TREC TOWARDS HEALTH

EnLite™ Neonatal TREC system
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 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).

**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.
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.
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

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Size</th>
<th>Part Number</th>
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<tbody>
<tr>
<td>EnLite Neonatal TREC kit</td>
<td>4 x 96 reactions</td>
<td>3401-001U</td>
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<tr>
<td>EnLite Neonatal TREC kit</td>
<td>1 x 384 reactions</td>
<td>3402-001U</td>
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<tr>
<td>EnLite Neonatal TREC kit</td>
<td>3 x 384 reactions</td>
<td>3403-001U</td>
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<td>EnLite 96-well PCR Plates, black</td>
<td>50 plates</td>
<td>3410-0010</td>
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<tr>
<td>EnLite Adhesive clear PCR seals</td>
<td>100 seals</td>
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<tr>
<th>Product Description</th>
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<tr>
<td>VICTOR EnLite (manual loading)</td>
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<td>1420-0220</td>
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<tr>
<td>VICTOR EnLite with stacker and robotic</td>
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<td>1420-0230</td>
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<tr>
<td>loading system</td>
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Labs 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](http://www.perkinelmer.com/SCID)

To learn about PerkinElmer Newborn Screening, visit [www.perkinelmer.com/newborn](http://www.perkinelmer.com/newborn)