

PredicineBEACON™

Tissue-Agnostic, Personalized, Actionable MRD Assay

Ultra-sensitive Minimal Residual Disease (MRD) detection that is not limited by baseline tissue sample availability

50

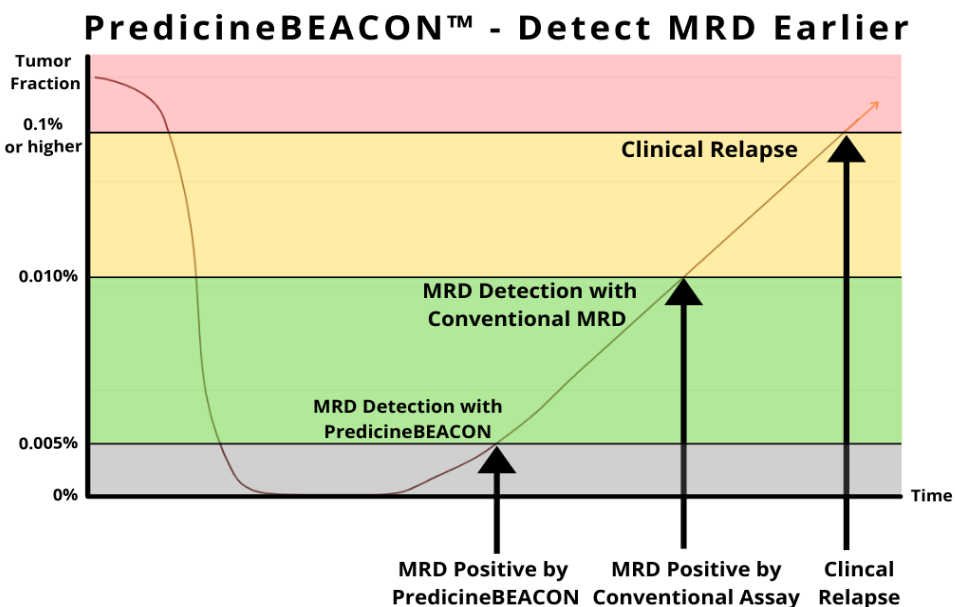
Up to 50 mutations personalized panel

500

Actionable and hotspot mutations tracked

≥0.005%

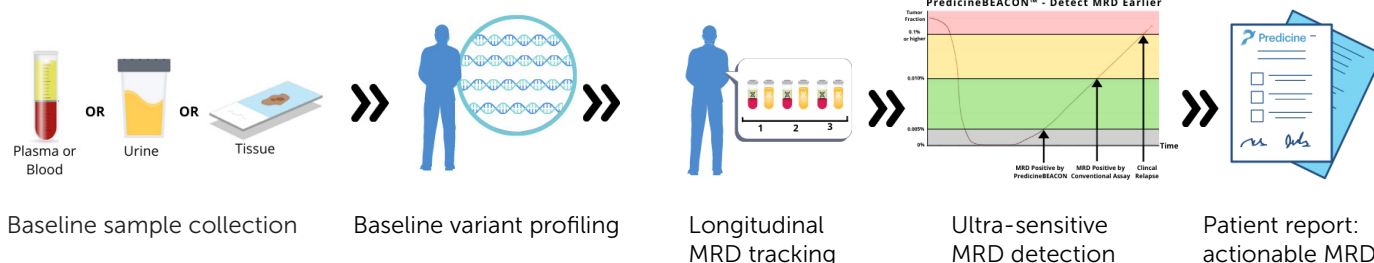
Limit of detection (LOD)



Methods and Reporting

- Flexibility in baseline profiling - tissue or liquid biopsy (including blood, plasma, and urine)
- Ultra-sensitive in MRD detection - down to 0.005% LOD
- 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
- Ultra-sensitive: Ability to identify alterations missed by less sensitive assays
- Multidimensional: Detects all types of DNA changes, including fusions and copy number changes
- Actionable MRD result: Upon recurrence, actionable and hotspot mutation analysis will provide clinically relevant information to guide treatment decisions

Product Details



Baseline Profiling
Blood, Urine, or Tissue



Multi-Dimensional MRD Detection
Mutations, Fusions, and Copy Number Changes



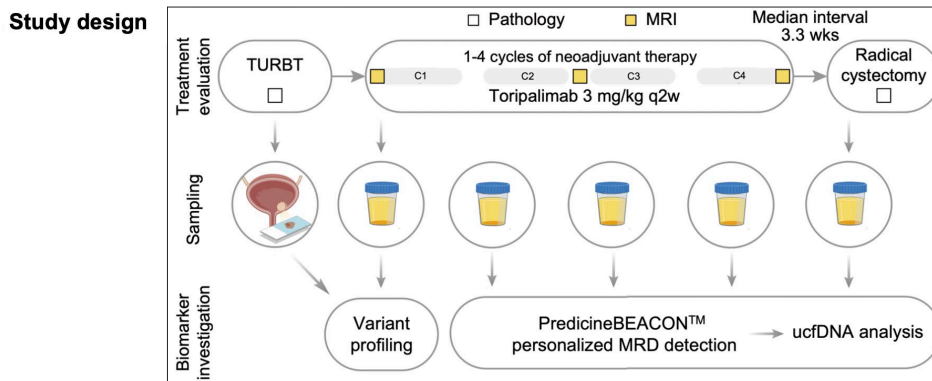
Ultra Sensitivity
0.005% Limit of Detection



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 from neoadjuvant immunotherapy trial RJBLC-12N003¹



Pathology	ypCR										non-ypCR									
RECIST1.1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
MRD @ baseline	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
MRD @ post PD1	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion:

PredicineBEACON™ urine-based MRD biomarker assessment identified MRD-positive patients that achieved pCR, demonstrating the potential clinical utility of longitudinal personalized 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.

Neoadjuvant administration of PD-1 blockade followed by surgical resection may represent a feasible and efficacious approach to treat MIBC.

¹https://www.predicine.com/wp-content/uploads/2022/02/ASCOGU2022_I2N003_Abstract_552-FINAL-UPLOAD.pdf