LymphoTrack® Low Positive Controls

LymphoQuant® Internal Controls

Bundled Solution for MRD Clonality Testing

Product Use

Minimal Residual Disease (MRD) is increasingly recognized as a biomarker, and potential surrogate endpoint for a number of hematologic malignancies. 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.

Key Benefits

- Globally standardize MRD testing
- Objectively identify, assess and track Ig and TR gene rearrangements
- Detect subject relapse earlier
- Evaluate clinical decisions based on longitudinally calibrated clonal load
- Bioinformatics software for experimental planning, longitudinal graphs and PDF reports

LymphoTrack MRD Software	Catalog# 7-500-0008	
LymphoTrack Assay	Low Positive Control	Internal Control
IGHV Leader, *IGH* FR1/2/3, *IGK*	LymphoTrack® B-cell Low Positive Control Catalog # 4-088-0098	LymphoQuant® B-cell Internal Control Catalog # 4-088-0118
Coming Soon! *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.

037 Rev A May 2019

invivoscribe
Improving Lives with Precision Diagnostics™

Invivoscribe, Inc
Tel +1 858.224.6600 | Fax +1 858.224.6601
sales@invivoscribe.com
10222 Barnes Canyon Rd., Bldg. 1
San Diego, CA 92121 | USA

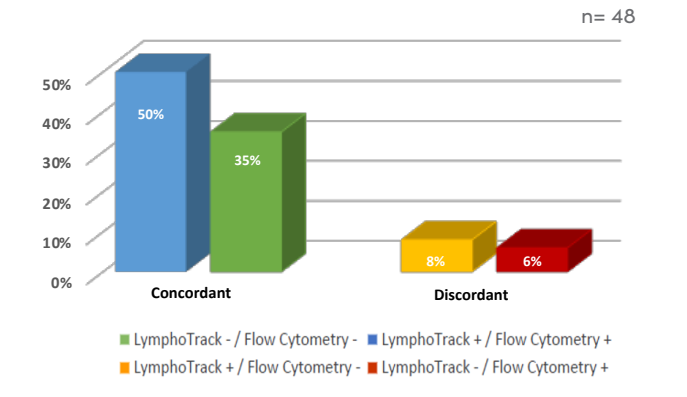
Invivoscribe, SARL
Tel +33 (0) 4.42.01.78.10 | Fax +33 (0) 4.88.56.22.89
sales-eu@invivoscribe.com
Le Forum - Bât B | 515 Avenue de la Tramontane
ZI Athélia IV | 13600 La Ciotat | France

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, FR3 and *IGK* .

High Concordance of NGS and MFC

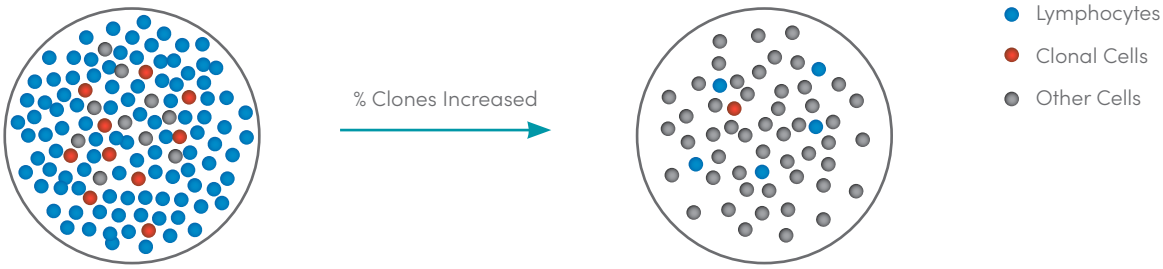


85.4% concordance (DNA Input > 700 ng) was evident between LymphoTrack *IGH* FR1 Assay - MiSeq® and multiparameter flow cytometry (MFC) despite the use of 1/10th the cell equivalents used for the MFC assessment. While no method is perfect, NGS testing is much easier to standardize and validate for regulatory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

LymphoQuant Internal Controls

The Principle Behind an Objective, Internal Calibration

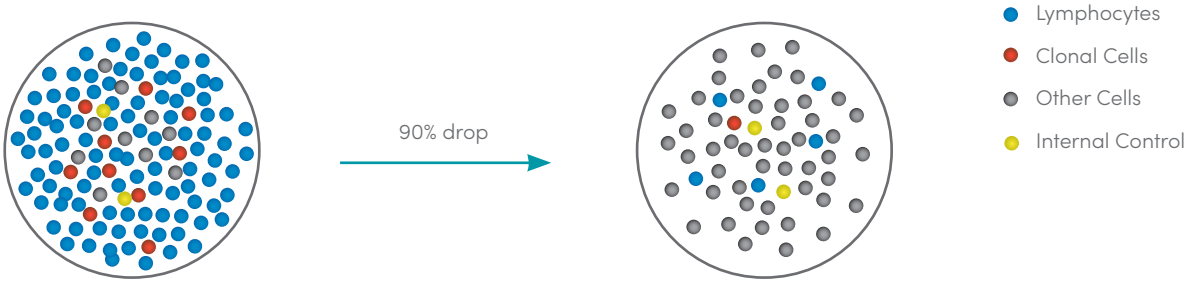
Test without Internal Control



10 clonal / 100 lymphocytes
= 10% clonality

1 clonal / 5 lymphocytes
= 20% clonality

Test with Internal Control



10 clonal cell equivalents

1 clonal cell equivalent