The future of Precision Oncology with 1 Day NGS

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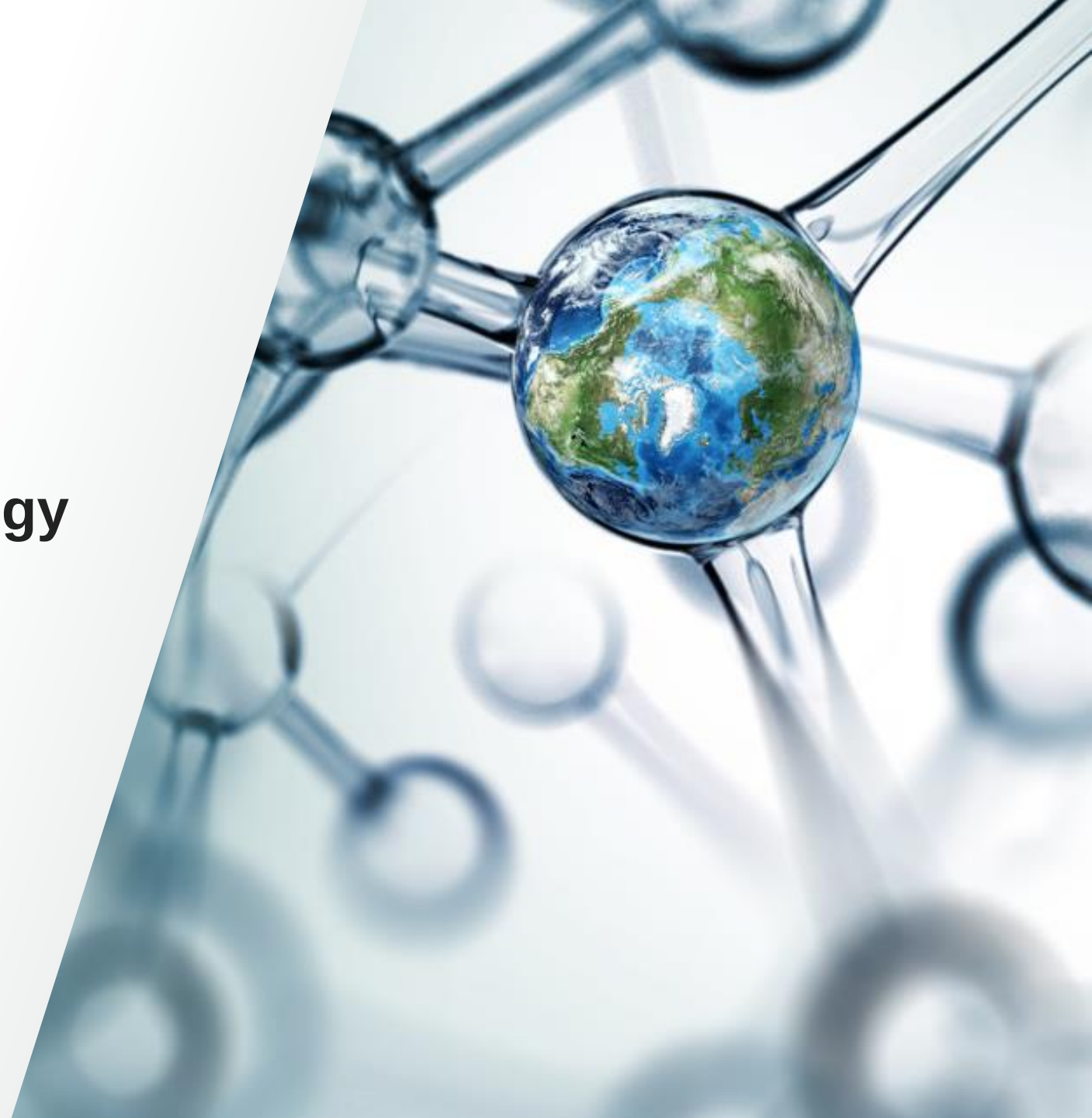


The world leader in serving science

Our mission–democratization of NGS

To improve access to personalized medicine, testing should be done close to the patient

Key points experts around the globe agree on

- Significantly faster time-to-results enables faster and optimal treatment decisions
- Small sample requirement provides biopsy stewardship, "tissue saving“
- It improves care coordination among multidisciplinary teams leading to true personalized medicine
- Allows for development of local expertise in biomarker testing to support the future of precision medicine

Ion Torrent - Oncomine Solutions

Enabling routine confident NGS testing in a broad spectrum of labs

Challenges Facing Pathology Laboratories

- MORE biomarkers /approved drugs with LESS tissue
- MORE testing with LESS resources and budget
- MORE results with LESS time

Barriers for Broad NGS Adoption

Too slow
Requires days and often weeks to get the results

Too complex
High level of user expertise required to run NGS
Modular workflows requiring multiple instruments and touchpoints

Too costly
Cost of hiring and training staff
Cost penalty for running small sample batches

Too limited
Tissue requirements / QNS (quantity not sufficient) related failures

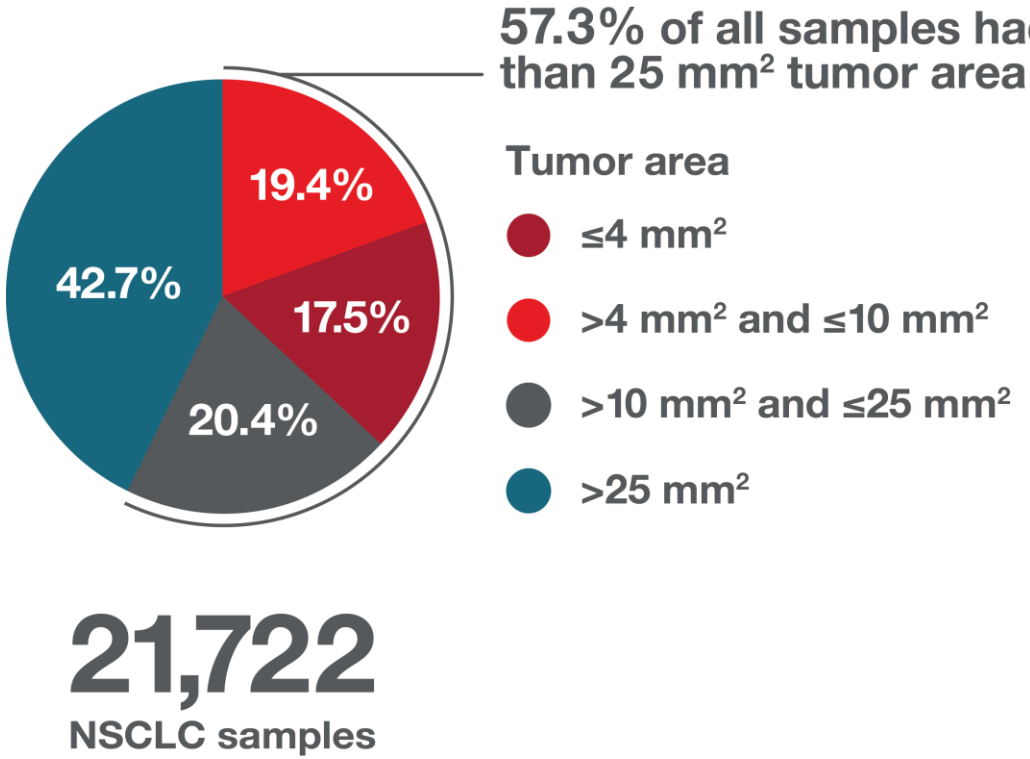
Ion Torrent Oncomine Solutions

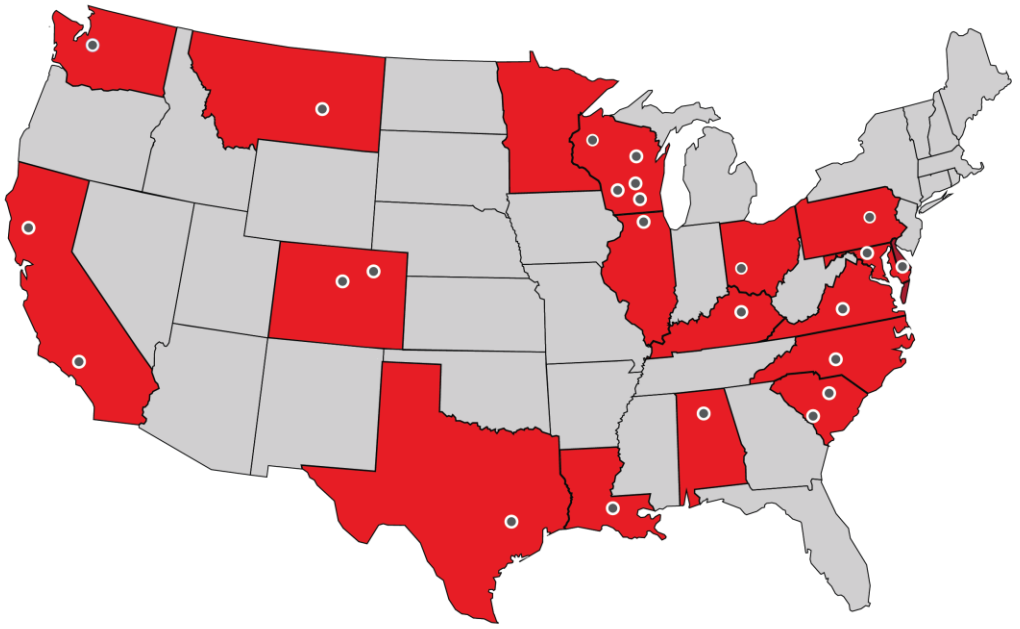
- **Faster NGS** workflow returns results sooner
- **Automated workflow** helps reduce labor time, and save lab operation cost
- **High success rate** widely published by customers
- **Lowest input** (10ng) helps save tissues and generates results from small samples
- **Highly sensitive** chemistry enables detection at low level

The solution to challenges and barriers for routine biomarker testing

Suboptimal technology can lead to limited access

42.7% - less than 1 out of 2 Samples was eligible for *Hybrid Capture-based NGS* based on input criteria**. 94.3%** was eligible for ***amplicon based NGS***





1 From: Scott, A, et al. (2020) Actionable CR-based comprehensive genomic profiling (PCR-CG P): Feasibility from >20,000 tissue specimens and predicted impact on actionable biomarker identification vs. hybrid capture (H)-CG P and plasma (P)-CGP. Presented at ASCO 2020.

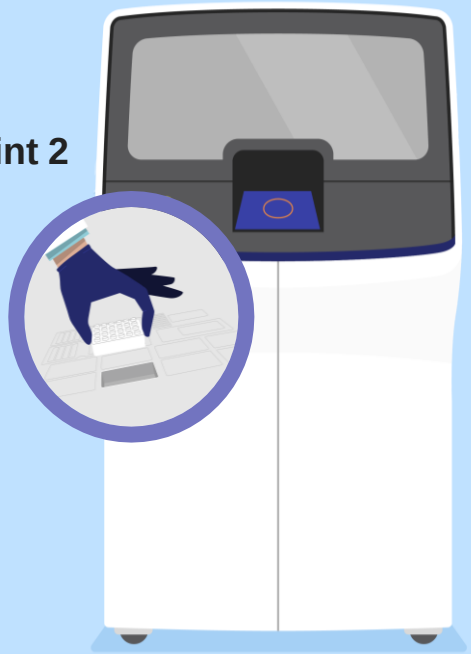
Maximizes detection of key actionable biomarkers

Two touchpoints, <20 minutes hands on time and 1-day easy NGS workflow

Touch Point 1

1. Nucleic Acid (NA) Extraction
2. NA quantification
3. Sequencing sample plate preparation
4. Storage NA plate preparation

Touch Point 2



1. Library preparation
2. Templating
3. Sequencing
4. Analysis

Ready-to-go reagents reduces setup time

Reliable and consistent nucleic acid purification

- **Ease of use**—as little as 15 minutes of total hands-on time and just 2 user touchpoints
- **Speed**—single-day turnaround time from biological specimen to report
- **Cost-effective for small projects**—analyze samples in small batch sizes so you can deliver results faster
- **One software solution**—enables tracking of sample and run-plan information through the final report
- **Broad range of applications**—complete DNA, RNA, and cfTNA purification from multiple samples types

Oncology assay menu 2021

Oncomine Precision Assay

- Mutations, CNV, and fusion variant types across 50 key genes
- Only 10 ng of DNA/RNA required
- FFPE tissue & liquid biopsy samples
- Novel fusion detection

Oncomine Myeloid Assay GX

- 40 DNA Targets
- 29 Fusion Drivers
- 687 Fusion Isoforms
- Biomarkers associated with AML, MPN, MDS
- Blood or Bone Marrow

Oncomine Comprehensive Assay Plus (H1 2022)

- 500+ unique genes
- SNVs, indels, CNVs, known and novel fusions, and splice variants
- Tumor mutational burden (TMB), microsatellite instability (MSI), Genomic Instability
- 20 ng DNA/RNA required

Oncomine BRCA Assay GX (H1 2022)

- BRCA somatic and germline mutations
- Large Indels and exon or whole gene deletion or duplication events
- 10 ng DNA input
- FFPE or whole blood

Oncomine TCR β LR Assay GX

- T cell repertoire diversity and clonal expansion
- Coverage of all three complementarity-determining regions (CDR1, 2, and 3)

1st step on our journey to democratize NGS based CDx

Thermo Fisher Scientific intends to take the Oncomine Dx Express Test on Genexus through regulatory approval as a next generation CDx solution

The CDx development agreement with Agios Pharmaceutical and following break through device designation of future Oncomine Dx Express Test is the first step in this direction

The designation is for the identification of low-grade glioma (LGG) patients with isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2) mutations who may be eligible for vorasidenib (AG-881), currently in an investigational phase in Phase 3 INDIGO study

FDA Grants Breakthrough Device Designation to Thermo Fisher Scientific's Oncomine Precision Assay to Identify IDH1 and IDH2 Mutations in Low-Grade Glioma Patients

Designation follows recent announcement on development of first companion diagnostic using the Oncomine Precision Assay on the new Ion Torrent Genexus System

NEWS PROVIDED BY
Thermo Fisher Scientific →
Jun 15, 2020, 07:00 ET

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CARLSBAD, Calif., June 15, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to Thermo Fisher Scientific's Oncomine Precision Assay to identify low-grade glioma (LGG) patients with isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2) mutations who may be eligible for vorasidenib (AG-881). The assay, first introduced to the market as a research product in November 2019, is designed to run on the new Ion Torrent Genexus System, the first fully automated next-generation sequencing (NGS) platform with a specimen-to-report workflow that delivers comprehensive genomic profiling results in a single day.

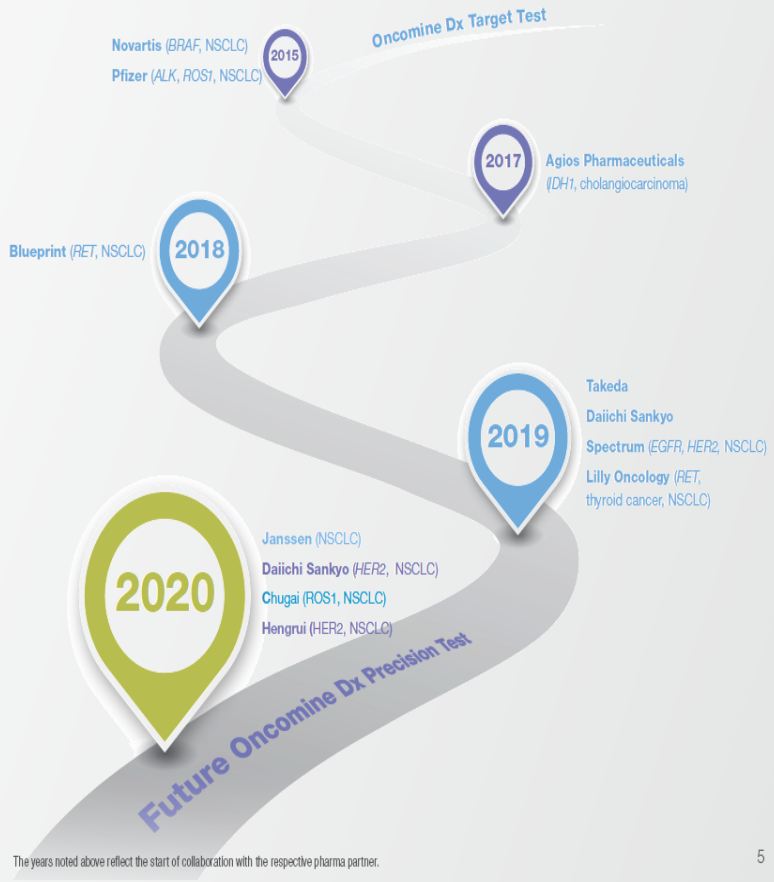
The Oncomine Dx Express Test is For investigational use only.
The content provided herein may relate to products that have not been fully validated by Thermo Fisher Scientific and is subject to change without notice.

Oncomine CDx Pharma Partnership

Oncomine Dx Target Test (OdxTT) 2015 – 2021

Pfizer, Novartis	Blueprint Medicines	Spectrum Pharmaceuticals	Daiichi Sankyo and Takeda Pharmaceuticals	Agios Pharmaceuticals	Lilly Oncology
Develop NGS test as CDx in NSCLC	Expand ODxTT to *RET* fusion markers to treat NSCLC patients	Enter NGS CDx Partnership with Thermo Fisher Scientific	Leverage FDA-approved test for clinical trials and drug development programs	Agreement for NGS Oncology CDx in Cholangiocarcinoma	Agreement CDx for RET inhibitor in NSCLC and Thyroid patients
FDA approved	FDA approved				

Janssen Oncology	Agios Pharmaceuticals	Daiichi Sankyo	Chugai (member of Roche)	Hengrui Therapeutics
Validate ODxTT for multiple biomarkers as CDx claims in NSCLC and additional Oncology indications	Co-develop a Global CDx for Low-grade Glioma using **ODxET**	Co-develop CDx using ODxTT for *HER2* mutations in NSCLC	CDx agreement in Japan to expand the use of ODxTT for entrectinib for *ROS1* in NSCLC	Develop a CDx leveraging **ODxET on Genexus System** for Her2 mutations in NSCLC



Continue to expand IVDR menu and claims to support pharma drug launch in EU

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Oncomine IVDR Journey

One system, seamless transition to IVDR

RUO

Anticipated IVDR launch

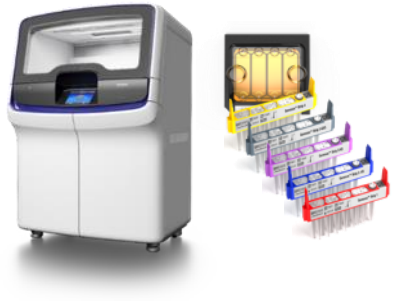
Anticipated IVDR assay expansion

2020

2022

2023

Genexus instrument, software, and consumables



IVDR Ready

NO hardware changes required

SW update only to comply with regulations

Oncomine assays

ODxET

IVDD launch and IVDR submission

Other assays to be announced

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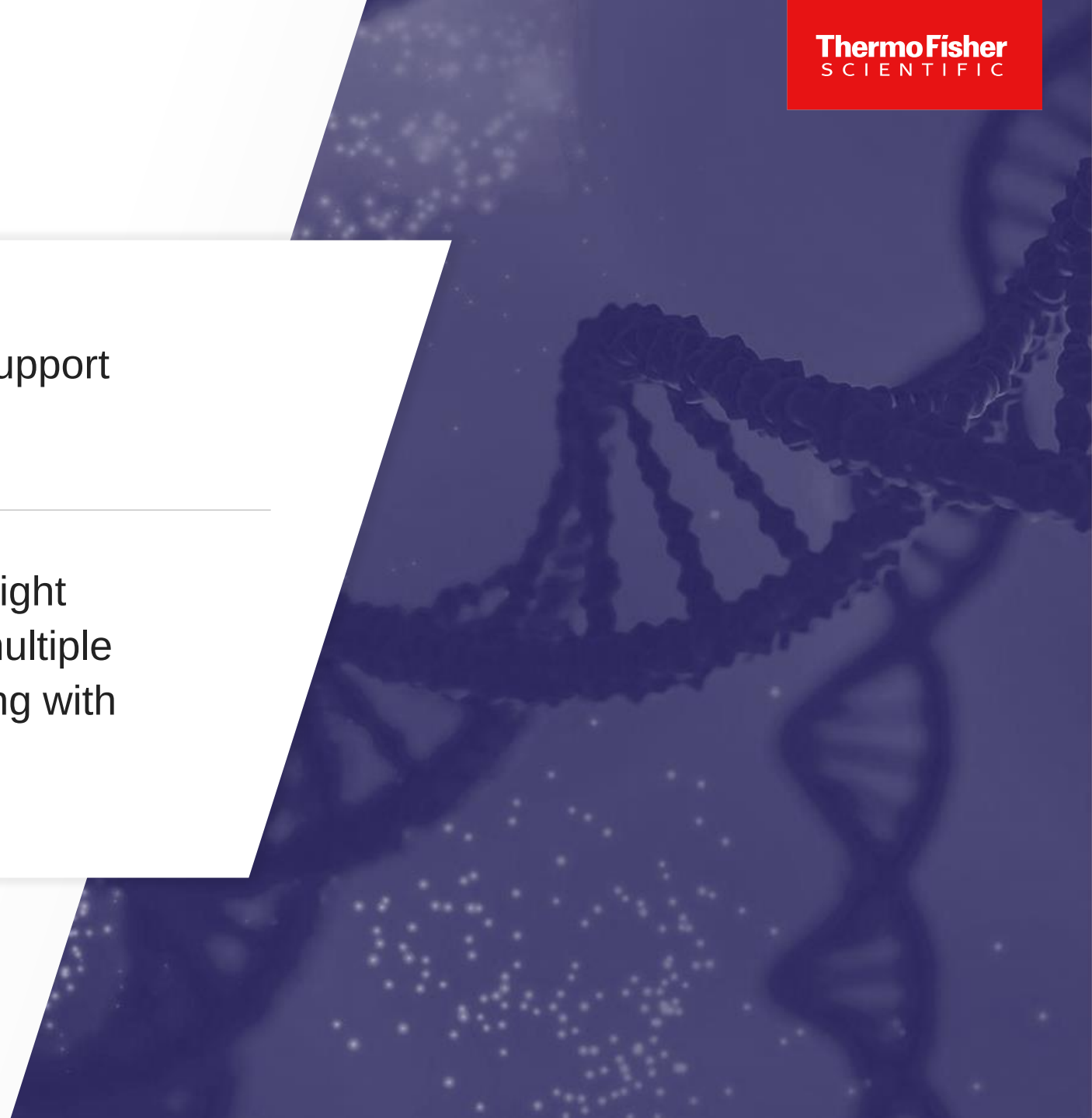
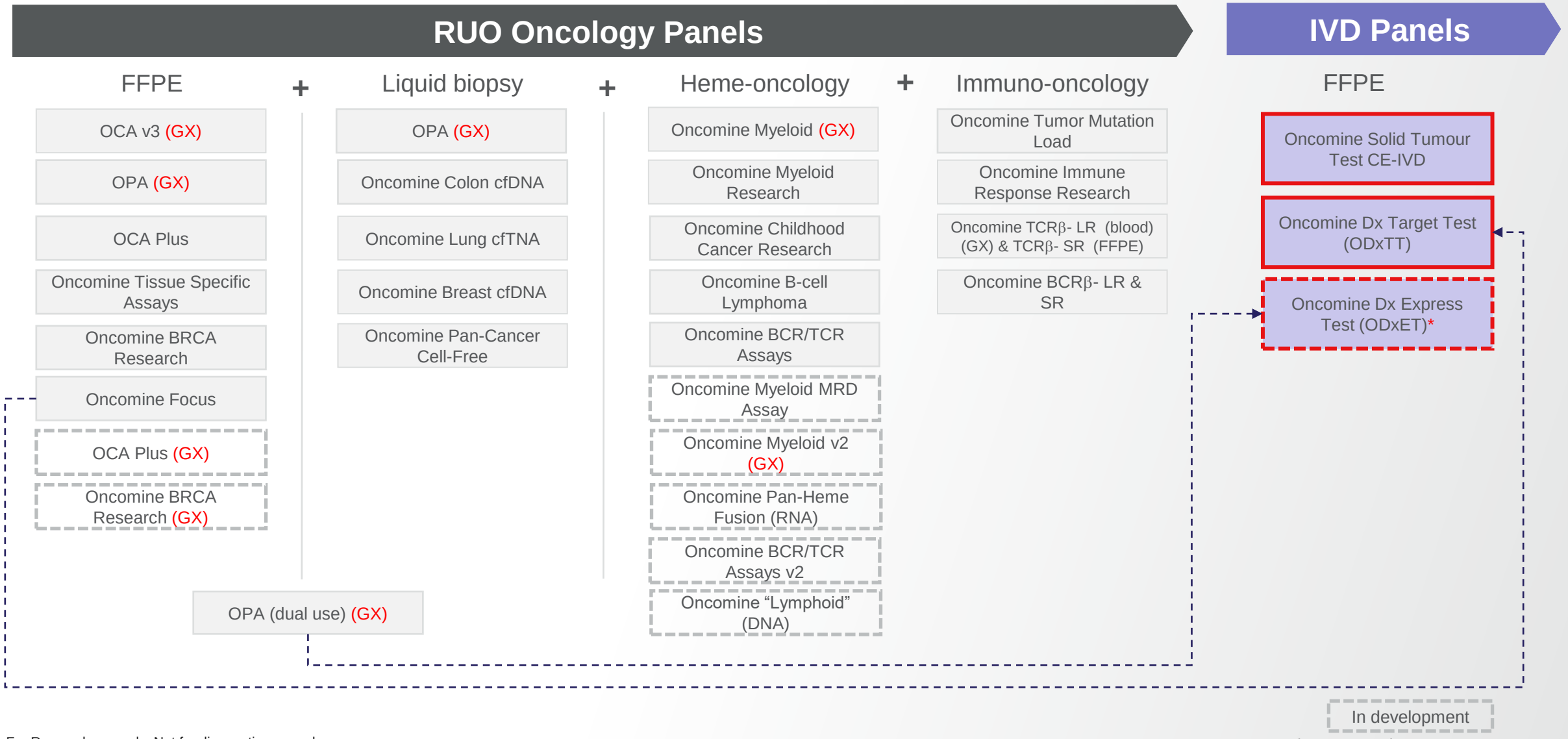
Summary

We are on a mission to democratize NGS to support patient access to the personalized medicines

We believe we have the best technology and right experience to succeed and are working with multiple pharma partners and look forward to be working with all of you



Oncomine Assay Portfolio

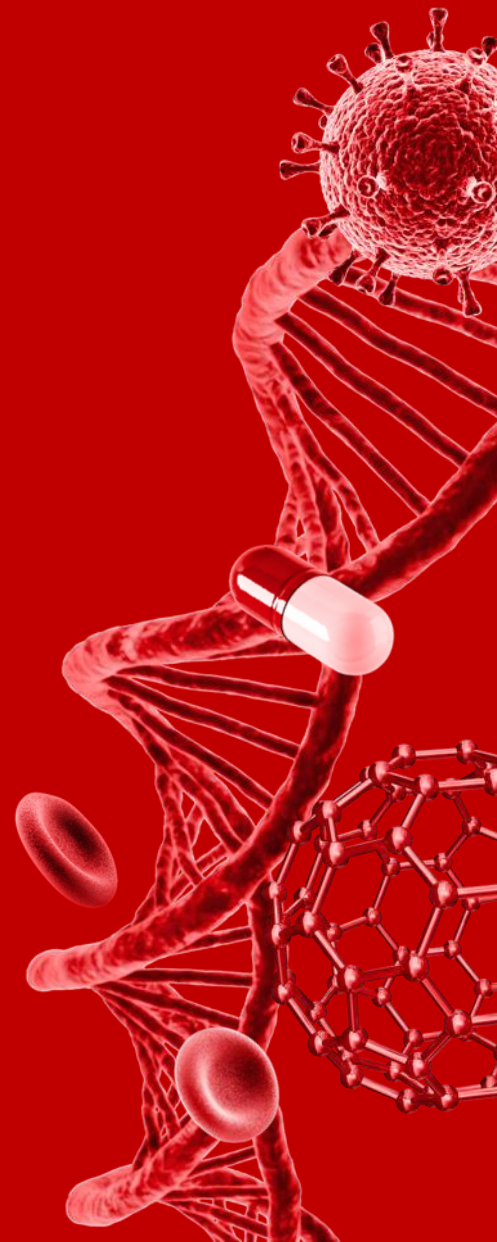


For Research use only. Not for diagnostics procedures

The OST and the OdxTT are for *In-Vitro* Diagnostic use.

The Oncomine Dx Express Test is For investigational use only.

Thank you



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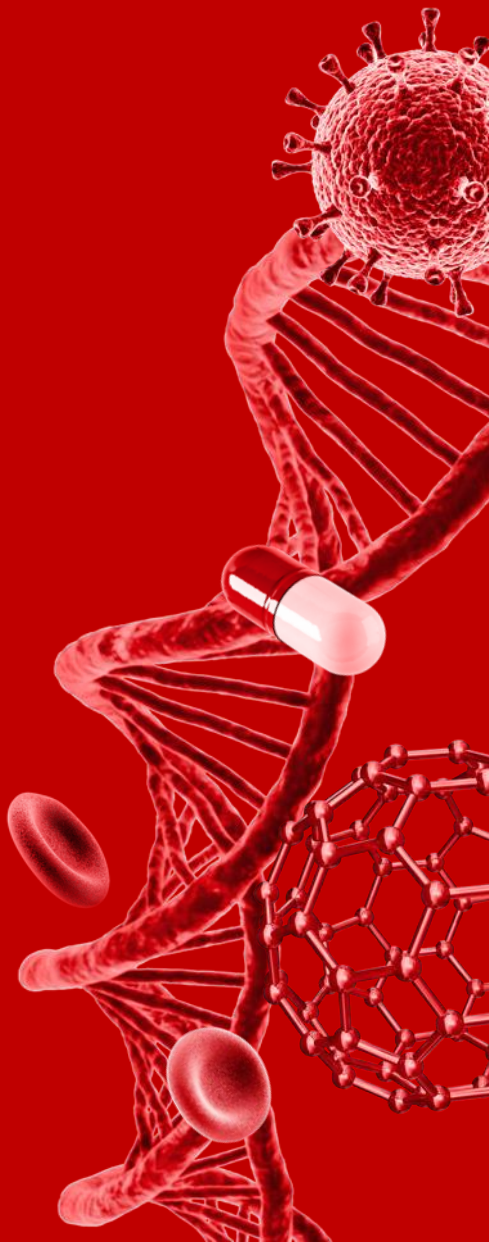
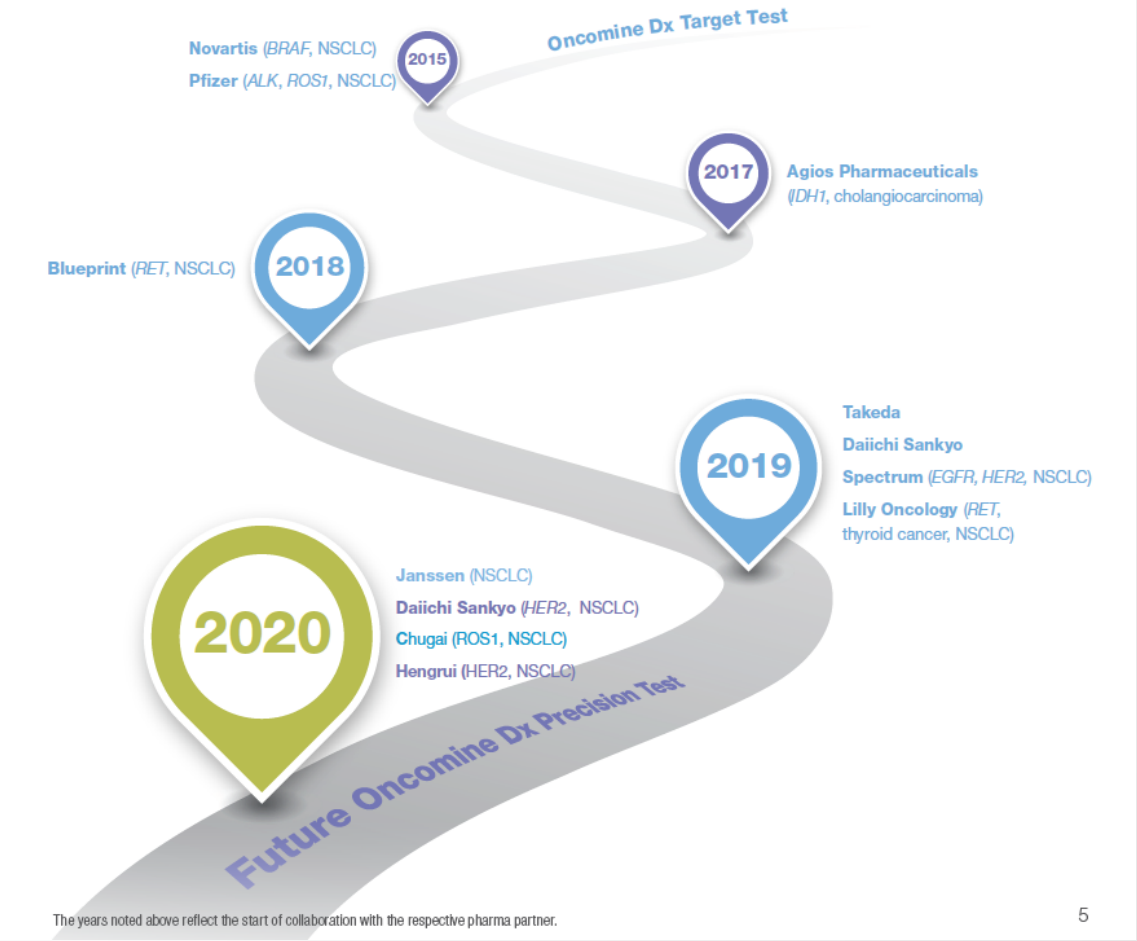
Q&A



Create a slide showing evolution of DX solutions



12 Oncomine CDx Pharma Partnership

2015 – 2020

Pfizer, Novartis

Announce agreement with Novartis and Pfizer to develop NGS test as CDx in NSCLC

approved

Blueprint Medicines

Agreement to expand Oncomine Dx Target Test with RET fusion markers to treat non-small cell lung cancer patients

approved

Spectrum Pharmaceuticals

Spectrum Pharmaceuticals Enters into a Next-Generation Sequencing Companion Diagnostic Partnership with Thermo Fisher Scientific

Daiichi Sankyo and Takeda Pharmaceuticals

Daiichi Sankyo and Takeda Pharmaceuticals to leverage FDA-approved test for clinical trials and drug development programs

Agios Pharmaceuticals

Agreement with Agios Pharmaceuticals for Next-Generation Sequencing Oncology Companion Diagnostic in Cholangiocarcinoma

Lilly Oncology

Thermo Fisher Scientific Signs Agreement with Lilly Oncology for Companion Diagnostics for RET inhibitor in NSCLC and Thyroid patients

Janssen Oncology

Agreement to validate Oncomine Dx Target Test for multiple biomarkers as CDx claims in NSCLC and additional Oncology indications

Agios Pharmaceuticals

Thermo Fisher Scientific to Co-develop a Global Companion Diagnostic for Low-grade Glioma with Agios Pharmaceuticals using **Oncomine Precision Test on Genexus System**

Daiichi Sankyo

Agreement to co-develop Companion Diagnostics using Oncomine Dx Target Test for Her2 mutations in NSCLC

Chugai (member of Roche)

Companion Diagnostics agreement in Japan to expand the use of Oncomine Dx Target Test for entrectinib for ROS1 in NSCLC

Hengrui Therapeutics

Agreement to develop a CDx that will leverage the **Oncomine Precision Test, on the Genexus System** for Her2 mutations in NSCLC

Driving global claim expansion

Future Plans for Oncomine Dx Express Test

One system, seamless transition to IVD

2020	2022	2024
RUO	Anticipated CE IVD	Anticipated IVDR launch with multiple idnications

- NO hardware changes required
- SW update only to comply with regulations

IVD label is expected to include instrumentation, core consumables and Oncomine Express Dx Test to provide a full end-to-end solution

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