

EXAMPLE REPORT INDICATING NORMAL SCREENING



TEXAS
Health and Human
Services

Texas Department of State
Health Services

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CONFIDENTIAL LABORATORY REPORT

SUBMITTER NAME - 00000004
123 MEDICAL STREET
AUSTIN, TX 78758

NEWBORN SCREENING REPORT -

Patient's Name: GIRL TEXAN
Mother's Name: MOTHER TEXAN
Date Of Birth: 05/30/2021
Medical Record: 334455B
Birth Weight: 2,750 grams
Race/Ethnicity:
Sex: Birth Order:
Feed:
Status:

Laboratory Number: 2021 152 3001
Form Serial No: 20-0123455
Date Collected: 05/31/2021
Date Received: 06/01/2021
Date Reported: 06/03/2021

Test:

Mother's Address:

Mother's Telephone :

Physician's Name:

Physician's Telephone:

Overall Specimen Result

NORMAL SCREEN

Disorder *	Screening Result
Amino Acid Disorders	Normal
Fatty Acid Disorders	Normal
Organic Acid Disorders	Normal
Galactosemia	Normal
Biotinidase Deficiency	Normal
Hypothyroidism	Normal
CAH	Normal
Hemoglobinopathies	Normal
Cystic Fibrosis	Normal
SCID	Normal
X-ALD	Normal
SMA	Normal

Result Table: Results in the table are listed by category of the disorder

Note clarifying the scope of Newborn Screening

Note clarifying lab developed testing

Disorders Screened: Complete listing of disorders screened in each category appearing in the result table

--- The newborn screen identifies newborns at increased risk for specified disorders. The reference value for all screened disorders is 'Normal'. Analyte results are only listed for abnormal disorder screening results. The recommended collection time period and the testing methodologies have been designed to minimize the number of false negative and false positive results in newborns and young infants. When the newborn screen specimen is collected before 24 hours of age or on older children, the test may not identify some of these conditions. If there is a clinical concern, diagnostic testing should be initiated. Specimens that are unacceptable are reported as Unsatisfactory.

---The SCID / SMA test is performed by multiplex quantitative real-time PCR to detect the presence of T-cell receptor excision circles (TRECs) and SMN1 gene homozygous exon 7 deletion.

The detection rate is estimated to be 95% of SMA cases. SCID, SMA, Biotinidase deficiency, and Hemoglobinopathy screening tests and CAH and X-ALD reflex panels were developed / modified and performance characteristics determined by DSHS. These tests have not been cleared or approved by the US Food and Drug Administration (FDA).

* Disorders Screened: **AMINO ACID DISORDERS:** ARG, ASA, CIT, CIT II, BIOPT(BS), BIOPT(REG), HCY, H-PHE, MET, MSUD, PKU, TYRI, TYRII, and TYRIII. **FATTY ACID DISORDERS:** CACT, CPT IA, CPT II, CUD, DE RED, GA2, LCHAD, MCAD, MCAT, M/SCHAD, SCAD, TFP, VLCAD. **ORGANIC ACID DISORDERS:** 2M3HBA, 2MBG, 3MCC, 3MGA, BKT, GA1, HMG, IBG, IVA, MAL, MMA (MUT, Cbl A, B, C, D), MCD, PROP. **GALACTOSEMIA, BIOTINIDASE DEFICIENCY, HYPOTHYROIDISM, CAH, HEMOGLOBINOPATHIES:** Hb S/S, Hb S/C, Hb S-Beta Th, Var Hb.

CYSTIC FIBROSIS, SCID and T-Cell related Lymphopenias, X-ALD, SMA. List of disorders screened available at www.dshs.state.tx.us/lab/NBSdisorderList.pdf