



IVD Immunoassay

CDMO Capabilities Overview

Comprehensive Immunoassay Development & Manufacturing

Clinical laboratories and OEM partners rely on Bio-Techne Diagnostics for robust assay design, stable calibrators and controls, and secure global reagent supply across major immunoassay platforms, including chemiluminescence, turbidimetry, high-sensitivity formats, and point-of-care systems. Our CDMO offering spans the full IVD lifecycle—from biomaterials sourcing and assay design to validation, filling, packaging, and on-market support—executed under ISO 13485 and GMP quality systems.






Phase-Gated Immunoassay Development Framework

A disciplined, auditable development framework with clear objectives, entry/exit criteria, defined deliverables, and quantitative KPIs govern decisions and de-risk downstream validation and manufacturing.

Extensive Biomaterial & Assay Content Capabilities

Access to peer-reviewed immunoassay content demonstrating performance and biological relevance on Bio-Techne platforms (Ella, Quantikine ELISA) provide high-confidence, ready-to-translate candidates for OEM menu expansion. Large catalogs of monoclonal/polyclonal antibodies including non-catalog sister clones, custom and recombinant antibody engineering capabilities, custom recombinant proteins, and stabilized liquid controls enables faster assay design and reduced sourcing risk.



-  **0. Research & Planning**
-  **1. Initial Optimization**
-  **2. Feasibility**
-  **3. Development**
-  **4. Transfer to Operations**
-  **5. Commercial Launch to Customer**

Regulatory-Aligned Analytical Validation

Validation programs aligned with CLSI, CLIA, and FDA expectations cover sensitivity, accuracy, interference, specificity, precision, linearity, recovery, detection capability, and stability studies. Bio-Techne's programs are structured to mirror CLSI EP-series and immunoassay guidance, supporting RUO-to-IVD/IVDR translation and regulatory submissions.

Quality & Regulatory Compliance

Bio-Techne Diagnostics operates under ISO 13485, FDA GMP and EU IVDR requirements supporting a variety of market authorization pathways including the EU, US, Canada, Brazil, Australia and more. Documentation includes comprehensive Certificates of Analysis, full traceability, and audit-ready QA/QC packages across all sites.

Scaled Manufacturing & Global Supply Chain

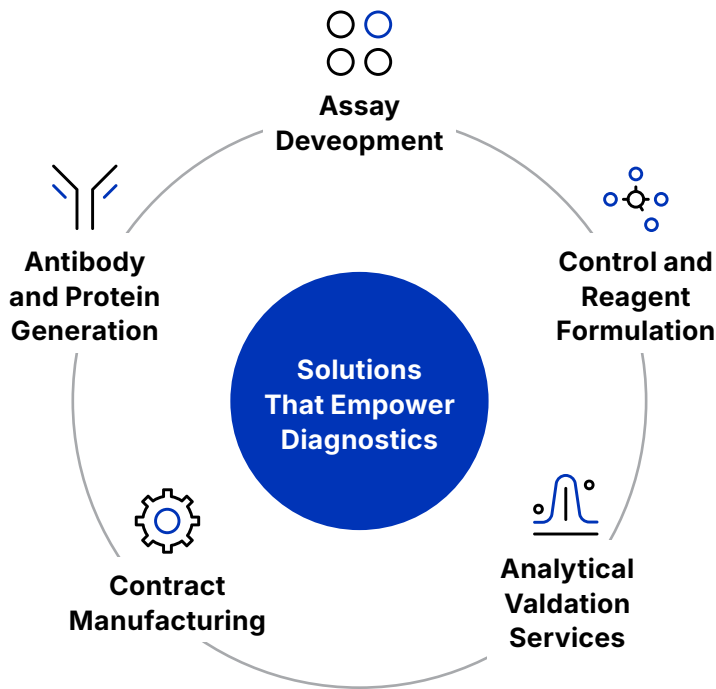
Capabilities include multi-thousand-liter liquid formulation, high-throughput liquid filling, dry formulation, powder blending, reagent tablets, lyophilization, in-line labeling, kit assembly, and global logistics.

Lifecycle Governance & KPI Management

OEM partners receive full program visibility through defined service agreements, KPI dashboards, performance reviews, stability milestones, and lot-sequestration strategies.

Risk Mitigation Across the Product Lifecycle

Risk-mitigation strategies include recombinant conversion for critical antibodies, diversified raw-material sourcing, inventory planning, and change control tied to analytical comparability protocols.



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