

PredicineBEACON™

CLIA Validated Tissue-Agnostic, Personalized, Actionable MRD Assay

Sensitive Minimal Residual Disease (MRD) detection not limited by baseline tissue sample availability

50

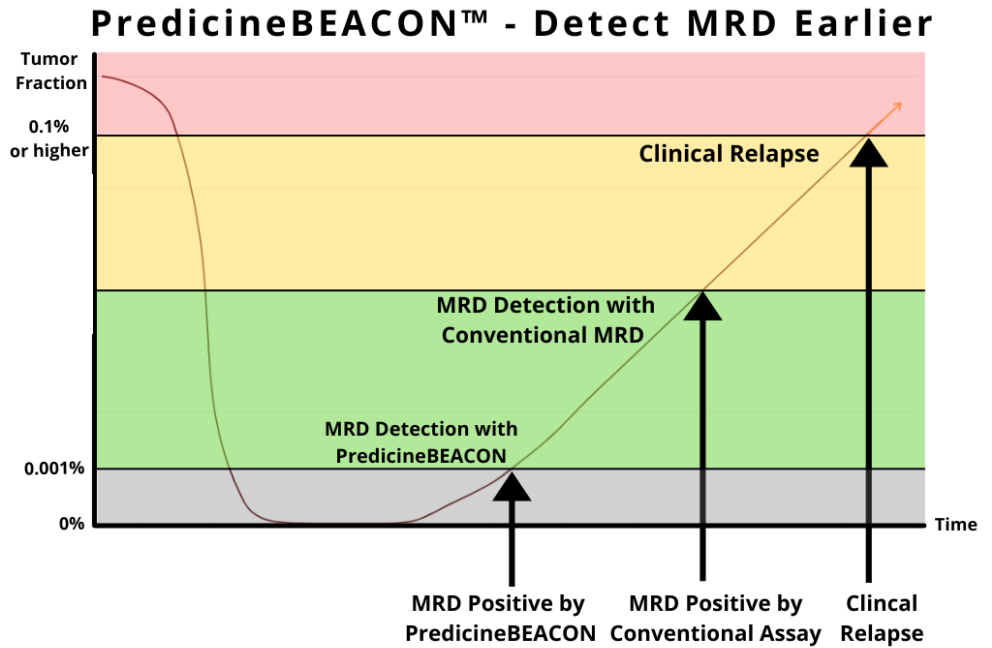
Up to 50 personalized mutations

500

Actionable and hotspot mutations tracked

≥0.001%

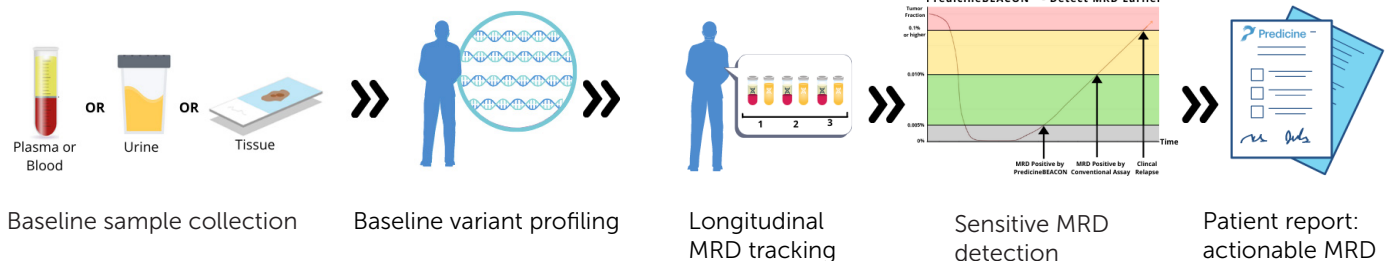
Tumor Fraction



Methods and Reporting

- Flexibility in baseline profiling: tissue or liquid biopsy (including blood, plasma, and urine)
- Sensitive MRD detection: limit of detection as low as 0.001% tumor fraction, when personalized panel contains 50 mutations
- Includes genome-wide copy number changes including copy number reductions
- Longitudinally tracks up to 50 personalized mutations
- Includes analysis of 500 actionable and hotspot mutations

Workflow



PredicineBEACON™ addresses the challenges faced by conventional MRD assays

- Tissue agnostic solution: Baseline analysis can be obtained via blood, urine, or tissue
- High sensitivity: Ability to identify alterations missed by less sensitive assays
- Multidimensional: Detects changes including single nucleotide variants (SNVs), copy number variations (CNVs), and DNA rearrangements
- Actionable MRD result: Upon recurrence, actionable and hotspot mutation analysis may provide clinically relevant information to guide treatment decisions

Product Details



Baseline Profiling
Blood, Urine, or Tissue



Multi-Dimensional MRD Detection
SNVs, CNVs, & DNA rearrangements



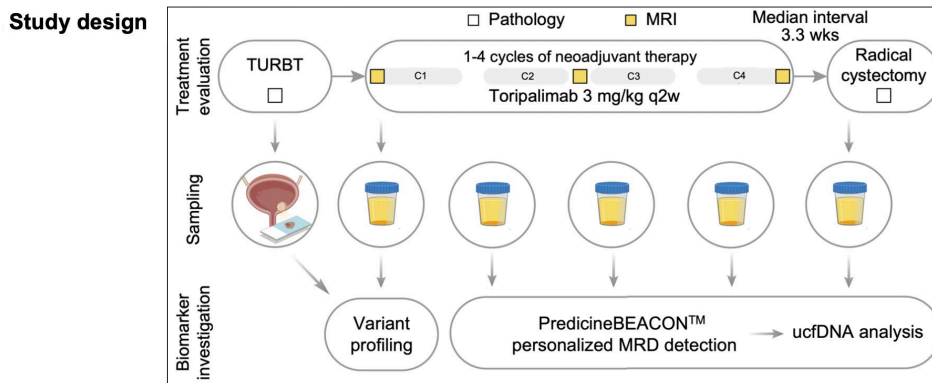
High Sensitivity
0.001% Tumor Fraction
Limit of Detection



Actionable MRD
500 Actionable and Hotspot
Mutations

Case Study: Tissue-free, urine-informed MRD in neoadjuvant MIBC

Longitudinal personalized urinary tumor DNA analysis in muscle invasive bladder cancer (MIBC) from neoadjuvant immunotherapy trial RJBLC-I2N003¹



	ypCR										non-ypCR									
Pathology	[Green]										[Red]									
RECIST1.1	[Green]										[Red]									
MRD @ baseline	+																			
MRD @ post PD1	-		+																	

Pathology
■ responder
■ non-responder

RECIST1.1
● responder
● non-responder

Conclusion:

PredicineBEACON™ urine-based MRD biomarker assessment identified MRD-positive patients that achieved pathological complete response (pCR), demonstrating the potential clinical utility of longitudinal personalized urinary tumor DNA (utDNA) analysis to complement existing trial endpoints. This study suggests that a urine-based MRD test could be used to identify MRD-negative MIBC patients after neoadjuvant therapy who could potentially avoid radical cystectomy.

¹Zhang, et al. Longitudinal personalized urinary tumor DNA analysis in muscle-invasive bladder cancer from the neoadjuvant immunotherapy trial RJBLC-IN003. Journal of Clinical Oncology. Volume 40, Issue 6 supplemental. 2022.