ctDNA Monitoring for Uveal Melanoma

Your Clinical Trial. Our Diagnostic Engine.

Oncular™

Uveal melanoma (UM) is the most common primary intraocular malignancy in adults and carries a high risk of metastatic progression, with up to 50% of patients developing metastatic disease.[1] Imaging-based surveillance may not fully capture molecular disease activity or early treatment response.[2] Circulating tumor DNA (ctDNA) provides a quantitative approach to assessing tumor burden and molecular response, requiring only a routine blood draw. Oncular™ focuses on the detection of recurrent uveal melanoma driver mutations in GNAQ and GNA11.[3*]

TEST DESCRIPTION

Specimen Types:
Plasma

Methodology:
Digital PCR (dPCR)

Results:
Quantitative MAF (%)

Turnaround Time:
3-5 Days

REGULATORY & QUALITY FRAMEWORK

Multi-Accredited
CLIA-certified & CAP-accredited

Audit-Ready Documentation
IQ/OQ/PQ, validation summaries, QC trends

Secure & Compliant
Data workflows meet HIPAA & sponsor compliance standards

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CLINICAL TRIAL CAPABILITIES

Patient Characterization & Stratification

- Molecular assessment of uveal melanoma disease burden using ctDNA
- Supports baseline characterization and exploratory stratification analyses across surveillance, treatment, and progression phases in clinical studies

Therapeutic Response & Longitudinal Disease Monitoring

- Quantitative ctDNA dynamics correlated with tumor burden and liver involvement
- Molecular changes associated with treatment response and likelihood of recurrence
- Supports pharmacodynamic and response assessment across therapies
- Enables longitudinal monitoring to complement imaging-based endpoints

Central Laboratory Services

- High-throughput diagnostic platforms for scalability
- 3-5 day result delivery
- Dedicated project managers aligned with sponsor timelines

WHY CHOOSE US?

Physician-Guided Expertise

- Physician-guided assay and diagnostic development, accelerating solutions with clinically-driven innovation

Research & Development Support

- Collaborative R&D expertise with academic and industry partners for novel test development
- Support scientific publications and presentations

Data Integration & Sponsor Connectivity

- API, portal, and system integrations
- Custom reporting aligned to protocol requirements
- Clean, analyzable datasets ready for biostatistical review

Global Trial Support

- Harmonized collection kits
- International logistics and customs coordination
- Cold chain management for long-distance transport

Regulatory Expertise & Audit Readiness

- Proven experience with FDA submissions and approval
- Audit-ready processes aligned with your needs

*GNA11 and GNAQ were developed and their performance characteristics determined by TrilliumBiO. They have not been cleared or approved by the U.S. Food and Drug Administration. References: 1. Damato B, et al. Uveal melanoma: epidemiology, metastatic risk, and outcomes. British Journal of Cancer, 2022. https://www.nature.com/articles/s41416-022-01723-8. 2. Rodrigues T et al. Prospective ctDNA monitoring identifies molecular response and predicts survival with Tebentafusp. Nat. Communications, 2024. https://www.nature.com/articles/s41467-024-53145-0. 3. Bustamante P et al. Circulating tumor DNA tracking through driver mutations as a liquid biopsy–based biomarker for uveal melanoma. JECCR, 2021. https://link.springer.com/article/10.1186/s13046-021-01984-w.

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