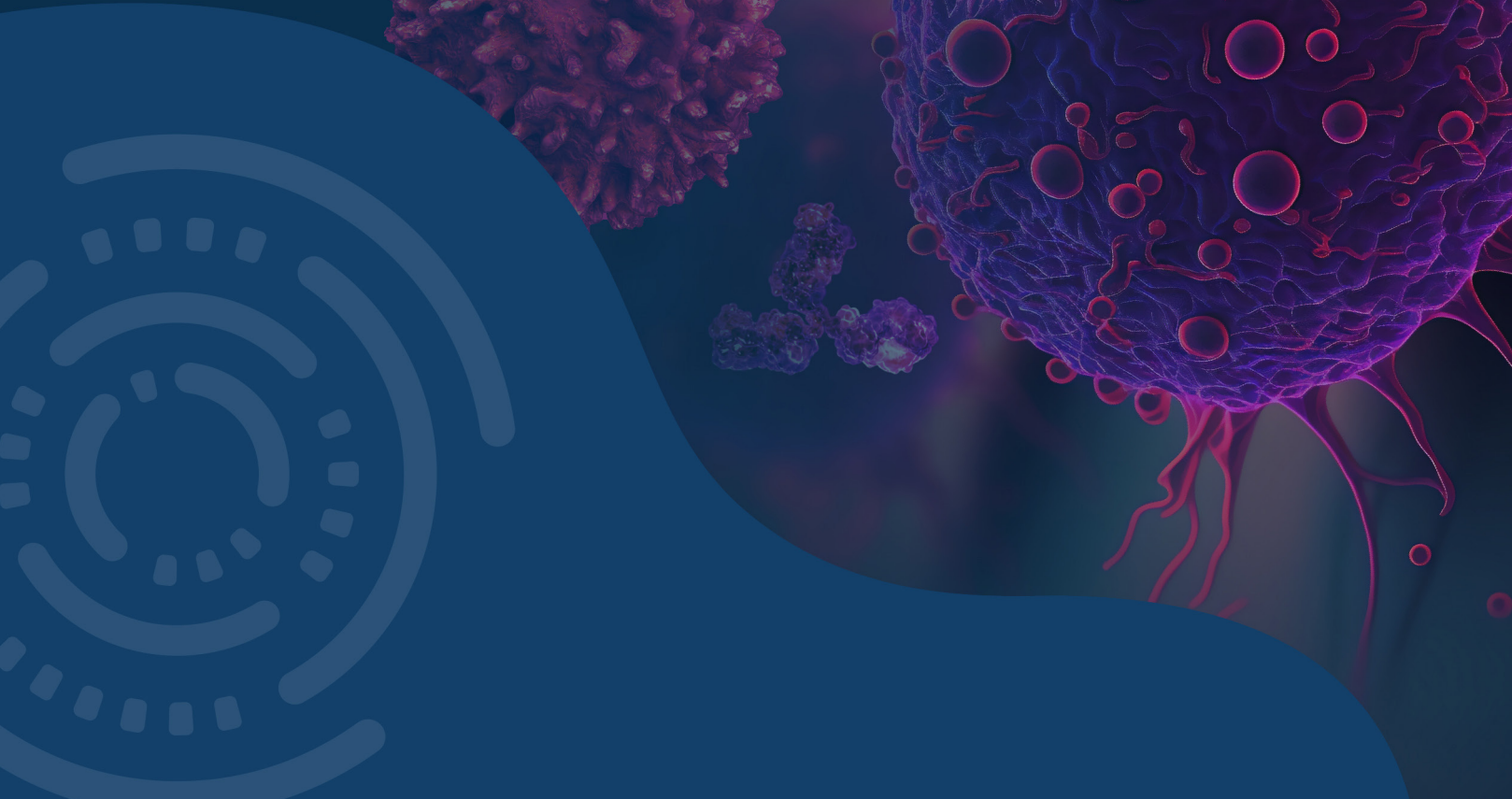
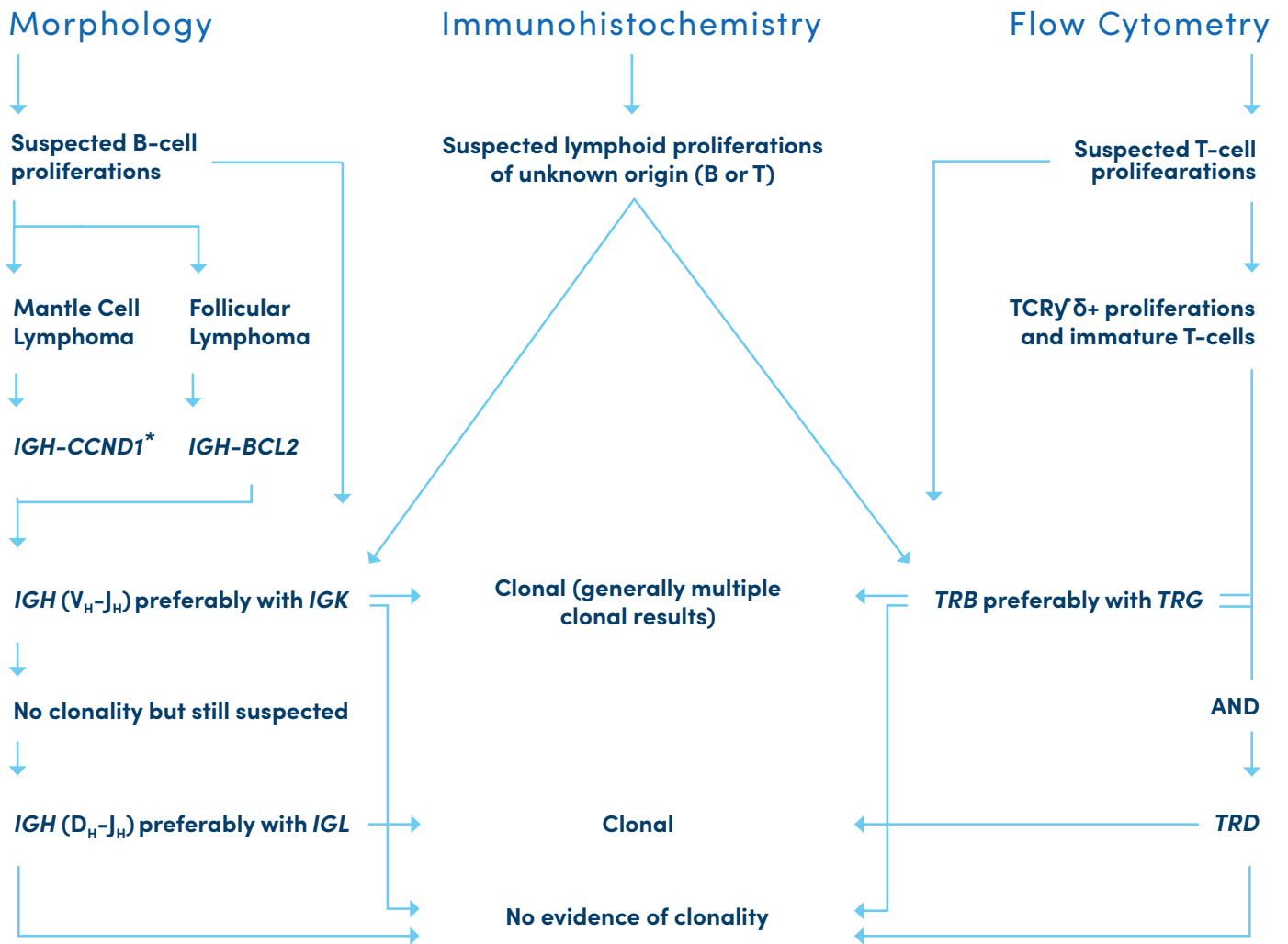


 **invivoscribe**<sup>®</sup>

# Product Catalog



If a definitive diagnosis is not possible following:



## Diseases

## Gene Rearrangement

## Translocation

## Mutation

	Gene Rearrangement								Translocation				Mutation	
	IGH V <sub>H</sub> -J <sub>H</sub>	IGH D <sub>H</sub> -J <sub>H</sub>	IGK	IGL	IGHV SHM	TRB	TRD	TRG	IGH- BCL1 (CCND1)	IGH- BCL2	BCR- ABL1*	PML RARA*	FLT3	NPM1
<b>Lymphoid/ Lymphoma</b>	Marginal Zone Lymphoma (MZL), extranodal <sup>12,13,27</sup>	88%	58%	84%	29%		23%	10%	16%					
	Marginal Zone Lymphoma (MZL), nodal <sup>13</sup>	100%	30%	80%	30%		10%	20%	10%					
	Mantle Cell Lymphoma (MCL) <sup>2,6,7,12,13,27,37</sup>	100%	11%	100%	44%	*	9%	4%	11%	75%				
	Follicular Lymphoma (FL) <sup>3,7,12,13,27,28</sup>	84%	19%	84%	21%		6%	5%	2%		90%			
	Diffuse Large B-cell Lymphoma (DLBCL) <sup>3,12,13,27</sup>	80%	30%	80%	28%		21%	14%	15%		30%			
	Multiple Myeloma (MM) and other Plasma Cell Neoplasms (PCN) <sup>2,9,10,20,25</sup>	84%	60%	57%	97%					20%				
	Chronic Lymphocytic Leukemia (CLL) <sup>1,12,13,15,23,27,35</sup>	100%	43%	100%	30%	*	25%	12%	18%					
	B-cell Acute Lymphoblastic Leukemia (B-ALL) <sup>4,12,14,19,21,22,27,29,30,31,32,33,34</sup>	96%	57%	95%	20%		81%	86%	75%		30%			
	Suspect B-cell Proliferations <sup>6,12,26,27,33</sup>	93%	93%	90%	40%		20%		20%					
	Peripheral T-cell Lymphoma (PTCL) <sup>12,13,14,24</sup>	35%	4%		2%		98%		94%					
	T-cell Acute Lymphoblastic Leukemia (T-ALL) <sup>12,14,21,22,29,31</sup>	24%	25%	4%			92%	68%	95%					
	Angioimmunoblastic T-cell Lymphoma (AITL) <sup>12,13,14</sup>	19%	11%	30%	5%		99%	35%	92%					
	Adult T-cell Leukemia/Lymphoma <sup>39</sup>						97%		96%					
	Anaplastic Large-Cell Lymphoma (ALCL) <sup>12,13,14</sup>						74%	12%	74%					
	T-cell Prolymphocytic Leukemia (T-PLL) <sup>12,13,14</sup>	3%	3%	3%	3%		100%	6%	94%					
	T-cell Large Granular Lymphocytic Leukemia (T-LGL Leukemia) <sup>12,13,14</sup>			4%	4%		97%	29%	96%					
Suspect T-Cell Proliferations <sup>6,26,40</sup>	10%		10%			90%	11%	90%						
<b>Myeloid</b>	Acute Myeloid Leukemia (AML) <sup>6,16</sup>											33%	64%	
	Acute Promyelocytic Leukemia (APL) <sup>1,5,16,17</sup>											90%		
	Chronic Myeloid Leukemia (CML) <sup>7,10,19,21,38</sup>										87%			
	Myeloproliferative Neoplasms (MPNs) <sup>38</sup>										10%			

Note: The percentage of samples within a given disease category were detected using each gene target. Percentages indicate the highest referenced value.

\*Some translocation assays, LymphoTrack®, and MRD applications are currently Research Use Only, not for use in diagnostic procedures. Illumina® and MiSeq™ are registered trademarks of Illumina®, Inc. Ion S5™ and Ion PGM™ are trademarks of Thermo Fisher Scientific®.

 Recommended Primary Test  Recommended Secondary Test

# Peripheral blood, Tissue, or FFPE sample



The Invivoscribe European Conformity marked *in vitro* diagnostics (CE-IVD) and Research Use Only (RUO) clonality assays detect clonal populations in just a few easy steps. These steps include PCR amplification of the immunoglobulin or T-cell receptor genes of interest, followed by detection with non-denaturing polyacrylamide gels, capillary electrophoresis, or next-generation sequencing using an Illumina® MiSeq™, Thermo Fisher Scientific® Ion S5™ or Ion PGM™ instrument. A flowchart illustrating this workflow is shown below.

\*Or equivalent DNA Polymerase.

\*\*For LymphoTrack and LymphoTrack Dx Assays run on the Ion S5 and PGM only.

CE-marked *in vitro* diagnostic products are not available for sale or use within North America.



# LymphoTrack<sup>®</sup> Dx and LymphoTrack<sup>®</sup> Workflow Summary

ILLUMINA<sup>®</sup> MiSeq<sup>™</sup>



**STEP 1** Prepare DNA samples

**STEP 2** Run PCR with a LymphoTrack<sup>®</sup> Assay

**STEP 3** Purify amplicons

**STEP 4** Quantify and prepare library

**STEP 5** Load onto MiSeq<sup>™</sup> flow cell and run

**STEP 6** Process raw data with bioinformatics software

**STEP 7** Analyze results

Notice: The LymphoTrack Dx Assays are *in vitro* diagnostic products and are available in regions that accept CE-IVD products.  
\*Image courtesy of Illumina, Inc.

## Summary of LymphoTrack\* Assays - Miseq

	IGHV Leader-SHM	IGH FR1	IGH FR2	IGH FR3	IGK	TRG	TRB
Target Size (bp)	483	295	243	104	222	147	290
Amplicon Size Including Target, Index, and Adaptors (bp)	660	450	390	260	410	300	400
DNA Input (ng/ PCR)	50						
Validated PCR Cycles	32						
Purification Method	AMPure XP Beads (1:1 ratio)						
Quantification Method	KAPA qPCR						
Sample Sheet Settings**	Cycles Read1: 301 Cycles Read2: 301	Cycles Read1: 251 Cycles Read2: 251	Cycles Read1: 151 Cycles Read2: 151	Cycles Read1: 251 Cycles Read2: 251	Cycles Read1: 151 Cycles Read2: 151	Cycles Read1: 151 Cycles Read2: 151	Cycles Read1: 251 Cycles Read2: 251
Recommended Sequencing Kit**	MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (300-cycle) or MiSeq v3 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (300-cycle) or MiSeq v2 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)	MiSeq v2 Reagent (500-cycle) or MiSeq v3 Reagent (600-cycle)

\*LymphoTrack® Dx Assays are *in vitro* diagnostic tests. Available outside of North America. LymphoTrack® Assays are Research Use Only. Not for use in diagnostic procedures.

\*\*When multiplexing amplicons of different gene targets it is important to use the appropriate sequencing chemistry. The number of sequencing cycles must be sufficient to sequence the largest amplicon in the multiplex.

# LymphoTrack<sup>®</sup> Dx and LymphoTrack<sup>®</sup> Workflow Summary

Thermo Fisher Scientific<sup>®</sup> Ion S5/PGM<sup>™</sup>



**STEP 1** Prepare DNA samples

**STEP 2** Run PCR with a LymphoTrack<sup>®</sup> Assay

**STEP 3** Purify amplicons

**STEP 4** Quantify, prepare, and enrich library

**STEP 5** Load onto Ion S5/PGM<sup>™</sup> chip and run

**STEP 6** Process raw data with bioinformatics software

**STEP 7** Analyze results



### Summary of LymphoTrack\* Assays - S5/PGM

	IGH FR1	IGH FR2	IGH FR3	IGK	TRG
Amplicon Size Range Including Target, Index, and Adaptors (bp)	350-600	300-500	150-300	200-1600	230-400
DNA Input (ng/PCR)	50				
Validated PCR Cycles	29				
Purification Method	AMPure XP Beads (1.8:1 ratio)				
Quantification Method	Agilent 2100 Bioanalyzer or Perkin Elmer LabChip® GX				
Planned Run Setting for Flows**	850			500 or 850	
Recommended Sequencing Kit**	<p>For Ion S5™ use: Ion 520™ &amp; Ion 530™ Kit - OT2 or Ion 510™ &amp; 520™ &amp; Ion 530™ Kit - Chef</p> <p>For Ion PGM™ use: Ion PGM™ Hi-Q™ View OT2 Kit &amp; Ion PGM™ Hi-Q™ View Sequencing Kit &amp; Ion PGM™ Wash 2 Bottle Kit</p>				
Sequencing Chip	<p>For Ion S5™ use: Ion 520™ Chip Kit or Ion 530™ Chip Kit For Ion PGM™ use: Ion 316™ Chip Kit v2 BC or Ion 318™ Chip Kit v2 BC</p>				

\*LymphoTrack® Dx Assays are *in vitro* diagnostic tests. Available outside of North America. LymphoTrack® Assays are Research Use Only. Not for use in diagnostic procedures.  
\*\*When multiplexing amplicons of different gene targets it is important to use the appropriate sequencing chemistry. When selecting a sequencing kit, ensure that it offers a sufficient number of sequencing cycles (flows) for valid interpretation of the largest amplicon and depth of coverage for each sample in the multiplex.

# Gel and Capillary Electrophoresis Menu

Inivoscribe offers assays that can be analyzed using two conventional methods of fragment analysis: gel electrophoresis or capillary electrophoresis. Gel electrophoresis kits offer a comparatively easy and inexpensive solution for clonality, translocation, and mutational testing and are often the method of choice for laboratories new to using these methods and techniques. PCR products are analyzed using non-denaturing polyacrylamide gels (PAGE) and often require a heteroduplex step for resolution of generated amplicons.

Capillary electrophoresis kits are supplied with fluorescently labeled primers, allowing the resulting PCR products to be analyzed on Applied Biosystems (ABI) platforms e.g. 3130, 3500, 3500xL, 3500xL Dx. Fragment analysis by capillary electrophoresis offers the ability to detect fragments with a high level of accuracy and analytical sensitivity and allows for greater sample throughput compared to gel detection methods. In addition, capillary electrophoresis detection often facilitates a more objective interpretation of results than gel-based detection.

The table below summarizes which detection methods are available for our clonality, translocation and *FLT3* mutation assays either as RUO, CE-IVD, or IVD.

## CE-Marked IVD Assays

	Gel	ABI
IdentiClone® <i>IGH</i> + <i>IGK</i> B-Cell Clonality Assay	NOT AVAILABLE	AVAILABLE
IdentiClone® <i>IGH</i> Gene Clonality Assay	NOT AVAILABLE	AVAILABLE
IdentiClone® <i>IGK</i> Gene Clonality Assay	NOT AVAILABLE	AVAILABLE
IdentiClone® <i>IGL</i> Gene Clonality Assay	NOT AVAILABLE	AVAILABLE
IdentiClone® <i>TCRB</i> Gene Clonality Assay	NOT AVAILABLE	AVAILABLE
IdentiClone® T-Cell Receptor Gamma Gene Rearrangement Assay 2.0	NOT AVAILABLE	AVAILABLE
IdentiClone® <i>TCRD</i> Gene Clonality Assay	NOT AVAILABLE	AVAILABLE
LeukoStrat® <i>FLT3</i> Mutation Assay 2.0	NOT AVAILABLE	AVAILABLE
LeukoStrat® CDx <i>FLT3</i> Mutation Assay (CE-marked)	NOT AVAILABLE	AVAILABLE

## IVD Companion Diagnostic Assays

	Gel	ABI
LeukoStrat® CDx <i>FLT3</i> Mutation Assay IVD (USA)	NOT AVAILABLE	AVAILABLE
LeukoStrat® CDx <i>FLT3</i> Mutation Assay (JP)	NOT AVAILABLE	AVAILABLE
LeukoStrat® CDx <i>FLT3</i> Mutation Assay (CE-IVD)	NOT AVAILABLE	AVAILABLE

## Research Use Only (RUO) Assays

	Gel	ABI
<i>FLT3</i> Mutation Assay	AVAILABLE	AVAILABLE
<i>IGH</i> + <i>IGK</i> B-Cell Clonality Assay	AVAILABLE	AVAILABLE
<i>IGH</i> Gene Rearrangement Assay	NOT AVAILABLE	AVAILABLE
<i>IGH</i> Gene Clonality Assay	AVAILABLE	AVAILABLE
<i>IGH</i> Somatic Hypermutation Assay v2.0	AVAILABLE	AVAILABLE
<i>IGL</i> Gene Clonality Assay	AVAILABLE	AVAILABLE
<i>TCRB</i> Gene Clonality Assay	AVAILABLE	AVAILABLE
T-Cell Receptor Gamma Gene Rearrangement Assay	NOT AVAILABLE	AVAILABLE
T-Cell Receptor Gamma Gene Rearrangement Assay 2.0	AVAILABLE	AVAILABLE
<i>TCRD</i> Gene Clonality Assay	AVAILABLE	AVAILABLE
<i>BCL1</i> /J <sub>H</sub> Translocation Assay	AVAILABLE	NOT AVAILABLE
<i>BCL2</i> /J <sub>H</sub> Translocation Assay	AVAILABLE	NOT AVAILABLE
<i>BCL2</i> /J <sub>H</sub> t(14;18) Translocation Assay	AVAILABLE	NOT AVAILABLE
BCR/ABL t(9;22) Translocation Assay	AVAILABLE	AVAILABLE
PML/RARα t(15;17) Translocation Assay	NOT AVAILABLE	AVAILABLE

## Available Inivoscribe DNA Controls

Catalog #	Description	Catalog #	Description
40880010	IVS-0001 Clonal Control DNA	40881090	IVS-0019 Clonal Control DNA
40880190	IVS-0004 Clonal Control DNA	40881210	IVS-0021 Clonal Control DNA
40880370	IVS-0007 Clonal Control DNA	40881390	IVS-0024 Clonal Control DNA
40880430	IVS-0008 Clonal Control DNA	40881690	IVS-0029 Clonal Control DNA
40880490	IVS-0009 Clonal Control DNA	40881750	IVS-0030 Clonal Control DNA
40880550	IVS-0010 Clonal Control DNA	40881810	IVS-0031 Clonal Control DNA
40880730	IVS-0013 Clonal Control DNA	40920010	IVS-0000 Polyclonal Control DNA

These controls are general purpose reagents (GPRs).

**NOTE:** Recommended storage conditions are 2°C to 8°C; long-term storage conditions are -85°C to -65°C.

## Quick Reference for DNA Controls

DNA Controls	IGH	IGK	IGL	IGHVSHM	IGH-CCND1	IGH-BCL2	TRB	TRG	TRD
IVS-0001						•			
IVS-0004							•	•	
IVS-0007	•	•	•			•			
IVS-0008	•						•	•	
IVS-0009							•	•	
IVS-0010	•	•			•				
IVS-0013	•	•							
IVS-0019	•	•							
IVS-0021		•					•	•	•
IVS-0024	•	•							
IVS-0029	•	•							
IVS-0030	•	•		•					
IVS-0031	•	•							



Produktübersicht 2023

Beratung und Vertrieb:

