LymphoTrack® Dx TRG Assay - MiSeq, Product Flyer

Interest in any of the products, request or order them at Bio-Connect Diagnostics.
Intended Use

The LymphoTrack® Dx TRG Assay for the Illumina MiSeq® is an in vitro diagnostic product intended for next-generation sequencing (NGS) based determination of the frequency distribution of TRG gene rearrangements in patients suspected with having lymphoproliferative disease. This assay aids in the identification of lymphoproliferative disorders.

Background

The LymphoTrack Dx TRG Assay – MiSeq represents a significant improvement over existing fragment analysis clonality assays by providing two important and complementary uses:

1. Detects initial clonal populations
2. Identifies sequence information required to track clonal rearrangements in subsequent samples

The human T Cell Receptor Gamma (TRG) gene locus on chromosome 7 (7q14) includes 14 V (variable region) genes (Group I, II, III, and IV), 5 J (joining region) gene segments, and 2 C (constant region) genes spread over 200 kilobases.

During development of lymphoid cells, antigen receptor genes undergo somatic gene rearrangements. Specifically during T-cell development, genes encoding TRG molecules are assembled from multiple polymorphic gene segments that undergo rearranged generating V-J combinations unique in both length and sequence. Since leukemias and lymphomas originate from the malignant transformation of individual lymphoid cells, all leukemias and lymphomas generally share one or more cell-specific or “clonal” antigen receptor gene rearrangement. Therefore, tests that detect TRG clonal rearrangements can be useful in the study of B- and T-cell malignancies.

Method

This assay utilizes a single multiplex master mix to target conserved V and J regions of TRG that are described in lymphoid malignancies. Primers are designed with Illumina adapters and up to 24 different indices; thereby, allowing amplicons generated from different TRG master mixes to be pooled together to generate a library for loading onto a single MiSeq flow cell for sequencing. The associated LymphoTrack Dx MiSeq Software provides interpretation of the data via a simple and streamlined method of analysis and visualization of data. By following the guidelines provided in the Instructions for Use, samples can be easily interpreted for the evidence or no evidence of clonality.

Specimen Requirement

50 ng of high quality DNA.

References


Ordering Information

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Products</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>9-227-0019</td>
<td>LymphoTrack Dx TRG Assay Kit A - MiSeq</td>
<td>8 indices - 5 sequencing reactions each</td>
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<tr>
<td>9-227-0009</td>
<td>LymphoTrack Dx TRG Assay Panel - MiSeq</td>
<td>24 indices - 5 sequencing reactions each</td>
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<td>9-500-0009</td>
<td>LymphoTrack Dx MiSeq Software</td>
<td>1 CD complimentary with purchase</td>
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This product is a CE-IVD assay for In Vitro diagnostic use.
Simplified Representation of TRG Gene

Performance Characteristics

The LymphoTrack Dx TRG Assay compared to laboratory diagnostic report were compared and the concordance, sensitivity (ST), specificity (SP), positive predictive value (PPV), and negative predictive value (NPV) were: 82% (47/57 cases), 67%, 97%, 95%, and 76%, respectively.

<table>
<thead>
<tr>
<th>Concordance Between NGS and Laboratory Diagnostic Report</th>
<th>Laboratory Diagnostic Report</th>
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<tbody>
<tr>
<td>LymphoTrack Dx TRG Assay - MiSeq</td>
<td>Clonal</td>
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<td>Clonal</td>
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<tr>
<td>Non-Clonal</td>
<td>9</td>
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