

HUMAN HEALTH

ENVIRONMENTAL HEALTH

TREC TOWARDS HEALTH

EnLite™ Neonatal TREC system


PerkinElmer[®]
For the Better

SCID screening at the start of life



The first commercially available solution for SCID screening

The EnLite™ Neonatal TREC Kit is an in vitro diagnostic device intended for the semi-quantitative determination of TREC (T-cell receptor excision circle) DNA in blood specimens dried on filter paper. The test is used in conjunction with the VICTOR™ EnLite Instrument and is an important aid in screening newborns for severe combined immunodeficiency disorder (SCID).

PerkinElmer is proud to introduce the first commercial T-cell Receptor Excision Circle (TREC) screening assay. The assay is part of a complete system for the effective and safe screening of Severe Combined Immunodeficiency (SCID).

The EnLite™ Neonatal TREC

Why choose PerkinElmer for SCID screening?

ONE-STOP SUPPLIER

- We cover every process stage – from DBS cards to software
- Ready-to-use reagents and devices from one supplier – no need to custom build
- Effective training and support included in every system delivery

QUALITY ABOVE ALL

- The first SCID screening solution to receive marketing authorization in the US
- Manufactured according to GMP and quality standards
- Improved sample integrity and a wide range quality control tools



Manufactured according to good manufacturing practice (GMP), the screening kit includes ready-to-use reagents, as well as control and calibrator materials supplied in DBS format to make them as closely representative of newborn screening specimens as possible.

This test is not intended for use as a diagnostic test or screening protocol for SCID-like syndromes such as DiGeorge Syndrome or Omenn Syndrome, nor for the screening of less acute SCID syndromes such as leaky-SCID or variant SCID.

A complete system for complete screening

As the global leader in newborn screening, PerkinElmer is dedicated to solutions that cover the entire screening process, from sample to results. We've innovated and integrated on your behalf, so you don't have to start your screening program from scratch.

- **EnLite™ Neonatal TREC assay**

EnLite Neonatal TREC is a duplex assay that detects TREC, the marker of SCID, and beta-actin, which is used as an internal control for each specimen.

- **VICTOR™ EnLite instrument**

VICTOR EnLite is a plate-reading fluorometer employing TR-FRET to provide simultaneous detection of the assay's dual labels.

- **EnLite Workstation software with Specimen Gate® option**

EnLite Workstation interprets the results from the instrument and provides flexible reporting options.

As well as supplying a complete product solution, we provide training and expert support to help you setup and maintain your SCID screening program.

Four steps to results



The effective approach to SCID screening



The screening process for SCID consists of four simple steps: punching, elution, amplification and measurement. With no need for DNA extraction and transfer steps, there is less risk to sample integrity. The assay is performed through the elution and amplification steps, and measured, all on the same microplate.

See the results

With EnLite Workstation software, you can interpret and report results effectively. One look and you see the results of your SCID screening program.

The EnLite workstation software can be run independently or linked up with Specimen Gate® for full integration of the EnLite TREC system into your existing screening programs.

EnLite™ Workstation software includes



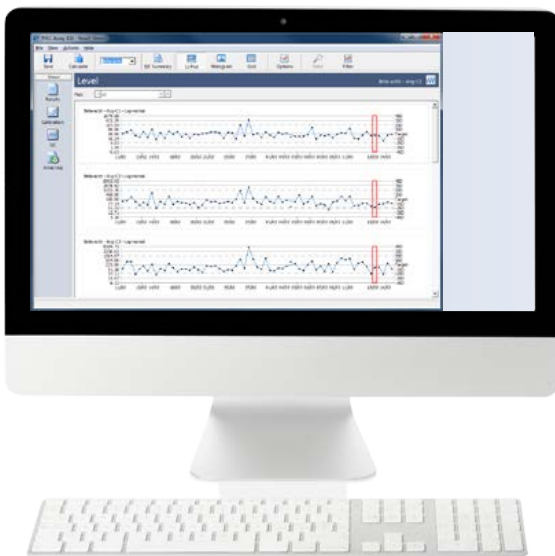
Plate view of results

Results can be viewed in different formats



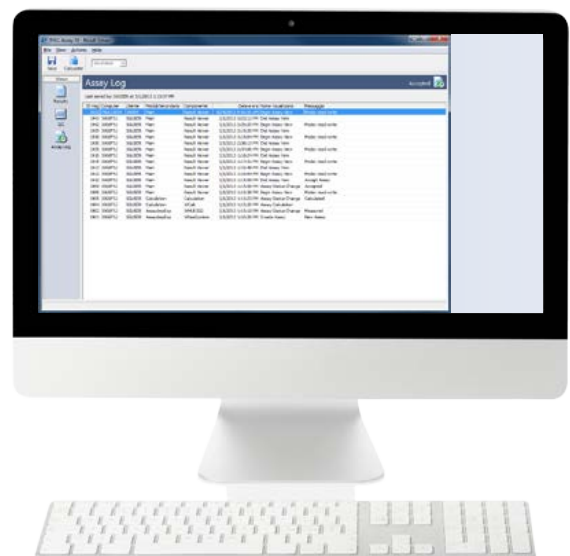
Worksheet view of results

Color coding for easier interpretation and processing of results



Quality control

Graphical display of data with automated QC flagging



Audit Trail

A detailed history of all user actions

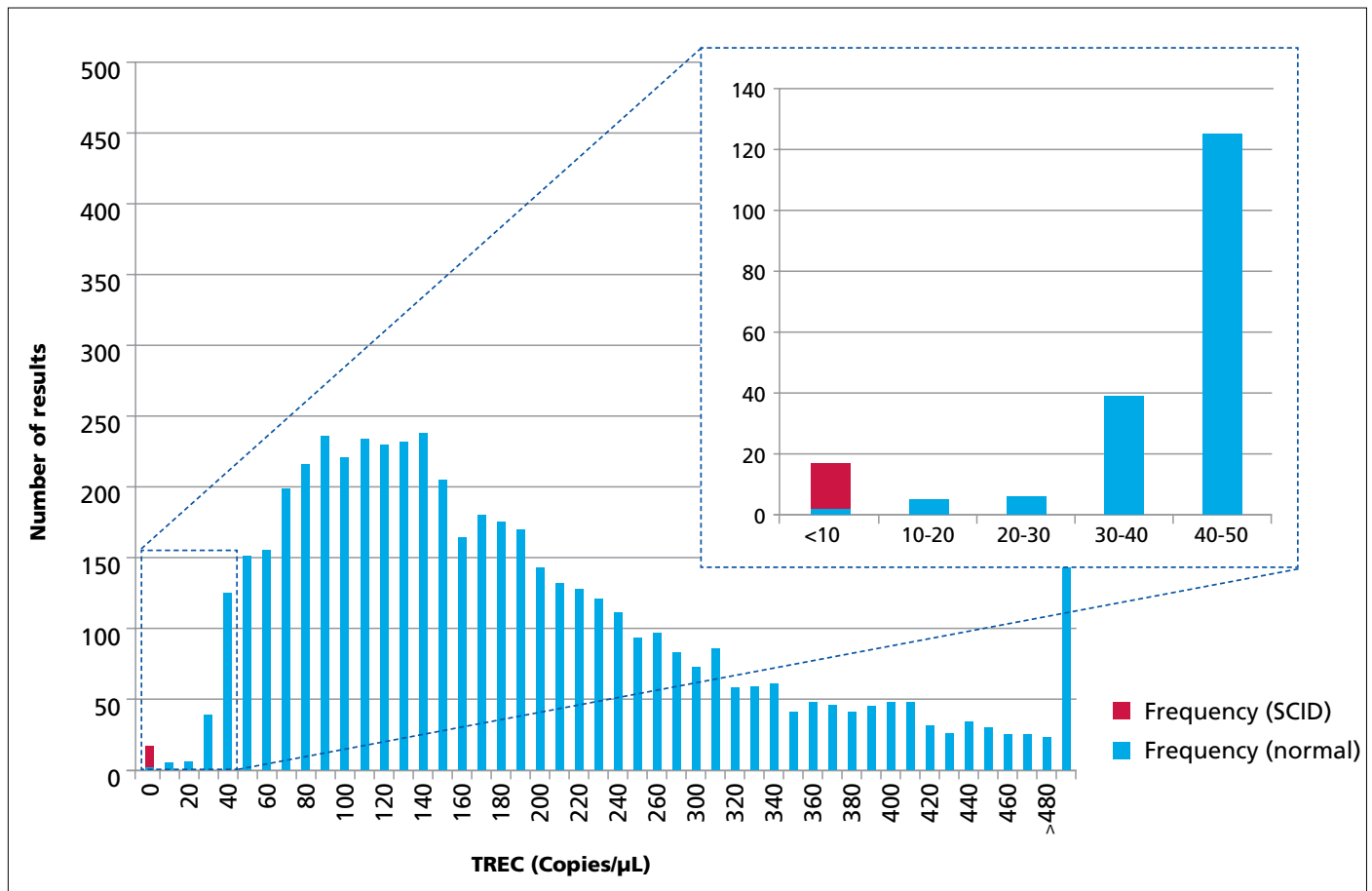
When performance matters

Excellent sensitivity and specificity

Clear separation of risk samples and fewer false positives

In a clinical study*, the EnLite TREC assay was used to test approximately 6,400 retrospective dried blood spot samples along side of 17 confirmed SCID positive blood spot samples. All 17 SCID DBS samples were successfully identified as SCID presumptive positive in the study.

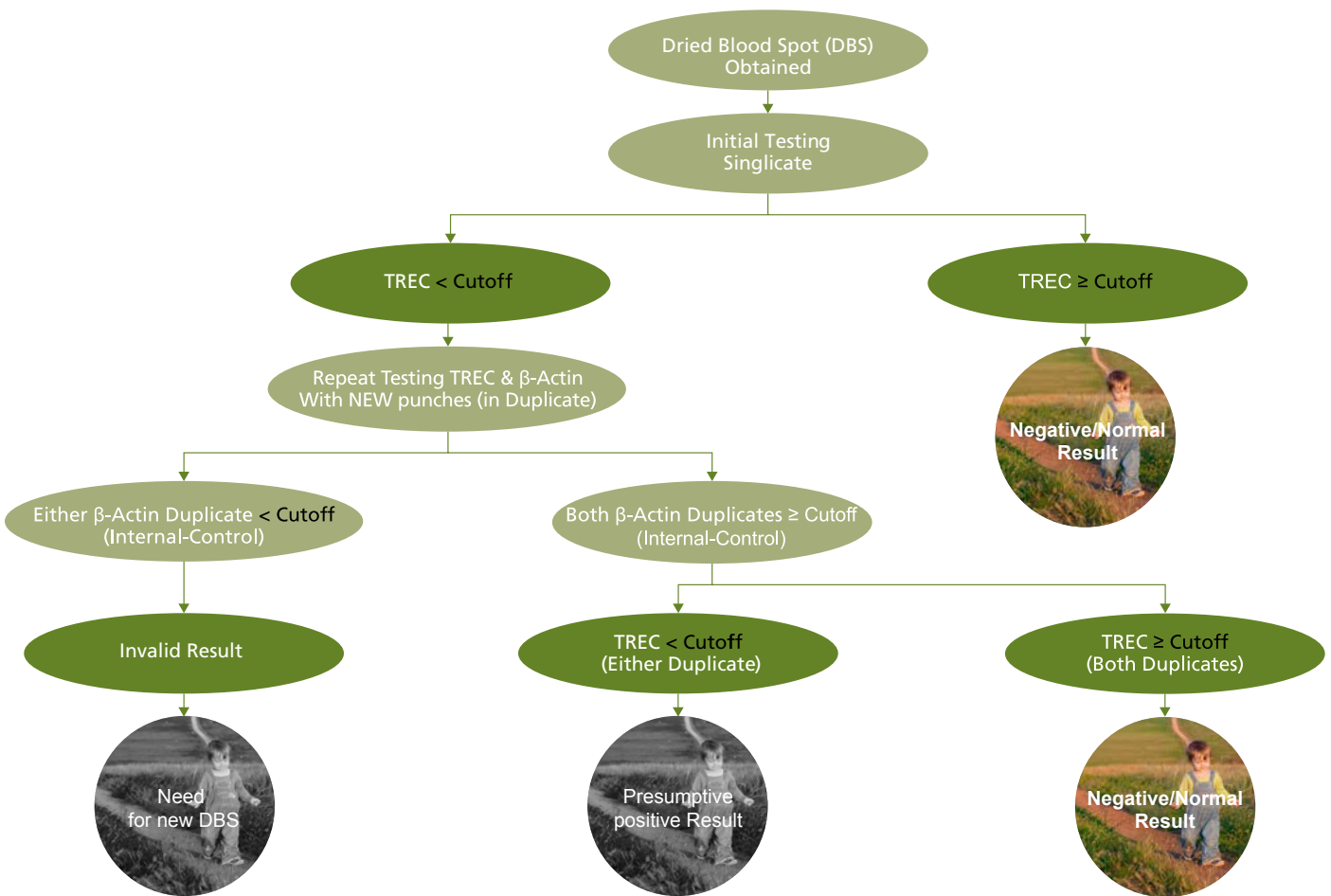
* Study performed by Statens Serum Institut, Copenhagen, Denmark for Wallac OY, Turku, Finland.



Histogram showing values obtained with assay for newborn specimens using singlicate measurements. Blue indicates normal sample (n=5426), red indicates the SCID samples (n=17).

In the study all the samples were initially tested in singlicate for TREC. The samples having a low TREC value were then retested in duplicate to confirm the low TREC result. The test results for beta-actin were simultaneously compared to the cut-off to identify any samples characterized by DNA amplification failure.

This two-round process minimizes the number of false positive samples, and identifies samples where amplification has failed and a new sample is needed. Each laboratory should establish their reference range for their newborn screening population.



ORDERING INFORMATION

Product Description	Size	Part Number
EnLite Neonatal TREC kit	4 x 96 reactions	3401-001U
EnLite Neonatal TREC kit	1 x 384 reactions	3402-001U
EnLite Neonatal TREC kit	3 x 384 reactions	3403-001U
EnLite 96-well PCR Plates, black	50 plates	3410-0010
EnLite Adhesive clear PCR seals	100 seals	3411-0010

Product Description	Size	Part Number
VICTOR EnLite (manual loading)		1420-0220
VICTOR EnLite with stacker and robotic loading system		1420-0230

Laboratories working with the products will also require a PCR machine, puncher with a 1.5mm punch head and plate spinners/centrifuges. Products are not available in Japan, China, Singapore, Mexico, Brazil, Argentina and some other Asian and Latin American countries. Please check availability from your local PerkinElmer representative.

For more information about PerkinElmer's new products for SCID screening, please visit: www.perkinelmer.com/SCID

To learn about PerkinElmer Newborn Screening, visit www.perkinelmer.com/newborn

PerkinElmer, Inc.
940 Winter Street
Waltham, MA 02451 USA
Phone: (800) 762-4000 or
(+1) 203-925-4602
www.perkinelmer.com

PerkinElmer, Inc.
Wallac Oy
PO Box 10
20101 Turku, Finland
Phone: + 358 2 2678 111
Fax: + 358 2 2678 357

ISO 13485
ISO 9001
CMDCAS
ISO 14001
OHSAS 18001



For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

Copyright ©2013, PerkinElmer, Inc. All rights reserved. PerkinElmer® is a registered trademark of PerkinElmer, Inc. All other trademarks are the property of their respective owners.