, and do not stockpile forms.

**Reminder:** The 29 Million series TRFs have expired. The last day to collect specimens on the 29 Million series TRF was November 30, 2015.

Any specimen collected on a form starting with 29 will be deemed inadequate and a new specimen must be collected on an unexpired TRF.



Expiration Date: Last day of November 2015



## Online Specimen Tracking System

To guarantee that every infant receives the mandatory Newborn Screening (NBS) Test, the California Newborn Screening Program implemented the Online Specimen Tracking (OST) System. OST is a connection to the Department's Screening Information System (SIS) and provides verification that every specimen collected at your facility has reached the screening lab within 2-5 days of being drawn. Modifications to Title 17 of the California Code of Regulations, if approved, would **require** NBS Collection Facilities to use OST to verify that the newborn specimen has been received by the Department by the 7th day of life. If a specimen has not been received, a missing specimen report must be entered into SIS.

### NBS Collection Facilities should use OST to:

- Verify that all of your newborn specimens have been transported and received at the screening lab within 2-5 days of collection. This ensures that all collected specimens are accounted for.
- Report a specimen as missing in OST if it is not found in the system within 7 days after birth. Timeliness of reporting will facilitate the collection of a new specimen and is essential to the health of any affected newborn. Once a specimen is reported as missing, follow up is handled by the NBS Program.
- Report a specimen as not drawn at your facility if it is on your OST screen in error. Early reporting will prevent results from being sent to the wrong facility and thereby a violation of the Health Insurance Portability and Accountability Act (HIPAA). Reporting also ensures that the correct facility is billed.

- Request a duplicate NBS Result Mailer. This is the only way to request a duplicate.

### NBS Collection Facility Responsibilities:

- Reconcile the hospital Admission/Census report daily against the Received Specimen List in OST. This list shows the last 8 days of specimens received by the screening lab and is updated nightly with new specimens. A newborn specimen should be in OST within 2-5 days after collection.
- Report a newborn specimen missing via OST when it is not located in OST by the 7th day after birth.
- Update the NBS Program of any staffing changes pertaining to the tracking of newborn specimens.

Developing an internal protocol may take coordination and collaboration between management and staff in the Laboratory, Nursery, NICU, and Health Information Management (HIM). This will ensure continual tracking of specimens so no baby will be missed from testing. Let us know what you need to help facilitate this endeavor.

For Online Specimen Tracking access, training, questions, assistance, and staff updates, please contact the OST Coordinator at **(510) 412-1586**.

*For more information about Newborn Screening or any of the topics covered in this newsletter, visit our website at: [www.cdph.ca.gov/nbs](http://www.cdph.ca.gov/nbs)*

## Rubber Stamps

An incorrect facility name or facility code on the Test Request Form can lead to NBS results to be sent to the wrong facility, which is a HIPAA violation. In addition, incorrect names or facility codes can mean a delay in obtaining result mailers and cause billing errors. To help prevent these problems, the NBS Program provided every specimen collection facility two rubber stamps free of charge. The rubber stamps provide legible, complete, and accurate facility names and facility codes. The cost for additional stamps will not be covered by the NBS Program.

To order more rubber stamps and/or get a quote, contact Dave Lavezzo (The Office City) by:

- Phone: **(650) 385-2621**
- Email: [davel@theofficecity.com](mailto:davel@theofficecity.com)

In order to process the order, the vendor will need the billing, credit card, and shipping information. Use the Reference Number-- **SPE-NBS1**-- in the Subject Line.

If you would like to use a different vendor, you will need to use the following specifications for the stamps:

- Length of the impression: 4.125 in. or 10.47 cm
- Facility code: start on 3.75 in. or 9.53 cm
- Font: Arial, 12 point



## Defective Test Request Forms

Errors can occur during the manufacturing of the Test Request Forms (TRFs). Usually, these are found before the TRFs are delivered, but on occasion, facilities may encounter TRFs with defects.

Some examples of defective TRFs that the NBS Program has seen in the past include:

- Filter paper cards with form numbers that do not match the demographic portion (the top white page of the form)
- Missing form numbers on the specimen filter paper card
- Insufficient glue on the frame of the specimen filter paper card
- Glue on specimen filter paper card
- Insufficient glue at the bottom of the TRF, which has led to the pages of the form to coming apart

If you think you have a defective TRF, please follow the procedures below:

- ✓ Do **NOT** use the forms.
- ✓ Check your supply for any other defective forms and set them aside for return to the NBS Program.
- ✓ Do **NOT** try to fix the forms yourself. Glue, tape, etc. may contaminate the specimen.
- ✓ Call the NBS Program at **510-412-1486** to report the form numbers of defective TRF. Replacements for defective TRFs will be provided at no charge.
- ✓ If a specimen was collected on a defective TRF, check with the NBS Program to determine if that specimen can be submitted or a new specimen must be collected.

If the defect is insufficient glue between the parts resulting in the specimen filter paper card separating from the demographic form (the top white page), and the specimen has already been collected, the baby's name, birthdate, and/or medical record number must be written on the specimen filter paper card. If the form is separated from the filter paper card, Clinical Laboratory Improvement Amendments (CLIA) requires 3 identifiers on the specimen filter paper card to match the demographic portion in order for the specimen to be considered adequate.

Since the form number is one of the identifiers, always check to make sure that the form number on the top white page matches the form number on the filter paper card.



**Write the baby's name, birthdate, and/or medical record number on these 2 lines**

## Ordering Newborn Screening Supplies

To order Newborn Screening Specimen Collection Forms, also known as TRFs, Special Forms (NBS-NO, NBS-OH, NBS-TR in English/Spanish) or *Important Information for Parents* (IIP) booklets:

- Call: **(510) 412-1542**
- Email: **NBSOrders@cdph.ca.gov**
- Order online: **www.cdph.ca.gov/nbs**



### Newborn Screening Area Service Centers (NBS-ASCs)

Kaiser Permanente, Northern CA (ASC 93)  
(510) 752-6192

Kaiser Permanente, Southern CA (ASC 94)  
(626) 564-3322

Stanford University (ASC 95)  
(650) 724-8120

Valley Children's Hospital (ASC 96)  
(559) 353-6416

UCLA Medical Center (ASC 97)  
(310) 826-4458

Harbor/UCLA Medical Center (ASC 98)  
(310) 222-3751

Rady Children's Hospital San Diego (ASC 99)  
(858) 966-8708



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**DIANA S. DOOLEY, SECRETARY**  
*California Health and Human Services Agency*

**EDMUND G. BROWN JR., GOVERNOR**  
*State of California*

**KAREN SMITH, M.D., MPH, DIRECTOR**  
*California Department of Public Health*