LymphoTrack® Low Positive Controls

LymphoQuant® Internal Controls

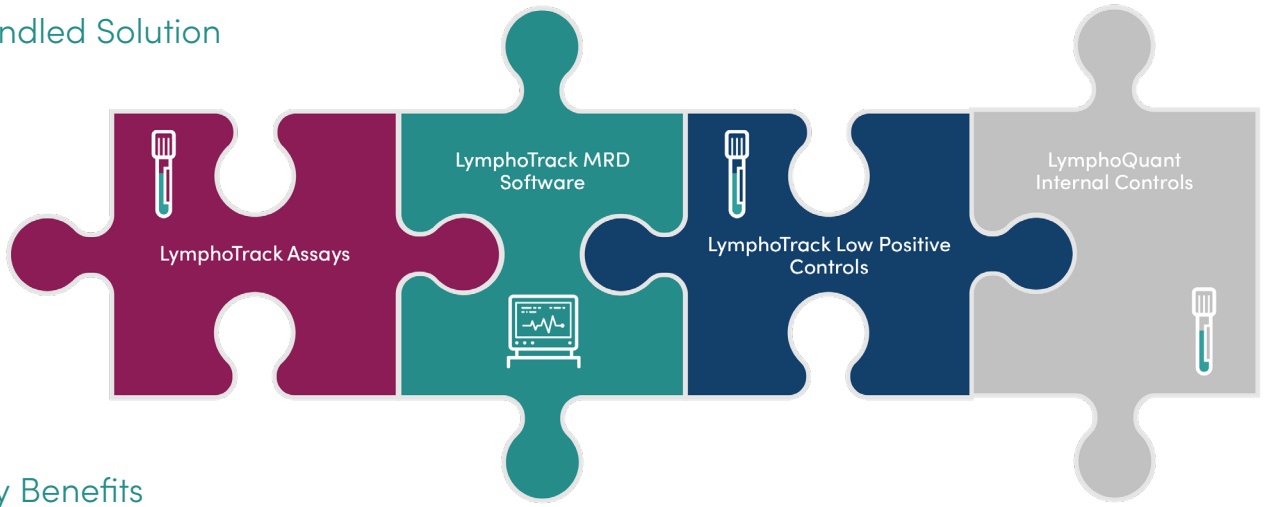
Bundled Solution for MRD Clonality Testing

Product Use

Minimal Residual Disease (MRD) is increasingly recognized as a potential biomarker surrogate endpoint for a number of hematologic malignancy studies. Innovative Next-Generation Sequencing (NGS) Assays, DNA controls and software are necessary to enable longitudinal MRD tracking.

The Invivoscribe Bundled MRD Solution provides two types of RUO DNA controls for laboratories to test samples with low target molecules using LymphoTrack® Assays. LymphoTrack® Low Positive Controls are used as an external quality control for each run, while LymphoQuant® Internal Controls are used as an internal control to be spiked into each sample. These RUO DNA controls are developed for use with LymphoTrack® Assays and LymphoTrack® MRD software to track clonal sequences on MiSeq®, Ion S5™ and Ion PGM™ platforms with unprecedented sensitivity and specificity.

Bundled Solution



Key Benefits

- Globally standardize MRD testing
- Objectively identify, assess and track Ig and TR gene rearrangements
- Bioinformatics software for experimental planning, longitudinal graphs and PDF reports

LymphoTrack MRD Software	Catalog # 7-500-0008	
LymphoTrack Assay	Low Positive Control	Internal Controls
IGHV Leader, *IGH* FR1/2/3	LymphoTrack® B-cell Low Positive Control Catalog # 4-088-0098	LymphoQuant® B-cell Internal Control Catalog # 4-088-0118
TRG, TRB	LymphoTrack® T-cell Low Positive Control Catalog # 4-088-0108	LymphoQuant® T-cell Internal Control Catalog # 4-088-0128

These products are for Research Use Only. Not for use in diagnostic procedures.

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invivoscribe®
Improving Lives with Precision Diagnostics®

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LymphoTrack® Low Positive Controls

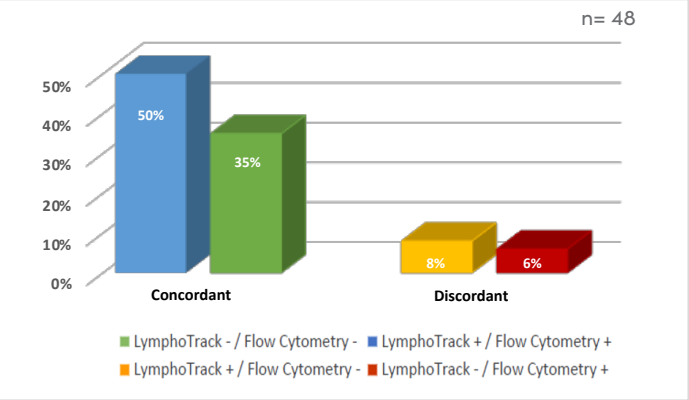
LymphoQuant® Internal Controls

Control Performance

Excellence in Linearity, Accuracy, and Limit of Detection (data not shown)

Excellent agreement between expected clonal cells and estimated clonal cell equivalents was demonstrated after spiking LymphoQuant Internal Control (LQIC) into mock MRD samples (clonal positive cell line DNA was diluted into clonal negative DNA at 10^{-2} to 10^{-5}). The LymphoTrack Assays yielded an R^2 value of 0.98 or greater for *IGHV* Leader, *IGH* FR1, FR2 and FR3.

High Concordance of NGS and MFC



85.4% concordance (DNA Input > 700 ng) was evident between LymphoTrack *IGH* FR1 Assay – MiSeq® and multiparameter flow cytometry (MFC) despite the use of 1/10th the cell equivalents used for the MFC assessment. While no method is perfect, NGS testing is much easier to standardize and validate for regulatory submissions.

LymphoQuant Internal Controls

The Principle Behind an Objective, Internal Calibration

Test without Internal Control

- Lymphocytes
- Clonal Cells
- Other Cells

10 clonal / 100 lymphocytes
= 10% clonality

1 clonal / 5 lymphocytes
= 20% clonality

Test with Internal Control

- Lymphocytes
- Clonal Cells
- Other Cells
- Internal Control

10 clonal cell equivalents

1 clonal cell equivalent