



## MOLECULAR DIAGNOSTIC INSTRUMENTS

Designing novel molecular diagnostic instruments requires a unique blend of systems design expertise and biological process understanding.

Simplerity helps clients navigate this complex development landscape through close collaboration with their assay and consumable team, establishing a well-defined interface and setting the common objective of designing a successful instrument.

### SIMPLEXITY BIOTECH EXPERTISE:

- Instrument architecture and development strategies
- Laboratory instrument product development
- Cartridge-to-instrument interfaces optimization
- Value engineering
- System integration and testbed delivery
- Production and characterization test tools
- New product introduction (NPI)
- Robotic systems
- Wireless connectivity
- ISO 13485:2016 certified quality management system

### COMMON CHALLENGES AND NEEDS that bring biotech clients to Simplerity:

- Product architecture expertise for new instrument platforms
- Technology feasibility evaluation or isolated technical hurdle resolution
- Proof-of-concept devices for technology demonstration
- Design of cost-reduced and design-optimized next-generation products
- Automated workflow testbeds for assay and cartridge development
- Production test tools for monitoring critical performance metrics
- Characterization tools to execute design of experiments during instrument development
- Comprehensive program planning, phase-gate build objectives, risk assessment, development budget, product cost estimation
- Manufacturing strategies with customer interests in mind (contract manufacturing selection, tooling strategy, test planning, quality management)
- Designing to medical device standards as required

### SIMPLEXITY BIOTECH EXPERTISE:



GENETIC TESTING



MOLECULAR TESTING



INFECTIOUS DISEASE TESTING

## SUPPORTED PRODUCT CATEGORIES:

Our large, fast-ramp team of expert product engineers and project managers have worked with biotech clients to design products and systems in the product categories of:

- Liquid handling instruments
- Point-of-care diagnostics instruments
- PCR instruments
- Library preparation instruments
- Sample preparation instruments
- Cell therapy manufacturing tools

## PRODUCT DEVELOPMENT COMPETENCIES:

As an engineering and technology-focused design company, we have assembled the best design team in the industry around our core competencies of product development and molecular diagnostics. These include:



### Subsystem Development

- Complete motion subsystems (gantries, robotic arms, actuators, cartridge loaders)
- Thermal systems (thermocycling, precision temperature control)
- Fluidic systems (pumps, valves, manifolds, tubing)
- Opto-mechanical systems
- Optical systems (machine vision, alignment and inspection, barcode readers)
- Magnetic systems



### Process and Test Development

- Characterization testbeds
- Workflow analysis and automation
- Characterization DOE and test
- Design analysis
- Production process analysis
- Tolerance analysis



### Cartridge Interfaces

- Pneumatic
- Valve actuation
- Sonication
- Thermocycling
- Magnetic
- Opto-mechanical



### Communications

- Ethernet
- WiFi
- USB
- Bluetooth Low Energy (BLE)
- RFID
- Cellular

## WHY SIMPLEXITY?

Simplexity understands the challenges of designing molecular diagnostics instruments. We speak your language. Working shoulder-to-shoulder with you, we are focused on transforming your novel idea or benchtop proof-of-concept prototype into a well-designed, integrated instrument ready for the marketplace.

Biotech instrument leaders choose Simplexity Product Development to accelerate and de-risk their product development. For almost 15 years, we have been a trusted partner in product commercialization, with a depth of expertise in product architecture, mechatronics, and complete system design for cost-effective manufacturing.

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