bio-techne®

Your Trusted Partner

for Exosome-based Biomarker Development

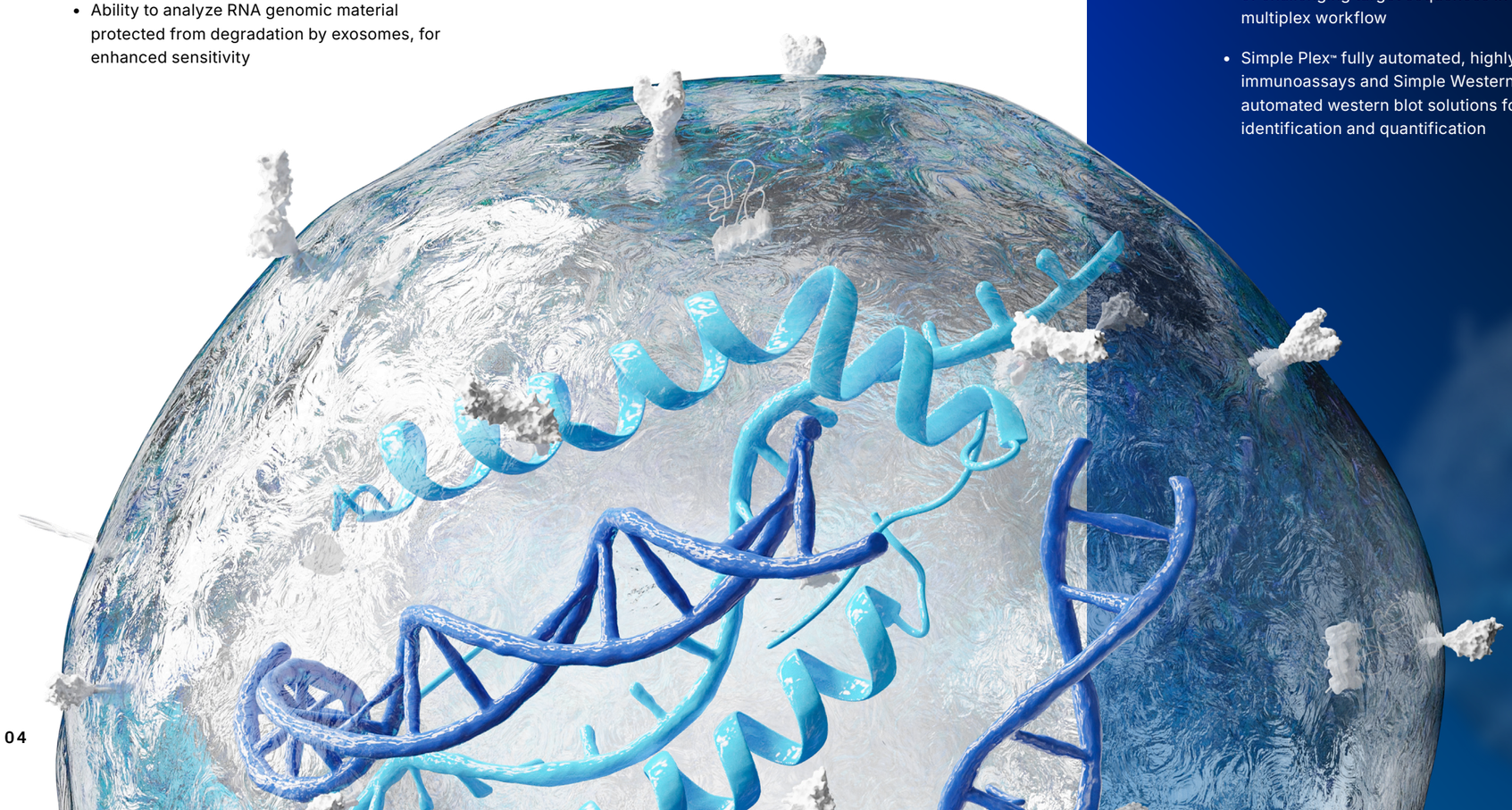
Tap into our expertise to accelerate your drug development and approval process.

Bio-Techne can support your drug development efforts with:

- Accessing relevant biomarkers in challenging biological compartments, such as the brain, with exosome isolation and analysis
- Accurately characterizing and stratifying patient populations
- Developing CLIA lab-based and/or kitted assays for clinical trials, CDx, and beyond
- Working with regulatory agencies to ensure that the approval of your targeted therapy is paired with a cleared assay ready for clinical use

Why Exosomes?

- Exosomes are secreted by all living cells into all biofluids and provide a snapshot of biological processes
- Allows for testing with a stable sample, amenable to frozen storage from CSF, plasma, or other biofluids
- Enables multiomic analysis of gene expression biomarkers (e.g. RNA-seq, splice variants, fusions), DNA (e.g. methylation, mutations), and proteins
- Exosome collection is non-invasive, so you can use biofluids for dynamic readouts rather than tissue-only biopsies
- Ability to analyze RNA genomic material protected from degradation by exosomes, for enhanced sensitivity



Bio-Techne CDx Services

Our team supports biomarker discovery and validation, as well as development of centralized CLIA lab-based testing and broadly deployable lab-ready kits, to support clinical trials, companion diagnostics, and more.

Our expertise includes isolation and analysis of molecular contents of exosomes to identify biomarker signatures that help stratify patient populations. We can combine exosomal RNA, DNA, and protein with more traditional biomarker sources, such as cell-free DNA, to increase assay sensitivity.

We are platform agnostic with broad capabilities including the entire Bio-Techne portfolio:

- Quantidex® and Amplidex® technologies that deliver sensitive, reproducible RNA and DNA amplification of challenging target sequences in a streamlined, multiplex workflow
- Simple Plex™ fully automated, highly sensitive immunoassays and Simple Western™ fully automated western blot solutions for protein identification and quantification
- Quantikine® ELISAs, the most trusted ELISA kits for over 30 years, master calibrated for superior quality and reproducibility
- Olink® Target 96 Gold-certified proteomic service provider and supplier of Luminex® multiplex assays for biomarker discovery

Bio-Techne takes validated biomarker signatures and builds robust diagnostic solutions – including reagents, controls, and automated software – to deliver high-quality, accurate results in any clinical laboratory.

We will develop your assay using current best practices to ensure it is ready for regulatory review whether through 510(k), PMA, or other type of submission.

- cGMP manufacturing in FDA-registered ISO 13485 facilities
- Our own CLIA-certified, CAP-accredited laboratories
- Direct experience with FDA, IVDR, and MDSAP certification with products registered in countries around the globe

CD

Case Study: *ESR1* Mutation Monitoring

The development of *ESR1* mutations in breast cancer patients undergoing endocrine treatment can be an early indicator of treatment resistance. Routinely monitoring these mutations via liquid biopsy samples is essential for ensuring that patients receive optimal care.

Bio-Techne has developed a qPCR-based test that combines analysis of circulating cell-free DNA with exosomal RNA for a highly sensitive assay capable of detecting even extremely rare *ESR1* mutations.

This project resulted in a fast, efficient, and sensitive exosome-based *ESR1* qPCR mutation assay* panel for use with liquid biopsy specimens. It uses Bio-Techne's proprietary ExoLution™ Plus* method to co-enrich exosomal RNA and cell-free DNA. The kitted product has been demonstrated to run robustly and consistently across users and can now be implemented in a variety of research laboratory settings.

FIGURE 1.

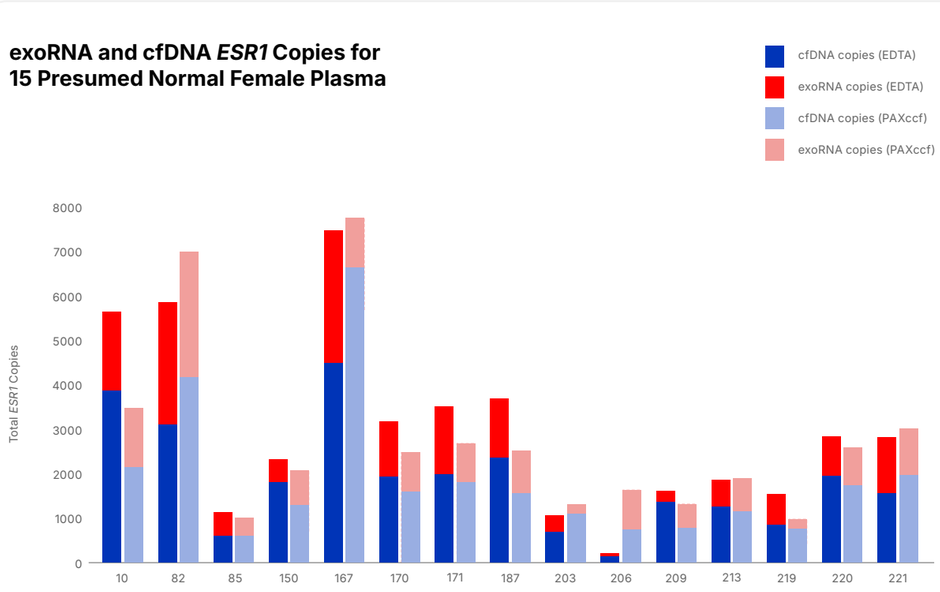


FIGURE 1. DISTRIBUTION OF EXOSOMAL RNA AND CELL-FREE DNA ACROSS 15 PRESUMED-NORMAL FEMALE SAMPLES SHOWS THE ABILITY TO DETECT MORE COPIES OF ESR1 MUTATIONS.

Fifteen presumed normal female plasma samples (2 mL) underwent exoRNA and cfDNA co-isolation from EDTA tubes processed within 4 hours and PAXgene Blood ccfDNA Tubes (PAXccf) processed within 3 days. RT with enzyme was completed on half the eluate and RT without enzyme (no RT) was completed on the other half. ddPCR was utilized to determine *ESR1* copies. *ESR1* copies calculated from the RT with enzyme reaction would include product from both exoRNA and cfDNA (labeled as total *ESR1* copies) whereas the *ESR1* copies calculated from the no RT reaction would include product only from the cfDNA portion, shown in blue. The calculated RNA fraction is shown in red. PAXccf had no marked impact on yields, showing the stability tube can preserve material up to 3 days post blood draw. Percentage of exoRNA contribution did vary by sample, with a median value of 38.1%.

Source: Statt S, et al. "A kit targeting detection of ESR1 mutations from circulating exosomal RNA and cell-free DNA supports longitudinal studies into endocrine therapy resistance in a broadly accessible RT-qPCR format." Poster #4626 presented at AACR 2024.

bio-techne®

Global Developer, Manufacturer, and Supplier of High-Quality Reagents, Analytical Instruments, and Precision Diagnostics.

INCLUDES R&D Systems™ Novus Biologicals™ Tocris Bioscience™ ProteinSimple™ ACD™ ExosomeDx™ Asuragen® Lunaphore™

Contact Us

Global bd.exosomedx@bio-techne.com

5000-176 Rev A
6605065732