bio-techne®

Partnership from Discovery to Commercialization

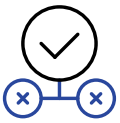
Bio-Techne Clinical Services

Clinical Biomarker Discovery

- NGS/RNASeq (long and short)
- Exosome and EV isolation
- High-multiplex proteomics (Olink®)

Clinical Assay Development

- ctDNA and exoRNA Liquid Biopsy
- PCR/CE, qPCR/dPCR
- Long read sequencing (Oxford Nanopore®)
- Jess™*/Leo™* Simple Western™, Ella™ Automated ELISA, Luminex®, plate-based ELISA.



Fit-For-Purpose Clinical Assay Validation

Support for:

- PK/PD, Target Engagement, Mechanism of Action
- Prognostic or Predictive Biomarker
- Patient Stratification, Patient Selection
- Dose Selection, Surrogate, Primary and Secondary Endpoints

Regulatory Expertise

- CAP accredited CLIA laboratories for CTA testing/ patient enrollment
- Quality Management System certified to ISO 13485:2016, MDSAP and IVDR (EU 2017/746)
- Global IVD registrations including Australia, Canada, Europe, Korea, the United Kingdom, and the United States
- 3rd party IVD platform partnered submissions

Manufacturing and Commercialization

- Kitted Solutions for global distribution
- Experience for market access and reimbursement strategies
- Commercial footprint and channels for global reach

Contact Us

www.bio-techne.com/diagnostics/companion-diagnostics

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