

Companion Diagnostics

Discover. Create. Accelerate.

Together Transforming Companion Diagnostics.

biotechne®

Your Partner from Discovery to Commercialization

Bio-Techne offers precision medicine services

to pharma partners spanning the continuum from biomarker discovery to post-market commercialization of companion diagnostic products. Our platform-agnostic approach to biomarker discovery and clinical trial assay development, paired with clinical trial sample testing readiness at our CLIA labs and international regulatory expertise allows us to offer customizable solutions so that a pharma partner can improve their drug's likelihood of success and deliver novel treatments to the patients most likely to benefit, faster.

1

Biomarker Discovery

Our unique approach leverages platform-independent, multi-omic solutions and spans liquid biopsy to tissue extraction.

- Bioinformatics expertise to discover signatures with clinical utility
- Specialized expertise as a leader in exosome-based R&D
- Proprietary chemistries for difficult repetitive and other structural variants
- Innovative technologies for spatial biology and automated protein-based discovery and detection

2

Clinical Trial Assay Development and Support

Our 20+ years of experience has led to the development of multiple US-IVD cleared products.

- Development of biomarker signatures and validation for clinical use
- Diagnostic systems comprising reagents and assay analysis software built for the most stringent regulatory requirements
- Development and commercialization of robust products with high quality, reduced complexity, and optimized workflow

3

Regulatory and Reimbursement Expertise

We have an established track record of regulatory engagement with FDA and international agencies.

- Multiple CLIA labs sites to support global testing needs
- Experienced regulatory team to support a broad range of submissions, including 510(k) and PMA
- Products registered in countries around the world

4

International Distribution of Kitted Products

We have 11 kits on the market, including products with FDA clearance, CE-IVD, Australian and Korean labeling.

- Commercial reach in over 50 countries, over 200 labs are active users
- cGMP manufacturing in our FDA registered ISO 13485 facility
- Technical support and scientific affairs team
- International field application support

Dynamic Expertise

Spanning Platforms, Sample Types, Analytes, and Diseases

Multi-omic Approaches

We offer genomic and proteomic solutions across a broad range of discovery platforms. From NGS and PCR to automated protein based discovery and detection, we offer the breadth and depth of platforms and R&D expertise needed for comprehensive biomarker discovery programs.

Widely available platforms to suit clinical needs



Specialized Capabilities in Exosomes

Exosomes are a treasure trove of biomarkers to enable:

- Analysis of DNA, RNA, and/or Protein
- Profile the Entire Transcriptome with RNAseq
- Complete Clinical Workflow Solution with cGMP Capabilities

Ability to Unlock Challenging Regions of DNA

We have an extensive history in the development of ultra-high sensitive assays for regions of DNA that are challenging to sequence.

Complex Molecular Testing Made Simple

We design diagnostic tests that are robust, information rich, and easy-to-use for clinical diagnostic labs.

Proprietary Chemistries & Standardized Reagents



Automated Interpretation Software

Fit-To-Purpose Diagnostic Instrument Options

We have the ability to unlock biomarkers in a wide variety of biofluids and solid tissues.

Expertise Spanning Oncology and Beyond

Bio-Techne has partnered with pharma companies to provide precision medicine solutions across a wide range of disease areas, such as:

- Neurodegenerative diseases
- Cancer and immuno-oncology
- Rare and complex genetic diseases
- Autoimmune diseases
- Genitourinary diseases
- Infectious diseases

Demonstrated Track Record of Success



**2,700+ Assays for
570+ Targets**



**50+ Clinical Tests
built for Pharma**



**15+ CLIA
Tests**



**20+ Year History of
Pharma Partnerships**

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Where Science Intersects Innovation™

Bio-Techne® | R&D Systems™ Novus Biologicals™ Tocris Bioscience™ ProteinSimple™ ACD™ ExosomeDx™ Asuragen®



Contact Us

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