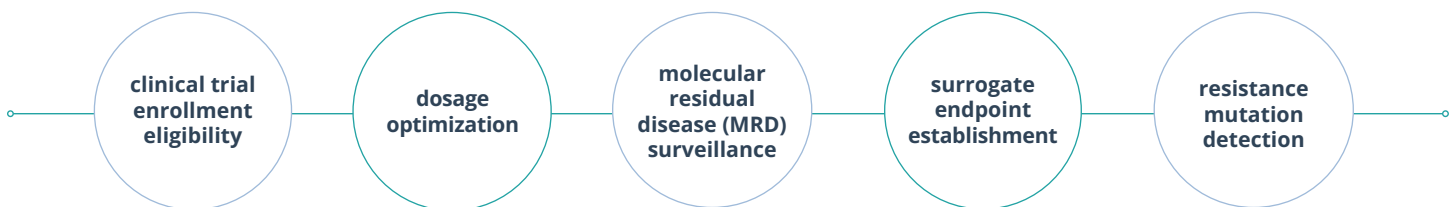


cfDNA/cfRNA Testing and Monitoring

PLATFORM + CAPABILITIES

Accurate, sensitive, and fast nucleic acid quantification is critical for robust clinical advancement. With an ultra-low limit of detection, absolute quantification abilities, rapid turn-around time, and low cost, allow Droplet Digital™ PCR (ddPCR™) to easily expose developmental clues via single time point testing or longitudinal monitoring of cell free DNA/RNA mutations.

Leverage ddPCR assays using either blood or tissue samples to accomplish:



Biodesix is deeply experienced in ddPCR through a long-standing relationship with Bio-Rad Laboratories, and our own development of five on-market clinical tests and over 200 research and development assays.

Many assays are pre-validated and readily available (NYS CLEP approved):

- KRAS: G12C, G12D, G12V
- EGFR: L858R, del19, del19 multiplex*, Uncommon Variants (G719A, G719C, G719S, S758I and L861Q) multiplex*, T790M, C797S multiplex (discriminating)
- ALK fusions
- ROS1
- RET
- BRAF: V600E

Examples of assays that have been functionally tested in our lab:

- Microsatellite instability (MSI)
- ESR1 multiplex*
- KRAS multiplex*
- AKT1: E17K
- YAP/TAZ fusions
- EGFR exon 20 INDELs
- HER2 exon 20 INDELs
- GNAQ/GNA11

*Multiplexed assays screen for the presence or absence of multiple mutations in a single sample. They can be discriminating or non-discriminating.

Thousands of assays are available in the Bio-Rad catalog and may be validated in the Biodesix laboratory. For target assays that are not readily available for clinical use, Biodesix facilitates validation. Additionally, Biodesix is able to design and develop custom assays for novel mutation targets. Please connect with our team for more information.

ASSAY PERFORMANCE SPECIFICATIONS (LIQUID BIOPSY)^{1,2}

ASSAY	LOD (%MVF)	SENSITIVITY, %	SPECIFICITY, %	CONCORDANCE, %
KRAS (G12C, G12D, G12V)	0.02	87.9	100	96.0
EGFR sensitizing (del19, L858R)	0.02	95.9	100	98.8
EGFR (T790M)	0.02	86.7	100	96.4
EGFR Uncommon Variants (G719A, G719C, G719S, S758I and L861Q)	0.02	100	100	100
ALK	0.02	~85	100	~92
ROS1	0.02	100	100	100
RET	0.02	100	100	100

Technology Specifications

QX200™ Droplet Digital™ PCR System:

- Dynamic range: 5 orders of magnitude
- Starting sample size: 20µl
- Capacity: 1-96 samples, 8 samples/cartridge
- **2 detection channels, allowing up to 4 discernible targets: FAM(EvaGreen), HEX(VIC)**
- Precision: ±10%

QX600™ Droplet Digital™ PCR System:

- Dynamic range: 5 orders of magnitude
- Starting sample size: 20µl
- Capacity: 1-96 samples, 8 samples/cartridge
- **6 detection channels, allowing up to 12 discernible targets: FAM, HEX, Cy5, Cy5.5, ROX, ATTO 590**
- Precision: ±10%

REFERENCES

1. Development and Clinical Utility of a Blood-Based Test Service for the Rapid Identification of Actionable Mutations in Non-Small Cell Lung Carcinoma, Mellert, Hestia et al. The Journal of Molecular Diagnostics, Volume 19, Issue 3, 404 – 416.
2. Reese, JM et al. Validation of the EGFR Uncommon Variants Multiplex ddPCR Assay for Blood-Based Testing in NSCLC. Poster presented at: The Association for Molecular Pathology Annual Meeting; November 7th, 2019; Baltimore, MD.



FOR MORE
INFORMATION