

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

**TREC
Quarterly Report**

Volume 4, No. 2

May 2014

INTRODUCTION

This report is the Quarterly summary of all data reported within the specified data-reporting period for the Quarter 2, 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 April 7, 2013, a panel of five unknown DBS specimens was distributed to 20 domestic laboratories and for the first time, 17 international laboratories (37 total participants) 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 214R1, 214R2, 214R3, 214R4, and 214R5).

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. No false-positive and no 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 July 14, 2014. ❖

ACKNOWLEDGMENTS

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Direct inquiries to:
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

Phone: 770-488-7945
FAX: 770-488-4255
E-mail: JMei@cdc.gov

Editors: Joanne Mei
Irene Williams



NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

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

Quarter 2 –May 2014

SPECIMEN CERTIFICATION

Specimen Number	No follow-up required (Screen Negative)	Follow-up required	Specimen Description
214R1	1		Normal specimen; medium TREC level, reference gene level within standard reference range
214R2		2	SCID-like specimen; low or no TREC, reference gene level within standard reference range
214R3	1		Normal specimen; below average TREC level, reference gene level within standard reference range
214R4		2	Blood with 'buffy-coat' removed - TREC and reference gene levels both below standard reference range.
214R5	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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Quarter 2 – May 2014

FREQUENCY OF REPORTED CLINICAL ASSESSMENTS

Specimen Number	No follow-up required (Screen Negative)	Follow-up required
214R1	29	0
214R2	0	29
214R3	29	0
214R4	0	29
214R5	29	0

FREQUENCY OF DNA PREPARATION METHODS

DNA Preparation Method	Number of Laboratories
1 In situ/on card (no DNA extraction) with washing step(s)	5
2 EnLite™ (no DNA extraction)	2
3 DNA extracted at 95°C with washing step(s)	12
4 DNA extracted at 70°C with washing step(s)	1
5 DNA extracted with no washing step	1
6 Other	8

FREQUENCY OF REFERENCE GENES

Reference Genes	Number of Laboratories
1 RNase P coding segments	13
2 Beta-actin	16
3 Serum albumin	0
4 TERT - Telomerase Reverse	0
5 Other	0

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

Specimen Number	1- Below normal range	2- Within normal range	3- Above normal range
214R2	3	25	1
214R4	20	0	9

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

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**.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director

Thomas R. Frieden, M.D., M.P.H.

Acting Director

National Center for Environmental Health

Robin Ikeda, M.D., M.P.H.

Director

Division of Laboratory Sciences

James L. Pirkle, M.D., Ph.D.

Chief

Newborn Screening and Molecular Biology Branch

Carla Cuthbert, Ph.D.



Contributors: Barbara W. Adam
Paul Dantonio
Victor R. De Jesus, Ph.D.
Marie C. Earley, Ph.D.
Sharon Flores
David Foreman
Stephanie Foster
Elizabeth M. Hall
Christopher Haynes, Ph.D.
Sarah Klass
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.
Nancy Meredith
Patrick Pickens
Kelsey Sheard
Jennifer Taylor, Ph.D.
Robert Vogt, Ph.D.
Irene Williams
Golriz Yazdanpanah
Hui Zhou, Ph.D.
Sherri Zobel

Production: Sarah Brown
Felicia Manning
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President

Christine Bean, Ph.D., M.B.A., MT(ASCP)

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrick Hopkin, B.S.



INQUIRIES TO:

Irene Williams, Editor • Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: IWilliams1@cdc.gov