

EXAMPLE REPORT INDICATING UNSATISFACTORY SCREENING



TEXAS Health and Human Services

Texas Department of State Health Services

LABORATORY SERVICES SECTION
CLIA #45D0660644

MAILING ADDRESS
PO BOX 149347
AUSTIN, TEXAS 78714-9347
1-888-963-7111

PHYSICAL ADDRESS
1100 W. 49th St
Austin, TX 78756

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: 05/24/2021
Medical Record: 334455B
Birth Weight: 2,750 grams
Race/Ethnicity:
Sex: FEMALE Birth Order:
Feed:
Status:

Laboratory Number: 2020 343 9001
Form Serial No: 20-0123457
Date Collected: 05/31/2021
Date Received: 06/01/2021
Date Reported: 06/02/2021

Test:
Mother's Address:
Mother's Telephone :
Physician's Name:
Physician's Telephone:

Overall Specimen Result

UNSATISFACTORY SPECIMEN-RESUBMIT

The specimen submitted for this patient was deemed unsatisfactory for the reasons listed below.
An immediate recollection is necessary to further evaluate this infant.

- 1) Blood did not completely fill specimen circles. Resubmit within 7 days.
2) Blood did not soak through paper due to incomplete saturation. Resubmit within 7 days.
3) Blood was caked, clotted, or layered onto the filter paper. Resubmit within 7 days.

The Screening Result Notes provide information on why the specimen was deemed unsatisfactory to test.
Please visit the Healthcare Provider Resources page of the Newborn Screening website for additional information on unsatisfactory specimens: NBS Unsatisfactory Specimen Examples
(http://www.dshs.state.tx.us/lab/unsatExamples.shtm)

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