MolecularMD
An ICON plc Company

ICON

ICON acquires oncology lab

ICON has acquired MolecularMD, a molecular diagnostic specialty laboratory that enables the development and commercialisation of precision medicines in oncology. The acquisition enhances ICON's laboratory offering in molecular diagnostic testing and brings to ICON expanded testing platforms, including next generation sequencing and immunohistochemistry (IHC).

MolecularMD brings over a decade of experience and scientific expertise helping clients effectively navigate through all stages of oncology biomarker assay development and validation. Founded in 2006, MolecularMD has supported numerous clinical oncology trials, including the first global Phase III BCR-ABL studies for Imatinib to the first FDA authorized companion diagnostic for treatment-free remission of Nilotinib-treated CML patients.

MolecularMD is a recognised leader in the analytical development and clinical validation of molecular diagnostic assays. It offers a comprehensive test menu in immune oncology development from two CLIA-certified and CAP accredited laboratories in Portland, Oregon and Cambridge, Massachusetts. MolecularMD services also include companion diagnostic development services which expand ICON's laboratory service offering and will help pharmaceutical and biotechnology customers to maximise the value of laboratory data from clinical development programs.

We scientifically assess the biomarker(s) at the start of the project, propose a validation process and align it with the diagnostic test's intended use—whether it is for a clinical trial or ultimately, a companion diagnostic test.

MolecularMD also complements ICON's Regulatory Affairs services with their proven regulatory affairs support from IDE and/or PMA submissions to CE markings. It provides advisory services for cGMP Manufacturing, FDA 21 CFR Part 820 Design Controls, and commercial planning for diagnostic distribution.

Extensive Portfolio of Molecular Technologies

Our specialty molecular oncology laboratories in Portland, Oregon and Cambridge, Massachusetts offer an extensive line up for assay design, development, and validation spanning full service histopathology capabilities and next generation sequencing technologies.

Method	Platform		Biomarker Assay
ddPCR	QX200™	BIO-RAD	Copy Number | Gene Expression | Mutations
IHC	Benchmark Ultra	VENTANA	Protein Expression
	BOND III	Leica	
	Dako OMNIS	Agilent	
NGS	MiSeq	illumina	Copy Number | Mutations | RNA Fusions | Gene Expression
	Ion PGM/ ION S5	ion torrent	
qPCR RT-qPCR	7500 Fast Dx QuantStudio™ Dx	applied biosystems	Mutations | Gene Expression
	Rotor-GeneQ MDx	QIAGEN	
CE	3730xL/3500xL Dx	applied biosystems	Sanger Sequencing | Fragment Analysis

Custom Diagnostic Development Services

Design

Establish test design requirements of analytical performance and clinical validation specific to the indication and clinical strategy of the targeted cancer therapy.

- Gather and assess product requirements
- Determine the optimal platform and sample handling method (qPCR, ddPCR, NGS, IHC, Sanger)
- Develop the assay procedure and generate appropriate reference samples for use in validation studies for clinical delivery

Biomarker

Sample type

Method

Develop & validate

Integrate the selected technology with the appropriate sample preparation, test workflow, and study logistics. Tests are developed and validated under ISO 13485:2016 and FDA QSR Part 820 design, development and product requirements.

- Assay transfer & method validation for clinical delivery
- Sample sourcing for validation
- Clinical trial sample management and testing
- Fit for purpose validation plan

Assay

Plan & report

Logistics

Implement

Meet the requirements and timelines of global clinical trial protocols.

- Regulatory pre-submission, risk assessment, and Investigational Device Exemption (if required)
- FDA 21 CFR Part 820 design controls
- IDE, PMA submissions, and CE marking
- Supply chain/delivery of reference sample and kits
- Clinical trial data delivery and review

Regulatory

Material delivery

Commercialise & distribute

Distribute and commercialise via centralised testing, CE/IVD kit distribution and Global OEM partners.

- cGMP manufacturing
- Custom kit configurations
- OEM platform partners
- Scalable distribution strategies for clinical testing

DX kit

Clinical test