

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

**TREC
Quarterly Report**

Volume 4, No. 3

August 2014

INTRODUCTION

This report is the Quarterly summary of all data reported within the specified data-reporting period for the Quarter 3, 2014, pilot proficiency testing (PT) program for T-cell receptor excision circle (TREC) analysis in dried-blood spots (DBS) to detect severe combined immunodeficiency (SCID). The attached tables provide the certification profiles for the distributed specimens, summary of reported categorical results and the verification of your reported data. We distribute this PT report to all participants, state laboratory directors, and program colleagues by request.

On July 14, 2014 a panel of five unknown DBS specimens was distributed to 22 domestic and 14 international laboratories to analyze TREC content in peripheral blood.

PARTICIPANT RESULTS

This panel consisted of five DBS specimens prepared from human blood, including cord blood from unaffected individuals and modified adult blood depleted of mononuclear cells or leukocytes (specimens 314R1, 314R2, 314R3, 314R4, and 314R5).

Evaluations are based on the source of specimen and previously established consensus categorical results from core laboratories.

All participants used laboratory-developed tests. We requested only qualitative, categorical results: 'No follow-up required (Screen Negative)' or 'Follow-up required' on each specimen since quantitative results vary significantly between laboratories using different test methods and calibrators.

We processed data from 29 participants. Four false-positive and two false-negative assessments were reported. False-positive assessments should be monitored and kept as low as possible.

The Newborn Screening Quality Assurance Program will ship next quarter's pilot PT specimens for TREC on October 6, 2014. ❖

ACKNOWLEDGMENTS

We would like to thank Barbara Waters-Pick (Duke University Medical Center) for the supply of umbilical cord blood.

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This program is cosponsored by the Centers for Disease Control and Prevention (CDC)
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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

T-CELL RECEPTOR EXCISION CIRCLE (TREC) ANALYSIS IN DRIED-BLOOD SPOTS

QUARTER 3 – AUGUST 2014

SPECIMEN CERTIFICATION

Specimen Number	No follow-up required (Screen Negative)	Follow-up required	Specimen Description
314R1	1		Normal specimen; below average TREC level, reference gene level within standard reference range
314R2		2	Blood with 'buffy-coat' removed - TREC and reference gene levels both below standard reference range.
314R3	1		Normal specimen; medium TREC level, reference gene level within standard reference range
314R4		2	SCID-like specimen; low or no TREC, reference gene level within standard reference range
314R5	1		Normal specimen; below average TREC level, reference gene level within standard reference range

1 = No follow-up required (Screen Negative)
 2 = Follow-up required

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FREQUENCY OF REPORTED CLINICAL ASSESSMENTS

Specimen Number	No follow-up required (Screen Negative)	Follow-up required
314R1	28	1
314R2	1	28
314R3	28	1
314R4	1	28
314R5	27	2

LABORATORY METHODS

Method	Number of Laboratories
63 Real Time PCR - Singleplex	12
71 Real Time PCR - Multiplex	14
70 EnLite™ Neonatal TREC kit	2
19 Other	1

FREQUENCY OF DNA PREPARATION METHODS

DNA Preparation Method	Number of Laboratories
1 In situ/on card (no DNA extraction) with washing step(s)	4
2 EnLite™ (no DNA extraction)	3
3 DNA extracted at 95°C with washing step(s)	12
4 DNA extracted at 70°C with washing step(s)	2
5 DNA extracted with no washing step	1
6 Other	7

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FREQUENCY OF REFERENCE GENE ASSESSMENT CATEGORY
(for expected Follow-up Required Specimens)

Specimen Number	1- Within normal range	2- Outside normal range
314R2	0	28
314R4	28	0

FREQUENCY OF REFERENCE GENES

Reference Genes	Number of Laboratories
1 RNase P coding segments	12
2 Beta-actin	15
3 Serum albumin	1
4 TERT - Telomerase Reverse	0
5 Other	1

This **NEWBORN SCREENING QUALITY ASSURANCE PROGRAM** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC)** and the **Association of Public Health Laboratories**.

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