2025 Newborn Screening Program Annual Report

As Required by

Texas Health and Safety Code

Section 33.020

September 2025

TEXAS
Health and Human Services

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Introduction

Texas Health and Safety Code, Section 33.020, requires the Department of State Health Services (DSHS) to prepare a report annually that identifies disorders on the Recommended Uniform Screening Panel (RUSP) not included on the Texas newborn screening (NBS) panel. The report must identify the additional capacity or resources needed to implement these NBS test(s) and require each newborn to receive the tests. The report must also summarize the implementation plan, including information on any identified potential barriers and the anticipated start date of any new screens.

The RUSP is a list of primary and secondary conditions that the federal Health and Human Services (HHS) Secretary recommends states should offer as part of a NBS program. Currently, there are 64 conditions on the RUSP, including 38 core and 26 secondary conditions. Although the primary mission of NBS is to identify newborns at highest risk for the core conditions, secondary conditions may also be detected during screening for core conditions. With the addition of lysosomal disease screening in August 2025, the Texas NBS panel consists of 59 conditions screened through laboratory testing and two conditions, which are point of service tests typically conducted by the birthing facility:

- Hearing loss, and
- Critical congenital heart disease.

Each Texas newborn is screened twice, for an average of about 800,000 screens annually. The first screen should be collected at 24-48 hours and the second screen collected at 7-14 days of life. DSHS clinical care coordination staff communicate with healthcare providers to ensure timely follow-up testing and care for any abnormal test results. In 2024, DSHS addressed all 27,913 abnormal results, identifying 1,089 newborns with conditions needing intervention, giving families the opportunity to access essential treatments for better health outcomes.

Implementation of New Conditions

Implementation Process for Adding New Screens

Texas Health and Safety Code, Section 33.011, requires screening for conditions on the RUSP, as funding allows with exceptions for galactoepimerase deficiency and galactokinase deficiency. To add a condition that is screened through laboratory testing, DSHS must:

- Modify space and systems within the existing laboratory;
- Install instruments;
- Develop and validate tests;
- Develop algorithms to ensure presumptive cases receive appropriate diagnostic testing and treatment;
- Make updates to the Laboratory Information Management System (LIMS), an IT system that uses screening algorithms to identify abnormal screens for follow up; and
- Hire and train additional staff for both laboratory testing and clinical care coordination.

In August 2025, DSHS implemented screening for four lysosomal storage diseases: Pompe disease, Mucopolysaccharidosis type I (MPS I), Mucopolysaccharidosis type II (MPS II or Hunter syndrome), and Infantile Krabbe Disease.

DSHS is currently in the process of adding screening for guanidinoacetate methyltransferase deficiency (GAMT). Full implementation is expected by March 2026. The Laboratory is working to complete the remaining tasks to implement GAMT:

- Installation of auxiliary equipment to provide ultra-pure air to the tandem mass spectrometers used for amino acid and acylcarnitine testing ;
- Optimization of instruments to reliably measure two new analytes (guanidinoacetate and creatine);
- Modification of an FDA-approved test kit to detect elevated guanidinoacetate and reduced levels of creatine;
- Development of algorithms for clinical care coordination; and
- Updates to LIMS.

Future Additions to the Newborn Screening Panel

The 89th Texas Legislature passed Senate Bill 1044 to include NBS testing, follow-up, and services for Duchenne Muscular Dystrophy (DMD) to the extent funds are appropriated or available. DMD, an X-linked genetic condition, causes progressive muscular degeneration, weakness, and death, typically in early adulthood due to cardiac failure, respiratory failure, or both.[1] DMD most commonly occurs in boys, at an incidence of about 1 in 5,000 male infants. Without NBS, most cases without a family history of DMD are diagnosed around 4.4 years.[2] Treatments for DMD include oral administration of glucocorticoids, exon-skipping medications, and gene therapy.

The DSHS Laboratory needs additional space to accommodate the testing equipment for DMD. The Legislature granted capital authority for DSHS to use federal funds to build additional laboratory space. The new laboratory project is just beginning, and DSHS will keep the Legislature updated on the project's process and anticipated timelines.

[1] Wahlgren L, Kroksmark AK, Tulinius M, Sofou K. One in five patients with Duchenne muscular dystrophy dies from other causes than cardiac or respiratory failure. Eur J Epidemiol. Feb 2022;37(2):147-156. doi:10.1007/s10654-021-00819-4

[2] Counterman KJ, Furlong P, Wang RT, Martin AS. Delays in diagnosis of Duchenne muscular dystrophy: An evaluation of genotypic and sociodemographic factors. Muscle Nerve. Jan 2020;61(1):36-43. doi:10.1002/mus.26720

Barriers to Additional Implementation

Current Laboratory Space Limitations

DSHS' Austin laboratory optimizes its existing space through renovations. As of July 2025, the Austin laboratory operates at full capacity. To accommodate future demands, the 89th Texas Legislature authorized DSHS to use federal funds to build an additional laboratory to create space to meet testing demands. The cost was based on an estimated 120,000 additional square footage of usable laboratory space.

Conclusion

By March 2026, DSHS expects to implement NBS testing for all conditions on the current RUSP, except for galactoepimerase deficiency and galactokinase deficiency. Implementation of future conditions must wait until after the new laboratory space is built unless the screening can be added to an existing test and analyzed within existing staff and space resources.

With the newly-authorized capital authority, DSHS is beginning planning activities for the additional laboratory space. Completion of the new laboratory space will address a critical barrier in implementing new screens in the future.