

Myriad's Precise MRD™ Test Shows Ultra-Sensitive Detection at ASCO 2026

Written by The Life Science Feed Editorial Team · Published 31 May 2026 · Edited by Mara Voss

Accurate detection of molecular residual disease (MRD) is critical for identifying cancer patients at high risk of recurrence and for guiding adjuvant therapy decisions. The Precise MRD™ test, presented at ASCO 2026, demonstrates ultra-sensitive detection capabilities, offering a potential advancement in personalised oncology management.

KEY TAKEAWAYS

- **The Pivot:** The Precise MRD™ test offers enhanced sensitivity for detecting circulating tumour DNA (ctDNA) compared to previous methods.
- **The Data:** The test achieved a sensitivity of 10⁻⁶ variant allele frequency (VAF), detecting ctDNA at levels previously undetectable.
- **The Action:** Clinicians may consider integrating ultra-sensitive MRD testing into surveillance protocols for certain solid tumours to inform adjuvant treatment strategies.

Molecular residual disease (MRD) refers to the presence of microscopic tumour cells or circulating tumour DNA (ctDNA) remaining after definitive treatment for cancer. Its detection is a prognostic indicator, with patients positive for MRD having a higher risk of disease recurrence. Current methods for MRD detection vary in sensitivity and specificity, leading to a clinical need for more precise tools to guide post-treatment surveillance and adjuvant therapy decisions. The ability to detect ctDNA at very low concentrations is paramount for identifying minimal residual disease early, potentially before clinical or radiological evidence of recurrence emerges. This early detection allows for timely intervention, which may improve patient outcomes. The Precise MRD™ test aims to address this need by offering ultra-sensitive detection capabilities.

What the study did

The Precise MRD™ test is a tumour-informed, personalised assay designed to detect ctDNA. The test begins by sequencing a patient's primary tumour tissue to identify a unique set of somatic mutations. Up to 16 patient-specific single nucleotide variants (SNVs) are selected for tracking in subsequent plasma samples. This personalised approach enhances the specificity of ctDNA detection by focusing on mutations known to be present in the patient's tumour. Plasma samples are then analysed using a proprietary high-throughput sequencing platform. The methodology employs deep sequencing with a reported analytical sensitivity of 10⁻⁶ variant allele frequency (VAF), meaning it can detect one mutant allele among one million wild-type alleles. This level of sensitivity is achieved through advanced bioinformatics algorithms and error correction techniques that distinguish true ctDNA signals from background noise and sequencing

artefacts. The study presented at ASCO 2026 evaluated the performance of the Precise MRD™ test in a cohort of patients with various solid tumours who had undergone curative-intent surgery. The primary objective was to assess the analytical sensitivity and clinical utility of the test in detecting MRD post-treatment. Secondary objectives included correlating MRD status with recurrence-free survival (RFS) and overall survival (OS).

The study enrolled N=450 patients across 12 academic centres. Patients were followed for a median of 24 months. Plasma samples were collected at baseline (pre-surgery), 4-6 weeks post-surgery, and every 3 months thereafter for 2 years. The Precise MRD™ test successfully identified ctDNA in 78% of patients with stage II/III colorectal cancer post-surgery who subsequently experienced recurrence, with a median lead time of 8.5 months prior to radiological recurrence. In patients with early-stage non-small cell lung cancer (NSCLC), a positive MRD status at 4-6 weeks post-surgery was associated with a significantly higher risk of recurrence (Hazard Ratio [HR] = 4.2, 95% Confidence Interval [CI]: 2.8-6.3, P 0.001). Conversely, patients who remained MRD-negative had a 2-year RFS rate of 88% compared to 35% for MRD-positive patients. The test demonstrated a specificity of 95%, with a low false-positive rate. The ultra-sensitive detection capability allowed for the identification of ctDNA in patients where conventional imaging showed no evidence of disease. The median turnaround time for results was 7-10 days from sample receipt.

While the Precise MRD™ test shows promising results, several limitations warrant consideration. The study cohort, while substantial, included a heterogeneous mix of solid tumours, and the performance may vary across different cancer types. Further validation in larger, prospective, tumour-specific cohorts is needed to establish its utility in specific clinical contexts. The cost-effectiveness of routine ultra-sensitive MRD testing also requires evaluation, particularly in healthcare systems with resource constraints. The clinical actionability of a positive MRD result, especially in the absence of established adjuvant therapies for all MRD-positive settings, remains an area of ongoing research. While the lead time to recurrence is significant, the optimal therapeutic intervention for MRD-positive patients is not yet fully defined. Future studies should focus on randomised controlled trials investigating MRD-guided adjuvant therapy escalation or de-escalation strategies. The impact of different tumour mutation burdens and clonal haematopoiesis on test performance also requires further investigation to refine the interpretation of results.

Readers seeking comprehensive insights into the evolving landscape of cancer diagnosis and treatment will find the Oxford Handbook of Oncology an invaluable resource.

CLINICAL IMPLICATIONS

The introduction of an ultra-sensitive MRD test like Myriad's Precise MRD™ could significantly alter post-treatment surveillance protocols. For clinicians, the ability to detect ctDNA at such low levels offers a more granular understanding of a patient's true disease status. This precision could move us closer to truly personalised oncology, allowing for earlier intervention in patients who are genuinely at high risk of recurrence, rather than relying solely on less sensitive methods or broad population statistics. The challenge, however, lies in translating this enhanced detection into actionable clinical decisions, particularly when the evidence for specific MRD-guided therapies is still evolving.

Patients stand to benefit from the potential for earlier detection of recurrence, which could lead to improved outcomes if effective interventions are available. However, the psychological impact of a positive MRD result in an otherwise asymptomatic patient, especially when the next steps are unclear, cannot be overlooked. It

places a greater burden on clinicians to communicate uncertainty and manage patient expectations carefully. Furthermore, the cost implications for healthcare systems and the accessibility of such advanced testing will be critical factors in its widespread adoption, potentially widening disparities in care if not managed thoughtfully. From an industry perspective, Myriad's entry into the ultra-sensitive MRD space intensifies competition and drives innovation in liquid biopsy technologies. This push for greater sensitivity and specificity is beneficial, but the market will demand robust clinical utility data, not just analytical performance. Payers will scrutinise the evidence for improved patient outcomes and cost-effectiveness before widespread reimbursement. The integration of such tests into national guidelines, like those from ESMO or NCCN, will be the ultimate arbiter of their clinical impact, and that requires more than just impressive analytical numbers; it requires clear, evidence-based pathways for intervention.

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