This is Invivoscribe

Corporate Overview

invivoscribe®

Improving Lives with Precision Diagnostics®

Leader in Personalized Molecular Diagnostics & Research

Biomarkers & B- and T-Cell Experts offering:

Products

For hematology-oncology including

- CE-IVD assays
- RUO assays
- Master mixes
- DNA & RNA controls

Lab Services

Offering internationally harmonized testing of biomarkers that are critically important for patient care through the LabPMM network.

Partnerships

Support to accelerate approvals of new drugs and treatments by supporting international clinical trials and CDx development.

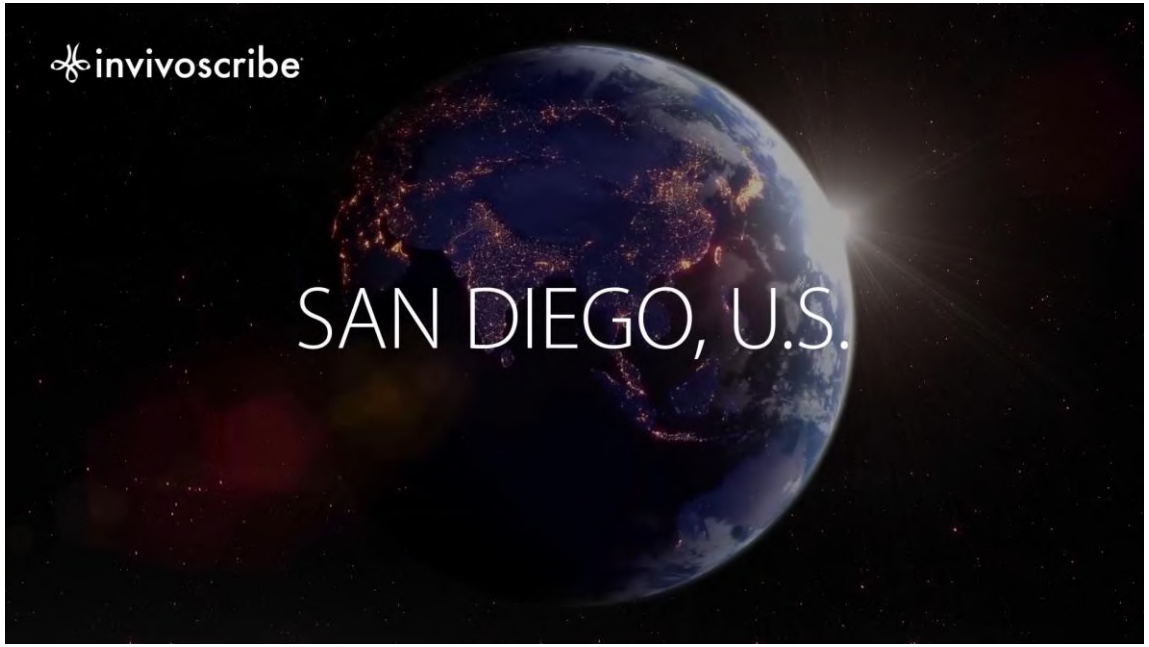
Our Vision

Harmonize Personalized Medicine through Internationally Standardized Molecular Diagnostics and Research Tools

Improving Lives with Precision Diagnostics

Our Vision

Harmonize Personalized Medicine Through Internationally Standardized Molecular Diagnostics



Improving Lives with Precision Diagnostics

Company Expansion Timeline

1995 Invivoscribe LLC
Company established
San Diego, CA USA

2005 Invivoscribe SARL
Regional distribution and sales support facility
La Ciotat, Provence, France

2007 LabPMM LLC
ISO15189; CLIA/CAP accredited
NY State Licensed
Clinical laboratory
San Diego, CA USA

2010 LabPMM GmbH
ISO15189 accredited
Clinical laboratory
Martinsried-Planegg, Germany

2012 Genection Inc.
Development of gene panels & bioinformatics software

2015 LabPMM GK 合同会社
Clinical Laboratory
FLT3 CDx testing for all Japanese labs
Kawasaki, Japan

2017 Launch of *FLT3* CDx
[EU and USA]
Testing Services

2017 Invivoscribe Diagnostic Technologies (Shanghai) Co., Ltd.
鹰维珂锐医疗科技（上海）有限公司
Clinical Trial Support
Shanghai, China

2018 Launch of *FLT3* CDx Assay Kits
Japan

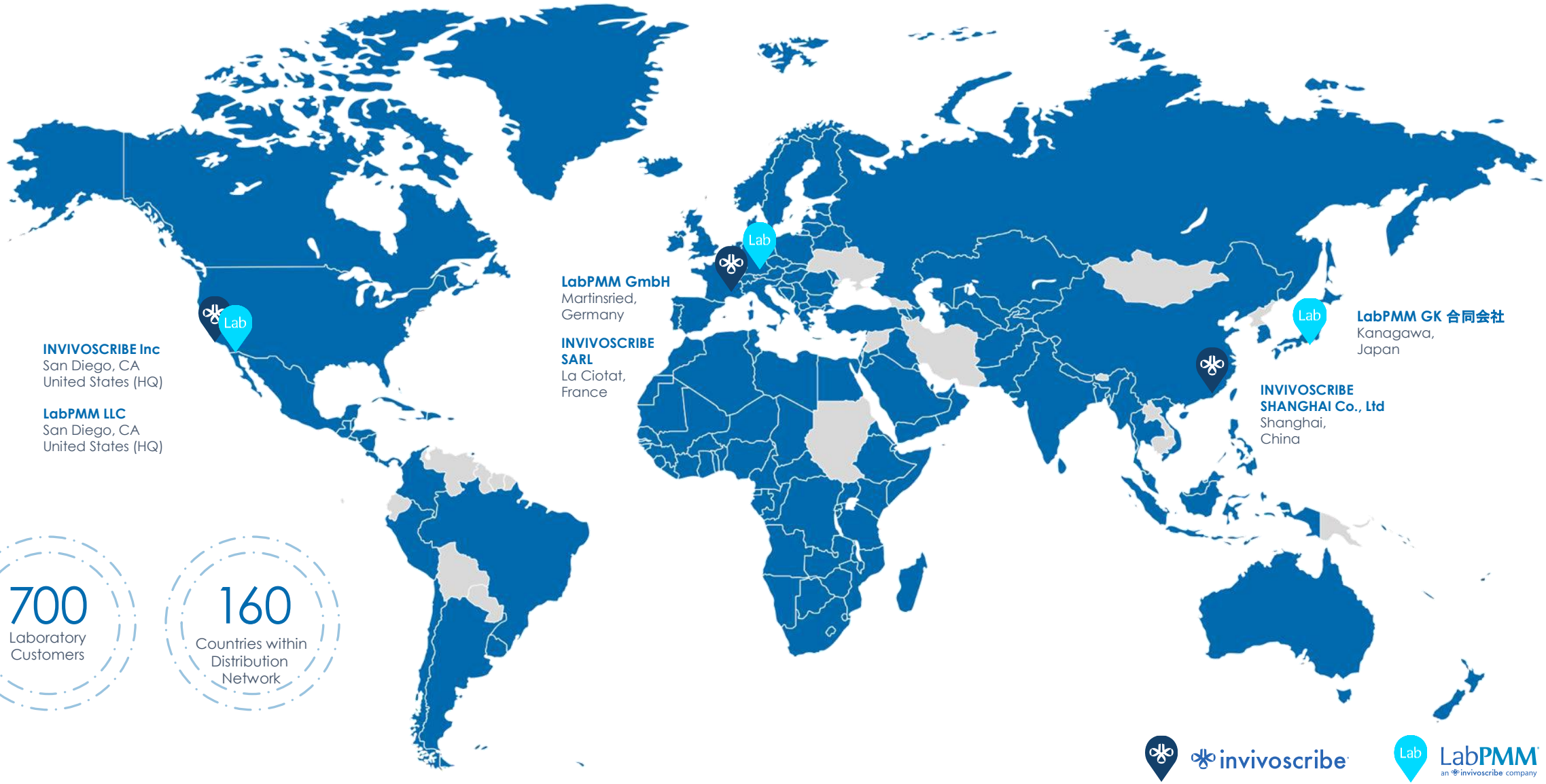
2019 Invivoscribe Therapeutics Inc.
Drug Development company
San Diego, CA USA

2020 Invivoscribe Therapeutics Inc.
Licenses IVS-020
candidate molecule from Domainex, UK

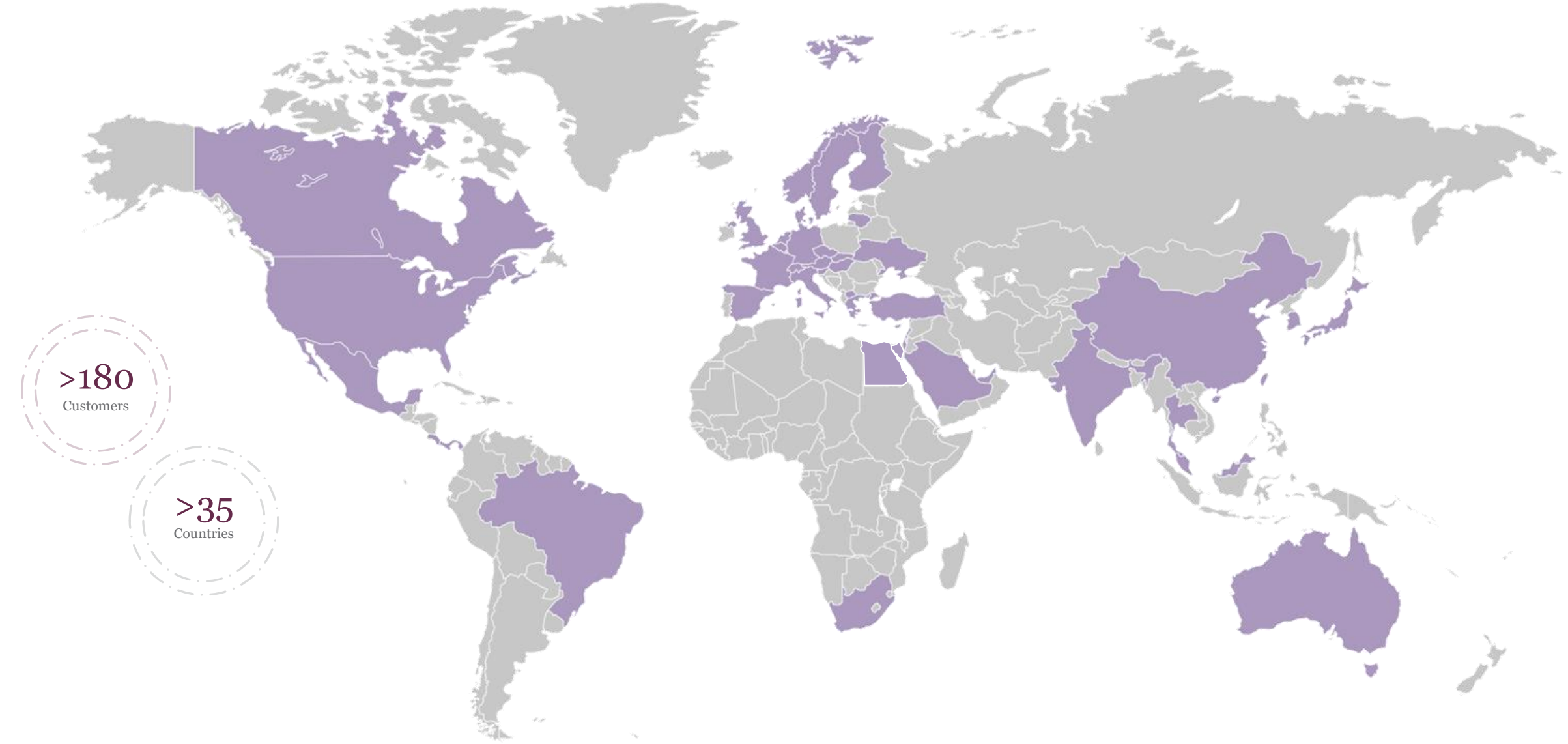
2020 Invivoscribe Diagnostic Technologies (Shanghai) Co., Ltd.
鹰维珂锐医疗科技（上海）有限公司
Testing Laboratory
Supporting clinical trials and Pharma partners

2020 Launch *FLT3* CDx Distributable Assay Kit
USA

Invivoscribe Geographical Expansion



Global NGS Customers



Invivoscribe

Founded in 1995

Build on collaboration with scientists, clinicians, and pathologists worldwide

- Fellow members of AMP
- Key opinion leaders at leading cancer centers
- BIOMED-2/EuroClonality Group

Continuing to partner with colleagues around the world, to **identify**, **develop**, and **commercialize** important new biomarkers of clinical interest.

Our Focus

PCR-based testing reagents & controls for identification, stratification, study of- and monitoring of hematological malignancies

Exclusive partnerships

- BIOMED-2/EuroClonality Group
- MonoQuant Ltd.

EuroClonality

Exclusive global licenses

- Gene rearrangement technologies
- 40+ patents covering other technologies
- Invivoscribe Therapeutics with IVS-020 license

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

Core Advantages

Efficient and reliable standardized tests, reagents, and controls

- International standardization allows for reproducible results across the globe

Extensive validation, quality control, and quality assurance

- Products developed and manufactured under cGMP conditions
- Ensure consistent products and laboratory results
- Streamlined throughput of molecular diagnostic laboratories

Knowledgeable Sales & Technical Support staff

- Rapid response worldwide

Cutting-edge Products for improving healthcare and Research Projects

- Diagnostic & prognostic tools to facilitate research projects and treatment strategies

Core Advantages

State-of-the-Art

R&D, Manufacturing, and Clinical Testing Facilities

- Quality
- Expertise
- Partnerships
- Scalability

Leader in Personalized Molecular Diagnostics

Focus for Distribution Network:

Products

For hematology-oncology including

- CE-IVD assays
- RUO assays
- Master mixes
- DNA & RNA controls

Lab Services

Offering internationally harmonized testing of biomarkers that are critically important for patient care through the LabPMM network.

Partnerships

Support to accelerate approvals of new drugs and treatments by supporting international clinical trials and CDx development.

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

Invivoscribe Products Portfolio

IdentiClone™ LeukoStrat®

LymphoTrack® Assays

MyMRD® MyAML®

Gel and Capillary

- CE-marked and RUO products for clonality, *FLT3,* and translocation testing
- SHM and B- & T-cell clonality Assays:
  - *IGH SHM, IGH, IGK, TRB, TRG*
- Translocations:
  - *BCL1/JH, BCL2/JH, BCR/ABL, PML/RARa*
- *Point Mutations*:
  - *FLT3*
  - *FLT3 CDx*

NGS Solutions

- Reagents for B- and T-cell Clonality
- CE-IVD and RUO Kits available for MiSeq® and Ion S5/PGM™
- Use the same reagents for clonality, SHM, and MRD
  - *IGHV leader, IGH* FR1/2/3, *IGK, TRB, TRG*
- Multiplexing capability
- Bioinformatics software included
- NGS Panels to identify clinically-actionable driver mutations

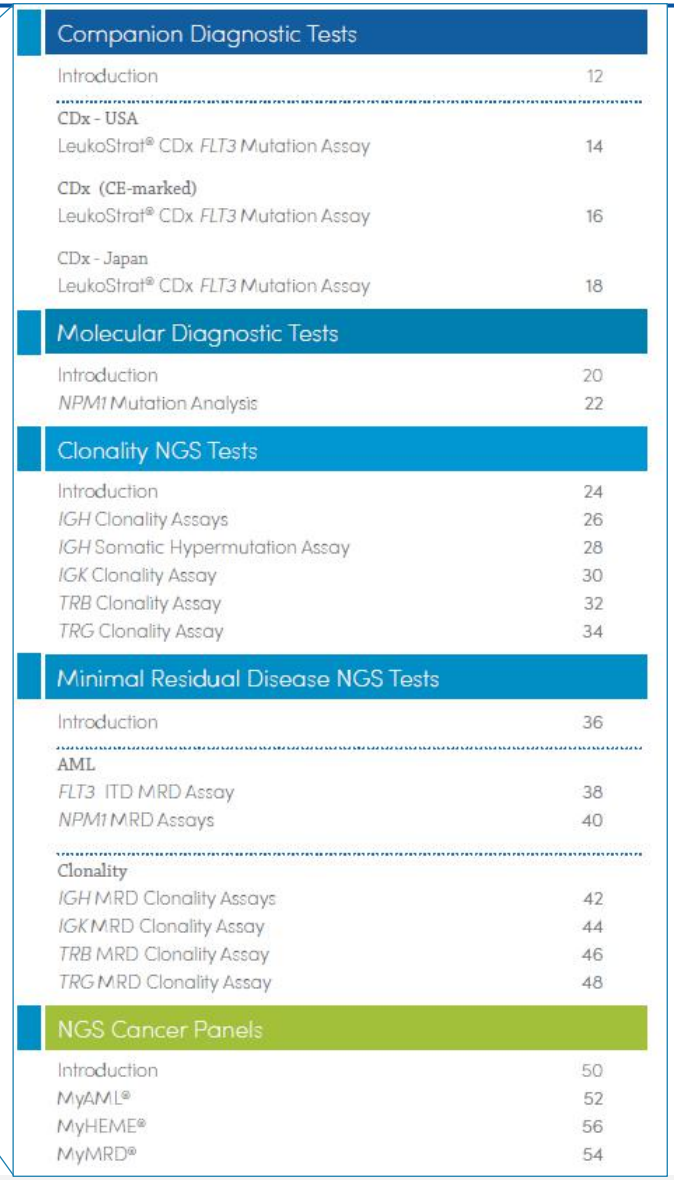
MRD Assessment

- Same reagents as for NGS B- and T-cell clonality detection
- Design Experiments with Desired Sensitivity
- Quantification of Residual Clones for Monitoring
- Flexibility to Track up to 5 Sequences Concurrently
- High sensitivity *FLT3* ITD- and *NPM1-MRD* testing*

Invivoscribe Services Portfolio

Available services include:

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



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. All MRD assays are for Research Use Only (RUO). Not intended for diagnostic purposes.

Invivoscribe Portfolio

Controls, Reagents and Enzymes

LymphoTrack® RUO NGS Controls

- LymphoTrack® B-Cell and T-Cell Low Positive Control
- LymphoQuant® B-Cell and T-Cell Internal Control

Controls, Reagents and Enzymes

- DNA Controls*
- RNA Controls*
- Master Mix Controls*
- Control Panels
- ABI Detection Reagents
- EagleTaq DNA Polymerase**

*The 100% DNA and RNA controls as well as Master Mix Controls are general purpose reagents (GPRs). All others are RUO.

**This product is for sale and use in the European Economic Area only. Taq DNA Polymerase (FalconTaq) worldwide commercialization planned for 2021.

Leader in Personalized Molecular Diagnostics

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

Past and Present Pharma Partnerships

For LeukoStrat CDx *FLT3* Mutation Assay:

- **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)	XOSPATA® [1,2,3] (gilteritinib fumarate)	VANFLYTA® [3] (quizartinib)
NOVARTIS	astellas	Daiichi-Sankyo

Leading to the respective approvals

Others in progress

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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

Instrument Partnerships

ThermoFisher SCIENTIFIC

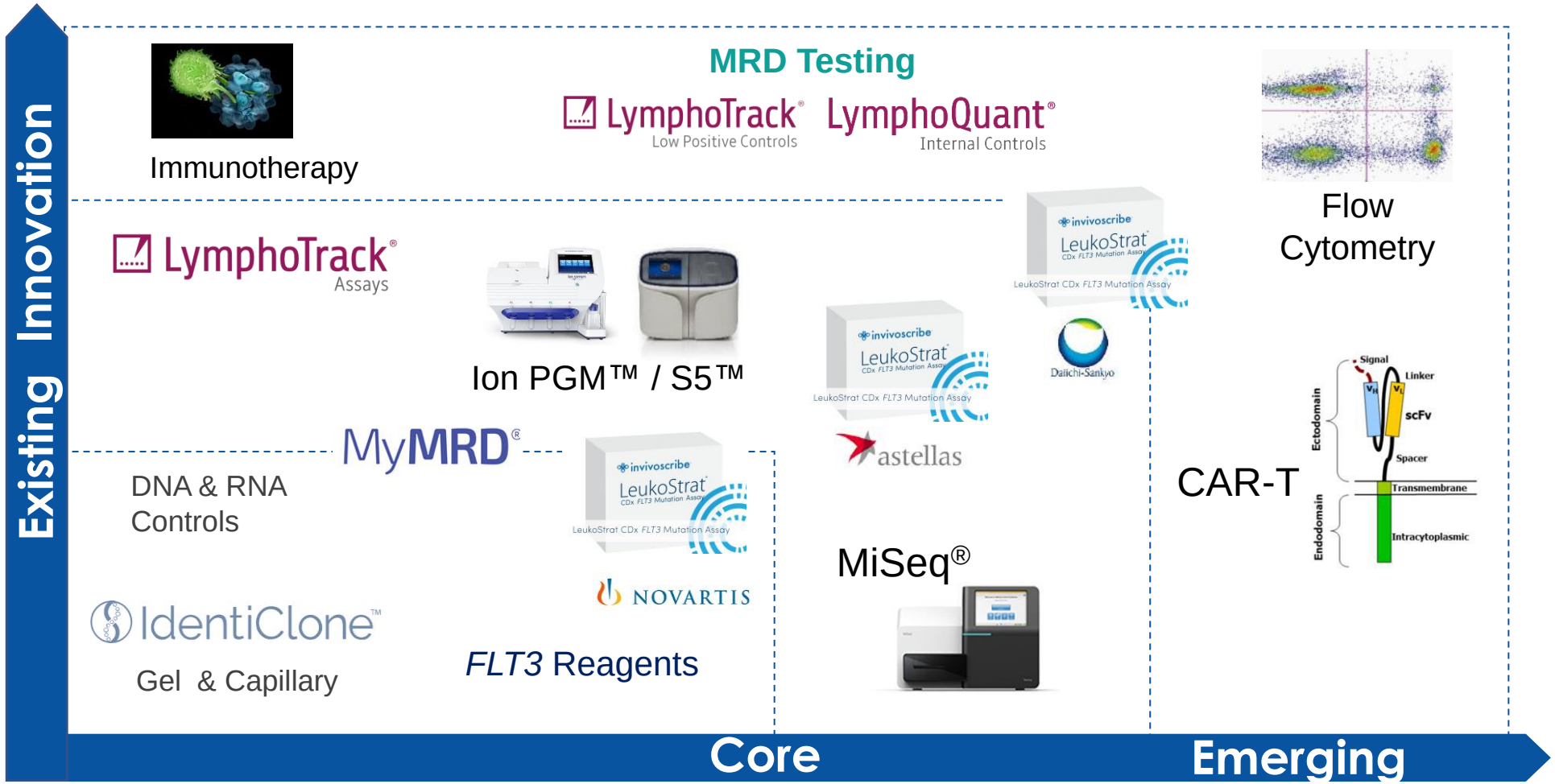
Applied Biosystems

and

illumina®

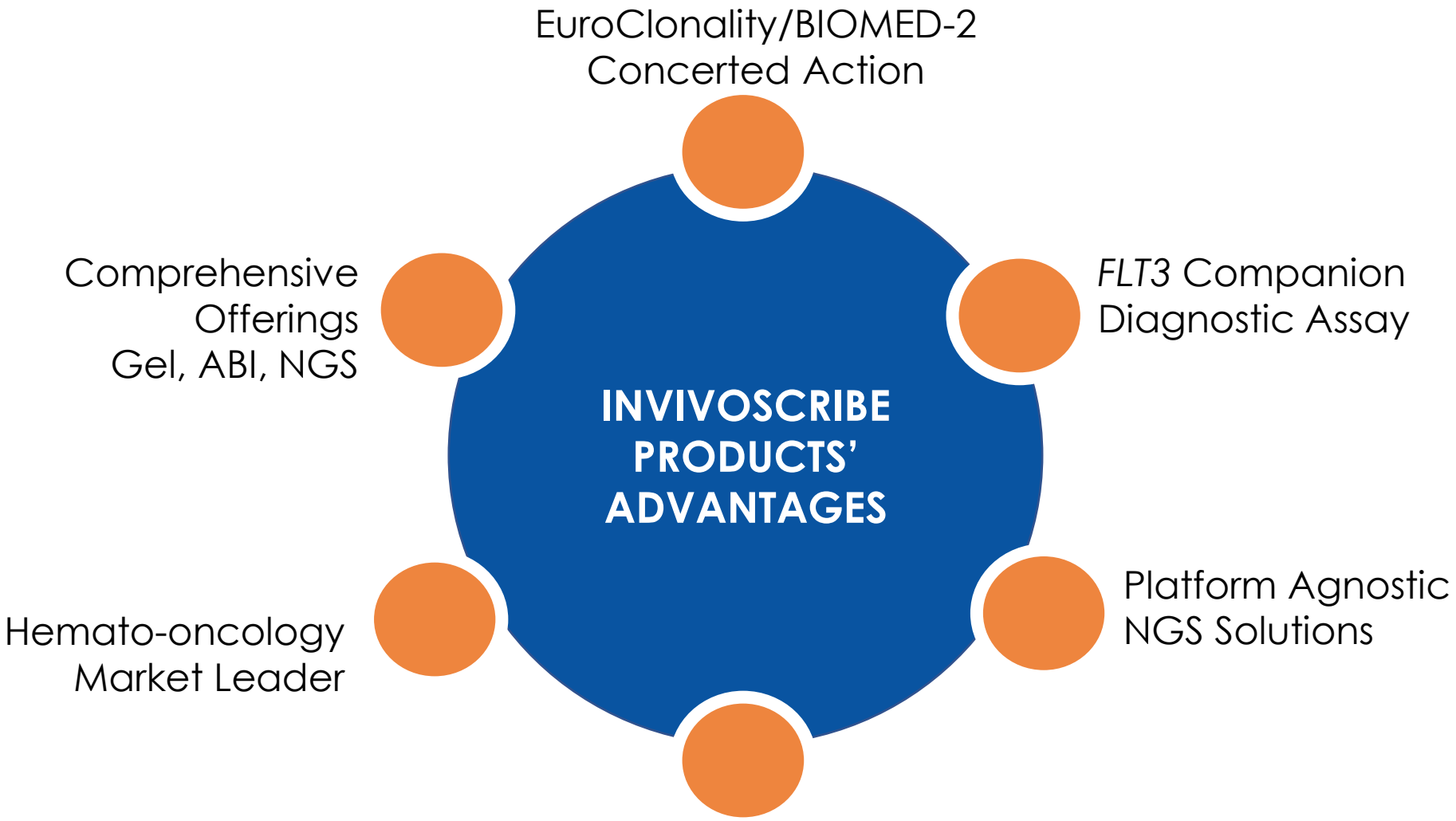
with complete freedom
to operate.

Invivoscribe Portfolio



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

Invivoscribe Advantages



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