HUMAN HEALTH

ENVIRONMENTAL HEALTH

TREC TOWARDS HEALTH

EnLite™ Neonatal TREC system

Brochure not for distribution in the US

PerkinElmer®
For the Better

SCID screening at the start of life

CE-marked solution for SCID screening

PerkinElmer is proud to introduce the first commercial TREC screening assay. The assay forms part of a complete system, CE-marked to assure safe and effective use as an aid in screening for SCID.

EnLite™ Neonatal TREC assay is a dried blood spot (DBS) assay employing PCR-based nucleic acid amplification and time-resolved fluorescence resonance energy transfer (TR-FRET) technology. Manufactured according to good manufacturing practice (GMP), the kit contains all reagents ready to use, and control and calibrator materials supplied in DBS format to make them as closely representative as possible.

Why screen for SCID?

Severe Combined Immunodeficiency (SCID) is a group of disorders characterized by a severe defect in T cell production and function. Typically, infants with SCID will die due to infection by one year of age unless the infant's immune system is restored through treatment [1].

The preferred treatment is bone marrow/stem cell transplantation. Evidence from large case series indicates that children receiving early stem-cell transplant for SCID have improved outcomes compared with children who are treated later [2].

What are TRECs?

T-cell Receptor Excision circles (TRECs) are circular DNA fragments generated during T-cell receptor rearrangement. In healthy neonates, TRECs are made in large numbers, while in infants with SCID, they are barely detectable.

A complete system: products, training and back-up

PerkinElmer, the first company in SCID screening, offers the reagents, measuring instruments and software you need. In developing its first-of-their-kind products, PerkinElmer has saved individual programs much of the work that earlier pioneering programs have had to perform for themselves. PerkinElmer has sourced and controlled the quality of all materials, observed GMP at all manufacturing stages, and met the requirements for CE certification, so that users can be confident in the products' safety and efficiency.

- **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 are very glad to place our expertise at your disposal in the form of training, advice and comprehensive support as you start to implement SCID screening.

Four steps to results

The practical approach to SCID screening

PUNCHING → ELUTION → AMPLIFICATION → MEASUREMENT

Starting with a dried blood spot specimen card, the assay itself has just four steps: punching, elution, amplification and measurement. There is no DNA extraction and there are no transfers. The assay is performed through the elution and amplification steps, and measured, all on the same microplate. The absence of transfers minimizes the risk to samples.

Clear interpretation and reporting of results

Dedicated software from the leading supplier of software for screening data management ensures easy and flexible result interpretation and reporting of results. EnLite Workstation software may be used on its own or with Specimen Gate® to allow full integration of the TREC assay into existing screening programs.

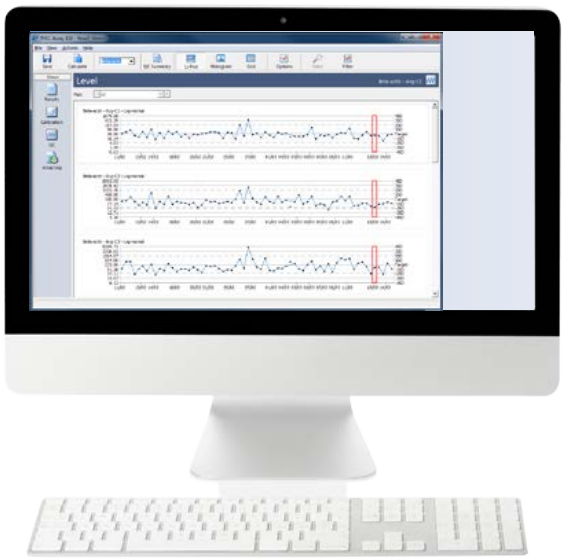
EnLite™ Workstation software includes

Plate view of results

Results can be viewed in alternative formats

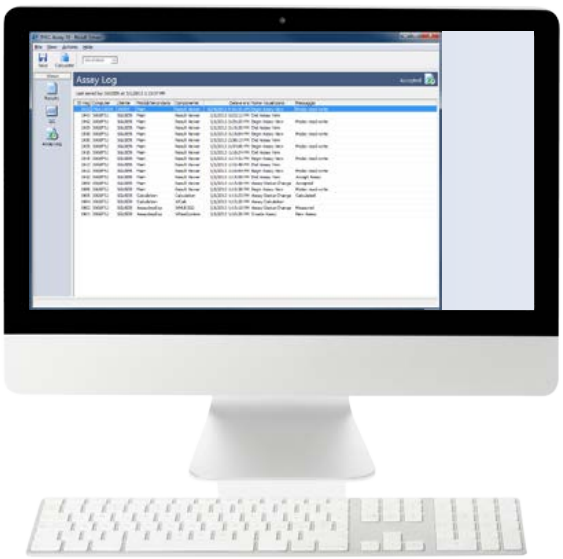
Worksheet view of results

Color coding makes the results easy to assimilate



Quality control

Graphical view of data with automated QC flagging



Audit Trail

A detailed history of all user actions

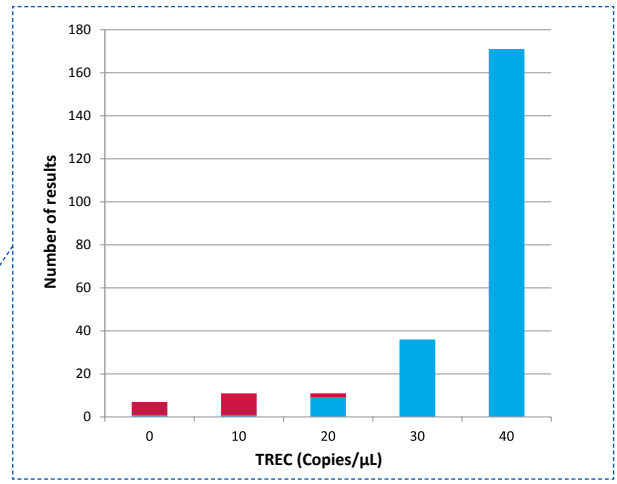
When performance matters

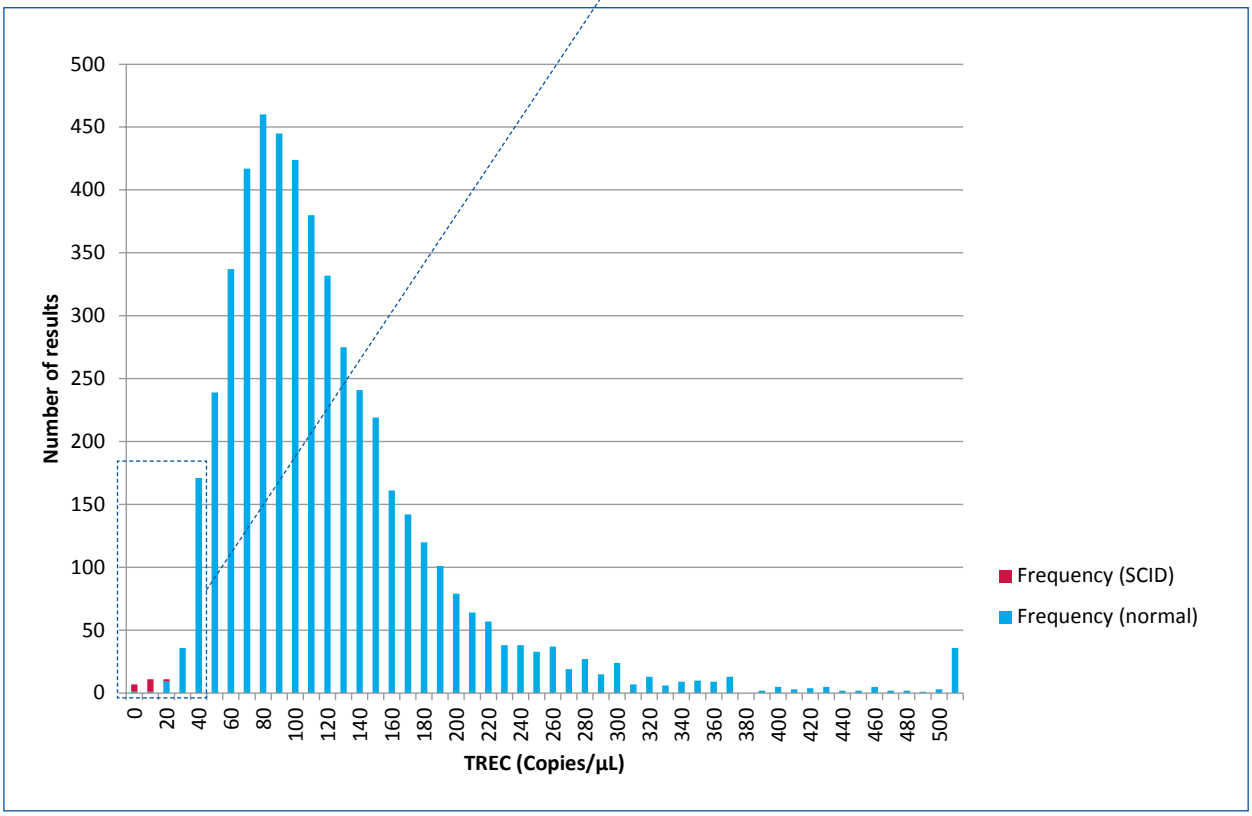
Excellent sensitivity and specificity

Clear separation of at risk specimens, with few false positives

In a recent study [3] the EnLite TREC assay was used to test over 5000 anonymous retrospective dried blood spots alongside 18 confirmed SCID positive blood spots.

All 18 SCID DBS samples were successfully identified as SCID positives in the study. The number of presumptive positives ranged from 0.04-1.00% of samples tested, depending on the TREC cut-off threshold settings.

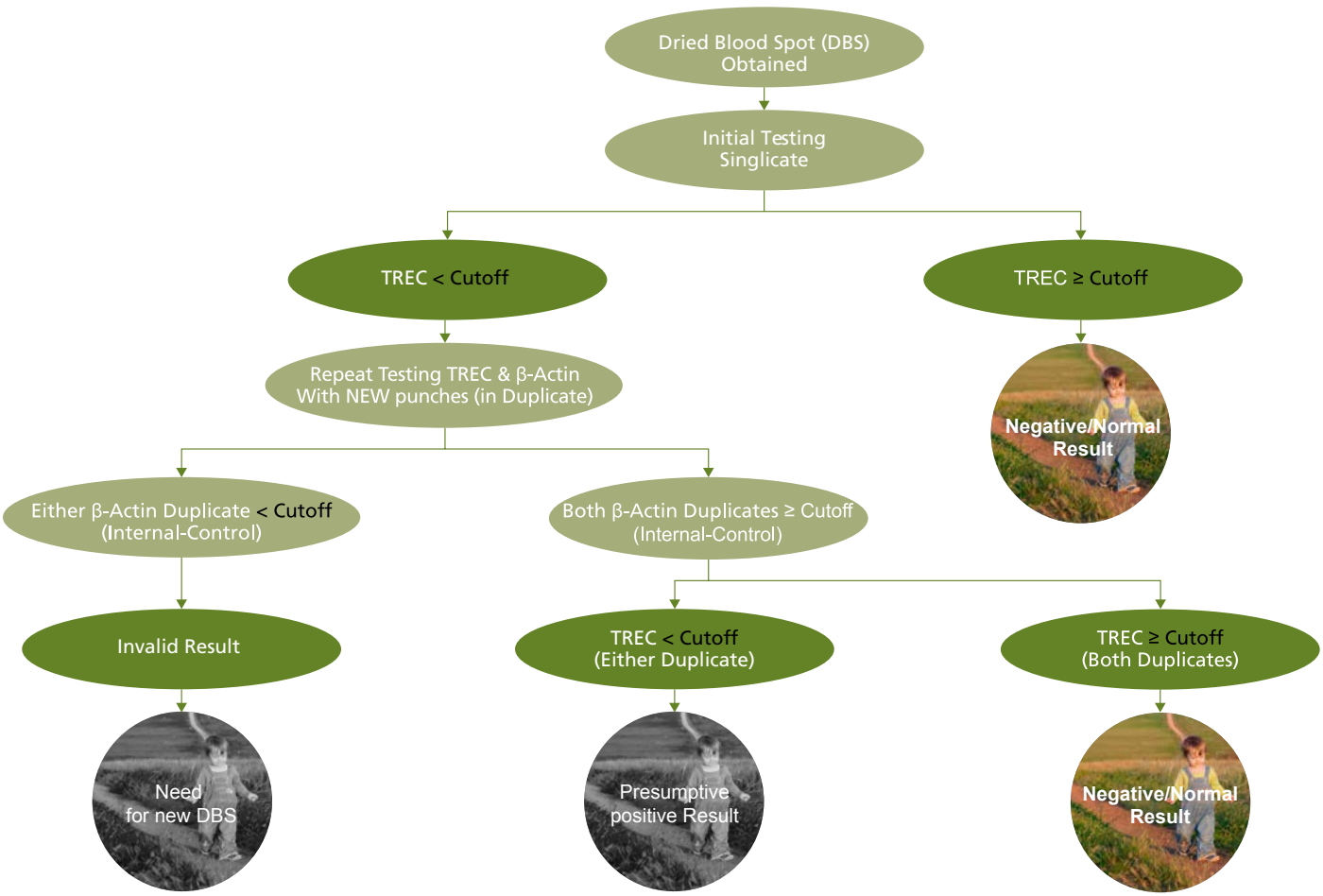




Histogram showing values obtained with the assay for newborn specimens using singlicate measurements. Blue indicates normal sample (n=5081), red indicates the SCID samples (n=18) [3].

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

The two-round process is designed to minimize the number of false positive specimens, and also to identify specimens where amplification has failed and a new specimen is needed. The users of the product can develop their own procedures and cut-offs to best meet the needs of their screening program.



Use of the EnLite™ Neonatal TREC test in a two-stage procedure

References

[1] Centers for Disease Control and Prevention (2004): MMWR Morb. Mortal. Wkly. Rep., 53 (No. RR-1), 1–29.

[2] Buckley RH (2000) Advances in the understanding and treatment of human severe combined immunodeficiency. Immunol Res 22, 237–251.

[3] Data from PerkinElmer study.

ORDERING INFORMATION

Product Description	Size	Part Number
EnLite Neonatal TREC kit	4 x 96 reactions	3401-0010
EnLite Neonatal TREC kit	1 x 384 reactions	3402-0010
EnLite Neonatal TREC kit	3x384 reactions (under development)	3403-0010
EnLite 96-well PCR Plates, black	50 plates	3410-0010

Product Description	Size	Part Number
EnLite Adhesive clear PCR seals	100 seals	3411-0010
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 the USA, Canada, Japan, China, Singapore, Mexico, Brazil, Argentina, Colombia 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 TREC assay, please visit: www.perkinelmer.com/SCID

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

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