BIOPHARMA services

biodesix®

At Biodesix, our vision is to be a trusted partner that the world relies on for data-driven diagnostic solutions in lung disease and beyond.

Complex diseases require broad and deep exploration into each patient's unique biology. One technology and one 'omic' cannot accurately paint the complete picture to answer critical clinical questions in patient care.

PROMPT DIAGNOSIS

RIGHT TREATMENT

DETECT PROGRESSION

We are focused on deciphering the complexity of disease through our multiomic approach and proprietary artificial intelligence (AI) techniques by providing biopharmaceutical companies with end-to-end diagnostic services for drug development and commercialization programs.

BIOMARKER RESEARCH

ASSAY DEVELOPMENT

CLINICAL TRIAL TESTING

COMPANION DIAGNOSTICS

WHY WORK WITH BIODESIX

We apply a unique diagnostic approach to precision medicine.

MULTIOMIC APPROACH

Our core belief is that no single technology will answer all diagnostic research questions that we encounter. We employ genomic, proteomic, and other technologies to uncover information about the genetic make-up of disease as well as the patient's immune response.

PROPRIETARY AI PLATFORM

We leverage our proprietary Diagnostic Cortex® AI platform for unbiased research to help answer specific clinical questions. Our platform has a high success rate for both discovery and blinded, independent validation of clinically relevant diagnostics.

OPERATIONAL EFFICIENCY

We recognize that time and resources are valuable, which is why we strive to customize each project based on our customers needs. We are a flexible, reliable, timely, and an easy to work with diagnostic partner.

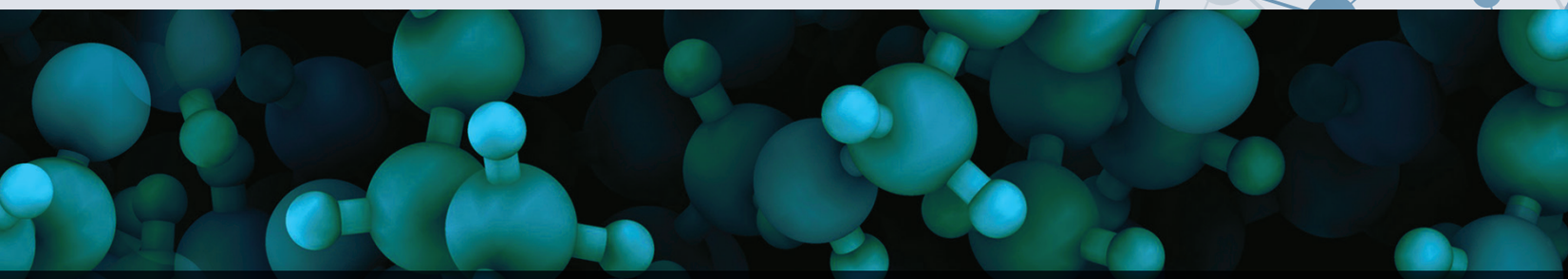
QUALITY-DRIVEN

We operate two, highly qualified clinical laboratories with certifications including CAP, CLIA, COLA, NYS CLEP, and ISO 13485. Additionally, we conduct testing with FDA EUA methods.

ESTABLISHED COMMERCIAL ENTITY

We have seven diagnostics on-market for patients with lung disease. We have a product development process that is compliant with global Quality Management Systems. Additionally, we have a commercial infrastructure necessary to support drug co-development and commercialization.

A market leader in the field of clinical proteomics



OUR PROTEOMIC TECHNOLOGIES

MALDI-ToF Mass Spectrometry

- Measures the relative abundance of a multitude of intact proteins and peptide fragments with our proprietary DeepMALDI® methods to produce highly sensitive, stable, and reproducible data.[1]
- A minimum of ~5-10µL plasma or serum.
- Best suited for unbiased research of immune response proteins to facilitate treatment selection and disease state monitoring.

PASEF timsToF Mass Spectrometry

- The next generation of shotgun proteomics allows for the analysis of hundreds of samples, with minimal sample input, high-speed sequencing, and uncompromised proteomic depth.
- A minimum of 200ng of protein from serum, plasma or tissue.
- Best suited for both unbiased and hypothesis-based proteomic research as well as MRM/PRM/SRM LC-MS studies.

Seer Proteograph™ Technology

- Rapid interrogation of the proteome utilizing a nanoparticle technology that allows for a deep, unbiased, and scalable analysis of proteins.[2]
- A minimum of 50 µL of plasma per nanoparticle.
- Best suited for unbiased proteomic research with the ability to identify up to 2,000 proteins and 15,000 peptides.[2]

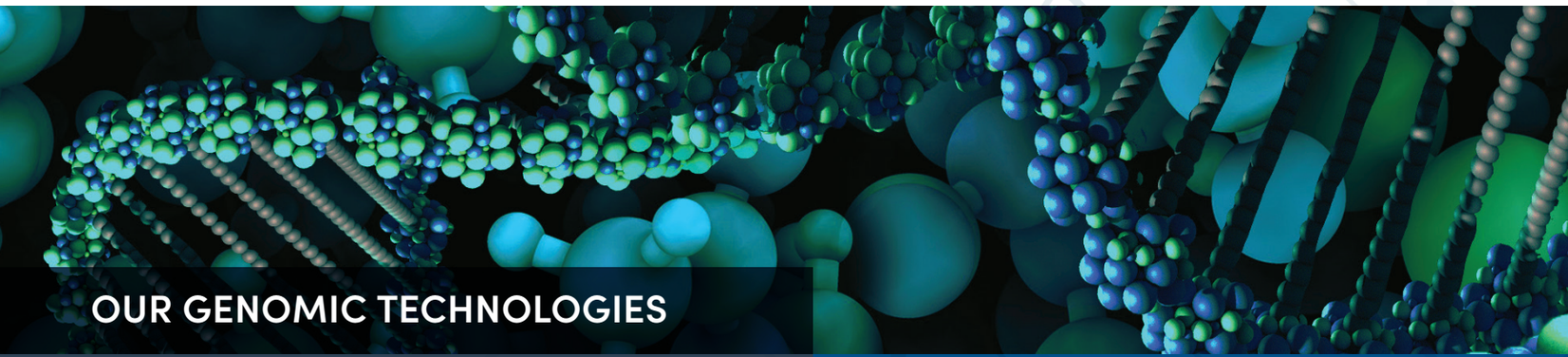
Multiple Reaction Monitoring (MRM) **Liquid Chromatography Mass Spectrometry** (LC-MS)

- Simultaneous quantitation of highly-multiplexed sets of target peptides from a single analysis with high sensitivity and specificity.
- A minimum of ~10µL plasma (exact quantities are protein-dependent).
- Best suited for detection of abundance changes in a large set of target peptides which can be used in disease detection, diagnosis, and treatment.

Enzyme Linked Immunosorbent Assay (ELISA)

- Targeted qualitative and quantitative assays for detection of proteins, antibodies or other biomarkers by exploiting the interaction between ligand and receptor. Is known for its sensitivity, reproducibility, and rapid results.
- Plasma, serum and other sample types; typically requires very low volumes (5-100µL).
- Best suited for immune response interpretation and monitoring by measuring levels of antibodies, quantifying target-engagement, and more.

Experts in blood-based genomic analyses



OUR GENOMIC TECHNOLOGIES

Droplet Digital PCR (ddPCR)

- Ultra-sensitive PCR that provides absolute nucleic acid quantitation for low-abundance targets, proven to be a highly sensitive, cost-effective, and fast technology.[3,4]
- Plasma (as little as 250µL per assay), FFPE tissue (as little as 2-3, 5 micron sections), preclinical models (cell-lines, murine models, etc.), and other sample types upon request.
- Best suited when there are limited variants of interest for monitoring the presence of residual disease, therapy response or resistance, and gene expression.
- Also well suited for cell and gene therapy applications including quantifying transgenes or edits at single cell resolution, monitoring viral vector shedding and bio-distribution, and assessing precise AAV viral titer measurements.[5]

Next Generation Sequencing (NGS)

- A high throughput, massively parallel sequencing technique that is highly sensitive and scalable to meet specific targeted or broad coverage requirements.[6]
- Plasma (as little as 20ng of cfDNA), PBMC (as low as 10ng DNA/RNA input), fresh frozen and FFPE (as little as 2-3, 4 micron sections), preclinical models (cell-lines, murine models, etc.), and other sample types upon request.
- Best suited when there are many variants of interest and is primarily used for treatment selection based on rare variant identification, tumor mutation burden status, and immune response analyses.

BIOMARKER RESEARCH CAPABILITIES

Employing both hypothesis-based and unbiased approaches to translational research

We combine molecular information derived from our technologies with our proprietary and classical analytics capabilities for biomarker research initiatives.

HYPOTHESIS-BASED RESEARCH

A classical approach for biomarker research where a single marker or panel of hypothesized molecular markers is selected for correlative analysis based on known biological mechanisms.

We can support hypothesis-based research with the following technologies:

- Protein panels with ELISA, MRM/PRM/SRM LC-MS or timsToF mass spectrometry
- Antibody assays with ELISA
- DNA and RNA-targeted assays with ddPCR or NGS

UNBIASED RESEARCH

A research approach that uses the power of big data to uncover biological insights not previously hypothesized. The Diagnostic Cortex platform is a proprietary AI methodology that incorporates extensively validated computational techniques and deep learning methods to enable unbiased discovery of diagnostics that can be further developed to perform reproducibly in the clinical testing environment.[7]

We can support unbiased research with the following technologies and our proprietary AI platform:

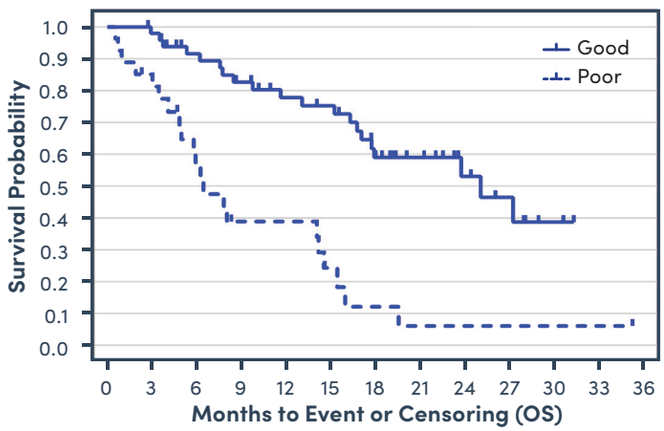
- Whole mass spectral analysis with MALDI-ToF and timsToF mass spectrometry
- Shotgun proteomics with timsToF mass spectrometry
- Whole genome and transcriptome sequencing with NGS
- Seer Proteograph Technology™

CASE STUDY WITH GENENTECH

Discovered a predictive test through unbiased research methods

An evaluation of immune-related markers in the circulating proteome and their association with atezolizumab efficacy in patients with 2L+ NSCLC.[8]

UNBIASED CLASSIFIER DISCOVERY



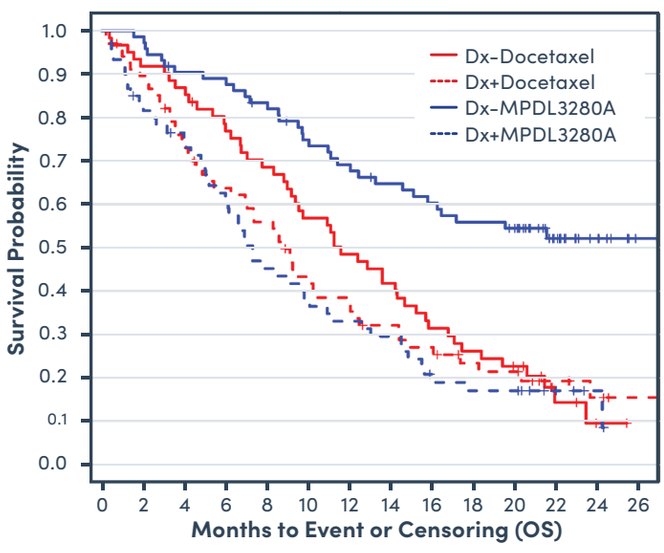
77 NSCLC patients treated with atezolizumab (NCT01375842)

	mOS (95% CI)
Good	25.1 months (17.1-undefined)
Poor	6.4 months (4.8-14.2)

Hazard Ratio (Good vs. Poor) = 0.23 (0.12-0.44)

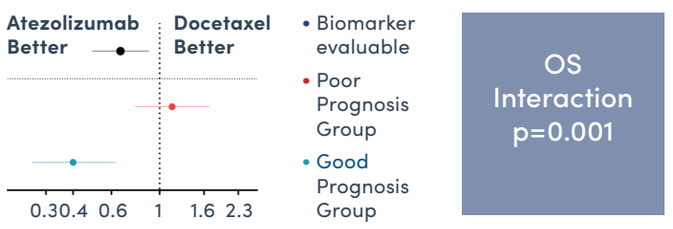
Source: Kowanetz, M et al. (*SITC* 2018 Poster)

BLINDED INDEPENDENT VALIDATION



270 NSCLC patients treated with atezolizumab or docetaxel in the POPLAR study (NCT01903993)

	OS HR (95% CI): doc vs. atezo	p-value
Good	0.40 (0.26-0.63)	<0.001
Poor	1.14 (0.77-1.69)	0.500



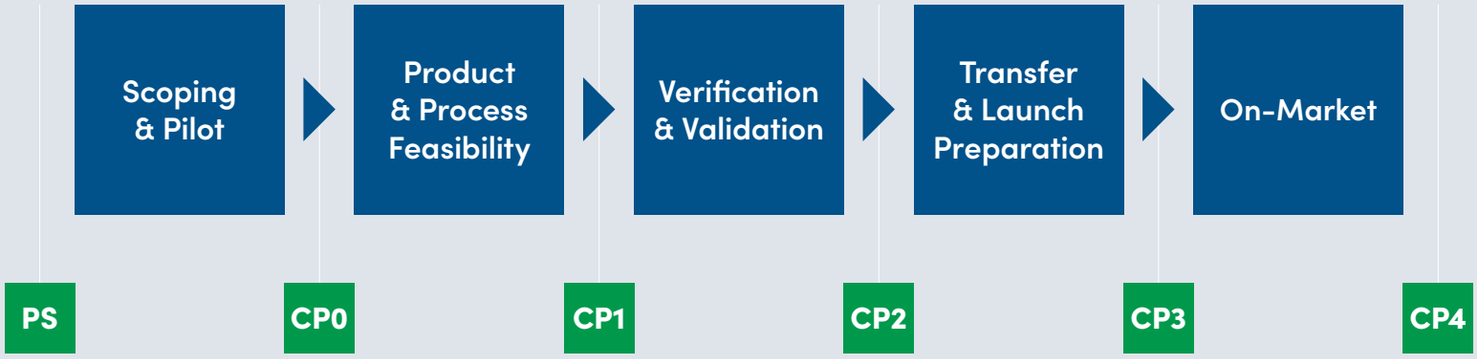
Source: Kowanetz, M et al. (*SITC* 2018 Poster)

Test classification was not associated with PD-L1 expression (IC p=0.88, TC p=0.98)

ASSAY DEVELOPMENT

Providing fit-for-purpose assay and product development services

We are capable of customizing our development process to fit the needs of our partners ranging from basic research assay development through to companion diagnostic product commercialization. Our complete process is inclusive of assay design, development, regulatory lab transfer, management within FDA-registrational requirements, and commercialization.



We are proud to have two, highly qualified and centralized clinical diagnostic testing laboratories in the United States.

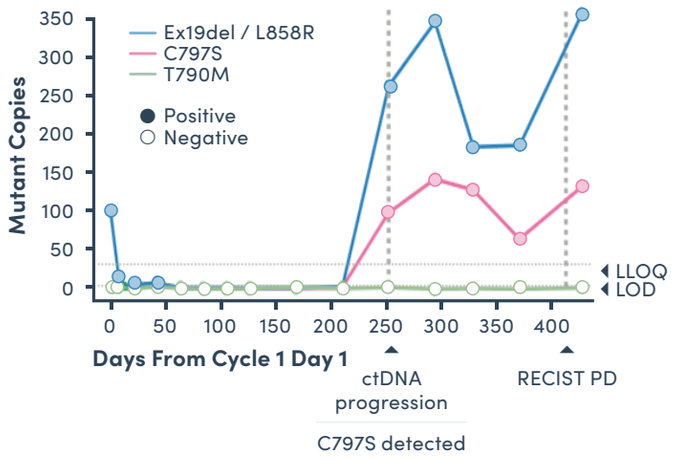
- ☑ CAP-accredited
- ☑ CLIA-certified
- ☑ COLA-accredited
- ☑ NYS CLEP-approved: Soluble Tumor Markers, Diagnostic Immunology, Molecular & Cellular Tumor Markers and Virology
- ☑ ISO 13485-certified

CASE STUDY WITH ASTRAZENECA

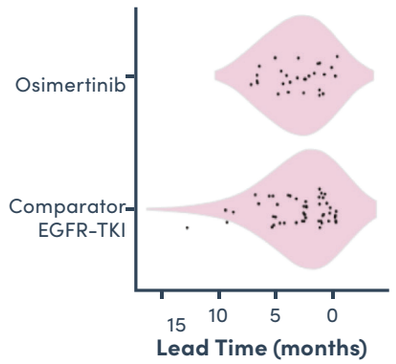
Developed multiple NYS CLEP-approved ddPCR assays for clinical trial sample testing

We developed the EGFR del19, EGFR T790M and EGFR C797S ddPCR tests in our CLIA-certified laboratory and obtained NYS CLEP approval for clinical sample testing by AstraZeneca. In one analysis of 122 patients with advanced NSCLC from the FLAURA clinical trial (NCT02296125), we tested longitudinal plasma samples to monitor for the clearance or emergence of EGFR sensitizing or resistance mutations.[9]

Osimertinib - Patient Case Study



ctDNA Progression Lead Time



ctDNA progression equivalent to* or earlier than RECIST PD, n (%)	Median lead time (IQR), months
28/42 (67)	3.0 (1.4–4.9)
52/80 (65)	2.6 (1.0–5.0)

- ctDNA progression preceded or co-occurred with RECIST Progressive Disease (PD) in 66% of patients with similar median lead times across both treatment arms (osimertinib and comparator EGFR TKI).
- Median ctDNA progression lead time was 2.7 months.
- Based on this analysis, longitudinal ctDNA monitoring has the potential to detect early signs of PD and acquired resistance mutations in advance of PD.

Source: Ahn, et al. (*WCLC* 2017 Poster)

CLINICAL TRIAL TESTING

Broad in-house capabilities for prospective clinical trial testing

We have extensive experience with preparing for and executing on diagnostic testing for prospective clinical trials. Our in-house capabilities support the following activities:

PROJECT & DATA MANAGEMENT

LAB MANUAL & SAMPLE COLLECTION PROTOCOLS

SAMPLE COLLECTION KIT DEVELOPMENT & TRACKING

IT SYSTEM SUPPORT

We have four ongoing, prospective clinical studies in support of our diagnostics on-market and in our pipeline. Additionally, we have a growing sample and data biobank of over 140,000 that is available for data mining, product feasibility and validation, and assay development.

LUNG NODULE DIAGNOSIS & MANAGEMENT

ALTITUDE (NCT04171492)

- 2,000 patient enrollment goal
- Incidental lung nodules (8-30mm)
- Nodify XL2® Proteomic Classifier

ORACLE (NCT03766958)

- 1,000 patient enrollment goal
- Newly identified lung nodules (8-30mm)
- Nodify XL2® and Nodify CDT® Proteomic Classifier tests

LUNG CANCER TREATMENT GUIDANCE & MONITORING

INSIGHT (NCT03289780)

- 5,000 patient enrollment goal
- All stages NSCLC
- VeriStrat, GeneStrat & other pipeline tests

BEACON-Lung (NCT04676386)

- 390 patient enrollment goal
- Stage IIIC/IV NSCLC, PD-L1≥50%
- Proteomic Classifier for Immunotherapy

COMMERCIALIZATION

Bringing diagnostics to market for patients with lung disease

We are an established commercial entity with nationally-based sales and medical affairs teams, outstanding customer service, and expertise in high-value diagnostic reimbursement.

OUR ON-MARKET DIAGNOSTICS

nodify lung® NODULE RISK ASSESSMENT

LUNG NODULE DIAGNOSIS:

Nodify Lung® testing consists of two blood-based proteomic tests (the Nodify CDT™ & Nodify XL2® tests) to help physicians reclassify risk of lung cancer and aid in stratifying patients into distinct nodule management pathways: intervention or surveillance.[10,11]

biodesix lung® REFLEX

LUNG CANCER TREATMENT GUIDANCE:

Biodesix Lung Reflex® testing consists of the GeneStrat® tumor profiling test and the VeriStrat® immune profiling test to provide physicians with timely molecular results to facilitate treatment decisions for patients with non-small cell lung cancer.[3,4,12,13]

biodesix WorkSafe™ COVID-19 TESTING PROGRAM

COVID-19 DIAGNOSTIC TESTING:

The Biodesix WorkSafe™ COVID-19 Testing Program consists of three FDA emergency use authorized tests: the Bio-Rad SARS-CoV-2 ddPCR molecular test for active infection, and the cPass™ SARS-CoV-2 Neutralization Antibody Test for neutralizing antibodies.[14,15,16]

OUR PIPELINE DIAGNOSTICS

RISK OF RECURRENCE TEST

We discovered a blood-based proteomic classifier that can help identify patients with stage 1 NSCLC pre-surgery who are at a higher risk of recurrence and may benefit from adjuvant therapy.

PRIMARY IMMUNE RESPONSE TEST

We discovered a blood-based proteomic classifier that selects patients with advanced NSCLC for immunotherapy regimens independent of, and complementary to PD-L1 expression status.[17]

BIOPHARMAservices

Biodesix provides biopharmaceutical companies with end-to-end diagnostic services inclusive of biomarker research, assay development, clinical trial testing, and commercialization of companion diagnostics.

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Please contact the Biodesix Business Development team to learn more about how Biodesix can support your diagnostic needs.

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