General Overview

- Company Overview
- Hematologic Malignancies
- Invivoscribe Portfolio
- Commercial Strategy

invivoscribe®
Improving Lives with Precision Diagnostics®

This presentation is intended for audience outside of the USA

invivoscribe®
Improving Lives with Precision Diagnostics®

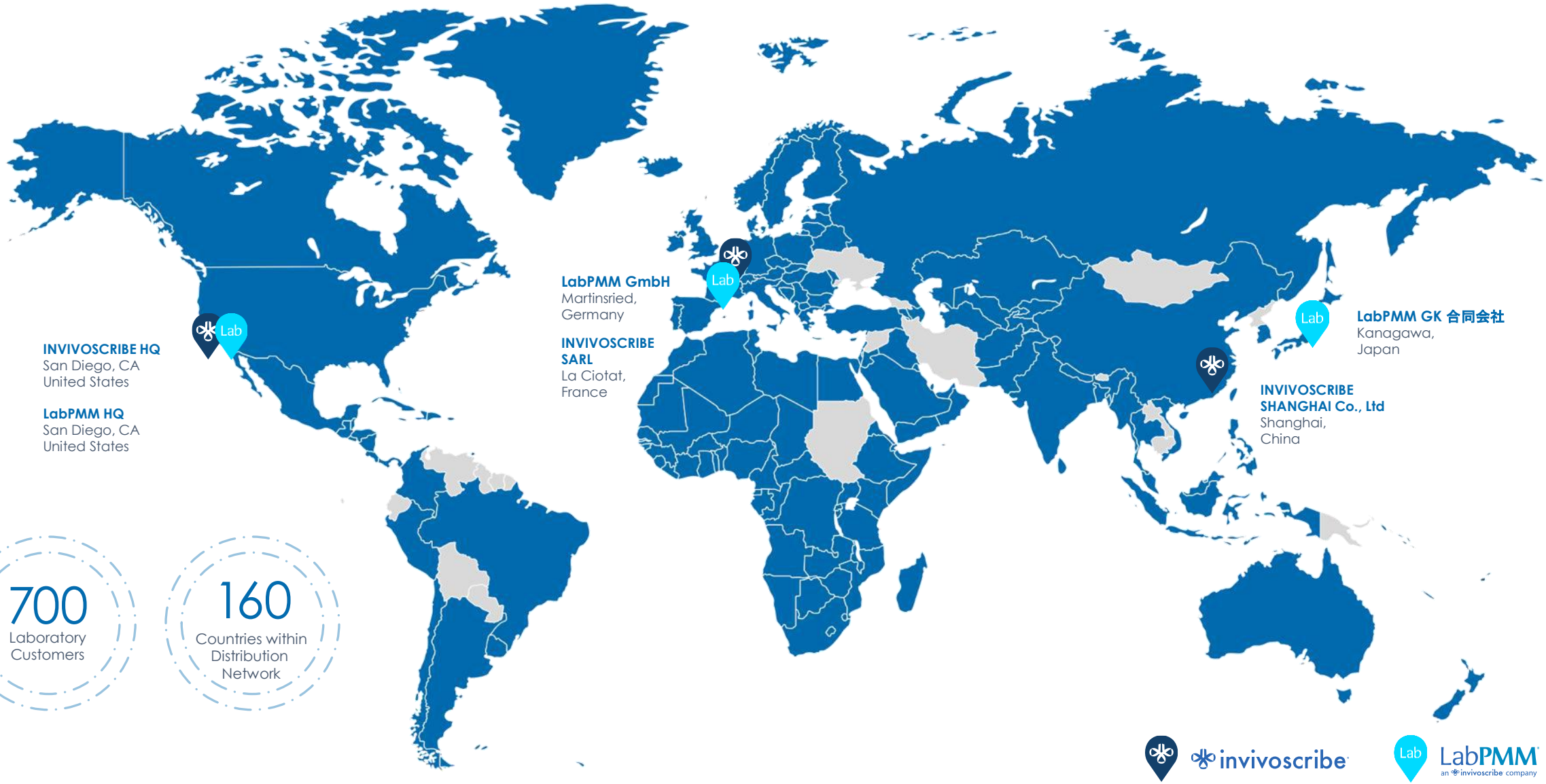
Company Overview

Our Vision

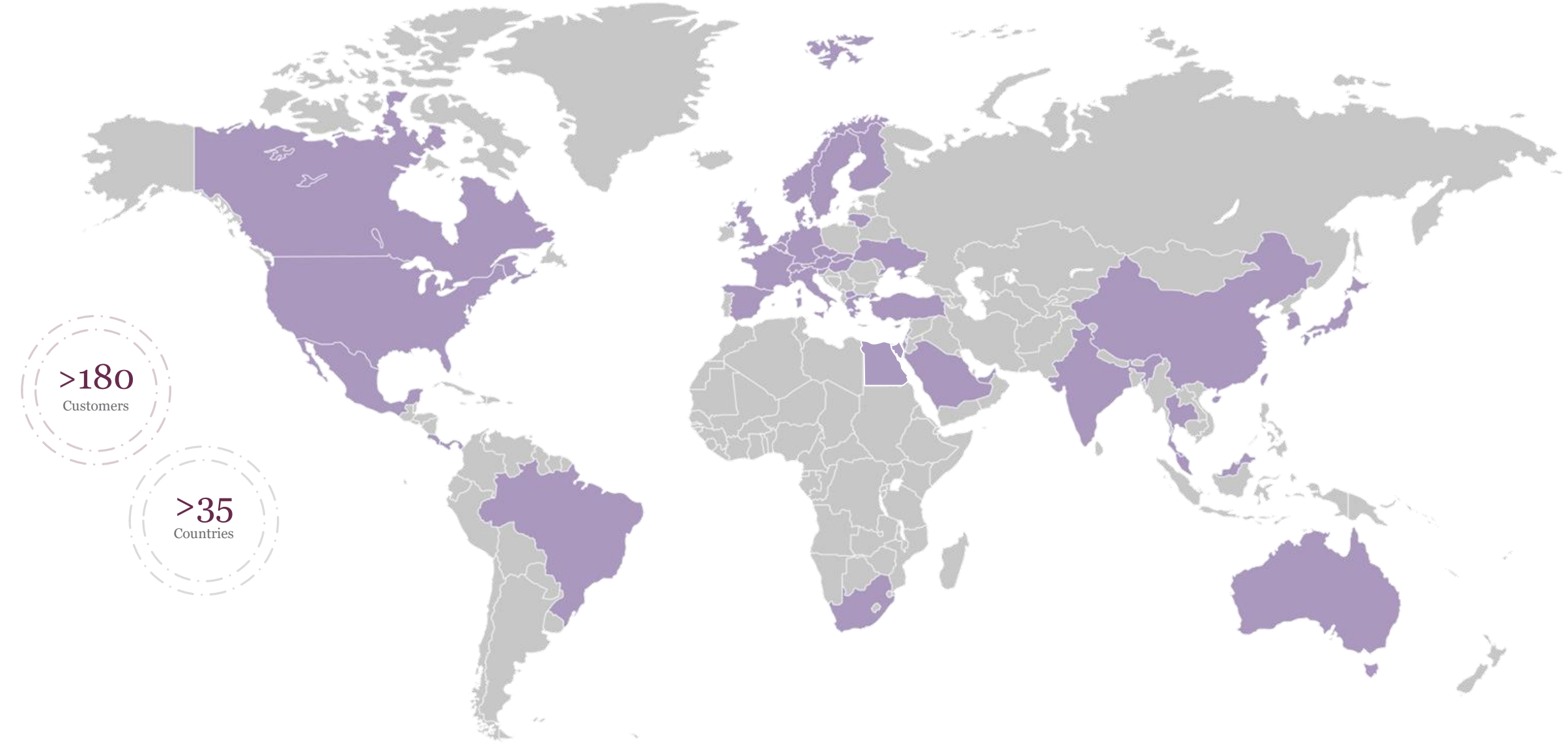
Harmonize Personalized Medicine through Internationally Standardized Molecular Diagnostics and Research Tools

Improving Lives with Precision Diagnostics

Invivoscribe Geographical Expansion



Global NGS Customers



Jeff Miller, PhD
CEO, CSO & Founder

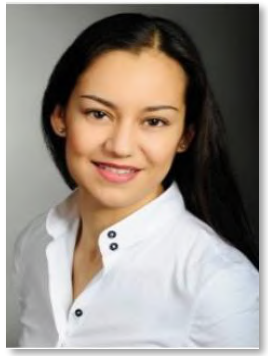
Meghna Bhatnagar
Chief Financial Officer

Bradley Patay
Chief Medical Officer

Paul McMullin
Global Head of Sales & Marketing

Our International Sales Team

Parth Sitlani
Field Application Specialist
& Distributor Manager



Fuensanta Martinez
Director of International Sales

Troels Meyer
Technical Account Manager

Taro Niikura
Technical Account Manager

Christian Schum
Technical Account Manager

Cindy Shen
Technical Account Manager

Sonia Lamime
Technical Account Manager

Our Marketing Team

Zephyr Fors
Product Marketing Manager

Kimberly Helzer
Product Marketing Manager

Ketti Mehlman
Associate Product Manager

Monika Deučman
Marketing Communications Specialist

Christopher Glover
Creative Director

Kayla Cline
Graphics and Marketing Coordinator

Customer Service Team in San Diego Office

Tina Williams

Customer Service Manager

Daniel Moorhead

Customer Service Representative II

Carlos Houston

Senior Customer Service Representative

Sherly Delgado

Customer Service Supervisor

Monica Sanchez

Customer Service Representative II

Customer Service Team in SARL French Office

Ashley Davidson-Fisher
Director of Operations

Severine Cellier
Customer Service Associate

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Hematologic Malignancies

Hematologic Malignancies

LEUKEMIA

Cancer that begins in the blood and bone marrow

LYMPHOMA

Cancer that begins in the lymphatic system

MYELOMA

Cancer that begins in the bone marrow (from plasma cells)

Hematologic Malignancies Figures

Hematologic Malignancies represents

10%

Of New Cancers Per Year

One Person in The USA is diagnosed with a Blood Cancer

EVERY 3 MINUTES

Incidence Worldwide

>600K

Lymphomas

Incidence Worldwide

>450K

Leukemias

Incidence Worldwide

>160K

Myeloma

www.lls.org;http://globocan.iarc.fr

Hematologic Malignancies Diversity

	SLOW-GROWING	AGGRESSIVE
BLOOD BONE MARROW	**CLL** Chronic Lymphocytic Leukemia	**AML** Acute Myeloid Leukemia
LYMPHATIC SYSTEM	**FL** Follicular Lymphoma	**DLBCL** Diffuse Large B-Cell Lymphoma

Most Common Types

Laboratory Diagnostic Tests

Routine Tests

Complete Blood Count
Peripheral Smear

Immuno-
histochemistry

Flow Cytometry

Confirmatory Tests

Molecular Testing

Invivoscribe is focused on Molecular Testing

Blood Cancers Treatments

Treatment Options

Radiation

Chemotherapy
& Targeted Drug Therapies

Stem Cell
Transplantation

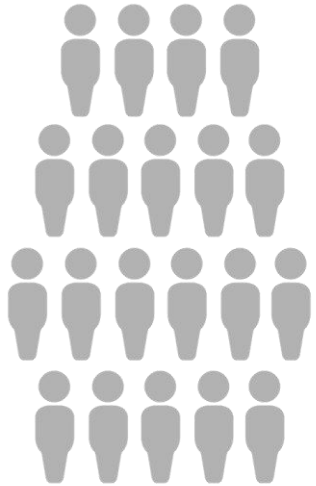
Depending on multiple factors such as :

- Age
- Gender
- Cancer type and stage

Precision Diagnostics

- **Diversity of blood cancers** means the "one size fits all" approach must evolve, when it comes to treatments.
- **Precision Diagnostics** allow to analyze genetic information and understand the disease at a molecular level.
- Precision Molecular Diagnostics leads to **Personalized Molecular Medicine.**

Patients unclassified



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Patients classified with Predictive Treatment Efficacy

The right treatment, to the right patient, at the right time.

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Invivoscribe Portfolio

Invivoscribe Portfolio

Invivoscribe offers a full range of **PCR-based molecular testing** products and services for detection and study of hematologic malignancies.

- Master Mixes – Controls – Software

Detection Methods

GEL

IdentiClone®
RUO Assays
LeukoStrat®*

ABI

IdentiClone®
RUO Assays
LeukoStrat®*
LeukoStrat®
CDx *FLT3* Mutation Assay

NGS

LymphoTrack®
Assays

LymphoTrack® Dx
Assays

LymphoTrack Dx, LeukoStrat CDx and IdentiClone Assays are *in vitro* diagnostic products. Available outside of North America.
LymphoTrack and RUO Assays are research use only. Not for use in diagnostic procedures.
*These Assays are available as CE-IVD and RUOs. CE-IVDs are not available within North America. RUOs are not for use in diagnostic procedures.

Invivoscribe Portfolio

Product Catalog

Contains comprehensive information on all kits and kits' content

Next-Generation Sequencing Assays

- with MRD Solutions (RUO) -

Gel & Capillary Assays

FLT3 Assays

Translocation Assays

Controls, Master Mixes, Enzymes

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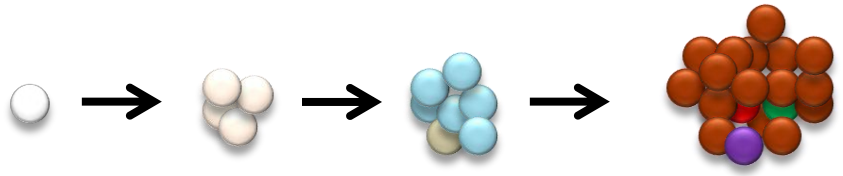
LymphoTrack Assays and MRD testing are research use only. Not for use in diagnostic procedures.
RUO Assay are for research use only. Not for use in diagnostic procedures.
LymphoTrack Dx, LeukoStrat CDx and IdentiClone Assays are *in vitro* diagnostic products. Available outside of North America.

Invivoscribe Portfolio

Blood Cancers & Clonality

- **Clonality** is a dominant feature of cancer cells

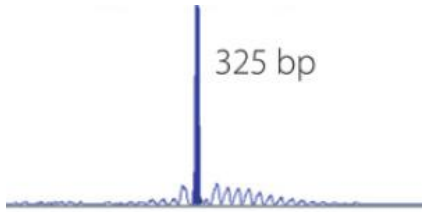


Pool of identical clonal cells

Highly indicative of B- or T-cell malignancy

Detection by gel electrophoresis

Detection by capillary electrophoresis



Detection by NGS

Rank	Sequence	% total reads
1	CATCTGGATAC	27.3066534
2	GCCTCTGGATTC	0.0268769
3	ACCTCTGCAATC	0.0255405

Our CE-IVD Offerings

Next-Generation Sequencing (NGS)

LymphoTrack® Dx Assays

- LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay
- LymphoTrack Dx *IGH* FR1/2/3 Assays
- LymphoTrack Dx *IGK* Assays
- LymphoTrack Dx *TRG* Assays
- LymphoTrack Dx *TRB* Assays
- LymphoTrack Dx Bioinformatics Software

Gel and Capillary

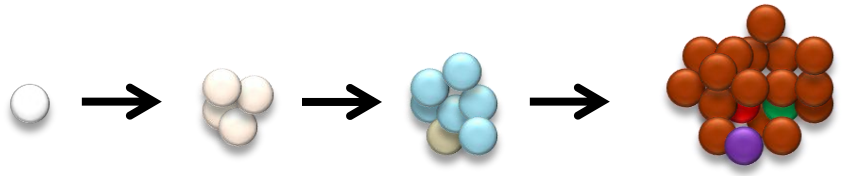
IdentiClone® Assays

- *IGH + IGK* B-Cell Clonality Assays
- *IGH* Gene Clonality Assays
- *IGK* Gene Clonality Assays
- *IGL* Gene Clonality Assays
- *TCRB + TCRG* T-Cell Clonality Assays
- *TCRB* Gene Clonality Assays
- T-Cell Receptor Gamma Gene Rearrangement Assay 2.0
- *TCRG* Gene Clonality Assays
- *TCRD* Gene Clonality Assays

Invivoscribe Portfolio

Blood Cancers & Clonality

- **Clonality** is a dominant feature of cancer cells



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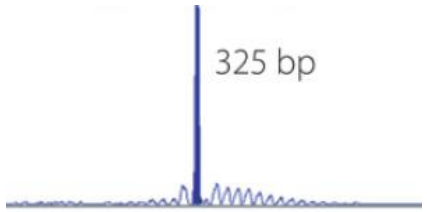
Detection by capillary electrophoresis



Detection by NGS

Rank	Sequence	% total reads
1	CATCTGGATAC	27.3066534
2	GCCTCTGGATTC	0.0268769
3	ACCTCTGCAATC	0.0255405

Our RUO Offerings

Next-Generation Sequencing (NGS)

LymphoTrack® - Research Use Only (RUO) Assays

- LymphoTrack *IGHV* Leader Somatic Hypermutation Assay
- LymphoTrack *IGH* FR1/FR2/FR3 Assays
- LymphoTrack *IGK* Assays
- LymphoTrack *TRG* Assays
- LymphoTrack *TRB* Assays
- LymphoTrack Bioinformatics Software

Gel and Capillary

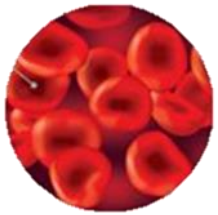
Gel and Capillary - Research Use Only (RUO) Assays

- *IGH* + *IGK* B-Cell Clonality Assays
- *IGH* Gene Rearrangement Assays
- *IGH* Gene Clonality Assays
- *IGK* Gene Clonality Assays
- *IGL* Gene Clonality Assays
- *TCRB* + *TCRG* T-Cell Clonality Assays
- *TCRB* Gene Clonality Assays
- T-Cell Receptor Gamma Gene Rearrangement Assay 2.0
- T-Cell Receptor Gamma Gene Rearrangement Assays
- *TCRG* Gene Clonality Assays
- *TCRD* Gene Clonality Assays

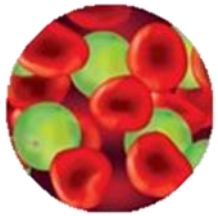
Invivoscribe Portfolio

Blood Cancers & MRD

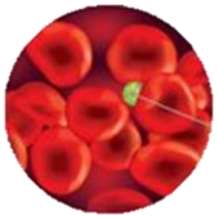
- MRD: **M**inimal **R**esidual **D**isease = Remnants of cancer cells



Healthy cells



Malignant cells



MRD

- MRD testing by NGS:
  - ✓ is used to detect the **remaining clonal cells** in follow-up samples
  - ✓ is being studied as a **prognostic indicator for relapse**
  - ✓ helps validate **treatment efficacy**

Our Offerings

- Same kits as for Clonality testing …

Next-Generation Sequencing (NGS)

LymphoTrack® Dx Assays

- LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay
- LymphoTrack Dx *IGH* FR1/2/3 Assays
- LymphoTrack Dx *IGK* Assays
- LymphoTrack Dx *TRG* Assays
- LymphoTrack Dx *TRB* Assays
- LymphoTrack Dx Bioinformatics Software

- … + dedicated software and controls

Next-Generation Sequencing (NGS)

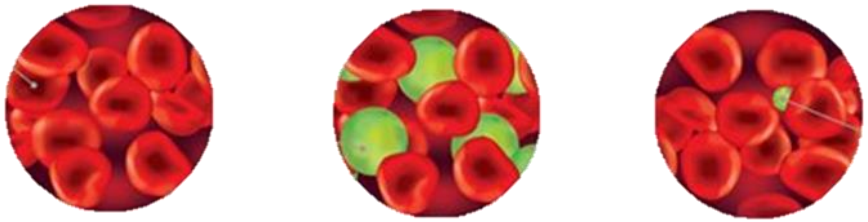
LymphoTrack® MRD Solution - Research Use Only (RUO)

- LymphoTrack Minimal Residual Disease (MRD) Software
- LymphoTrack B-cell & T-cell Low Positive Controls
- LymphoQuant B-cell & T-cell Internal Control

Invivoscribe Portfolio

Blood Cancers & MRD

- MRD: **M**inimal **R**esidual **D**isease = Remnants of cancer cells



Healthy cells | Malignant cells | MRD

- MRD testing by NGS:
  - ✓ is used to detect the **remaining clonal cells** in follow-up samples
  - ✓ is being studied as a **prognostic indicator for relapse**
  - ✓ helps validate **treatment efficacy**

Our RUO Offerings

- Same kits as for Clonality testing …

Next-Generation Sequencing (NGS)

LymphoTrack® - Research Use Only (RUO) Assays

- LymphoTrack *IGHV* Leader Somatic Hypermutation Assay
- LymphoTrack *IGH* FR1/FR2/FR3 Assays
- LymphoTrack *IGK* Assays
- LymphoTrack *TRG* Assays
- LymphoTrack *TRB* Assays
- LymphoTrack Bioinformatics Software

- … + dedicated software and controls

Next-Generation Sequencing (NGS)

LymphoTrack® MRD Solution - Research Use Only (RUO)

- LymphoTrack Minimal Residual Disease (MRD) Software
- LymphoTrack B-cell & T-cell Low Positive Controls
- LymphoQuant B-cell & T-cell Internal Control

Invivoscribe Portfolio

CLL & Somatic Hypermutation

- CLL: **C**hronic **L**ymphocytic **L**eukemia is the most common type of leukemia overall
- **SHM: S**omatic **H**yper**M**utations are point mutations found in clonal cells
- Assessment of SHM is used as an **aid in disease prognosis**:
  - ✓ Presence of SHM is strongly predictive of a good prognosis
  - ✓ Absence of SHM predicts a poor prognosis
- *IGHV* SHM testing is recommended as **standard** for all newly diagnosed CLL cases[1]

Our Offerings

- Same kits as for Clonality testing

Next-Generation Sequencing (NGS)

LymphoTrack® Dx Assays

LymphoTrack Dx *IGHV* Leader Somatic Hypermutation Assay

LymphoTrack Dx *IGH* FR1/2/3 Assays

Rank	Sequence	% total reads	Mutation rate to partial V-gene (%)
1	CATCTGGATAC	27.3066534	12.1

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[1]Should *IGHV* status and FISH testing be performed in all CLL patients at diagnosis? A systematic review and meta-analysis Blood 2016 127(14): 1752-60

Invivoscribe Portfolio

Somatic Hypermutation

- **SHM: S**omatic **H**yper**M**utations are point mutations found in clonal cells
- Assessment of SHM is used in the study of **disease prognosis**

Our RUO Offerings

- Same kits as for Clonality testing …

Next-Generation Sequencing (NGS)

LymphoTrack® - Research Use Only (RUO) Assays

LymphoTrack *IGHV* Leader Somatic Hypermutation Assay

LymphoTrack *IGH* FR1/FR2/FR3 Assays

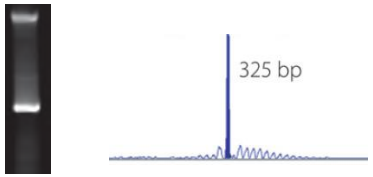
Rank	Sequence	% total reads	Mutation rate to partial V-gene (%)
1	CATCTGGATAC	27.3066534	12.1

- … or other options for Gel and Capillary

Gel and Capillary

Gel and Capillary - Research Use Only (RUO) Assays

IGH Somatic Hypermutation Assays v2.0



Invivoscribe Portfolio

AML & *FLT3* Gene Mutation

- AML: **A**cute **M**yeloid **L**eukemia is the most common type of aggressive leukemia
- **Mutations in the *FLT3* gene** are the most common mutations found in AML patients
- The presence of *FLT3* mutations is the most important **prognostic indicator**
- *FLT3* testing is required to **stratify disease** and determine appropriate **treatment options**

Our Offerings

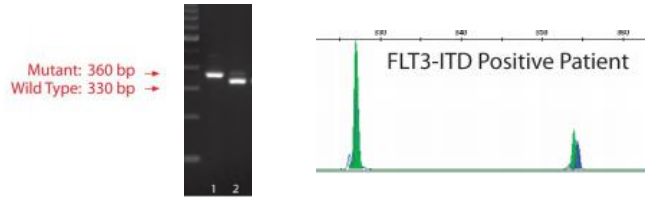
- LeukoStrat® Product Line…

Gel and Capillary

LeukoStrat® Assays

FLT3 Mutation Assay – Gel Detection

FLT3 Mutation Assay 2.0 – ABI Fluorescence Detection



- … includes a Companion Diagnostic Assay

Gel and Capillary

LeukoStrat® Assays

CDx *FLT3* Mutation Assay (CE-marked)

CDx *FLT3* Mutation Assay – AUS

CDx *FLT3* Mutation Assay – Japan

Sample			
Sample Name	EC ID	Pos/Neg/Fail	Signal Ratio
SampleA01_ITD_SAMPLE_A01	4e614e4d9b70	Positive	0.06

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The LeukoStrat CDx FLT3 Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia [1,2(AML)]. **1**The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered. The test is for use on the 3500xL Dx Genetic Analyzer. **2**In regions where midostaurin is available, the LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. In regions where gilteritinib fumarate is available, the LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib fumarate) treatment is being considered. **3**The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom Gilteritinib Fumarate treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom Quizartinib Hydrochloride treatment is being considered.
Approvals: **1**. US **2**. CE-IVD and **3**. Japan

Invivoscribe Portfolio

Blood Cancers & Translocations

- ***BCL1/JH***: Important marker for Mantle Cell Lymphoma
- ***BCL2/JH***: Important marker for Follicular Cell Lymphoma

Our CE-IVD Offerings

- CE IVD assays

Gel and Capillary

IdentiClone® Assays

*BCL1/*JH Translocation Assay

*BCL2/*JH Translocation Assay

Invivoscribe Portfolio

Blood Cancers & Translocations

- ***BCL1/JH***: Important marker for the study of Mantle Cell Lymphoma
- ***BCL2/JH***: Important marker for the study of Follicular Cell Lymphoma
- ***BCR/ABL***: Important marker for the study of Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia
- ***PML/RARa*:** Important marker for the study of Acute Promyelocytic Leukemia, a form of Acute Myeloid Leukemia

Our RUO Offerings

- RUO assays

Gel and Capillary

Gel and Capillary - Research Use Only (RUO) Assays

*BCL1/*JH Translocation Assay
*BCL2/*JH t(14;18) Translocation Assay
*BCL2/*JH Translocation Assay
BCR/ABL t(9;22) Translocation Assays
PML/RARa t(15;17) Translocation Assays

Invivoscribe Portfolio

Product Catalog

CLONALITY	MRD	SOMATIC HYPERMUTATION	*FLT3* GENE MUTATION	TRANSLOCATIONS
Gel	-	Gel	Gel	Gel
ABI	-	ABI	ABI	ABI
NGS	NGS	NGS	-	-

Invivoscribe Portfolio

Services Catalog

Available services include:

- CDx *FLT3*
- NGS Gene Panels
- Clonality testing (*IGH, IGK, TRG & TRB*)
- MRD assays
- Custom assays

All MRD assays are for Research Use Only (RUO). Not intended for diagnostic purposes.
FLT3 ITD MRD, *NPM1* MRD and MyAML Testing is provided by our partner laboratory LabPMM LLC, San Diego, California, USA.
LabPMM LLC is an ISO15189, CLIA/CAP accredited and New York State Licensed international reference laboratory.

Invivoscribe Portfolio

Product & Services Catalog

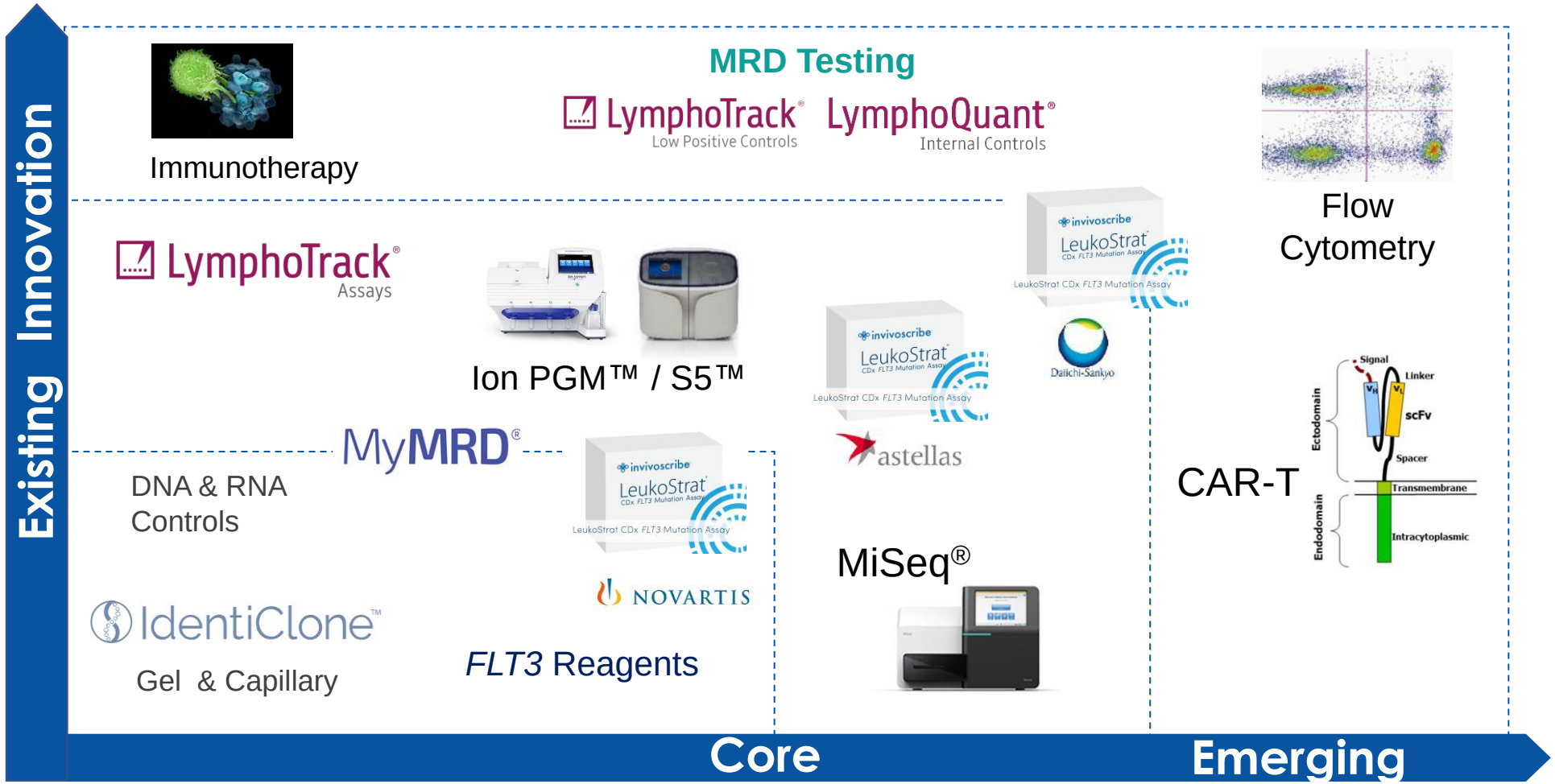
Product / Services

CLONALITY	MRD	SOMATIC HYPER MUTATION	*FLT3* GENE MUTATION	TRANSLOCATIONS
Gel	-	Gel	Gel	Gel
ABI	-	ABI	ABI	ABI
NGS	NGS	NGS	-	-
NGS	NGS	NGS	ABI	-

Services

NPM1 MUTATION	*FLT3* ITD MRD	*NPM1* MRD	CANCER PANELS
ABI	NGS	NGS	NGS

Invivoscribe Portfolio



Portfolio includes RUO, FDA, CE-IVD, MHLW/PMDA and TGA approved and/or registered tests

Invivoscribe Portfolio Flyers

General overview of Product offerings

Invivoscribe is dedicated to improving the quality of healthcare worldwide by providing high quality, reliable, cutting-edge tools for molecular biology, molecular diagnostics, and Personalized Molecular Medicine™. Our GMP facility manufactures PCR-based reagents and controls for gene rearrangement, chromosome translocation, somatic hypermutation, and gene mutation testing. Our CE-marked IVD products target biomarkers with demonstrated clinical utility. Our tests are used to identify, stratify and monitor hematologic cancers.

Invivoscribe provides solutions for hematologic diseases, offering best in class assays, services, and state-of-the-art bioinformatics.

Our portfolio includes an unparalleled range of gold standard technologies including immunoglobulin (Ig) and T-cell receptor (TCR) clonality detection, products and services for studying minimal residual disease (MRD), and a comprehensive menu of clinical assays for diseases such as AML. With an expanding global footprint, Invivoscribe and its subsidiary, LabPMM, offer commercial test services and distributable kits, including the LeukoStrat CDx *FLT3* Mutation Assay companion diagnostic.

invivoscribe

Global Leader in Personalized Molecular Medicine, Reagents, and Services for Leukemias and Lymphomas

invivoscribe

invivoscribe.com

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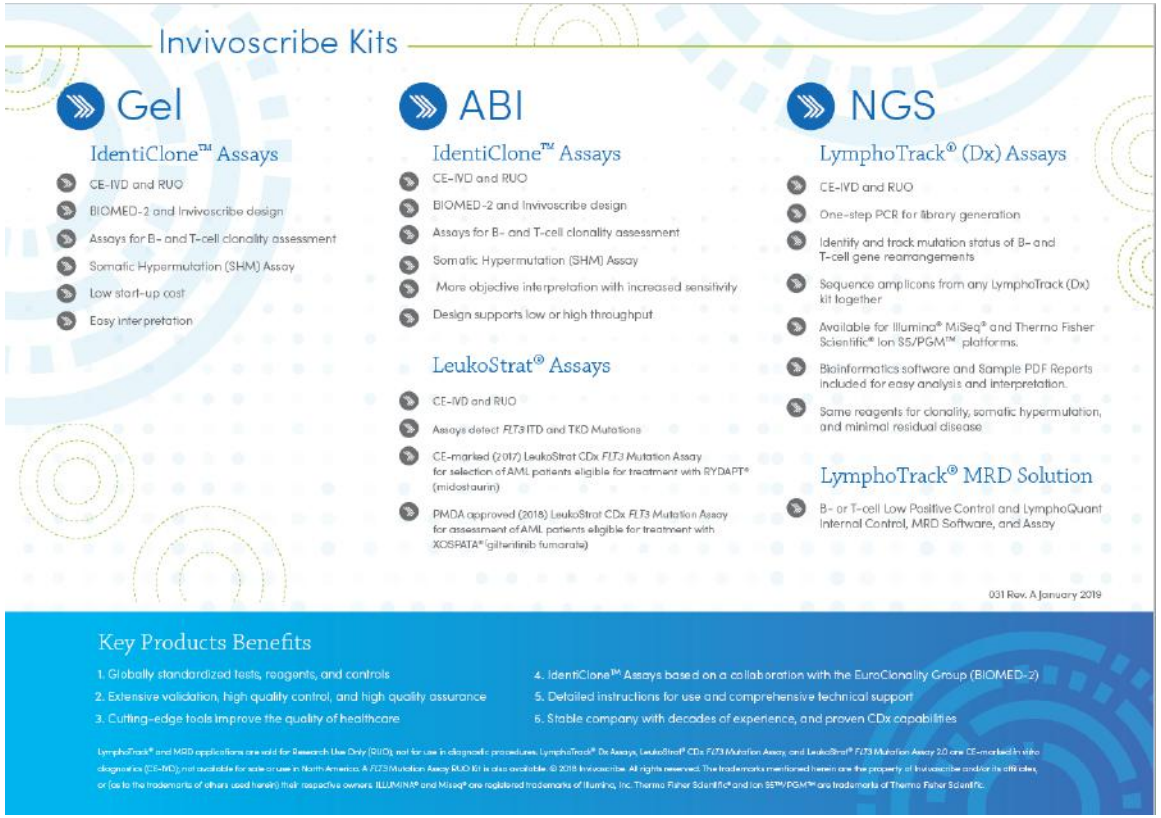
sales@invivoscribe.com

Corporate Headquarters:
10222 Barnes Canyon Road | Building 1
San Diego, CA 92121 | USA



Invivoscribe Kits

Gel

IdentiClone™ Assays

- CE-IVD and RUO
- BIOMED-2 and Invivoscribe design
- Assays for B- and T-cell clonality assessment
- Somatic Hypermutation (SHM) Assay
- Low start-up cost
- Easy interpretation

ABI

IdentiClone™ Assays

- CE-IVD and RUO
- BIOMED-2 and Invivoscribe design
- Assays for B- and T-cell clonality assessment
- Somatic Hypermutation (SHM) Assay
- More objective interpretation with increased sensitivity
- Design supports low or high throughput

LeukoStrat® Assays

- CE-IVD and RUO
- Assays detect *FLT3* ITD and TKD Mutations
- CE-marked (2017) LeukoStrat CDx *FLT3* Mutation Assay for selection of AML patients eligible for treatment with RYDAPT® (midostaurin)
- PMDA approved (2018) LeukoStrat CDx *FLT3* Mutation Assay for assessment of AML patients eligible for treatment with XOSPATA® (gilteritinib fumarate)

NGS

LymphoTrack® (Dx) Assays

- CE-IVD and RUO
- One-step PCR for library generation
- Identify and track mutation status of B- and T-cell gene rearrangements
- Sequence amplicons from any LymphoTrack (Dx) kit together
- Available for Illumina® MiSeq® and Thermo Fisher Scientific® Ion S5/PGM™ platforms.
- Bioinformatics software and Sample PDF Reports included for easy analysis and interpretation.
- Same reagents for clonality, somatic hypermutation, and minimal residual disease

LymphoTrack® MRD Solution

- B- or T-cell Low Positive Control and LymphoQuant Internal Control, MRD Software, and Assay

031 Rev. A January 2019

Key Products Benefits

1. Globally standardized tests, reagents, and controls
2. Extensive validation, high quality control, and high quality assurance
3. Cutting-edge tools improve the quality of healthcare
4. IdentiClone™ Assays based on a collaboration with the EuroClonality Group (BIOMED-2)
5. Detailed instructions for use and comprehensive technical support
6. Stable company with decades of experience, and proven CDx capabilities

Invivoscribe Portfolio Flyers

Clinical Services - How to Order a Test

SHIPPING

For the LeukoStrat® CDx *FLT3* Mutation Assay test:
Samples must be shipped cooled (2–8°C) only. Do not freeze.

For all other tests:
DNA, blood and bone marrow samples should be shipped ambient or cooled. Do not freeze.

Follow IATA regulations when shipping patient samples. Please refer to IATA Dangerous Goods Regulations for specific details.

RESULTS

You will receive your results either via encrypted email or fax.

CONTACT

LabPMM GmbH

Bunsenstraße 7a
82152 Martinsried
Germany

invivoscribe.com

+49 (0) 89 8994 80780
+49 (0) 89 9218 5748

internationalsales@invivoscribe.com
info@labpmm.de

Hours Open:
Monday – Thursday: 8:00am – 5:00pm
Friday: 8:00am – 4:00pm

The Laboratory for Personalized Molecular Medicine® (LabPMM®) at Invivoscribe offers internationally standardized testing of novel and proprietary biomarkers that are critically important for patient care.

LabPMM GmbH
an invivoscribe company

LabPMM GmbH
an invivoscribe company

Invivoscribe's wholly-owned Laboratories for Personalized Molecular Medicine® (LabPMM®) is a network of international reference laboratories that provide the medical and pharmaceuticals communities with worldwide access to harmonized and standardized clinical testing services.

CLINICAL SERVICES

Single Genes 1–3 Day Turnaround Time
Capillary Electrophoresis

NPM1
LeukoStrat® CDx *FLT3* Mutation Assay

MRD Tests[‡] 7–10 Day Turnaround Time
Next-Generation Sequencing

FLT3 ITD MRD[†]
NPM1 MRD[†]

Gene Panels[‡] 7–14 Day Turnaround Time
Next-Generation Sequencing

MyAML®[‡]
MyMRD®[‡]

Clonality Tests 5–14 Day Turnaround Time
Next-Generation Sequencing

IGH FR1, FR2, FR3
IGHV Leader (SHM)
IGK
TRB
TRG

MRD Clonality Tests (RUO)
5–10 Day Turnaround Time
Next-Generation Sequencing

IGH FR1, FR2, FR3
IGHV Leader (SHM)
IGK
TRB
TRG

[†] Testing provided by our partner LabPMM LLC, San Diego, California, USA.
[‡] Tests are currently not accredited by DAkkS

HOW TO ORDER A TEST

Please contact our Sales team, or your Technical Account Manager in order to receive the necessary forms to initiate a services ordering account.

internationalsales@invivoscribe.com
+49 89 8994 80780

SAMPLE COLLECTION

Peripheral blood and bone marrow samples should be collected using local standard protocols. Label samples with two patient identifiers according to local procedures.

SAMPLE REQUIREMENTS

For the LeukoStrat® CDx *FLT3* Mutation Assay test:

- 3 mL of Peripheral Blood in Sodium Heparin tubes only
- 1 mL of Bone Marrow in Sodium Heparin tubes only
- Isolated DNA is not accepted

For all other tests:

- 1 – 3 mL of Peripheral Blood in Heparin, EDTA, or ACD
  - (Gene Panels min. 3 mL)
- 0.25 – 1 mL of Bone Marrow in Heparin, EDTA, or ACD
  - (Gene Panels min. 1 mL)
- Previously isolated DNA
  - Single Genes (*NPM1*): 250 ng per assay
  - MRD Tests: 1 µg per assay
  - Gene Panels: min. 1 µg per assay
  - Clonality Tests: min. 500 ng per assay
  - MRD Clonality Tests: 700–3500 ng per assay

Quiz

The associations below are correct. True or False?

- NGS CE IVD and RUO Assays : LymphoTrack® Dx
- Gel and Capillary CE IVD Assays : Identiclone®
- *FLT3* Assays : LeukoStrat®

- **FALSE**

Quiz

Invivoscribe provides additional kits exclusive for MRD testing. True or False?

- **FALSE**

Quiz

What is included in the Invivoscribe portfolio in addition to clonality testing?

- Minimal Residual Disease (MRD)
- Somatic Hypermutation (SHM)
- *FLT3* Gene Mutation
- *NPM1* Gene Mutation
- Translocations
- Controls
- All of the above

Quiz

Invivoscribe services portfolio does not contain any extra assay compared to the products portfolio. True or False ?

- False

invivoscribe®
Improving Lives with Precision Diagnostics®

Commercial Strategy

Target Markets

Clinical laboratories

Hospitals

Research laboratories

Inconclusive cases go to molecular testing for clonality confirmation

Molecular testing is being adopted in routine diagnostics

- When is the test ordered? / Who orders the test? / Who runs the test?
- Which drugs available in the country? / Which sites are prescribing them?

Laboratories performing studies in hematology–oncology research

Target Markets

With an instrument

- **Commercial kits:** Promote the appropriate assays compatible with the instrument.
  Gel or ABI: Clonality, SHM, *FLT3*, Translocations NGS: Clonality, MRD, SHM

With an instrument

- **Laboratory Developed Tests (LDTs):** Also called In-house or Homebrew tests.
  Controls Master Mixes Services

Without instrument

- Plan of expansion in the future – Use our Services as a door opener

Key Target Markets

Reference Sites

Key Opinion Leaders

Key markets with high potential

Those targets are key to spread the word:

- Identify these customers
- Initiate collaborations
- Support publication of results
- Organize user group meetings (workshops, case studies, etc.)

Invivoscribe Advantages

EuroClonality

Standardized and Validated Approach

EuroClonality/BIOMED-2 Concerted Action & Invivoscribe Developments

- Development and standardization of PCR protocols and primers for clonality
- Application of multiple complementary targets in parallel allows for high overall detection rate

47 Institutes

07 Countries

90 Participants

Invivoscribe is the EXCLUSIVE commercial partner

- All IdentiClone ® assays are based on EuroClonality/BIOMED-2 Concerted Action
- except TCRG 2.0 assay, developed by Invivoscribe, evaluated by EuroClonality/BIOMED-2

Invivoscribe Advantages

Market Leader

First to the market with

- NGS clonality assays for MiSeq® and Ion S5/PGM™ platforms
- Internationally validated *FLT3* Companion Dx assay
- Commercial NGS clonality assay kits and testing services
- MRD controls
- Expertise in the Molecular Diagnostic Market

Invivoscribe Advantages

LeukoStrat® CDx *FLT3* Mutation Assay

Companion Diagnostic (CDx)

- **Only** *FLT3* mutation analysis for assessment of AML patients-eligibility for treatment with the following drugs
- Assay clinical performance validated across **international studies**

Used as the CDx in clinical trials

RATIFY	ADMIRAL	QuanTUM-R
RYDAPT® [1,2] (midostaurin) NOVARTIS	XOSPATA® [1,2,3] (gilteritinib fumarate) astellas	VANFLYTA® [3] (quizartinib) Daiichi-Sankyo

Leading to the respective approvals

- **Software included:** automated signal ratio calculation and interpretation

invivoscribe®
Improving Lives with Precision Diagnostics®

1,2,3 The LeukoStrat CDx FLT3 Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia [1,2(AML)]. **1**The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered. The test is for use on the 3500xL Dx Genetic Analyzer. **2**In regions where midostaurin is available, the LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. In regions where gilteritinib fumarate is available, the LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib fumarate) treatment is being considered. **3**The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom Gilteritinib Fumarate treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom Quizartinib Hydrochloride treatment is being considered. Approvals: **1**. US **2**. CE-IVD and **3**. Japan

Invivoscribe Advantages

NGS Platform Agnostic

Assays compatible with:

- Illumina® MiSeq ®
- ThermoFisher® Ion PGM™
- ThermoFischer® Ion S5™

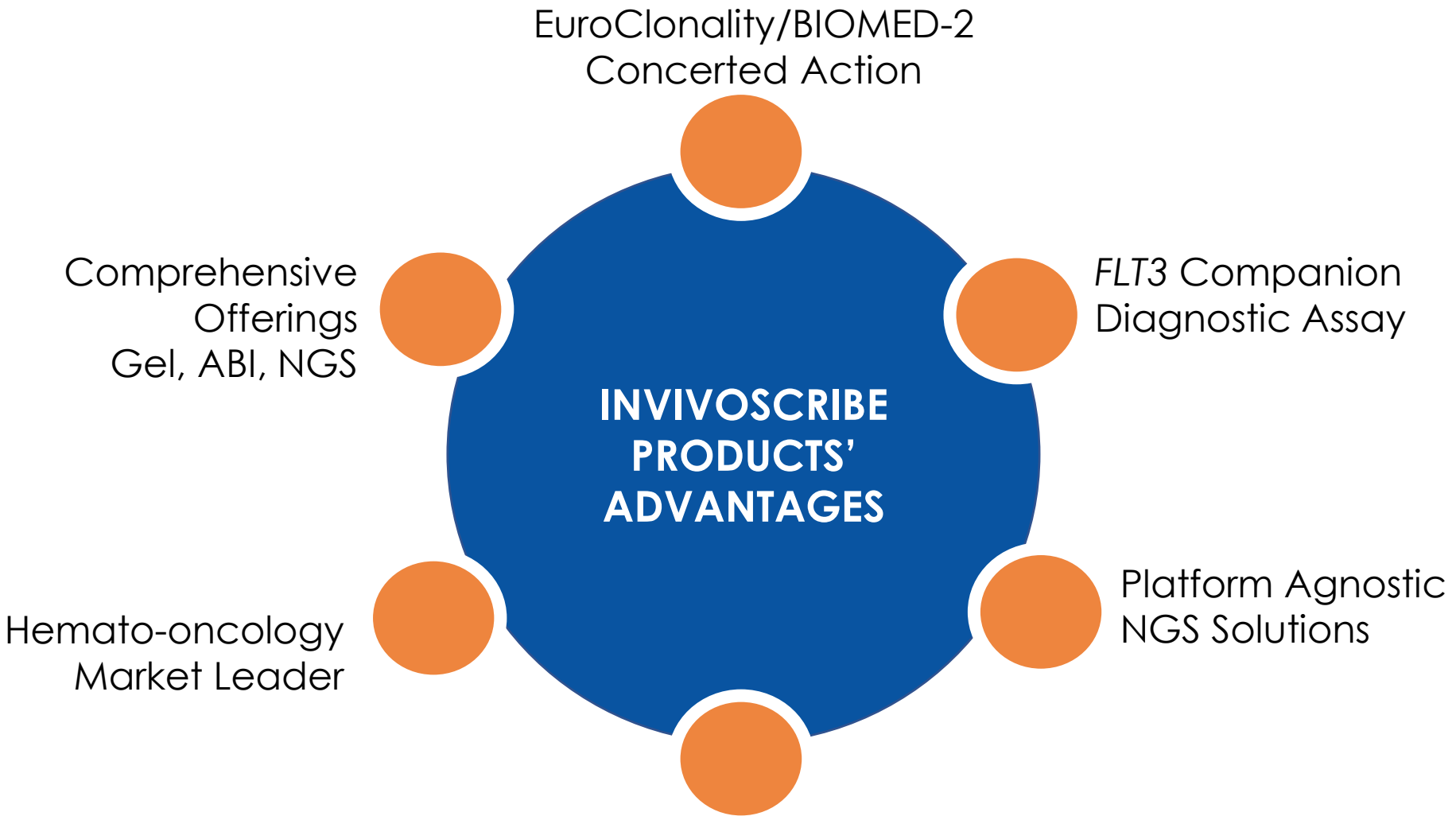
Invivoscribe Advantages

Bioinformatics Software

Provided with the purchase of an NGS assay kit

- Easy interpretation and analysis
- Full PDF report generated per sample and per target
- No network requirement, runs locally
- No need to compromise confidential patient data in the cloud
- Installation possible on multiple devices

Invivoscribe Advantages



Quiz

Select the NGS platforms validated with Invivoscribe assays for clonality testing:

- Illumina® MiniSeq®
- Illumina® MiSeq®
- Illumina® NextSeq ® 550
- Roche 454 GS FLX
- ThermoFisher® Ion PGM™
- ThermoFisher® Ion S5™

Quiz

All Invivoscribe assays are based on the EuroClonality/BIOMED-2 Concerted Action. True or False ?

- False

Take Home Message

- Invivoscribe offers a full range of PCR-based **molecular testing products** and **services** for Hematology-Oncology.
- **PCR-based clonality testing** of B- and T-cell Gene Rearrangements is the worldwide Gold Standard.
- **NGS** allows for unprecedented **detection levels** and information.
- ***FLT3*** testing is required to **stratify** disease and determine appropriate **treatment** options.