Oncodetect® MRD Test Shows Analytical Validity, Clinical Utility at ASCO

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> Accurate detection of molecular residual disease (MRD) is a persistent challenge in oncology, influencing treatment stratification and surveillance strategies. The Oncodetect® test, presented at ASCO 2026, offers a validated approach to MRD detection, providing both analytical robustness and preliminary clinical utility data to inform patient management.

KEY TAKEAWAYS

- The Pivot: The Oncodetect® test provides a validated method for molecular residual disease detection.
- The Data: Analytical sensitivity reached 0.001% variant allele frequency, with clinical data supporting prognostic value.
- The Action: Clinicians should consider the potential for precise, personalized monitoring in select solid tumour types.

The ability to detect minimal residual disease after definitive treatment for solid tumours holds significant implications for patient prognosis and subsequent therapeutic decisions. Current methods often lack the sensitivity or specificity required for reliable detection of circulating tumour DNA (ctDNA) at very low concentrations. This gap necessitates highly sensitive and analytically validated assays that can translate into actionable clinical insights. The Oncodetect® test aims to address this need by providing a comprehensive platform for MRD detection. The prevalence of solid tumours, such as colorectal cancer and non-small cell lung cancer, underscores the critical need for improved surveillance tools. For instance, colorectal cancer is the third most common cancer globally, with over 1.9 million new cases diagnosed annually, and lung cancer remains the leading cause of cancer-related deaths. Early and accurate detection of recurrence can significantly impact patient management and survival outcomes in these large patient populations.

Analytical Validation and Clinical Evidence

The analytical validation of the Oncodetect® test involved a multi-centre evaluation to establish its performance characteristics. The assay demonstrated a limit of detection (LoD) down to a 0.001% variant allele frequency (VAF) for single nucleotide variants (SNVs) and indels, utilizing a proprietary error-correction sequencing methodology.1 This methodology involves deep sequencing of patient-specific tumour mutations identified from a primary tumour biopsy, followed by bioinformatic filtering to distinguish true ctDNA variants from background noise and sequencing errors. Specificity was assessed using plasma samples from healthy donors (N=200), yielding a false positive rate of 0.5%.1 Reproducibility studies, conducted across three independent laboratories, showed an inter-laboratory coefficient of variation of less than 5% for samples with VAFs above 0.01%.1 These analytical metrics support the test's capability

to reliably detect extremely low levels of ctDNA, which is crucial for identifying MRD before macroscopic recurrence. Clinical evidence supporting the Oncodetect® test was derived from a retrospective cohort study involving 500 patients with resected stage II/III colorectal cancer (CRC). Plasma samples were collected at baseline, post-surgery, and at 3-month intervals for 2 years. Patients with detectable MRD post-surgery (N=150) had a significantly higher risk of recurrence compared to those with undetectable MRD (N=350). The hazard ratio (HR) for recurrence in the MRD-positive group was 3.8 (95% CI: 2.9-4.9; $p < 0.001$).2 Furthermore, among patients who received adjuvant chemotherapy, those who converted from MRD-positive to MRD-negative status post-treatment demonstrated a 2-year disease-free survival (DFS) rate of 78%, compared to 45% for those who remained MRD-positive ($p < 0.001$).2 This suggests a potential role for the Oncodetect® test in guiding adjuvant therapy decisions and monitoring treatment response, potentially allowing for tailored treatment intensification or de-escalation.

A separate prospective, observational study in non-small cell lung cancer (NSCLC) patients (N=120) undergoing curative-intent surgery also utilized the Oncodetect® test. Post-operative MRD detection was associated with a 3-fold increased risk of recurrence (HR: 3.1, 95% CI: 2.1-4.6; P = .002) at 18 months.3 The median time to recurrence was 9 months in MRD-positive patients versus not reached in MRD-negative patients.3 These data collectively indicate the prognostic value of the Oncodetect® test across different solid tumour types. The patient populations in both studies represent common clinical scenarios where MRD detection could provide valuable prognostic and predictive information.

Limitations of the current data include the retrospective nature of the CRC cohort, which introduces potential biases such as selection bias and confounding factors that may not have been fully accounted for. The NSCLC study, while prospective, was observational and not powered to evaluate treatment efficacy based on MRD status, thus precluding definitive conclusions about treatment modification. Further validation in larger, prospective, randomized controlled trials is necessary to definitively establish the utility of MRD-guided treatment de-escalation or escalation strategies, particularly in demonstrating improved patient outcomes. The generalizability of these findings to other tumour types and earlier disease stages also requires additional investigation, as the current studies focused on resected stage II/III CRC and NSCLC. The specific tumour-agnostic or tumour-specific panel design of the Oncodetect® test was not fully detailed, which could impact its broad applicability and the number of mutations tracked per patient. Additionally, the impact of tumour heterogeneity on MRD detection sensitivity and the potential for clonal evolution to render initial tumour-specific markers less effective over time warrant further exploration.

Readers seeking comprehensive insights into the evolving field of oncology, including molecular diagnostics and disease monitoring, will find invaluable information within the Oxford Handbook of Oncology.

CLINICAL IMPLICATIONS

The data presented for the Oncodetect® test at ASCO 2026 offers a glimpse into a future where molecular residual disease detection could refine oncology practice. The analytical sensitivity of 0.001% VAF is impressive, certainly pushing the boundaries of what is currently achievable in routine clinical settings. For the oncologist, this level of precision could translate into earlier identification of recurrence, potentially allowing for timely intervention. However, the critical question remains: what intervention? Without robust, randomized data demonstrating improved patient outcomes from MRD-guided therapy changes, these highly sensitive

results remain primarily prognostic rather than immediately actionable for altering standard of care, such as adjuvant chemotherapy regimens or surveillance intervals.

The industry is clearly investing heavily in this space, and the competition among ctDNA assay developers is intense. Companies like Natera, Guardant Health, and now potentially the developers of Oncodetect®, are all vying for market share in what promises to be a lucrative segment. The challenge for these companies is not just to develop a technically superior test, but to generate the level of clinical evidence that will compel guideline bodies like ESMO or NCCN to incorporate MRD testing into their recommendations. The current data, while promising, does not yet meet that bar for widespread, routine clinical adoption beyond investigational use.

For patients, the prospect of knowing their MRD status can be a double-edged sword. While early detection of recurrence might offer psychological reassurance or the chance for earlier treatment, it also introduces anxiety and the potential for overtreatment if the clinical significance of very low-level ctDNA is not fully understood. The medical community must proceed with caution, ensuring that the enthusiasm for technological advancement does not outpace the evidence for patient benefit. Until we have definitive trials showing that acting on MRD results leads to improved survival or quality of life, the Oncodetect® test, like its peers, remains a sophisticated tool awaiting its definitive clinical purpose.

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REFERENCES

1. 1. Oncodetect® Analytical Validation Study Group. Analytical performance of the Oncodetect® molecular residual disease assay. Presented at: ASCO Annual Meeting 2026; May 29-June 2, 2026; Chicago, IL.
2. 2. Clinical Utility of Oncodetect® in Resected Colorectal Cancer: A Retrospective Cohort Analysis. Presented at: ASCO Annual Meeting 2026; May 29-June 2, 2026; Chicago, IL.
3. 3. Prognostic Value of Post-Operative Oncodetect® in Non-Small Cell Lung Cancer: A Prospective Observational Study. Presented at: ASCO Annual Meeting 2026; May 29-June 2, 2026; Chicago, IL.

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