

MOLECULAR ONCOLOGY DIAGNOSTICS / WHITEPAPER

ONCODIAX™

*Oncology Molecular Diagnostic Intelligence &
Optimization Framework*

AUTHOR

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— EXECUTIVE SUMMARY

Turning fragmented molecular data into diagnostic intelligence.

Molecular oncology increasingly depends on genomic testing, circulating tumor DNA (ctDNA), methylation analysis, protein biomarkers, and other technologies for cancer detection and monitoring.

Yet laboratories must still manage specimen variability, assay performance, quality control, workflow complexity, reproducibility, and turnaround time.

ONCODIAX™ is an **Oncology Molecular Diagnostic Intelligence & Optimization Framework** developed to address these challenges.

Through four pillars — **Assess, Predict, Optimize, and Improve** — ONCODIAX™ helps laboratories:

- ◆ Strengthen molecular diagnostic intelligence.
- ◆ Identify assay vulnerabilities earlier.
- ◆ Improve testing reliability.
- ◆ Optimize laboratory workflows.
- ◆ Measure diagnostic performance.

The framework provides a structured approach to more reliable, efficient, and performance-driven molecular oncology diagnostics.

ASSESS**PREDICT****OPTIMIZE****IMPROVE**

01 INTRODUCTION

From disconnected data to an integrated diagnostic system.

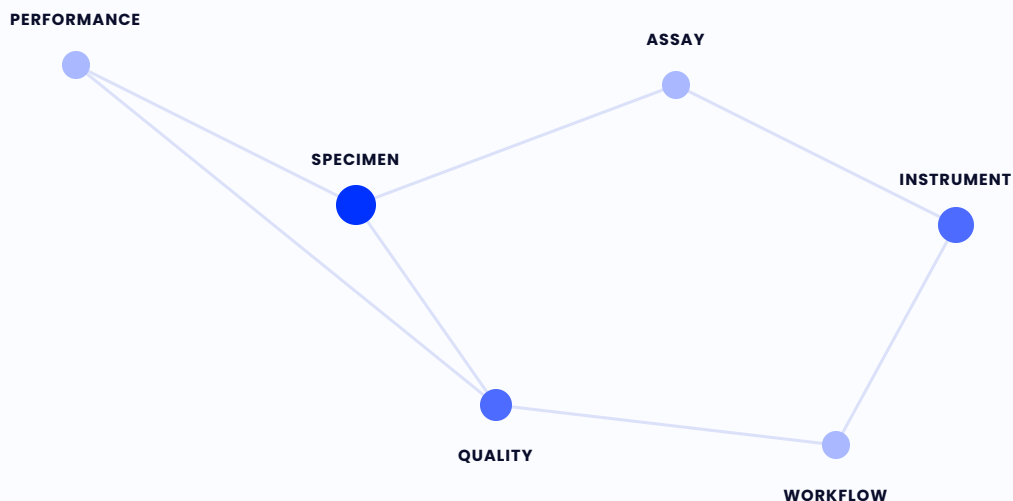
Molecular laboratories generate extensive information across specimen processing, DNA/RNA extraction, amplification, biomarker detection, instrumentation, quality control, and diagnostic workflows.

However, this information is often evaluated at separate stages rather than as an integrated diagnostic system.

ONCODIAX™ addresses this gap by transforming specimen, assay, quality, workflow, and performance information into structured molecular diagnostic intelligence.

02 THE PROBLEM ONCODIAX™ SOLVES

Molecular oncology laboratories commonly face:



— 02 THE PROBLEM, CONTINUED

Five recurring gaps in molecular oncology labs.

Fragmented Diagnostic Information

Specimen, assay, instrument, and quality data may exist across disconnected processes.

Reactive Quality Management

Analytical problems may only become visible after control failures, repeat testing, or nonconformances.

Assay Variability

Specimen quality, molecular integrity, amplification, and instrumentation can affect reproducibility.

Workflow Inefficiency

Testing queues, equipment downtime, repeat testing, and quality interruptions can affect capacity and turnaround.

Disconnected Performance Measurement

Quality, workflow, and diagnostic outcomes may be monitored independently.

ONCODIAX™ integrates these areas into **one improvement architecture.**

03 THE ONCODIAX™ SOLUTION

Four pillars, one molecular diagnostic architecture.

MOLECULAR DIAGNOSTIC INTELLIGENCE INDEX

Convert specimen, molecular, and quality information into actionable diagnostic intelligence.

DIAGNOSTIC PERFORMANCE & RELIABILITY INDEX

Connect laboratory improvements with measurable diagnostic performance.



BIOMARKER & ASSAY RELIABILITY SCORE

Identify analytical vulnerabilities before they significantly affect testing reliability.

MOLECULAR WORKFLOW OPTIMIZATION MATRIX

Improve molecular testing efficiency and resource utilization.

— 03 THE ONCODIAX™ SOLUTION — PILLAR DETAIL

PILLAR 1

Molecular Diagnostic Intelligence Index (MDII™)

OBJECTIVE

Convert specimen, molecular, and quality information into actionable diagnostic intelligence.

MATURITY

Fragmented → Integrated → Intelligent

QUICK WIN

Identify fragmented specimen, molecular, and quality information.

MEASURES

Specimen integrity, pre-analytical quality, molecular-data completeness, nucleic-acid quality, process traceability, and testing readiness.

DIAGNOSTIC QUESTION

Can the laboratory readily identify the information required for reliable molecular testing?

PILLAR 2

Biomarker & Assay Reliability Score (BARS™)

OBJECTIVE

Identify analytical vulnerabilities before they significantly affect testing reliability.

MATURITY

Reactive → Risk-Informed → Predictive

QUICK WIN

Detect recurring assay and quality-control patterns requiring investigation.

MEASURES

Molecular signal quality, assay sensitivity, amplification consistency, controls, instrument outputs, reproducibility, and repeat-testing trends.

DIAGNOSTIC QUESTION

Can emerging assay-performance problems be identified before they result in significant testing failures?

— 03 THE ONCODIAX™ SOLUTION — PILLAR DETAIL

PILLAR 3

Molecular Workflow Optimization Matrix (MWOM™)

OBJECTIVE

Improve molecular testing efficiency and resource utilization.

MATURITY

Fragmented → Coordinated → Optimized

QUICK WIN

Identify avoidable delays, repeat processes, and resource constraints.

MEASURES

Specimen processing, extraction workflows, testing queues, instrument utilization, equipment downtime, repeat testing, and turnaround time.

DIAGNOSTIC QUESTION

Where are workflow bottlenecks reducing testing capacity or delaying analysis?

PILLAR 4

Diagnostic Performance & Reliability Index (DPRI™)

OBJECTIVE

Connect laboratory improvements with measurable diagnostic performance.

MATURITY

Activity-Based → Performance-Driven → Intelligent Improvement

QUICK WIN

Connect quality interventions with existing performance indicators.

MEASURES

Assay reproducibility, quality-control performance, repeat testing, nonconformance, instrument reliability, workflow consistency, and turnaround time.

DIAGNOSTIC QUESTION

Are laboratory improvements producing measurable improvements in molecular diagnostic performance?

04 HOW ONCODIAX™ WORKS

Diagnostic & scoring.

ONCODIAX™ analyzes specimen-quality data, assay information, quality controls, instrument outputs, workflow records, repeat testing, nonconformances, and laboratory-performance indicators.

The resulting **Molecular Diagnostic Readiness Score (MDRS™)** provides a composite assessment across the four ONCODIAX™ pillars.

PERFORMANCE IS CLASSIFIED AS



CORE ANALYTICS

Specimen Acceptance Rate

$\text{Acceptable specimens} \div \text{total specimens} \times 100$

First-Pass Testing Rate

$\text{Tests completed without repeat analysis} \div \text{total tests} \times 100$

Assay Reliability Rate

$\text{Valid assay runs} \div \text{total assay runs} \times 100$

Workflow Efficiency

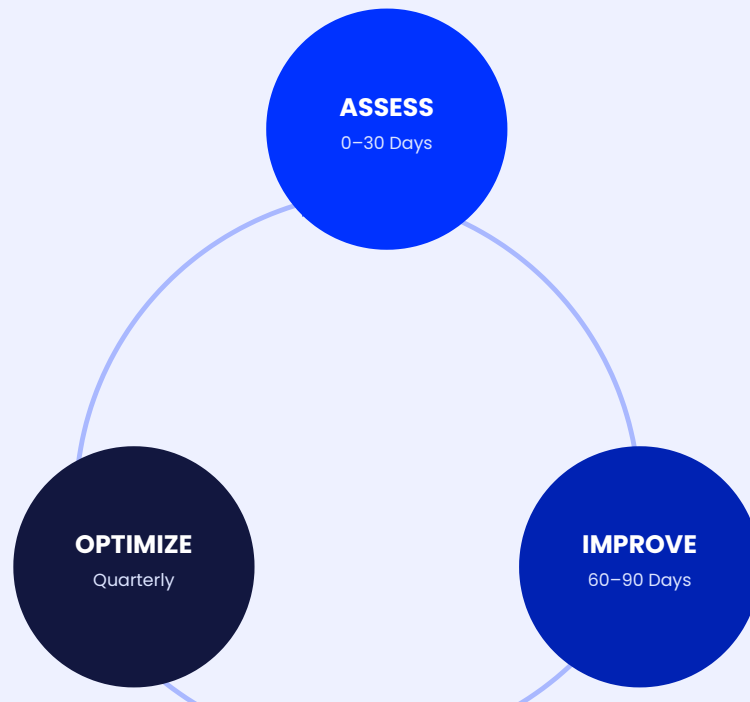
$\text{Value-added testing time} \div \text{total processing time} \times 100$

Nonconformance Improvement

$(\text{Baseline rate} - \text{current rate}) \div \text{baseline rate} \times 100$

05 IMPLEMENTATION ROADMAP

A continuous improvement cycle.



Collect baseline data, map molecular workflows, identify quality gaps, and establish the MDRS™.

Implement priority interventions involving specimen quality, assay reliability, laboratory workflow, and performance.

Review KPIs, reassess MDRS™, identify remaining gaps, and establish new improvement priorities.

06 OPERATING MODEL

Laboratory Leadership: Strategic oversight.

Molecular Laboratory Team: Testing, specimen processing, and workflow implementation.

Laboratory Informatics: Data integration, analytics, dashboards, and security.

ONCODIAX™ Lead: Assessment, scoring, implementation, and reporting.

Quality Team: Quality indicators, nonconformances, and corrective actions.

ONCODIAX™ can be reviewed weekly for operational issues, monthly for performance, and quarterly for maturity reassessment.

07 MOLECULAR ONCOLOGY APPLICATIONS

One architecture, five diagnostic contexts.



Personalized ctDNA Testing — Supports specimen-quality, assay-reliability, workflow, and performance assessment within personalized cancer-monitoring environments.

Colorectal Cancer Screening — Applicable to mutation detection, methylation analysis, PCR-based testing, and multi-biomarker workflows.

Clinical Research — Supports assay readiness, reproducibility, workflow assessment, and translation of molecular research into diagnostic applications.

Multi-Cancer Early Detection — Supports complex molecular and biomarker workflows involving methylation, protein biomarkers, and high-throughput testing.

Genomic Oncology — Supports PCR, qPCR, NGS, and related technologies used to identify cancer-associated molecular alterations.

08 ONCODIAX™ WEBAPP

Digitizing assessment, scoring, and analytics.

The ONCODIAX™ WebApp digitizes framework assessment, scoring, analytics, and improvement monitoring.

CORE MODULES

Assessment Studio

Four-pillar assessment and MDRS™ scoring.

Molecular Intelligence Dashboard

Specimen and molecular-data visibility.

Reliability Engine

Assay and analytical-risk assessment.

Workflow Optimizer

Laboratory workflow analytics.

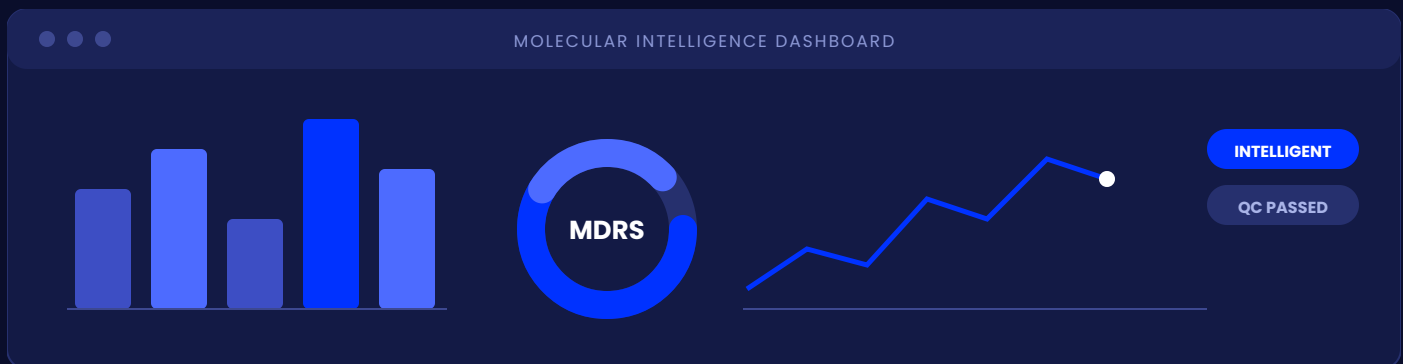
Performance Hub

Quality and diagnostic-performance monitoring.

Evidence Vault

Validation and implementation records.

The platform can incorporate role-based access, encryption, audit trails, controlled reporting, and appropriate data de-identification.



— 09 AI INTEGRATION

Supporting — not replacing — scientific judgment.

Future ONCODIAX™ capabilities may include:

- ◆ Assay anomaly detection.
- ◆ Quality-control pattern recognition.
- ◆ Predictive workflow analysis.
- ◆ Instrument-performance monitoring.
- ◆ Molecular performance analytics.

AI is intended to support not replace validated assays, laboratory protocols, regulatory requirements, or professional scientific judgment.

— 10 KEY DIFFERENTIATORS

ONCODIAX™ combines:

**MOLECULAR DIAGNOSTIC
INTELLIGENCE**

BIOMARKER AND ASSAY RELIABILITY

**LABORATORY WORKFLOW
OPTIMIZATION**

**DIAGNOSTIC-PERFORMANCE
MEASUREMENT**

TECHNOLOGY-ENABLED ASSESSMENT

CONTINUOUS QUALITY IMPROVEMENT

Rather than evaluating these areas independently, ONCODIAX™ connects them within **one molecular oncology diagnostic architecture.**

— 11 ENGAGEMENT MODEL

From baseline to continuous improvement.

1

Assess

Baseline diagnostic assessment and MDRS™ scoring.

2

Enable

Implement priority quality, assay, workflow, and performance interventions.

3

Operate

Reassess performance, benchmark results, and continuously improve.

— 12 ROADMAP

PHASE 1

Framework development, scoring methodology, research, and pilot validation.

PHASE 2

ONCODIAX™ WebApp deployment and external implementation.

PHASE 3

AI-enabled analytics, expanded validation, and molecular diagnostic benchmarking.

— 13 CREATOR

Rukayat Olayemi Oni, MSc, MB(ASCP)



Rukayat Olayemi Oni, MSc, MB(ASCP) is an ASCP-certified Technologist in Molecular Biology whose experience spans personalized ctDNA testing, Multi-Cancer Early Detection, colorectal cancer screening, genomic testing, cancer research, laboratory quality systems, and molecular workflow improvement.

Her professional experience at **Natera**, **Exact Sciences**, **Lagos State University Teaching Hospital**, and **Georgia State University** has exposed her to molecular technologies including PCR, RT-qPCR, QuARTS, NGS, methylation-based biomarkers, DNA extraction and amplification, immunoassays, assay quality control, and regulated diagnostic workflows.

This combination of molecular oncology diagnostics, scientific research, laboratory quality, and process improvement forms the professional foundation for ONCODIAX™.

PROFESSIONAL EXPERIENCE

Natera**Exact Sciences****Lagos State University Teaching Hospital****Georgia State University**

MOLECULAR TECHNOLOGIES

PCR

RT-QPCR

QUARTS

NGS

METHYLATION-BASED BIOMARKERS

DNA EXTRACTION & AMPLIFICATION

IMMUNOASSAYS

ASSAY QC

— 14 CALL TO ACTION

Assess. Predict. Optimize. Improve.

Use the **ONCODIAX™ Molecular Diagnostic Intelligence Assessment** to identify diagnostic gaps, establish a **Molecular Diagnostic Readiness Score (MDRS™)**, strengthen assay reliability, optimize laboratory workflows, and build a measurable improvement roadmap.

ONCODIAX™

Oncology Molecular Diagnostic Intelligence & Optimization Framework

Turning Molecular Diagnostic Data into Reliable Intelligence for Smarter,
More Precise Cancer Diagnostics.